

Access to Medicine Index 2022

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INDEX



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Veronika J. Wirtz
Prashant Yadav

RESEARCH TEAM

James W. Hazel
Emma Shiffman
Alexa Ruiz
Moy Bracken
Kasper Blom
Sjors van Gijzel
Elisabetta Cesari
Marina Plazas Domènech
Diane Dinar-Farjon

EDITORIAL TEAM

Eleanor Bley Griffiths
Jana Jacobs
Tessa Wiles

OTHER CONTRIBUTORS

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ACCESS TO MEDICINE FOUNDATION

The Access to Medicine Foundation is an independent non-profit organisation that seeks to transform the healthcare ecosystem by motivating and mobilising companies to expand access to their essential healthcare products in low- and middle-income countries.

Naritaweg 227-A
1043 CB, Amsterdam
The Netherlands

For any queries about the 2022 report, please contact
James Hazel
Research Programme Manager
jhazel@accesstomedicinefoundation.org
+31 (0) 20 215 3535
www.accesstomedicineindex.org

FOREWORD

Beyond COVID-19: learning the lessons on equitable access



The COVID-19 pandemic has shown us the power of science, as unprecedented R&D efforts have brought life-saving vaccines and therapies to market in record time. But it has also underscored the divide between rich and poor countries, exposing alarming gaps that still leave hundreds of millions of people without adequate access to medicine.

The past three years have demonstrated that the need for equitable access to medicine has never been more important or more urgent. Pharmaceutical industry leaders and policy-makers must now learn the lessons of the worst healthcare crisis in a century to tackle the chronic lack of affordable healthcare beyond the pandemic.

Our 8th Access to Medicine Index finds that, while R&D efforts against COVID-19 have clearly paid off, sadly there has been little progress in addressing R&D gaps for other emerging infectious diseases and future pandemic threats. This is a major missed opportunity, given the great strides in vaccine technology that could help people worldwide.

My team has been monitoring the pharmaceutical industry's role in global health for nearly two decades. By benchmarking leading players – based on actual performance, not just promises – the Access to Medicine Index provides a unique insight into how individual companies are performing.

It also acts as a roadmap to the tried-and-tested measures that companies can deploy to remove access barriers. The aim is simple: to ensure that people in low- and middle-income countries (LMICs) get the choice of affordable medicines they deserve, from vaccines against emerging infections to treatments for diabetes and cancer.

By taking the appropriate steps, pharmaceutical companies will not only help some of the world's poorest people facing the highest burden of disease. They also stand to improve the sustainability of their businesses by opening up new markets for their products.

Overall, our latest insights show there has been progress in a few key areas, although the picture is patchy.

Encouragingly, non-exclusive voluntary licensing (NEVL) is now being used beyond products targeting HIV, hepatitis and tuberculosis, with the inclusion of both COVID-19 therapeutics and a treatment for leukaemia. This is an important step

forward since such licences – which allow generic manufacturers to supply patented products in many LMICs – are one of the most effective ways to get medicines to under-served communities.

However, while multinational companies have implemented more access plans and strategies in LMICs, the quality and geographic spread of this work still varies widely. Access strategies are less likely to cover low-income countries and plans for non-communicable diseases lag well behind those for infectious diseases.

Unfortunately, COVID-19 has only widened the inequities in global health, having taken the greatest toll on vulnerable populations in low-resource settings. Our latest Index therefore comes at a pivotal time in determining if pharmaceutical companies are now ready to put sustainable access front and centre in their strategies. The conclusion must be that – despite some progress – there is still a way to go.

A handwritten signature in blue ink that reads "Jayasree K. Iyer". The signature is fluid and cursive, with a long horizontal line extending from the end.

Jayasree K. Iyer
Chief Executive Officer
Access to Medicine Foundation

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Executive Summary

INTRODUCTION

Globally each year, millions of people suffer illness or lose their lives because the vaccines, medicines and diagnostic tests that they need are either unavailable or unaffordable – and this lack of access to medicine is acute in low- and middle-income countries (LMICs). While the COVID-19 pandemic laid this inequity bare, it also saw the pharmaceutical industry develop and bring new vaccines and treatments to market at unprecedented speed. As the world emerges from the worst of this crisis, pharmaceutical companies are now at an important juncture, where lessons learned from the pandemic can prove pivotal in finding solutions to bridge long-standing gaps in access to medicine in LMICs.

Every two years, the Access to Medicine Index evaluates and compares 20 of the world's leading research-based pharmaceutical companies according to their efforts to improve access to medicine in LMICs.* These 20 companies account for more than half of global pharmaceutical revenue, with pipelines, portfolios, resources, and global reach that give them the unique capacity to develop and market the innovative health products that people in LMICs need. The Index ranks companies on their performance on priority access-to-medicine topics, while identifying best practices and examples, and highlights areas where progress has been made and areas where critical action is required. The methodology is updated every two years in line with developments in access to medicine and global health following a wide-ranging multi-stakeholder dialogue.

The 2022 Access to Medicine Index report marks the eighth edition of the Access to Medicine Index, which was first published in 2008. A total of 31 metrics cover the core role for pharmaceutical companies on access to medicine in strategy, compliance, R&D, pricing and product delivery, making up the framework within which company performances are analysed over two years (1 June 2020 to 31 May 2022). Data analysed relates to 83 diseases, conditions and pathogens that disproportionately impact people living in the 108 LMICs in scope of the Index where better access to medicine is most urgently needed.

This report outlines the key findings and overall ranking analysis of the 2022 Access to Medicine Index before presenting a detailed analysis of company performances and rankings in each of three Technical Areas assessed by the Index: Governance of Access, Research & Development, and Product Delivery. The report concludes with 20 detailed, tailored company report cards. These explain each company's rank in the Index by providing a contextualised analysis of the company's access-to-medicine performance, its relevant product portfolio and R&D pipeline, and company-specific opportunities to improve access to medicine.

* Indexes have been published in 2008, 2010, 2012, 2014, 2016, 2018 and 2021. The publication date of the previous Index was postponed from November 2020 to January 2021 due to the impact of the COVID-19 pandemic. However, the

period of analysis was not extended and remained the same. Each Index analyses two years' worth of data.

HOW DID THE INDUSTRY PERFORM?

The 2022 Access to Medicine Index finds that more companies stepped up their access efforts – including some companies that were previously less likely to take action.

Overall, there has been an industry-wide improvement in R&D access planning; for 77% of projects nearing the end of the R&D pipeline, companies now have a plan in place to promote access after product launch, compared with 40% in the previous Index. The Index also finds examples of companies that are strengthening delivery of their products, with standout companies reporting strong equitable access strategies across different country income groups. For the first time, all 20 companies in scope report an access-to-medicine strategy, with 19 integrating this into their overall corporate strategy. Additionally, three more companies have engaged in voluntary licensing agreements, which means 50% of the companies in scope are allowing generic manufacturing of specific on-patent products in certain countries. This can increase regional availability, supply and affordability of new and innovative medicines that would otherwise not reach many people living in LMICs.

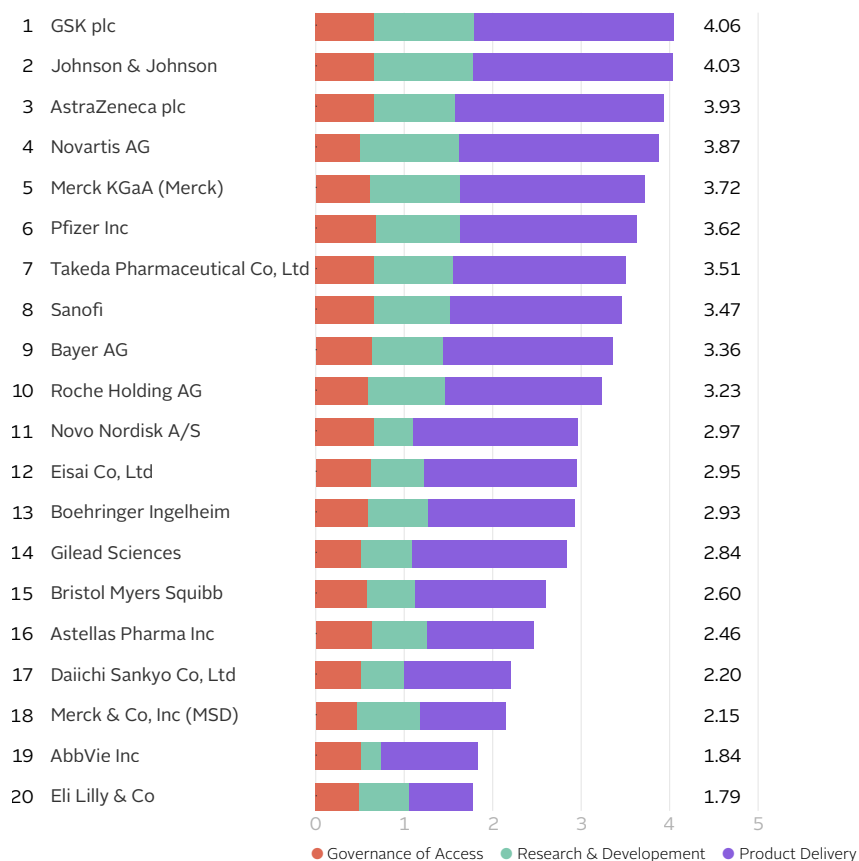
However, much of this progress is disproportionate, with low-income countries still widely overlooked. Only 15% of access plans include at least one of the 27 low-income countries in scope; conversely, 85% include at least one of the 26 upper-middle income countries. Upper-middle income countries are thus six times more likely to be included in companies' access plans for a late-stage R&D project. Furthermore, companies' R&D access plans, and their access strategies for products in their portfolios, are often limited in depth and breadth, sometimes only containing one or a few of the most basic elements. When this is the case, such plans and strategies are less likely to secure long-term, sustainable access to a product.

While sustainably expanding access to healthcare products across LMICs – particularly low-income countries – is a complex challenge, some companies have reported ambitious commitments to improving access in these countries. If such commitments are successfully translated into action going forward, and current access efforts are scaled across portfolios and across countries, more people with the greatest need stand to benefit.

2022 KEY FINDINGS

- **R&D pipeline for emerging infectious diseases mainly empty:** Successive editions of the Index show that prior to the COVID-19 pandemic, companies were largely not engaging in R&D for emerging infectious diseases (EIDs). Apart from an increase in R&D for coronaviral diseases, this picture has not changed. Only five of the 20 companies in scope – Bayer, Johnson & Johnson, Merck, MSD and Takeda – are active in this area, and they target a small number of the EIDs identified as those with the potential to trigger the next pandemic or epidemic.
- **Breakthrough voluntary licence for a cancer treatment is a promising sign:** More companies are newly engaging in voluntary licences and technology transfers. Six companies entered into new licensing agreements covering at least one LMIC in scope, with AstraZeneca, Eli Lilly and Novartis doing so for the first time. A significant milestone is Novartis signing a voluntary licence for a leukaemia drug with the Medicines Patent Pool, the first such agreement covering a non-communicable disease.
- **More access plans and strategies, but limited breadth and depth:** Six companies – Astellas, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis and Takeda – now have access plans in place for 100% of late-stage R&D projects, and the proportion of projects covered by such plans has increased overall among the 20 companies in scope. In addition, more products in companies' portfolios are now covered by access strategies. However, many company R&D access plans, and many strategies for existing products, consistently overlook the poorest countries and are not yet comprehensive enough to ensure access on the scale required.

2022 ACCESS TO MEDICINE INDEX – OVERALL RANKING



2022 RANKING ANALYSIS

Although GSK retains the number one spot, it is by a very narrow margin ahead of Johnson & Johnson, which has moved up from third in 2021. AstraZeneca has newly joined the top three, having risen from the seventh spot in the previous Index. These three companies are also in the top three for the Product Delivery Technical Area, with AstraZeneca taking the lead by excelling in its approach to patent transparency and technology transfers.

GSK leads the 2022 Index ranking by engaging in R&D to develop treatments for diseases that disproportionately affect people living in LMICs and by applying tailored access strategies across product categories. For some products, these access strategies include voluntary licences.

For the first time, Bayer has joined the top ten, improving its performance in R&D – with the broad geographic reach of its R&D access plans highlighted as a best practice in the 2022 Index. Merck joins GSK, Johnson & Johnson, AstraZeneca and Novartis in the top five. It excels in R&D access planning, with access plans in place for all late-stage R&D projects, in addition to performing strongly in its approach to patent transparency.

LEADERS PER TECHNICAL AREA

▶ **Governance of Access**

Pfizer leads with AstraZeneca, GSK, Johnson & Johnson, Novo Nordisk, Sanofi and Takeda following closely behind. These companies score highly in all areas related to governance and strategy, as well as in most areas of responsible business practices.

▶ **Research & Development**

GSK leads with the largest pipeline comprised of projects that target well-established treatment priorities. Johnson & Johnson and Novartis follow closely behind, scoring well across all assessment criteria including R&D access planning and R&D capacity building.

▶ **Product Delivery**

AstraZeneca leads, with improved performance across several areas including tailored access strategies across different country income classifications in all product categories, as well as supply and manufacturing capacity building. GSK, Johnson & Johnson and Novartis follow closely behind, GSK and Novartis with new licensing agreements in place and Johnson & Johnson leading in its approach to access strategies for supranationally procured products.

FINDINGS PER TECHNICAL AREA

▶ Governance of Access

- For the first time, all 20 companies report a defined access-to-medicine strategy, with 19 companies integrating this into their overall corporate strategy; only 11 companies had integrated strategies in the 2021 Index.
- Over half of the companies have a governance system that includes direct board-level responsibility for access-to-medicine activities and access-related incentives for the CEO, senior management and in-country/regional managers to encourage them to perform towards achieving access goals.
- The number of companies decoupling sales' agents rewards from sales targets has steadily increased over time, with all but two companies now taking this step. Compensation is increasingly tied to qualitative performance indicators, such as technical knowledge or compliance adherence

▶ Research & Development

- The 20 companies have 1,060 R&D projects in the pipeline for the 83 diseases, conditions and pathogens in scope. Most of these R&D projects (64%) target non-communicable diseases.
- Over 70% of the internationally identified R&D priorities for LMICs remain unaddressed by the companies in scope. This includes maternal health conditions such as hypertensive disorders during pregnancy, and infectious diseases such as bunyaviral diseases.
- 15 companies participate in R&D capacity building, with the Index identifying 52 R&D capacity building initiatives. These initiatives range from building clinical trial capacity to empowering R&D researchers in LMICs to facilitate drug development.
- The Index shows 77% of late-stage R&D projects are accompanied by an access plan (compared to 40% in 2021), but the quality and geographic scope of access plans vary widely.
- Six companies now have access plans in place for 100% of their late-stage R&D projects – the first time any company has reported this to the Index.

▶ Product Delivery

- Products are more likely to be filed in upper-middle income countries such as Brazil, Mexico and Thailand, rather than in low-income countries. The countries with no filings for registration include the Pacific Islands, Djibouti, Guinea-Bissau and Lesotho.
- Access strategies with the biggest potential impact in terms of equitable access are those that aim to make products affordable for all patients across the income pyramid. Of the products assessed by the Index, 83% are covered by an access strategy in at least one of the LMICs in scope, compared with 58% in the previous Index.
- Despite the progress, the Index finds that the access gap is widening for low-income countries, for which 65% of products analysed do not have an access strategy (compared to 19% of products in upper-middle income countries).
- The Index identified 13 companies that take a comprehensive approach to ensuring uninterrupted supply of their products while paving the way for continuous supply of products outside of their portfolios. These companies have processes in place for mitigation of supply risks like demand surges and active pharmaceutical ingredient (API) shortages. At the same time, they show evidence of building capacity of local suppliers and manufacturers in LMICs.

Access to Medicine Index 2022

The 2022 Access to Medicine Index provides a finely detailed picture of how 20 of the world's largest pharmaceutical companies take action to address access to medicine. This first section of the report provides the core analyses of how the companies in scope performed. It includes:

INDEX RANKING & ANALYSIS

- Companies approach access to medicine more systematically, yet show stagnation in some key areas
- How the companies compare in 2022

KEY FINDINGS

- Some companies engaging in R&D for emerging infectious diseases, but pipeline mainly empty
- First voluntary licence for a cancer treatment is a promising sign for future expansion of access to innovative medicines
- More access plans and strategies to expand access to more products, but with limited breadth and depth

SPECIAL REPORTS

- Assessing pharma companies' response to COVID-19 and the threat of future pandemics
- Are pharma companies addressing sexual and reproductive health access barriers for women and girls?
- Is the industry making progress on improving access to medicine?

INDUSTRY TRENDS

Companies approach access to medicine more systematically, yet show stagnation in some key areas

In assessing how the pharmaceutical industry is performing as a whole, the 2022 Access to Medicine Index can identify some signs of progress, with more companies taking an increasingly systematic approach to access to medicine. This includes addressing access as part of corporate strategy, and implementing systematic approaches to ensure that products are already covered by 'access plans' while they are still in the R&D phase. The 20 companies in scope are also using a variety of access strategies to improve access to the products in their portfolios in low- and middle-income countries (LMICs), including voluntary licensing, equitable pricing strategies, and manufacturing capacity building, with an increase in the use of these strategies.

However, progress is not uniform across the companies, particularly when it comes to product delivery, i.e., ensuring healthcare products are accessible, affordable and available to people living in LMICs. There have also been limited changes in the makeup of the R&D pipeline, leaving significant gaps. For example, there is little R&D activity to address the majority of emerging infectious diseases, and new and improved treatments are still urgently needed for conditions including mycetoma, river blindness, and postpartum haemorrhage. Areas of stagnation are holding the industry back from making wholesale progress on ensuring equitable access to medicine for people living in LMICs.

Improvements in governance of access

For the first time, all 20 companies have a defined access-to-medicine strategy, up from 17 in the previous three Indexes. This is a number that has risen significantly over time since the 2010 Index, when the figure was eight. Further, all but one of the companies have now also integrated their access-to-medicine strategies into their overall corporate strategy. An increase in good practice can be seen in most areas of Governance of Access, in particular a move towards engaging in more responsible sales and promotional practices, e.g., decoupling sales agents' financial rewards from sales targets.

Pre-launch, companies increasingly plan for access to new products

Companies have progressed in introducing frameworks for access planning and integrating this approach into their R&D process. Fifteen companies now have a structured policy in place to create an access plan for each late-stage R&D project in the pipeline, compared to eight companies in 2021. Notably, this year both Boehringer Ingelheim and Bayer have introduced comprehensive new policies to plan for access during the R&D stage. In a sign that this systematic approach can lead to results, 77% of late-stage R&D projects are now accompanied by an access plan (compared to 40% in 2021), and six companies now have access plans for all of their late-stage R&D projects, up from zero in the 2021 Index. However, the quality of these access plans varies greatly. The industry has less-robust plans for non-communicable diseases (NCDs) compared to communicable diseases, and many companies' plans are limited in scope and scale.

IN BRIEF

- ▶ For the first time, all 20 companies have an access-to-medicine strategy. 19 have integrated this into their overall corporate strategy.
- ▶ Companies are increasingly putting access plans in place before launching new products, but analysis shows plans have limited depth and breadth.
- ▶ During the period of analysis, companies pursued 68 R&D projects focused on coronaviral diseases. Non-communicable diseases otherwise continue to dominate the pipeline.
- ▶ Companies have access strategies in place for a greater proportion of products, but are less likely to have strategies to expand access to their products in the poorest countries.
- ▶ Encouragingly, the use of voluntary licensing has grown, which could increase the supply and affordability of more products.

Little change in R&D pipeline, gaps remain

The total number of projects in development has remained relatively consistent with the last Index (1,060 in 2022 and 1,073 in 2021). Companies continue to focus on developing products targeting NCDs; almost half of all R&D projects analysed by the Index target a type of cancer.

For projects targeting communicable diseases, companies continue to invest R&D resources in malaria, HIV/AIDS and tuberculosis, as well as coronaviruses such as COVID-19. Seventeen of the companies engaged in R&D for coronaviruses during the period of analysis. For emerging infectious diseases such as Nipah and Marburg, none of the companies have projects in the pipeline, and the number of projects targeting neglected tropical diseases has also dropped. However, both the quantity and quality of companies' R&D capacity building initiatives in LMICs have increased since the previous Index.

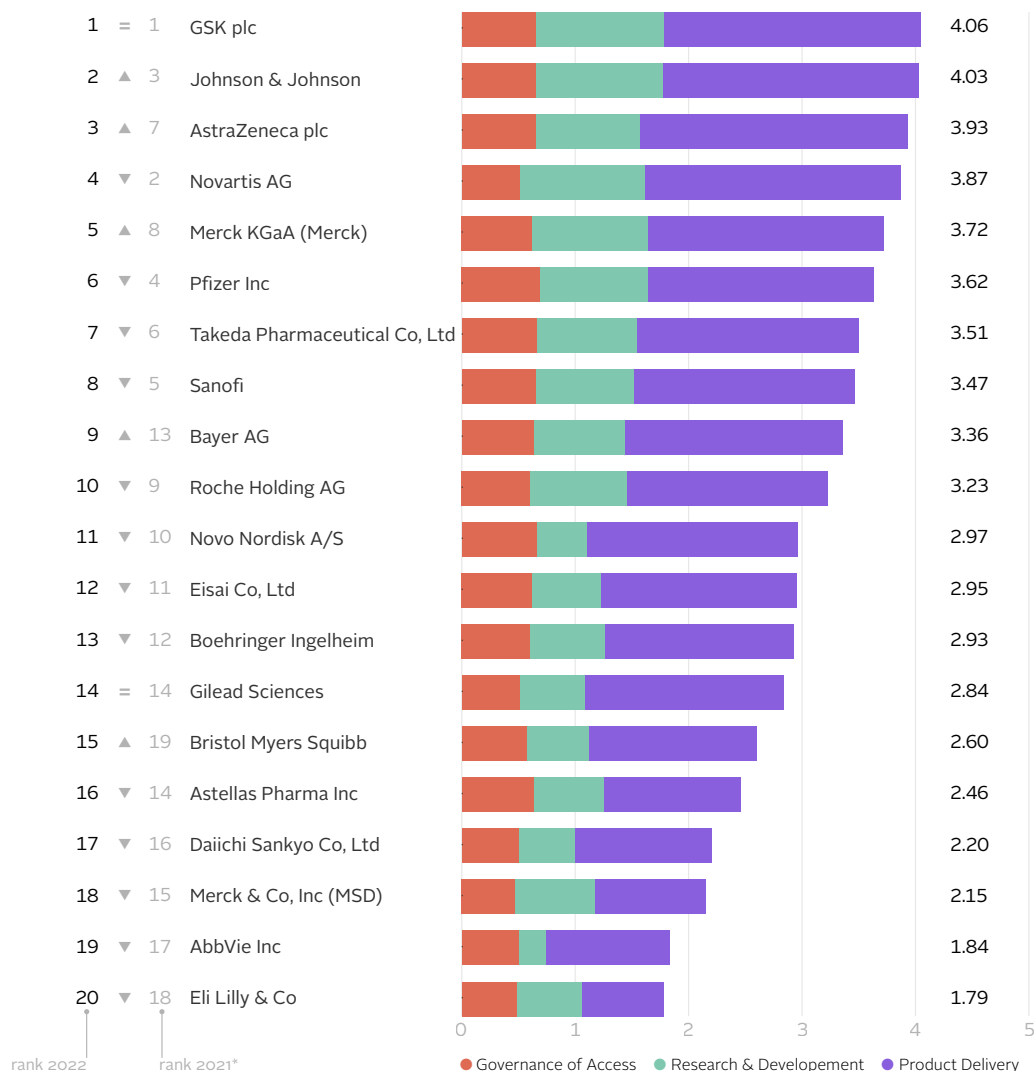
Tentative signs of improvement in product delivery

Companies are using access strategies to expand access to more of their products. This refers to, for example, the use of equitable pricing strategies, patient assistance programmes, or voluntary licences. Of the products assessed by the Index, 83% are covered by an access strategy in at least one country in scope, up from 58% in the previous Index. However, the increase in the proportion of products covered by an access strategy is disproportionately observed in middle-income countries, compared to low-income countries. There is also variation in the quality of companies' access strategies.

One tentative sign of progress is the increased use of voluntary licensing, which can be used by pharmaceutical companies to enable generic medicine manufacturers in LMICs to produce generic versions of their on-patent drugs, thereby increasing accessibility and affordability. Half of all companies in scope now engage in at least one voluntary licence, and there are now more licences among the companies overall – with COVID-19 products accounting for most of that increase. In addition, for the first time, the use of voluntary licensing has expanded to cover a compound targeting an NCD.

The 2022 Index also finds that companies are engaging in more manufacturing capacity building initiatives, most notably technology transfers related to the licences for COVID-19 vaccines and therapeutics, although these are taking place in only a handful of the countries in scope.

2022 ACCESS TO MEDICINE INDEX – OVERALL RANKING



GSK in top spot, Johnson & Johnson close second

GSK ranks in first place, a position it has held since the first Index was published in 2008. However, Johnson & Johnson comes in very close second, rising from 3rd place.

AstraZeneca leaps up to join the top three

AstraZeneca is one of the biggest movers in the 2022 Index ranking. The company has moved up to 3rd place, compared to 7th place in the previous Index.

Bayer and Merck** climb the Index ranking

Bayer has newly joined the top ten, rising from 13th to 9th. Merck has joined the top five, moving up from 8th place in the previous Index.

A group of top-ten companies has emerged

The group of companies included in the top ten remains relatively consistent with the previous Index, with these companies leading on addressing access to medicine.

*In the 2021 Index, dense ranking was used. In the 2022 Index, standard competitive ranking is used. Therefore, a direct comparison with the previous ranks of AbbVie, Astellas, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly and Merck & Co, Inc (MSD) is not possible.

**Merck KGaA (Darmstadt, Germany)

RANKING ANALYSIS

How the companies compare in 2022

The Access to Medicine Index assesses how 20 of the world's leading pharmaceutical companies perform on ensuring access to medicine for people living in LMICs. The ranking is based on their scores in each Technical Area, with Product Delivery weighted most highly, followed by R&D and Governance of Access.

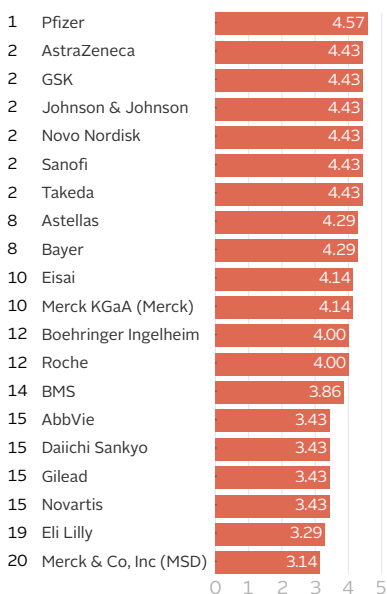
Four companies stand out as leaders

In the 2022 Index, GSK retains the number one spot, followed closely by Johnson & Johnson. AstraZeneca has risen to third, with Novartis in fourth. These four companies are the clear leaders among the companies assessed by the Index.

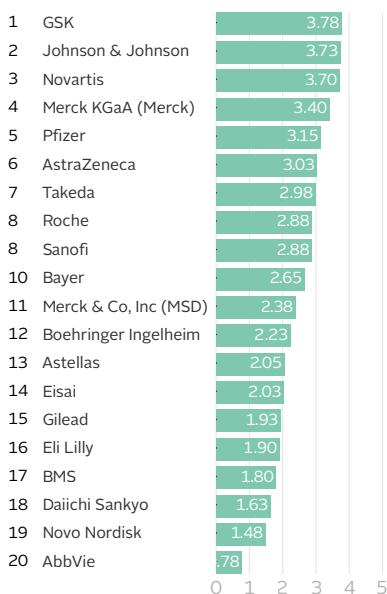
GSK (1st) tops both the overall ranking and the R&D sub-ranking. The company develops treatments and vaccines for diseases that disproportionately affect people in LMICs. It is also in the top three of the other two Technical Areas, and its access-to-medicine strategy is central to its approach to ensuring that medicines reach those that need them most. **Johnson & Johnson** (2nd) demonstrates strong performance in all three Technical Areas and performs well across all assessment criteria including access strategies, R&D access planning and capacity building. **AstraZeneca** (3rd) has newly joined the top three, ranking as the number one company in the Product Delivery Technical Area by excelling in its approach to patent transparency and technology transfers. The company also performs highly in Governance of Access. **Novartis** (4th) performs well in R&D access planning and equitable access strategies and was the first company to agree a non-exclusive voluntary licence covering a product for a non-communicable disease.

FIGURE 1 Ranking per Technical Area

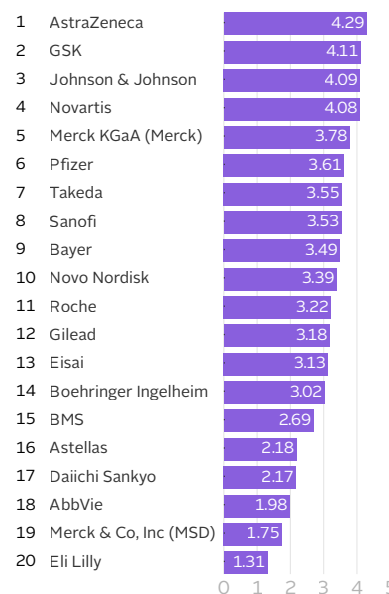
GOVERNANCE OF ACCESS



RESEARCH & DEVELOPMENT



PRODUCT DELIVERY



Below the four leaders at the top of the Index ranking, the companies fall into three different categories.

A high-performing group stands out by taking the lead in specific areas and consistently performing above average across the three Technical Areas, while companies in the middle-performing group still score relatively well but miss out on a higher ranking due to below average performance in one or more areas such as R&D or Product Delivery. The lowest-ranked group comprises five companies that particularly fall behind in Product Delivery and perform below average in R&D.

The high-performing companies

The companies ranked 5th to 10th are high performers on access to medicine, competing closely in the overall ranking. **Merck** (5th) excels in R&D access planning, with access plans in place for all late-stage R&D projects and performs strongly its approach to patent transparency. **Pfizer** (6th) leads in Governance of Access for its approach to incentivising responsible promotional practices. **Takeda** (7th) is a top-performing company in R&D access planning and equitable access strategies for products that are administered by healthcare practitioners. **Sanofi** (8th) performs well in engaging in supranational procurement mechanisms to supply products in LMICs; it also engages in R&D for neglected diseases that disproportionately affect people in poorer countries. **Bayer** (9th) has joined the top ten, improving its performance in R&D access planning and demonstrating best practice with the broad geographic reach of its plans. **Roche** (10th) engages in high-quality health systems strengthening initiatives and has improved in its approach to R&D access planning.

The middle-performing companies

Novo Nordisk (11th) has strong policies governing access and builds capacity by engaging in health systems strengthening. **Eisai** (12th) has an average performance overall across the three Technical Areas, with a particularly strong performance in long-term product donations. **Boehringer Ingelheim** (13th) has an average performance in the Technical Areas, but has introduced a comprehensive new framework for R&D access planning, and performs well in expanding access via inclusive business models. **Gilead** (14th) is a leading company in non-exclusive voluntary licensing, but its performance in R&D and Governance of Access is below average. **Bristol Myers Squibb** (15th) has greatly improved its ranking this year, strengthening its performance in Product Delivery through engaging in health systems strengthening and access strategies. In R&D it is carrying out several clinical trials in countries in scope and commits to registering successful R&D candidates in those countries.

The low-performing companies

The bottom of the ranking is rounded out by five companies whose performance is below average for much of the criteria assessed by the Index. **Astellas** (16th) has strengthened its access planning processes during R&D and has comparatively strong policies in place for Governance of Access, but falls behind its peers in applying equitable access strategies to its products in LMICs. **Daiichi Sankyo** (17th) performs relatively well in intellectual property (IP) sharing, but lags in all Technical Areas. **MSD** (18th) has improved in R&D with the introduction of a new access planning policy. Yet it has a comparatively poor performance in the other two Technical Areas, Governance of Access and Product Delivery, and is among the least transparent companies in scope. **AbbVie** (19th) scores poorly across all Technical Areas but particularly lags in R&D, in both product development and R&D access planning. **Eli Lilly** (20th) performs poorly, ranking in the bottom five in all three Technical Areas. The company chooses not to disclose information across a range of issues, nor to make relevant information available in the public domain.

KEY FINDING 1: R&D PRIORITIES

Some companies engaging in R&D for emerging infectious diseases, but pipeline mainly empty

- ▶ Only 5 of the 20 companies analysed by the Index are currently engaging in R&D for emerging infectious diseases other than COVID-19.
- ▶ Approvals of Johnson & Johnson's Ebola vaccine and Bayer's vector control product for mosquito-borne diseases are significant, but more companies need to invest in preventing future outbreaks.

The COVID-19 pandemic has underlined the urgent need for pharmaceutical companies to address other emerging infectious diseases (EIDs) via R&D. It is not a question of whether EIDs pose a significant global health risk – it's a case of being prepared for when the next crisis hits. Yet, the 2022 Index shows that only five companies of the companies in scope are targeting EIDs other than COVID-19, and for the majority of EIDs identified as a priority, there are no projects in the pipelines of the world's largest R&D-based pharmaceutical companies.

The rising global threat of emerging infectious diseases

Many people living in low- and middle-income countries (LMICs) already face the threats posed by EIDs. Recent outbreaks of Ebola, Marburg virus and Lassa Fever illustrate the urgent need for vaccines and treatments. Without access to products that target infectious diseases, many of the world's most vulnerable people will continue to suffer.

In addition, there are several factors that are already increasing the risks these diseases pose globally, including climate change, urbanisation, globalisation and migration.

Defining R&D priorities for emerging infectious diseases

The number of pathogens that pose a potential global health risk is vast, globally. The World Health Organization (WHO) lists priority diseases and pathogens based on their epidemic potential and/or whether there are no or insufficient countermeasures. This list aims to ensure R&D efforts against EIDs are focused and productive.

Global warming means that more places are reaching suitable temperatures for transmission of climate-sensitive diseases. The devastation left in the wake of unprecedented natural disasters also provides the perfect environment for infectious diseases to thrive. As more people migrate, moving to cities and across borders, these diseases will not remain confined to specific countries. The COVID-19 pandemic proved beyond doubt that pathogens can and will travel indiscriminately.

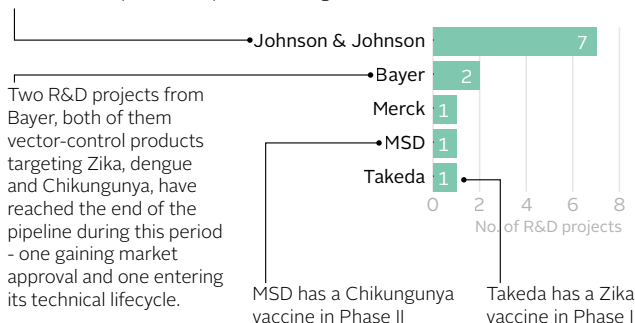
Some companies show the way, but more to be done

In spite of the COVID-19 pandemic, the 2022 Index shows little change in companies' R&D efforts against emerging infectious diseases. Companies still have very few R&D projects targeting the EIDs considered to be the highest priorities for R&D; excluding projects targeting coronaviruses, the total number of EID projects is 12, compared to 13 and 15 in the previous two Indexes. Such an empty pipeline for so many dangerous diseases puts the world at risk of future epidemics and pandemics.

Bayer, Johnson & Johnson, Merck, MSD and Takeda are the companies in scope that engage in R&D efforts for EIDs other than COVID-19. However, these companies target a small number of priority pathogens, which means most diseases and pathogens capable of triggering the next pandemic or epidemic are going unaddressed. While there are companies outside the scope of the Index that are engaged in R&D projects targeting some of these diseases, the 20 company pipeline assessed by the Index are some of the world's largest and most well-resourced pharmaceutical companies, and greater investment from more of these companies could move the dial on tackling EIDs.

FIGURE 2 Just five of the 20 companies engage in R&D for emerging infectious diseases other than COVID-19

Of these, 1 is a clinical trial for a new and innovative product, and 1 (the two-shot Ebola vaccine) has reached the end of the pipeline, achieving market approval. Johnson & Johnson's other projects involve testing existing products on additional patient populations such as children and pregnant women, to expand their potential usage.



Successes in R&D

Despite this stark picture, the few companies that are currently engaging in R&D for other EIDs have had some significant

successes. For example, Zabdeno® & Mvabea®, Johnson & Johnson's two-shot Ebola vaccine regimen, was approved by the European Medicines Agency (EMA) in 2020. In April 2021, WHO granted prequalification status to the regimen.* This could accelerate registration in countries with high disease burdens, where an outbreak is likely to occur.

Bayer's Fludora® Co-Max is a vector control product used to control adult mosquitos (*Aedes spp.* and *Culex spp.*). With its dual mode of action, it has the potential to prevent mosquito-borne diseases such as Zika and Chikungunya. The product has now received WHO prequalification, and Bayer also provided evidence that it plans to register the product in several countries in scope of the Index. In addition, after the period of analysis for the 2022 Index had ended, MSD announced that is working with the International AIDS Vaccine Initiative (IAVI) toward a formal agreement to produce and donate investigational vaccine doses for IAVI's vaccine development programme targeting the Sudan ebolavirus.

What can be learned from R&D efforts against COVID-19?

Successive editions of the Index show that prior to the COVID-19 pandemic, pharmaceutical companies were largely not engaging in R&D for EIDs. This included coronaviruses, a group of viruses that had already been identified as having pandemic potential, but for which there were no R&D projects in the 2018 Index. Yet, by the end of May 2020, the number of R&D projects targeting the virus had already skyrocketed to 63, as shown in the 2021 Index.

This R&D effort led to results. During the period of analysis for the 2022 Index, between the 20 companies in scope, four preventative vaccines and ten medicines for COVID 19 were registered and approved.¹ The circumstances surrounding COVID-19 were unique, in that governments and international

funds invested huge sums of money into private companies' R&D and into contracts to buy COVID-19 vaccines and treatments. However, the number of COVID-19 products launched during the pandemic, and the speed with which they were launched, does indicate that companies have the capabilities to rapidly respond to urgent R&D needs and dedicate expertise and resources to finding solutions. Even without the same level of financial incentives seen during COVID-19, companies can now choose to invest – potentially with a public or private co-investor – in R&D for other EIDs that pose a grave danger both to people living in LMICs, and also to people worldwide.

What next?

The rapid development and authorisation of medicines and vaccines for COVID-19 indicates that the pharmaceutical industry is willing and able to respond quickly to public health emergencies. Through the 2022 IFPMA Berlin Declaration, pharmaceutical companies pledged to draw on lessons learned from the COVID-19 pandemic to ensure equitable access to vaccines and medicines in future pandemics. This includes manufacturing, sustainable supply and accelerating R&D to develop new health products. To fulfil this commitment, companies can make use of insights on how to accelerate R&D in order to create medicines, vaccines, diagnostics, and platform technologies to prevent future outbreaks of diseases that have been identified as posing a global health risk.

Companies that are serious about targeting EIDs must not only invest resources into R&D pre-emptively, but they need to engage in access planning in tandem with developing products. This will ensure that essential vaccines and products will reach those who need them – preventing unnecessary loss of life as well as curbing the spread of disease.

FIGURE 3 R&D pipeline empty for most emerging infectious diseases

This figure shows the number of R&D projects* and companies targeting emerging infectious diseases identified by WHO and Policy Cures Research as posing pandemic or serious epidemic risk.

	R&D projects			Active companies		
	2018	2021	2022	2018	2021	2022
Disease flagged as an epidemic/pandemic risk						
Arenal haemorrhagic fevers (incl. Lassa fever)	0	0	0	0	0	0
Chikungunya	3	4	5	3	4	3
Crimean-Congo haemorrhagic fever (CCHF)	0	0	0	0	0	0
Ebola virus disease (EVD)	7	5	4	5	4	1
Emergent non-polio enteroviruses (incl. EV71, D68)	1	1	0	1	1	0
Marburg viral disease (MVD)	1	1	0	1	1	0
Middle East respiratory syndrome coronavirus (MERS-CoV)	0	0	0	0	0	0
Nipah	0	0	0	0	0	0
Bunyaviral diseases (other than CCHF, RVF and SFTS)	0	0	0	0	0	0
Filoviral diseases (other than EVD and MVD)	0	0	0	0	0	0
Henipaviral diseases (other than Nipah)	0	0	0	0	0	0
COVID-19 and other coronaviral diseases (other than SARS and MERS-CoV)	0	63	68	0	17	17
Rift Valley fever (RVF)	0	0	0	0	0	0
Severe acute respiratory syndrome (SARS)	0	0	0	0	0	0
Severe fever with thrombocytopenia syndrome (SFTS)	0	0	0	0	0	0
Zika virus disease	3	4	7	3	4	4
Disease X**	0	0	0	0	0	0

Takeda's enterovirus 71 vaccine project has been discontinued. No projects in the companies' pipelines now target these enteroviruses.

A project that was previously being tested against multiple diseases in scope, including Marburg, has moved further down the pipeline and now specifically targets Ebola. No projects in the companies' pipelines now target Marburg.

¹ This includes projects that were granted emergency use authorisation or conditional marketing authorisation because of the urgent nature of the COVID-19 pandemic. Some have since received full regulatory approval.

* As four projects target Zika, dengue and/or Chikungunya, these have been included in several categories in the table.

** 'Disease X', added to this list in 2018, represents the knowledge that a serious epidemic or pandemic could be caused by a pathogen currently unknown to cause human disease. COVID-19 can be seen as a first example of Disease X.

KEY FINDING 2: LICENSING

First voluntary licence for a cancer treatment is a promising sign for future expansion of access to innovative medicines

- ▶ Milestone development as Novartis signs a voluntary licence for a leukaemia drug with the Medicines Patent Pool, the first such agreement covering a non-communicable disease.
- ▶ More companies newly engaging in voluntary licences and technology transfers, especially for COVID-19 products – but in a small number of countries.

To address chronic inequity in access to new and innovative medicines, rapid action is needed by pharmaceutical companies to expand access to their on-patent products in low- and middle-income countries (LMICs). Enabling a product to be manufactured by multiple manufacturers is important, and one key way to do this is to engage in voluntary licensing, which can improve availability and affordability in different regions of the world. Non-exclusive voluntary licences (NEVLs) have been used very successfully for HIV and hepatitis, and recently more companies have agreed to NEVLs for their COVID-19 medicines and vaccines. One company has now expanded the use of NEVLs to include a non-communicable disease (NCD) for the first time, with a voluntary licence for a cancer product.

As part of these licensing efforts, pharma companies can carry out technology transfers. This is a crucial additional step companies can take to ensure the uptake and success of NEVLs, and can include, e.g., transferring knowledge on processes such as active pharmaceutical ingredient (API) production, equipment use and raw material handling. Technology transfers can be used to sustainably scale up access in LMICs and ensure that local manufacturers are adequately equipped to efficiently produce high-quality medicines in the long term.

First voluntary licence for a cancer medicine
Significantly, during the period of analysis, Novartis

What is a non-exclusive voluntary licence?

A voluntary authorisation given by the patent holder to a generic manufacturer, allowing it to develop and manufacture generic versions of patented medicines. When a licence is ‘non-exclusive’, this means that the patent holder can issue licences to multiple manufacturers, often in different countries. The Medicines Patent Pool (MPP) is a key organisation that can facilitate this.

announced plans for a NEVL covering nilotinib (Tasigna®), a medicine indicated for chronic myeloid leukaemia. This drug had been on the MPP’s Priority List, and an agreement with the MPP was ultimately signed in October 2022.

This is the first time that the use of NEVLs has expanded beyond products or compounds targeting communicable diseases – specifically HIV, hepatitis, tuberculosis and COVID-19 – and is a particularly hopeful sign as the burden of NCDs, such as cancer and diabetes, is rising globally. In 2030, around three-quarters of deaths from cancer are expected to occur in LMICs, yet essential on-patent oncology medicines are often unavailable or unaffordable in these countries.

The potential impact of the NEVL will be limited by the fact that it does come less than a year before the expiry of the main patent for nilotinib (Tasigna®). In addition, Novartis had previously chosen not to file for patents in several of the countries included in the NEVL. However, if generic medicine manufacturers do take up the opportunity offered by Novartis via the MPP, this agreement could accelerate the expansion

FIGURE 4 Use of voluntary licences has increased, primarily due to new agreements for COVID-19 and cancer compounds

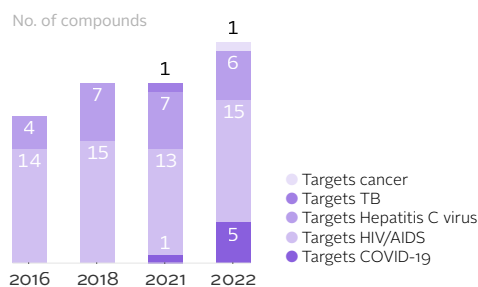
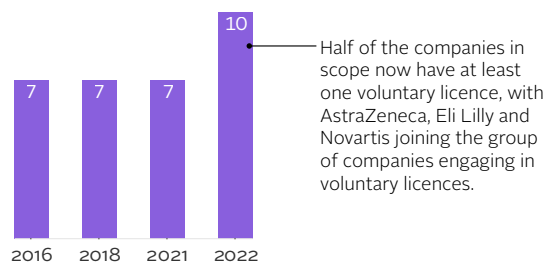


FIGURE 5 More companies now engage in voluntary licensing



of availability and affordability of this cancer drug – which is classed as an “essential medicine” by the World Health Organization – to patients living in LMICs. It also sets a precedent for other companies to sign NEVLs for medicines targeting NCDs. Novartis has committed to reinvesting all royalties from this agreement into the Access to Oncology Medicines (ATOM) Coalition, a new global initiative launched in 2022 to sustainably expand access to quality-assured essential cancer medicines in low- and lower-middle income countries.

The rise of NEVLs, driven by COVID-19

Companies including AstraZeneca, Eli Lilly, GSK, MSD, Novartis and Pfizer entered into new licensing agreements during the period of analysis, with ten of the companies in scope now engaging in at least one voluntary licence – up from seven in the previous Index. The number of licensed compounds has risen from 22 to 27.

Much of this trend is driven by companies engaging in voluntary licensing for COVID-19 products. Out of the eight companies in scope with COVID-19 products in their portfolios, four companies now have at least one NEVL (and one further company has a private voluntary licence, not analysed here). MSD agreed to a NEVL with the MPP before the launch of its oral antiviral molnupiravir (Lagevrio®), as did Pfizer for nirmatrelvir/ritonavir (Paxlovid®). Gilead signed a royalty-free voluntary licensing agreement and carried out a technology transfer for the manufacture of its injectable antiviral remdesivir (Veklury®) in India, Egypt and Pakistan. Eli Lilly signed a royalty-free NEVL with Cipla, Sun Pharma, and Lupin covering its COVID-19 treatment baricitinib in India. In addition, for its COVID-19 vaccine (ChAdOx1-S [recombinant]) (Vaxzevria), AstraZeneca has engaged in a sequence of exclusive voluntary licences (rather than NEVLs) in different parts of the world.

Quality and scope of voluntary licensing agreements

At least 80% of the countries in scope of the Index are covered by at least one of the four NEVLs for COVID-19

products, with India included in the greatest number (three). If a country is covered, that means generic versions of the originator product can be introduced in that country; it does not, however, mean that generic medicine manufacturers have taken up the licence, or that the product is actually being made available to people living in that country.

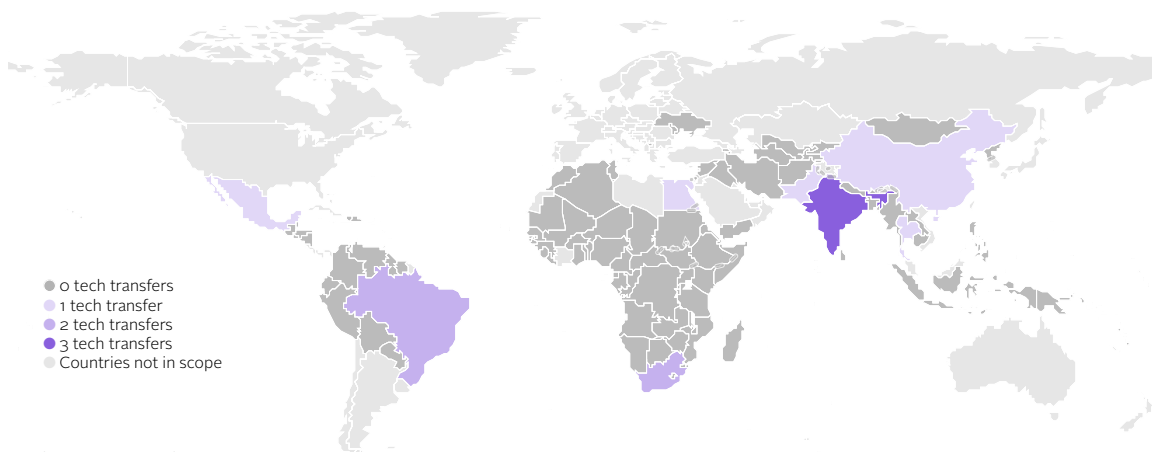
While companies’ engagement in NEVLs and their commitments not to file or enforce patents in particular countries can lead to positive outcomes for access, the gold standard is to back up this approach with technology transfers. Yet, although many countries are covered by NEVLs for COVID-19 products, actual technology transfers – with specific generic medicine manufacturers – have been carried out in just a handful of countries, as seen in the map below.

What next?

Companies have demonstrated growing willingness to engage in voluntary licensing. However, the momentum must continue - with more NEVLs for more products, from more companies, covering a wider range of diseases and countries, earlier in products’ lifecycles, and with access-oriented clauses. This will be especially important in the context of novel therapies and NCD medicines. Companies can also expand the geographic scope of existing NEVLs, especially to include more upper-middle income countries, which are often excluded from these agreements.

Companies should take advantage of existing resources to guide their licensing decisions, such as the MPP’s list of medicines that should be prioritised for NEVLs, which included Novartis’s nilotinib at the time of signing.* Companies with other products on the priority list can take similar actions, such as Boehringer Ingelheim with empagliflozin (Jardiance®) and AstraZeneca, with its lung cancer treatment osimertinib (Tagrisso®). Companies can also supplement current and future NEVLs with technology transfers and other capacity building efforts.

FIGURE 6 Technology transfers for COVID-19 products are concentrated in just a few of the 108 countries in scope of the Index



*Medicines Patent Pool. Prioritisation of medicines for in-licensing by the Medicines Patent Pool. MPP; 2022. Accessed 01/11/22: <https://medicinespatentpool.org/what-we-do/prioritising-medicines-for-licensing>

KEY FINDING 3: ACCESS PLANNING & STRATEGIES

More access plans and strategies to expand access to more products, but with limited breadth and depth

- ▶ While companies are taking steps to improve access to their products in low- and middle-income countries, their plans and strategies consistently overlook the poorest countries.
- ▶ For some products, companies are moving to consider availability, affordability and sustainable supply, signalling possibility for change.

Out of the 20 companies assessed by the Index, six now have access plans in place for 100% of late-stage R&D projects. This is the first time any single company has hit that milestone, and is an encouraging sign that companies will make their new products more available to the people who need them in low- and middle-income countries (LMICs). For products already on the market, the data also demonstrates progress; 83% of the products assessed by the Index are covered by an access strategy in at least one of the LMICs in scope, compared with 58% in the previous Index.

Yet, analysis of companies' access plans and strategies shows that they are often limited in depth and breadth, sometimes only containing the most basic elements. As ever, low-income countries are paid the least attention. A few examples from a handful of companies show, however, that this situation is not inevitable, and that it is possible to expand access to essential healthcare products so that people worldwide get the treatments they need.

Steps forward in R&D access planning, but low-income countries left out

Astellas, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis and Takeda have now provided evidence that they have developed project-specific access plans for all their late-stage R&D projects in scope of the Index.¹

Yet, despite an industry-wide expansion of access planning

Access plans are ways for companies to ensure they take account of public health needs while new products are still in development, so that people in LMICs can gain access to products more rapidly and affordably following their market entry. Companies should have plans in place for products in the pipeline from at least Phase II of R&D.

Access strategies are ways that companies can ensure equitable access to the products in their portfolios. Companies are expected to apply access strategies to key products across LMICs, maximising the availability of these products to those with less income.

during the R&D stage, the number of countries included in plans is low. On average, an access plan includes only six of the 108 countries in scope of the Index. Only 15% of access plans include at least one of the 27 low-income countries; conversely, 85% include at least one of the 26 upper-middle income countries. Upper-middle income countries are six times more likely to be included in companies' access plans for an R&D project.

Currently, 52% of the access plans assessed by the Index consist solely of plans to register products in at least one LMIC, once approved. Companies mostly commit to filing for registration in the countries where clinical trials have been conducted – predominantly in upper-middle income countries such as South Africa, China, Mexico, Colombia and Brazil. Registering a product is a vital step, but it should not be the only element of an access plan.

However, some companies have access plans that are more

FIGURE 7 Six companies now plan for access for all late-stage projects

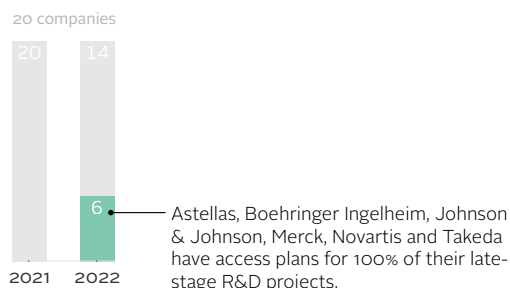
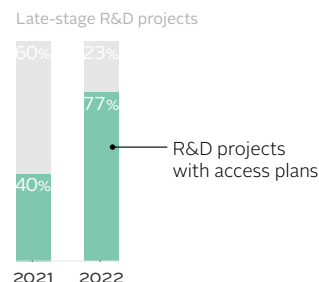


FIGURE 8 More R&D projects now covered by access plans

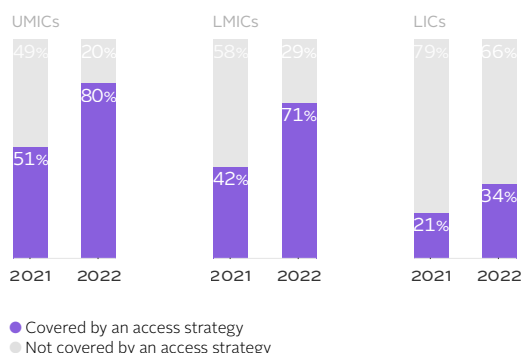


¹ Projects from Phase II and onwards (late-stage) were selected for analysis based on their priority disease designation

or if they were identified as having a public health benefit in LMICs.

FIGURE 9 Products covered by an access strategy in at least one upper-middle, lower-middle, and low-income country

More of the products in scope are now covered by access strategies. However, this improvement disproportionately favours upper-middle and lower-middle income countries.



comprehensive, and include low-income countries. For example, Novartis includes five low-income countries in clinical trials for cipargamin (KAE609), for the treatment of severe malaria; in line with its post-trial access policy, the company commits to registering the medicine in those countries once approved. Takeda’s access plan for its dengue vaccine QDENGAR[®] (TAK-003) considers burden of disease in its plans for where to file for registration, as well as innovative equitable pricing models and methods to ensure sustainable cold chain supply.

Companies’ efforts to ensure existing products reach patients still overlook low-income countries

Although the number of products in scope covered by access strategies has increased overall, companies are still far less likely to include low-income countries in their strategies, despite the urgent need for greater access to medicine in these countries.

Expanding access in low-income countries can present complex challenges for companies, for example if the country lacks regulatory capacity, has weak healthcare infrastructure, or is less likely to provide a high yielding market. Even though there is no ‘one-size-fits-all-products’ approach, companies can utilise a wide range of tools and approaches to directly address access and affordability in LMICs. Companies can implement equitable pricing strategies, or can work with other stakeholders, e.g. by using non-exclusive voluntary licensing agreements (NEVLs) to facilitate an increase in generic supply in LMICs, or by engaging with supranational procurement organisations.

Some companies are already taking steps to implement access strategies in low-income countries (see figure, right). Yet, when companies were asked to provide an example of a strategy used to expand access in a low-income country for each of up to 10 products from their portfolios, the positive examples outlined above were the exception, not the rule. Two thirds of all products analysed by the Index were still not covered by any access strategies in a low-income country.

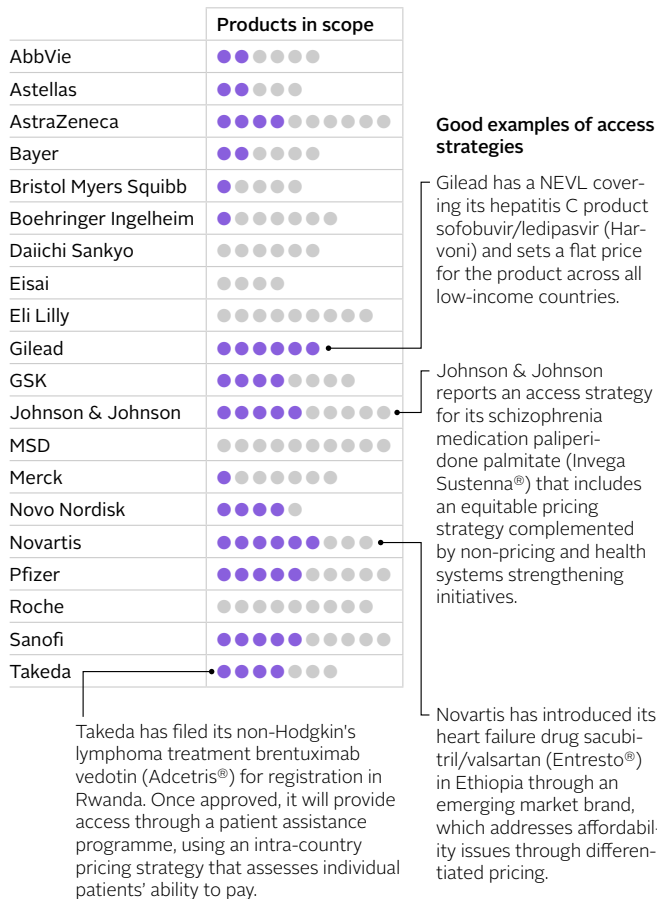
What next?

More companies can now ensure all their late-stage R&D projects have comprehensive access plans in place that contain a variety of measures to increase access, and cover more countries – including low-income countries.

Companies can also expand the quality and quantity of their access strategies to cover a wider range of countries, people and treatments. To sustainably expand access in low-income countries, companies need business plans that account for such challenges and facilitate access across all LMICs. Some companies are already seeking ways to develop such plans; Sanofi, for example, launched a new Global Health Unit in 2021, though which it commits to expanding access to 30 of its products in 40 of the world’s poorest countries, while Pfizer has made a commitment to creating sustained and equitable access to all of its patented products in 45 low-income countries through its 2022 Accord for a Healthier World. These are signs that the companies are taking the challenge of expanding access in low-income countries seriously, but their success will depend on their implementation.

FIGURE 10 Two thirds of products scope of this analysis* are not covered by any access strategies in low-income countries

● Product covered by an access strategy in at least one low-income country
 ● Product not covered by an access strategy in any low-income country



*Companies were requested to submit up to 10 products each for this analysis, including healthcare practitioner-administered and self-administered products.

**SPECIAL REPORT: COVID-19 & PANDEMIC
PREPAREDNESS**

Assessing pharma companies' response to COVID-19 and the threat of future pandemics

The COVID-19 pandemic has had enormous consequences globally, not least in low- and middle-income countries (LMICs). It has shown the pharmaceutical industry's capacity to quickly bring products to market, but has also highlighted the inequitable distribution of new vaccines and therapeutics.

The Index analyses data about 'coronaviral diseases,' a category that covers all coronaviruses including COVID-19, Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome (SARS). However, during the period of analysis for the 2022 Index, the overwhelming majority of products developed for coronaviral diseases targeted COVID-19.

This Special Report looks at how companies responded in the initial phase of the COVID-19 pandemic by rapidly engaging in research and development (R&D) to develop products targeting COVID-19. It also analyses how companies perform in terms of registration and applying equitable access strategies for COVID-19 vaccines. Additionally, the report outlines how some companies engaged in voluntary licensing agreements and technology transfers to enable generic supply of COVID-19 vaccines and therapeutics. Finally, the Index looks forward towards how companies are preparing for future epidemics and pandemics.

CONTEXT

Where we are now: the impact of the COVID-19 pandemic in LMICs

The COVID-19 pandemic has had a devastating effect in LMICs. It placed a huge burden on weak health systems and disrupted other important public health services, such as routine childhood immunisation campaigns. For example, in 2020, an additional 3.7 million children did not receive their DTP (diphtheria, pertussis, and tetanus) vaccine.¹ Further, the World Health Organization (WHO) estimates that the COVID-19 pandemic resulted in an additional 14 million cases of malaria and 69,000 deaths from malaria in 2020.² Alongside the direct effects on people's health, lockdowns and COVID-19 prevention measures have prevented individuals from conducting their usual social and economic activities, thereby increasing poverty and inequality.

In LMICs, lack of access to COVID-19 vaccines and treatments has exacerbated the effects of the pandemic. According to one study, an estimated 600,000 deaths in LMICs could have been prevented in the period up to December 2021 if WHO vaccination targets of 40% had been achieved.³

The inequitable distribution of vaccines has been observed in previous pandemics, such as during the H1N1 pandemic in 2009. This resulted from the greater purchasing power of high-income countries in comparison to LMICs, and also due to the lack of global vaccine production capacity.⁴ Despite efforts from global health organisations, a similar situation has been observed during the COVID-19 pandemic.

What is the role of pharmaceutical companies in ensuring equitable access to COVID-19 products?

Several factors have contributed to the inequitable supply of COVID-19 vaccines globally, including a lack of capacity to immediately scale up production, poor supply chain infrastructure and weak health systems.

Furthermore, early large-scale buying of most available stock by high-bidding high-income countries left little for international procurement for LMICs. Donation programmes, while important, were not sufficient to bridge the gap in access and ensure sustainable global supply. When public investments are made in R&D, as they have been during the COVID-19 pandemic, conditions for future investments could include obligations to reserve part of the early production capacity for people in LMICs to help increase access and limit health inequities.

Pharmaceutical companies have a public health responsibility to ensure people have equitable access to COVID-19 products by taking steps both during drug development and after products are launched on the market. Examples of important steps for the future include investing in innovative R&D projects to target diseases with epidemic or pandemic potential. Planning ahead for access during the R&D stage, or 'access planning,' is also necessary to ensure products can be made rapidly and universally available.

On the supply side, companies can engage in technology transfers and voluntary licensing with local manufacturers to scale up production in LMICs. Additionally, they must ensure that these products are affordable in LMICs. These steps are needed not only to ensure equitable access to COVID-19 products, but also to ensure all countries have the necessary knowledge, infrastructures, strategies and tools prepared for inevitable future pandemics.

RESEARCH & DEVELOPMENT

R&D for COVID-19 accelerated in response to urgent need

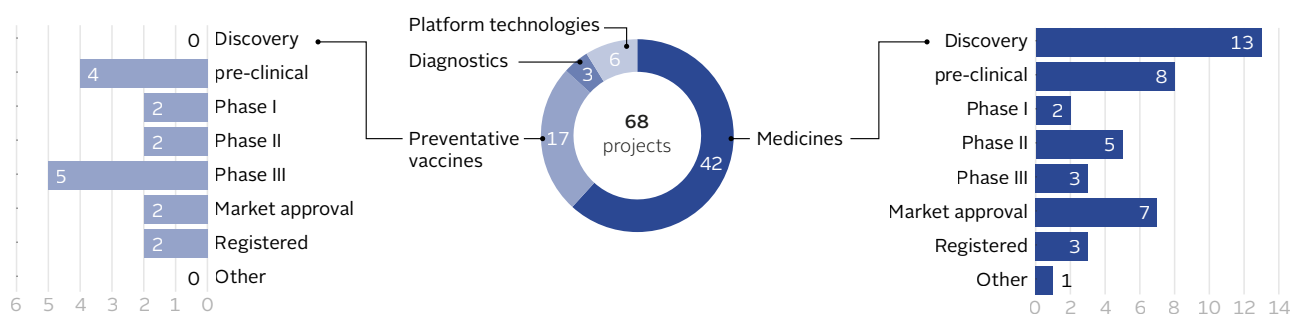
During the period of analysis,* four preventative vaccines and ten medicines were registered or received regulatory approval.** Several of these products received US Food and Drug Administration (FDA) Emergency Use Authorisation (EUA) or European Medicines Agency (EMA) conditional marketing authorisation, which are mechanisms designed to facilitate availability during a public health emergency. Such provisional authorisations enabled products targeting COVID-19 to be accelerated through the pipeline, indicating that companies can rapidly respond to urgent R&D needs and dedicate resources and investments towards finding solutions.

In addition to new innovations, some companies in scope of the Index invested resources into researching whether they could repurpose products that were already approved for other diseases and conducted trials to test products from their portfolios against COVID-19. For example, Roche's tocilizumab (Actemra®/RoActemra®) and Eli Lilly's baricitinib (Olumiant®), both of which were originally indicated for rheumatoid arthritis, received FDA EUA for the treatment of COVID-19 in hospitalised patients.

Of the 20 companies in scope, 17 were engaged in projects targeting COVID-19 during the period of analysis. During this two-year period, the companies collectively had 68 R&D projects in the pipeline targeting coronaviral diseases, including vaccines, medicines, diagnostics and platform technologies. This represents the second highest number of R&D projects in development for any disease in scope, after cancer. The number of projects in development surpasses those of other diseases including malaria (55 projects), HIV/AIDS (46 projects) and tuberculosis (34 projects). Unsurprisingly, the number of projects correlates with investment in R&D; in 2020, USD 3.87 billion was quickly made available for COVID-19 R&D.⁵

FIGURE 11 Multiple R&D projects targeting COVID-19 have already resulted in approved** and/or registered products

Of the 68 R&D projects devoted to COVID-19 or unspecified coronaviral diseases during the period of analysis, 42 were medicines and 17 were vaccines.



*Period of analysis for the 2022 Index: 1 June 2020 to 31 May 2022.

**This number includes vaccines that received emergency use authorisation or conditional marketing approval during the period of analysis

PRODUCT DELIVERY

Companies launched key vaccines and therapeutics targeting COVID-19

Pharmaceutical companies have been key stakeholders in the fight against COVID-19, having quickly developed vaccines, treatments and diagnostics for the virus and brought them to market. Due to the rapid progression from development to product launch during the two-year period of analysis, several projects/products are not only included in the Index's scope of analysis as R&D projects, but are also already assessed as products in the companies' portfolios. To be included in the Index portfolio, a product must have received regulatory approval (or EUA), the first necessary step to ensure a product is available.

The Index found that eight of the 20 companies in scope had COVID-19 products in their portfolios, with a combined total of 17 products – including vaccines, therapeutics, diagnostics and platform technologies. Three COVID-19 vaccines are included in the portfolio: AstraZeneca's COVID-19 vaccine ChAdOx1-S [recombinant] (Vaxzevria), Pfizer's BioNTech's COVID-19 mRNA vaccine (nucleoside-modified) (Comirnaty®) and Johnson & Johnson's COVID-19 vaccine (Ad26.COV2-S [recombinant]). Of these three, Johnson & Johnson's was filed most widely for registration in countries in scope of the Index (41), followed by Pfizer's COVID-19 vaccine (37) and AstraZeneca's COVID-19 vaccine (14). Furthermore, for both Johnson & Johnson and Pfizer, their COVID-19 vaccines were the most widely registered of any the products selected from their portfolio for analysis.

This suggests that, despite weak regulatory capacity in many LMICs, pharmaceutical companies were still able to successfully file their COVID-19 vaccines for registration, although much of this was facilitated through EUA in response to the urgency of the pandemic. Going forward, however, companies can explore other facilitated registration pathways to overcome regulatory barriers in order to file other products in their portfolios for registration in LMICs with weak regulatory capacity.

What access strategies were used to ensure COVID-19 vaccines and therapeutics reach LMICs?

Pharmaceutical companies should use access strategies to expand access to key products in their portfolios so that they reach people across LMICs, including those at the base of the income pyramid. Such strategies can include equitable pricing, voluntary licensing, product donations and technology transfer. When setting pricing strategies, companies are expected to aim for affordability, and to integrate a payer's ability to pay for the product in their pricing approach. The Index identified three key mechanisms that companies have used to increase access in LMICs for COVID-19 products: non-exclusive voluntary licensing (NEVL), technology transfers, and supranational procurement agreements.

FIGURE 12 How many companies have COVID-19 products?

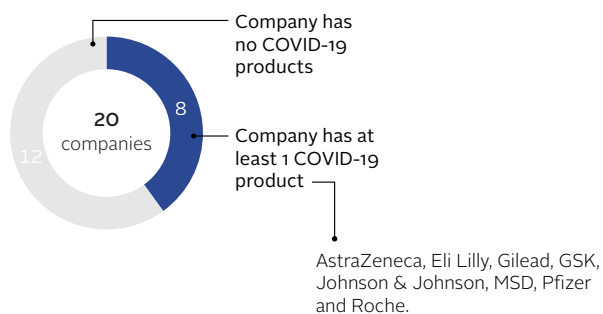
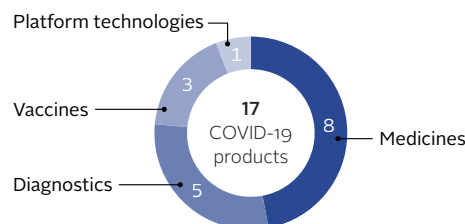


FIGURE 13 What types of COVID-19 products are in companies' portfolios?



PRODUCT DELIVERY

Companies engage in voluntary licensing to enable generic manufacturing, but with limitations

Pharmaceutical companies can engage in voluntary licensing by transferring intellectual property (IP) rights to a licensee, enabling them to produce generic versions of their product under certain terms and conditions. Voluntary licensing agreements can expand availability and affordability by facilitating generic supply, and are particularly valuable for expanding access in countries where the originator company does not intend to market the drug that it has patented.

For companies that hold patents for COVID-19 products, one approach has been to engage in direct licensing agreements to build global manufacturing networks. Another approach has been to agree to voluntary licences through an intermediary such as Medicines Patent Pool (MPP). When a licence is between a company and multiple sub-licensees (generic manufacturers), it is deemed to be a NEVL.

Of the eight companies with COVID-19 products in their portfolios, five (AstraZeneca, Eli Lilly, Gilead, MSD and Pfizer) have engaged in licensing agreements to facilitate access to COVID-19 products.

Voluntary licences for COVID-19 products

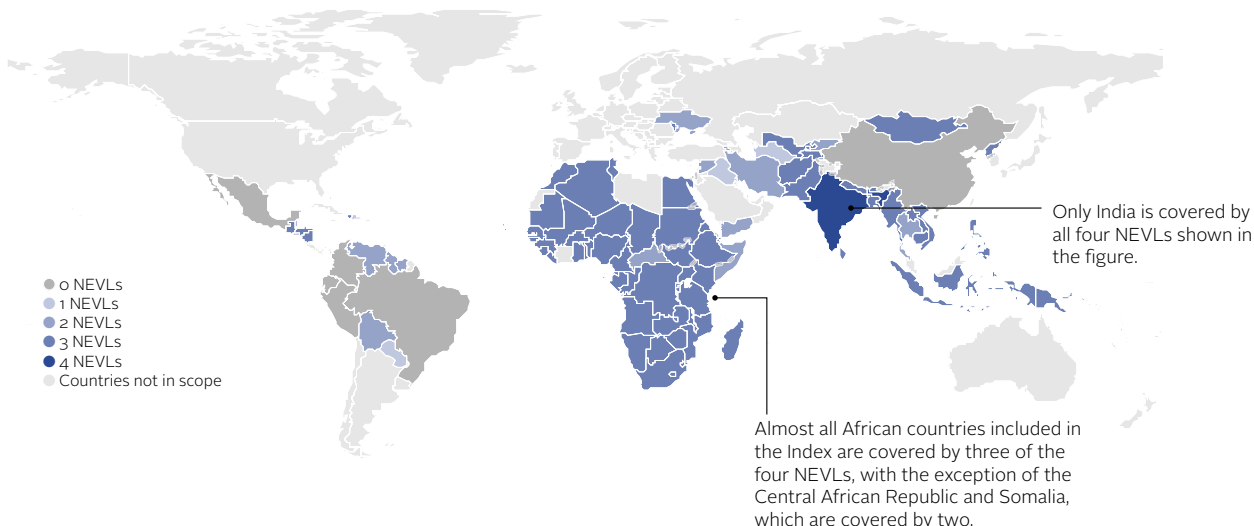
- AstraZeneca pursued a sequence of exclusive voluntary licences with Serum Institute of India, among others, for its COVID-19 vaccine (Vaxzevria). Details of these licences remain private.
- Eli Lilly signed royalty-free voluntary licensing agreements for baricitinib, an oral COVID-19 therapeutic, with three Indian pharmaceutical companies: Cipla, Sun Pharmaceuticals and Lupin.
- Gilead signed a royalty-free voluntary licensing agreement for its injectable antiviral medication remdesivir (Veklury®) with technology transfer included.
- MSD's product molnupiravir (Lagevrio®) was the first oral antiviral to be included in WHO treatment guidelines for COVID-19. MSD signed a NEVL with the MPP when the drug was still in development, before it reached regulatory approval.
- Pfizer signed a NEVL with MPP for nirmatrelvir, one of the compounds in its COVID-19 antiviral nirmatrelvir/ritonavir (Paxlovid®). The company will not receive royalties from sales of nirmatrelvir while COVID-19 is considered a public health emergency of international concern by WHO. After that period, sales to low-income countries will remain royalty free.

Three of the licences analysed (for molnupiravir, nirmatrelvir and remdesivir) include a large number of countries in scope. However, a consistent finding is that upper-middle income countries, such as Colombia, Ecuador and Peru are not included in voluntary licences. This means sizeable low-income populations in these countries will only have access to the more expensive branded version of the drug, without the option of a more affordable generic version.

Furthermore, inclusion of a country in the geographic scope of a licence does not guarantee that generic medicine manufacturers will choose to make use of the licence to manufacture the product and market it in that country. Additional follow-up is required to monitor the uptake and impact of these licences.

FIGURE 14 Which LMICs are covered by NEVLs for COVID-19 products?

This map highlights the number of NEVLs per country in scope of the Index for the four COVID-19 licensing agreements analysed (baricitinib, molnupiravir, nirmatrelvir and remdesivir), showing the countries in which generic medicine manufacturers are able to produce and market the companies' COVID-19 products. Three of these agreements cover at least 80% of the countries in scope of the Index.*



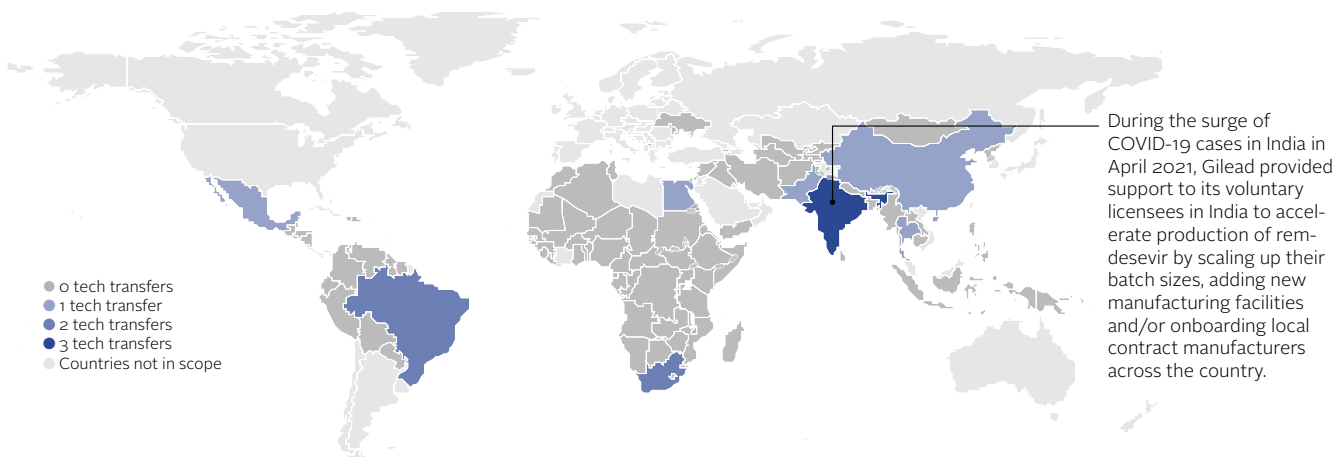
Key developments in transferring technology for COVID-19 products

Technology transfers – i.e., the transfer of manufacturing processes and expertise from the pharmaceutical company to local manufacturers – are a valuable tool in expanding access. The approach boosts the capacity of generic medicine manufacturers to efficiently and effectively manufacture quality-assured medicines and vaccines.

Four companies have transferred technology for COVID-19 products during the period of analysis: AstraZeneca, Gilead, Johnson & Johnson and Pfizer. For example, Gilead transferred technology as part of its NEVL agreement for remdesivir,

FIGURE 15 Technology transfers for COVID-19 are focused in India, Brazil and South Africa

Ten technology transfers were conducted for medicines (1) and vaccines (9) to treat COVID-19. Technology transfers are concentrated in India, Brazil and South Africa.



*Companies submitted information regarding the NEVLs and/or non-assert declarations to the Index for analysis. AstraZeneca's sequence of exclusive voluntary licences was not shown in the graph, as details remain private. Eli

Lilly's licence (baricitinib) is only reported for India.

while AstraZeneca transferred technology to manufacturers in LMICs in combination with its private licensing agreements across a selection of LMICs. AstraZeneca reports technology transfers with more than 20 partners across more than 15 countries, including countries in Asia and Latin America.

The Index finds that technology transfers for COVID-19 vaccines and therapeutics are concentrated in a select few countries, particularly in India, South Africa and Brazil. Within these countries, the third-party manufacturers that receive the know-how to produce these products often have a high level of capacity for manufacturing vaccines and medicines already (e.g., Bio-Manguinhos/Fiocruz, Serum Institute of India and Dr. Reddy's Laboratories).

These technology transfers can help improve the supply of COVID-19 products. They can also help ensure resilience in supply chains in LMICs for future production, including production of other healthcare products. Therefore, companies can do more to ensure that more LMICs with an industrial base have access to these technologies – for example in Senegal, which is already producing COVID-19 vaccines via its Pasteur Institute, or in Algeria, which received a technology transfer to facilitate the production of the Russian COVID-19 Sputnik V vaccine.⁶

PRODUCT DELIVERY

Some – but not enough – company action to ensure procurement and supply of COVID-19 vaccines in LMICs

When participating in pooled procurement, companies supply their products through organisations (supranational procurers), which in turn distribute them internationally to LMICs. Previously, these supranational agreements have been successfully used to improve access to antiretroviral medicines for HIV and products for other diseases of public health concern, such as tuberculosis.

During the pandemic, COVID-19 vaccines have been supplied in LMICs through supranational agreements. The Index analysed the sale of the three COVID-19 vaccines in scope through the COVID-19 Vaccines Global Access (COVAX) programme, a global initiative co-led by WHO, Gavi, the Vaccine Alliance (GAVI) and the Coalition for Epidemic Preparedness Innovations (CEPI), which aimed to accelerate the development and distribution of COVID-19 vaccines.

Despite COVAX's aim to facilitate an equitable global vaccine supply, a disparity in access to vaccines between high-income countries and LMICs persists. Moreover, this pandemic has also shown that the world cannot rely on such procurement programmes alone. Because of this, bilateral agreements are an additional step that companies should take to facilitate access.

AstraZeneca and Johnson & Johnson engaged in technology transfers and licensing agreements to increase supply of their vaccines with local partners. Although Pfizer transferred technology to bolster manufacturing capacity of its vaccine in some countries in scope, the Index did not find evidence that it had engaged in licensing agreements to enable generic supply of its COVID-19 vaccine.

AstraZeneca performs best in the field of technology transfer and licensing, with technology transfers of its vaccine across more than 15 countries, perhaps reflecting the sources of funding for the vaccine; it is reported that 97% of the funding for R&D behind AstraZeneca's vaccine came from public and charitable funds.⁷

In the event of a future pandemic, governments must work with companies to ensure that the terms of supranational procurement agreements are transparent and consider equitable pricing and global access. This could help to reduce disparities and ensure that people globally get the vaccines and treatments they need. However, companies should especially engage in technological transfers and knowledge sharing, as a step in fighting against a pandemic.

TABLE 1: Supranational procurement for vaccines in LMICs

Company	Vaccine	Supranational procurement for LMICs*	Price via COVAX
AstraZeneca	COVID-19 vaccine (Vaxzevria)	<ul style="list-style-type: none"> • One agreement via COVAX facility: COVAX Advance Market Commitment (AMC)** • Four regional sub-licensing agreements, including with the Serum Institute of India 	Cost-based price: 4 USD per dose. Information is available on UNICEF website. Price applies in 91 countries funded by the COVAX Advance Market Commitment.
Johnson & Johnson	COVID-19 vaccine	<ul style="list-style-type: none"> • Three agreements via COVAX facility: COVAX Advance Market Commitment; Procurement agreement; COVAX Humanitarian Buffer*** • Procurement agreement with the African Vaccine Acquisition Trust (AVAT) 	Not-for-profit price: USD 7,50 per dose. Information is available on UNICEF website.
Pfizer	COVID-19 vaccine (Comirnaty®)	<ul style="list-style-type: none"> • One agreement via COVAX facility 	Not-for-profit price; price is not disclosed.

TABLE 2: Examples of national procurement for vaccines in LMICs

Each of the three companies provided an example to the Index about an access strategy being used to expand access to their vaccine in one of the 108 LMICs in scope, outside of the COVAX programme and any other supranational agreements.

Company	Vaccine	Specific country example
AstraZeneca	COVID-19 Vaccine (Vaxzevria)	<p>Brazil</p> <ul style="list-style-type: none"> • Licence and technology transfer to a local manufacturer, the Oswalda Cruz Foundation (Fiocruz). • Brazil is also covered by a COVAX supply agreement, and received 9,122,400 doses of AstraZeneca's COVID-19 vaccine via COVAX in 2021.
Johnson & Johnson	COVID-19 vaccine	<p>South Africa</p> <ul style="list-style-type: none"> • Vaccines were provided via two advance procurement agreements at a not-for-profit price. • Technology transfer agreement with local manufacturer Aspen Pharmacare Limited. • Drug substance supply agreement with Aspen SA Operations (Pty) Ltd.† • Collaboration with local government to make vaccine doses immediately available to healthcare workers via the Sisonke study in South Africa. • Health systems strengthening initiative, including cold chain strengthening initiatives. • While disaggregated bilateral data about patient reach in South Africa has not been made available, the company reports it has shipped approximately 270 million doses to the African continent.
Pfizer	COVID-19 vaccine (Comirnaty®)	<p>Rwanda</p> <ul style="list-style-type: none"> • Supply agreement at not-for-profit price. • Health systems strengthening initiative focused on country delivery readiness. • Covered by COVAX supply agreement. • 7.4 million doses supplied in support of both COVAX and the Rwandan government's vaccination programme.

*The data in this table is not comprehensive, but is based on publicly-available information and data provided by the companies to the Access to Medicine Index.

**The AMC is one strand of COVAX, that finances the supply of COVID-19 vaccines

to LMICs. The AMC is funded by voluntary contributions from richer countries and private donors.

***The Humanitarian Buffer is a novel additional initiative established within the COVAX Facility to act as a measure of 'last resort' to ensure access to COVID-19 vac-

cines for high-risk and vulnerable populations in humanitarian settings.

†The agreement enables Aspen SA Operations (Pty) Ltd, using COVID-19 vaccine drug substance supplied by Johnson & Johnson, to produce Aspen-branded finished vaccine and make doses avail-

able to the public sector in Africa, including all 55 Member States of the African Union and key multilateral entities supporting Africa's COVID-19 vaccination drive, inclusive of the African Vaccine Acquisition Trust (AVAT), and the COVAX Facility.

RESEARCH & DEVELOPMENT

R&D for pandemic preparedness has not increased, despite COVID-19

In July 2022, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) released the Berlin Declaration, in which the pharmaceutical industry pledged to draw on lessons learned from the COVID-19 pandemic to ensure equitable access to vaccines and medicines in future pandemics.⁸ This includes provisions for manufacturing, sustainable supply and accelerating R&D to develop new health products. Collaboration between actors and their awareness of responsibilities is a key component to prepare for the next pandemic. Although it is too soon to measure the impact such a declaration may have on access, the Index has analysed the pipelines of companies in scope to see what products they are developing to target other diseases with the potential to cause a pandemic.

Investment in R&D is important for the development of products which target diseases with epidemic potential. To encourage innovation, the WHO has compiled a list of priority emerging infectious diseases (EIDs) that pose the greatest public health risk due to their epidemic potential and/or lack of measures to counter them. The Index analyses R&D projects for 17 EIDs, based on the priorities identified by WHO and Policy Cures Research.

Among these is 'Disease X', a term which WHO adopted to refer to a pathogen that is currently unknown to cause human disease but could cause a serious international epidemic in the future. In 2020, the emergence of the SARS-CoV-2 virus (COVID-19) was deemed to be the first example of Disease X, since the inception of the term in 2018. The 'Disease X' designation seeks to incentivise cross-cutting R&D that can be easily adapted for emerging strains of infectious diseases, for example, platform technologies or diagnostics. The development of such underlying technologies could facilitate a rapid response to counteract an outbreak should one arise. The Index found that none of the companies in scope have R&D projects in development to target Disease X. This suggests that despite the rapid R&D response to COVID-19 (68 projects for coronaviral diseases), companies in scope are not investing in R&D for projects that could limit the spread of future unknown infectious diseases.

When no product is currently available on the market to sufficiently treat, diagnose or prevent a priority disease, this is defined as a 'product gap.' These products may be medicines, vaccines, diagnostics, medical devices or vector control products. Every company, regardless of size or therapeutic focus, can play a role in addressing these gaps.

FIGURE 16 While significant products have reached the market for some EIDs, the companies in scope have nothing in the pipeline for the majority of priority EIDs

Even though the number of Ebola projects in the pipeline has decreased over the last years, improvements have been made. In July 2020, the Johnson & Johnson preventative two-shot vaccine regimen Zovavax[®] and Mvabea received EMA marketing authorisation for the prevention of Ebola (*Zaire ebolavirus*) species.

Zika is the only disease for which a positive trend can be seen, excluding COVID-19. R&D projects devoted to this infectious disease have increased over the years. In 2020, the WHO prequalified Bayer's Fludora[®] Co-Max. This vector control product, a space spray for indoor and outdoor, can not only prevent the spread of Zika, but also that of dengue and chikungunya by targeting *Aedes* mosquitos.

Disease flagged as an epidemic/pandemic risk	R&D projects			Active companies		
	2018	2021	2022	2018	2021	2022
Arenal haemorrhagic fevers (incl. Lassa fever)	0	0	0	0	0	0
Chikungunya	3	4	5	3	4	3
Criean-Congo haemorrhagic fever (CCHF)	0	0	0	0	0	0
Ebola virus disease (EVD)	7	5	4	5	4	1
Emergent non-polio enteroviruses (incl. EV71, D68)	1	1	0	1	1	0
Marburg viral disease (MVD)	1	1	0	1	1	0
Middle East respiratory syndrome coronavirus (MERS-CoV)	0	0	0	0	0	0
Nipah	0	0	0	0	0	0
Bunyaviral diseases (other than CCHF, RVF and SFTS)	0	0	0	0	0	0
Filoviral diseases (other than EVD and MVD)	0	0	0	0	0	0
Henipaviral diseases (other than Nipah)	0	0	0	0	0	0
COVID-19 and other coronaviral diseases (other than SARS and MERS-CoV)	0	63	68	0	17	17
Rift Valley fever (RVF)	0	0	0	0	0	0
Severe acute respiratory syndrome (SARS)	0	0	0	0	0	0
Severe fever with thrombocytopenia syndrome (SFTS)	0	0	0	0	0	0
Zika virus disease	3	4	7	3	4	4
Disease X*	0	0	0	0	0	0

*Disease X', added to this list in 2018, represents the knowledge that a serious epidemic or pandemic could be caused by a pathogen currently unknown to cause human disease. COVID-19 can be seen as a first example of Disease X.

Out of the 20 companies in scope, only five – Bayer, Johnson & Johnson, Merck, MSD and Takeda – engage in R&D efforts for EIDs other than COVID-19. There are currently no projects in development for 13 of the 17 priority EIDs analysed by the Index, meaning that many product gaps remain unaddressed. For example, for Lassa fever, G-FINDER and WHO recommend a preventative vaccine to be developed which can protect for at least three years in healthy adults and children, against all four strains.⁹ Unfortunately, no such vaccine exists and no companies in scope of the Index target this EID.

This disparity indicates that, although companies responded quickly to develop COVID-19 products, the world remains ill-equipped to prevent future epidemics caused by other priority diseases. For companies in scope, the number of projects targeting some EIDs has remained relatively stable since the last Index.

Despite R&D gaps for most priority EIDs going unaddressed, companies have made some important advancements in addressing two diseases with epidemic potential during the period of analysis. Both products are accompanied by a robust plan to overcome barriers to access in LMICs.

What access issues should companies consider when developing products to prevent future epidemics and pandemics?

When developing products to combat infectious diseases, companies should consider factors that may hinder the supply, storage and administration of vaccines or therapeutics in LMICs. As observed with the COVID-19 vaccines, there are many factors which can impede vaccination campaigns. This includes complicated multi-dose regimens, ultra-cold chain storage requirements and routes of administration that require skilled health workers. To overcome such obstacles, a product should ideally be easily administrable and heat stable. For example, despite having a lower efficacy than mRNA vaccines, the single-dose Johnson & Johnson COVID-19 vaccine offered advantages in terms of ease of use and storage in LMICs.⁴ The Index identified one sublingual vaccine in development for COVID-19 during the period of analysis, i.e., a vaccine that could be dissolved under the tongue; this route of administration offers many advantages to people living in LMICs with weak health systems, as it does not need to be administered by health professionals.

To address these challenges and the development of health products, WHO lists target product profiles (TPPs) and product profile characteristics (PPCs) in its R&D Roadmaps. These outline the desired 'profile' or characteristics of a target product that is aimed at a particular EID, including potential new vaccines for MERS-CoV and Zika virus disease.¹⁰

How can industry contribute to pandemic preparedness?

The COVID-19 pandemic has shown that companies have the capacity to rapidly shift R&D focus to quickly develop new products when required. While urgent investments to develop COVID-19 vaccines and therapeutics were necessary, companies should now use this opportunity to work with global health stakeholders and shift focus to develop products for other infectious diseases with the potential to cause outbreaks.

Furthermore, companies need to put the lessons learned in the COVID-19 pandemic into practice and consider barriers to access during R&D and beyond. This includes developing heat-stable formulations, easily administrable products and planning for access in the early stages of development. Pricing, procurement and supply must also be considered to ensure equitable access. With infectious diseases with pandemic potential, the issue of equitable access is even more pertinent because “no one is safe until everyone is safe”.

Conclusions

The rapid development and authorisation of medicines and vaccines for COVID-19 indicates that the pharmaceutical industry is willing and able to respond quickly to public health emergencies. However, the disparity in vaccination rates between high-income countries and low-income countries highlights the inequitable supply of COVID-19 vaccines in LMICs. Although there are multiple obstacles to the supply of vaccines in LMICs, some companies work to improve access by engaging in equitable access strategies for their products.

The industry can also build on its successful approaches to equitable access during the COVID-19 pandemic and expand these approaches to other products and countries. This includes engaging in more non-exclusive voluntary licensing and technology transfers.

Although the COVID-19 pandemic is still ongoing, companies must address gaps that exist for the prevention and treatment of other potential EIDs by engaging in more R&D. Even when no public investment in R&D is involved, pharmaceutical companies should plan early on to ensure any innovations are easily accessible in LMICs.

REFERENCES

1. United Nations International Children's Emergency Fund (UNICEF). COVID-19 pandemic leads to major backsliding on childhood vaccinations, new WHO, UNICEF data shows. Published July 15, 2021. Accessed August 4, 2022. <https://www.unicef.org/press-releases/covid-19-pandemic-leads-major-backsliding-childhood-vaccinations-new-who-unicef-data>
2. World Health Organization. *World Malaria Report 2021*; 2021. Accessed October 11, 2022. <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2021>
3. Watson OJ, Barnsley G, Toor J, Hogan AB, Winskill P, Ghani AC. Global impact of the first year of COVID-19 vaccination: a mathematical modelling study. *Lancet Infect Dis*. 2022;0(0). doi:10.1016/S1473-3099(22)00320-6/ATTACHMENT/CF5CA979-59F2-496B-81AB-FB356D7881BD/MMC1.PDF
4. Wouters OJ, Shadlen KC, Salcher-Konrad M, et al. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. *Lancet*. 2021;397(10278):1023. doi:10.1016/S0140-6736(21)00306-8
5. Chapman N, Doubell A, Tuttle A, et al. G-FINDER - *Landscape of Emerging Infectious Disease Research and Development: From Pandemic Response to Pandemic Resilience*; 2022
6. Loembé MM, Nkengasong JN. COVID-19 vaccine access in Africa: Global distribution, vaccine platforms, and challenges ahead. *Immunity*. 2021;54(7):1362. doi:10.1016/j.IMMUNI.2021.06.017
7. Cross S, Rho Y, Reddy H, et al. Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine? *BMJ Glob Health*. 2021;6(12):e007321. doi:10.1136/bmjgh-2021-007321
8. International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). *Berlin Declaration Biopharmaceutical Industry Vision For Equitable Access In Pandemics*; 2022. Accessed July 22, 2022. <https://www.ifpma.org/resource-centre/berlin-declaration-biopharmaceutical-industry-vision-for-equitable-access-in-pandemics/>
9. Chapman N, Doubell A, Tuttle A, et al. G-FINDER | Landscape of Emerging Infectious Disease Research and Development: Preventing the Next Pandemic.; 2020. Accessed July 5, 2022. https://s3-ap-south-east-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/09/16021708/EID20_Report_Web_1_FINAL.pdf
10. World Health Organization (WHO). Research and Development (R&D) Roadmaps. Accessed October 27, 2022. <https://www.who.int/teams/blueprint/r-d-roadmaps>

SPECIAL REPORT: WOMEN'S HEALTH AND SRHR

Are pharma companies addressing sexual and reproductive health access barriers for women and girls?

Sexual and Reproductive Health and Rights (SRHR) are human rights for all people. However, the ability to exercise these rights is not accessible for all. SRHR range from having access to safe, effective and affordable forms of contraception, access to skilled healthcare providers and services to support safe pregnancies and births, to access to treatments and products for various sexual and reproductive diseases and health needs. SRHR are a key component to achieving the Sustainable Development Goals (SDGs) set by the United Nations General Assembly and Universal Health Coverage set by the World Health Organization (WHO). To achieve these by 2030, action needs to focus on ensuring women and girls, no matter where they live, have access to medicines, products and services for sexual and reproductive health.

Although addressing SRHR requires global efforts from various stakeholders, pharmaceutical companies have a key role to play.

This Special Report in the 2022 Access to Medicine Index highlights critical areas where companies can do more to address access issues for SRHR-related diseases and health needs impacting women and girls. The diseases and health needs covered were selected based on existing definitions of SRHR, with a focus on those that disproportionately impact women and girls in low- and middle-income countries (LMICs). It examines the extent to which companies are conducting research on new products and formulations for SRHR-related health needs, as well as strategies companies are applying in LMICs to make products accessible through mechanisms such as registration and pricing strategies. The report also analyses company capacity building efforts and engagement in inclusive business models that reach women and girls living in LMICs.

CONTEXT

SRHR and women's health is a critical priority for expanding access to medicine

In the past half century, progress has been made to improve women and girls' access to SRHR (Sexual and Reproductive Health and Rights) products, services and information, but stark inequalities persist both within and between countries that prevent women from realising their full rights to health.¹ Particularly in low- and middle-income countries (LMICs), women's health services, specifically SRHR services, are often not provided at a level of quality that meets minimum medical and human rights standards.² The COVID-19 pandemic and related mitigation efforts have also disrupted access and utilisation of sexual and reproductive health services such as contraceptive services, testing for sexually transmitted infections (STIs) and safe abortion services.³

In many LMICs, women's ability to attain SRHR services may be impacted by several barriers, such as a lack of trained staff, limited access to epidemiological data, or inability to source or fund supply of medicines and contraceptives. These barriers exist alongside gaps in research and development (R&D) for some SRHR-related diseases and health needs, for example new products or adaptations that would be suitable for women living in LMICs.⁴

However, global shifts are in motion, with the United Nations identifying universal access to SRHR as a global health priority and its inclusion in the 2030 agenda for Sustainable Development.⁵

SRHR should be afforded to everyone regardless of gender. However, the Access to Medicine Foundation is focusing on women's health in this report given the impact of gender inequality on the sexual and reproductive health of women and girls and the need for increased focus and improvements within the space.⁷

Defining the scope of this Special Report on SRHR of women and girls

Under its broadest definition, Sexual and Reproductive Health and Rights include the rights to the prevention and treatment of sexually transmitted infections (STIs), including HIV/AIDS, and other genitourinary diseases; affordable and acceptable methods of contraception; effective services for healthy pregnancy and birth; prevention and management of reproductive cancers; safe abortion and post-abortion care; safe and hygienic management of menstruation; and management of sub-fertility, infertility and other fertility issues. It also extends to concepts of care and services related to sexuality and sexual and/or gender identity, sexual dysfunction, and gender-based and intimate partner violence.^{4,6}

TABLE 3 Products and R&D projects that target SRHR-related diseases and health needs

Of the 83 diseases and health needs in scope of the Index, 19 (23%) are related to SRHR. Of the total 1,060 projects in the pipeline, 171 (16%) address SRHR-related diseases and health needs and of the 740 products in the portfolio, 176 (24%) are related to SRHR diseases and health needs.

SRHR-related diseases and health needs in scope of the Index		Approved products in portfolio	R&D projects in pipeline
Hypertensive disorders of pregnancy		3	0
Maternal abortion and miscarriage		1	0
Maternal sepsis		3	2
Obstructed labour		0	0
Maternal haemorrhage		3	2
Contraceptive methods		17	1
Endometriosis		6*	3
STIs	Chlamydia	1*	2*
	Gonorrhoea	2*	3*
	HTLV-1	0	1
	HSV-2	0	0
	Syphilis	1	0
	Hepatitis B	17*	22
	HIV/AIDS	62*	30
M. genitalium		0	2*
Uterine cancer		0	13*
Ovarian cancer		17*	36*
Breast cancer		47*	62*
Cervical cancer (including HPV-related)		10*	20*
All diseases/health needs		176	171

*One or more of these projects/products may be indicated for multiple disease areas (e.g., a treatment for both endometriosis and cancer, or a diagnostic for both chlamydia and gonorrhoea) and therefore may be included more than once in the

table. The total overall number of products/projects is given in 'All diseases/health needs'.

RESEARCH & DEVELOPMENT

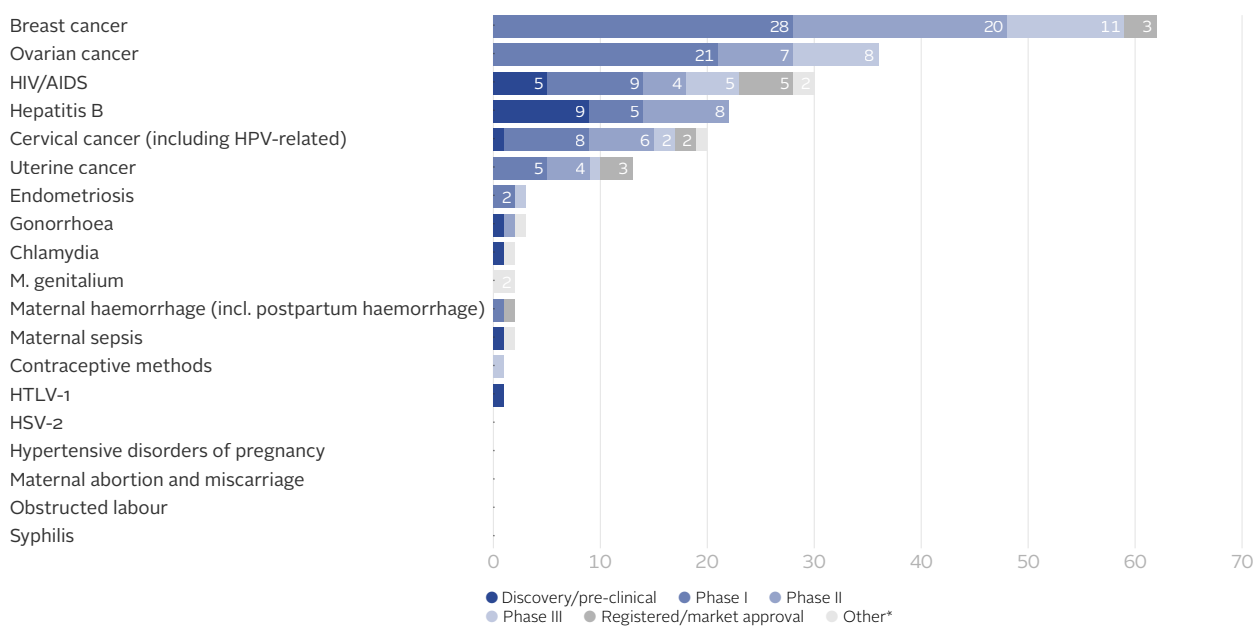
R&D projects and priorities for SRHR – what are companies doing to fill the gaps?

Cancers (i.e., breast, ovarian, cervical and uterine) are a well-addressed category within the SRHR-related diseases and health needs in scope of the Index, with 105 (60%) projects in the SRHR pipeline targeting one of these cancer types. However, of the four cancer types, breast and ovarian cancer account for the highest number of projects. This finding mirrors the makeup of the pipeline for all diseases in scope, where companies invest resources into developing products for non-communicable diseases (NCDs), where significant commercial potential is more likely in comparison to other diseases and health needs like contraceptives or maternal health conditions.

R&D for some SRHR-related diseases and health needs in scope of the Index is particularly under-resourced. For example, five diseases and conditions are not addressed at all by any R&D project. Conditions related to maternal health are especially underrepresented, with just four projects split between maternal haemorrhage and maternal sepsis.

FIGURE 17 **Almost all SRHR-related pipeline projects are directed towards cancer types, HIV/AIDS and hepatitis B**

All SRHR projects, split per phase of development:



Opportunities for R&D efforts to address specific therapeutic gaps in SRHR

An R&D 'product gap' exists when there is an urgent need but low commercial incentive to engage in R&D for products to sufficiently treat, diagnose or prevent a disease or condition. Examples of product gaps for SRHR include human papilloma-virus (HPV) diagnostics and medicines for postpartum haemorrhage.

A Policy Cures Research report on R&D for SRHR identified several product gaps specific to LMICs for SRHR conditions and health needs through an in-depth consultation with an expert advisory group.⁴ Eleven SRHR diseases or health needs in scope have R&D product gaps; HPV-related cervical cancer, hypertensive disorders of pregnancy (pre-eclampsia), maternal haemorrhage (postpartum haemorrhage), STIs (particularly hepatitis B, herpes simplex virus type 2 (HSV-2), chlamydia, gonorrhoea, syphilis, human T-cell lymphotropic virus type 1 (HTLV-1) and HIV/AIDS),

Other is defined as projects which follow a different development cycle than R&D projects which target the treatment of a disease, such as a technical lifecycle for devices.

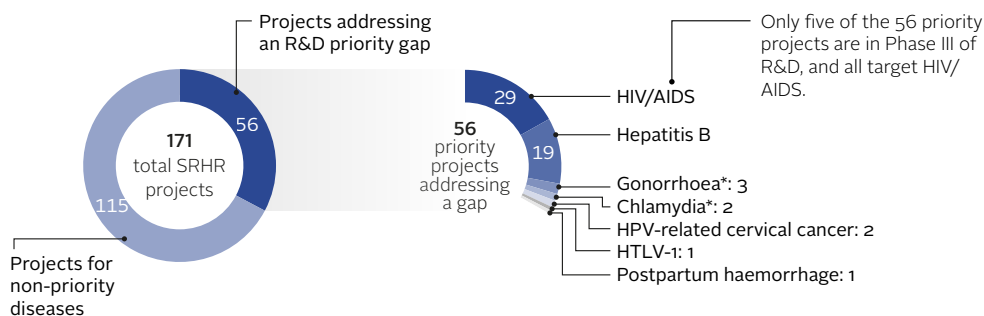
and contraceptives. The Index defines R&D projects in the pipeline that address product gaps as 'priority projects.'

Of the 171 SRHR-related projects in the R&D pipeline, 56 are projects in development that address product gaps for a priority disease (see Appendix I). The remaining R&D projects address other SRHR diseases in scope such as ovarian cancer.

To ensure the necessary therapeutics can be developed and ultimately reach more women and girls, more companies need to invest in R&D for SRHR-related diseases and health needs. Currently, only eight of the 20 companies included in the Index are conducting R&D for gaps in any of these therapeutic areas. These companies are AbbVie, Daiichi Sankyo, Gilead, GSK, Johnson & Johnson, MSD, Roche and Sanofi.

FIGURE 18 Almost all SRHR priority projects in the pipeline are directed towards HIV/AIDS and hepatitis B, while many other diseases remain unaddressed

There are 56 priority projects in the pipeline targeting at least one R&D gap covering six different SRHR-related priority diseases or health needs. There are no projects that address HSV-2, pre-eclampsia and syphilis, although they are diseases or health needs with R&D product gaps.



Missing R&D for products targeting STIs and HPV-related cervical cancer

Research is currently underway to address certain gaps (e.g., a preventative chlamydia vaccine), however, many gaps are unaddressed – such as therapeutic vaccines and medicines for HPV-related cervical cancer. Although HIV/AIDS and hepatitis B comprise 30% of all SRHR projects in the pipeline, there are no projects in development to address two of the identified product gaps – namely, microbicides for HIV and diagnostics for hepatitis B. There are also no R&D projects currently in development targeting product gaps for HSV-2 (commonly referred to as genital herpes), due to the termination of a project to develop a preventative vaccine for the virus.

Addressing specific R&D gaps for maternal health could reduce mortality in LMICs

Maternal mortality rates are disproportionately high in low-income countries, with an average of 462 deaths per 100,000 live births, compared with an average of 11 deaths per 100,000 in high-income countries.⁸ Several factors influence this, including distance to hospitals, inadequate healthcare services and a lack of access to existing medicines.

While addressing health system barriers is an important step in addressing high maternal mortality, R&D investment is also a key element that can help in this regard. One key gap in R&D for maternal health is for diagnostics for pre-eclampsia. None of the companies in scope have priority projects addressing this gap. An accurate diagnostic suitable for use in LMICs could lead to earlier detection and appropriate

*There is one diagnostic project in the pipeline targeting both chlamydia and gonorrhoea.

management of the condition, including timely referral, reducing rates of mortality.

Another notable R&D product gap is for products to treat postpartum haemorrhage, the leading cause of maternal deaths. Currently, treatment for this condition requires intravenous or intramuscular administration of oxytocin by a skilled healthcare worker.⁴ A new formulation is needed that is both heat stable and can be easily and quickly administered as an alternative. Currently, among the companies in scope, there are no projects in development to address this need. However, through Merck for Mothers, MSD collaborated with Ferring Pharmaceuticals and WHO to support the advancement of Ferring's proprietary and investigational heat-stable carbetocin, for the prevention of postpartum haemorrhage. It's well-suited to use in LMICs as it can be stored and transported at much higher temperatures than oxytocin, and it was added to the 21st WHO Model List of Essential Medicines. It addresses part of the gap with its heat stability, but still needs to be administered intramuscularly. While a step in the right direction, companies can take further steps to address gaps in ease of administration.

Spotlight on clinical research during pregnancy

Pregnant and lactating women have been historically excluded from clinical trials for non-obstetric conditions, with safety concerns, ethical and legal considerations cited as reasons for their exclusion.⁹ As a result, the body of evidence to support clinical decision-making for medicines used during pregnancy is lacking, despite many women still needing and using medically necessary medicines throughout the course of their pregnancy.¹⁰ The underrepresentation of pregnant women in clinical trials means that the mechanism by which physiological changes in pregnancy alter the absorption and metabolism of medicines is poorly understood.¹¹

In 2021, the World Health Organization (WHO), alongside the International Maternal Paediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and the International AIDS Society, issued a call to action to accelerate the study of new medicines for HIV in pregnant and breastfeeding women.¹² The report makes several recommendations for how the pharmaceutical industry can play its part to close the knowledge gap created by the exclusion of pregnant women from clinical research.

PRODUCT DELIVERY

Registration of many products in LMICs is lacking, but positive exceptions for essential HIV/AIDS medicines and contraceptives

The Index looks at how companies are utilising mechanisms such as registration and pricing strategies to improve access to their products in LMICs.

Despite standout examples, many SRHR-related products are not widely filed for registration in LMICs

Filing for registration with a national regulatory authority is the first step required to gain 'approval' before a product is launched on the market. Despite a high disease burden and unmet healthcare needs for SRHR-related products in LMICs, some products may never receive regulatory approval in countries in scope. When a product is not registered in a country, it limits choice and potentially leaves women and girls without essential and life-saving SRHR products.

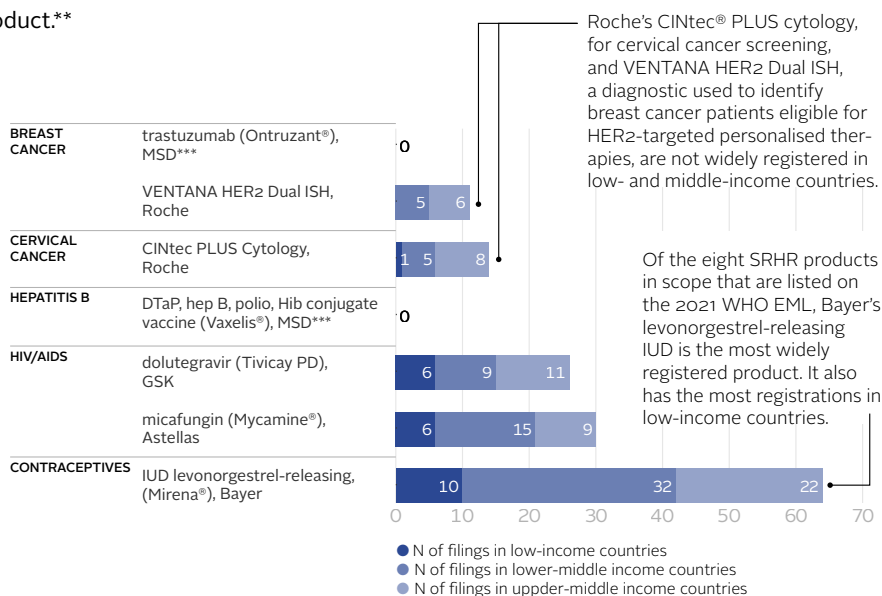
Of the 190 products analysed in the Index in terms of registration data, 39 were for SRHR-related diseases and health needs.* In general, older products like Bayer's levonorgestrel-releasing intrauterine system (Mirena®), which received its first global regulatory approval in 1990, are most widely registered in LMICs. The levonorgestrel-releasing intrauterine system is a form of long-term contraception, and is the most filed product within the SRHR-related scope of the Index, with a total of 64 filings in LMICs.

Although more recently-launched products are less widely registered across LMICs, some examples of good practice are seen. For example, trastuzumab/hyaluronidase-oysk (Herceptin Hylecta™) from Roche, approved by the US FDA in 2019, has been filed for registration in 58 countries within the scope of the Index.

Data analysed by the Index on which products have been registered, and where, suggests that – of the countries in scope – companies are most likely to register their products in middle-income countries. Only 18 (46%) out of the 39 products have been filed for registration in any low-income countries. For example, Uganda has 11 products filed, while Mozambique has 5 and both Ethiopia and Rwanda have 4. Although several barriers may make registration in some countries more challenging, companies should now ensure more SRHR products are filed consistently across low-income countries, with a particular focus on the countries with a high burden of the disease targeted by their particular product.**

FIGURE 19 Number of registration filings in LMICs for SRHR-related products defined as “essential” by the World Health Organization

Among the products in scope of this analysis, eight are on the WHO Model List of Essential Medicines (EML), which is a list of the medicines considered to be most effective and safe to meet the most important needs in a health system. The companies have marketing rights for seven of these products. This figure shows the number of the 108 LMICs in which these products are filed for registration, broken down by whether the filing is in a low-, lower-middle or upper-middle income country.



*A maximum of ten recently-launched products were included in the Index for analysis of product registration. As some newer products are not indicated for SRHR-related diseases and health needs, information is not available for all 176 products in scope of this special report. For Eli

Lilly and MSD the exact registration status of their latest products within LMICs could not be reported as no data was provided/verified or available in the public domain during the period of analysis.
 **High disease burden countries are those that are among the ten countries with

the highest disability-adjusted life year (DALY) value, for any particular disease. One DALY equals one lost year of healthy life, allowing for an estimation of the total number of years lost due to specific causes (e.g., diseases and injuries).

***No data about filings for Ontruzant® and Vaxelis® was submitted by MSD, and no evidence was found in the public domain. DTaP: Diphtheria, tetanus pertussis (acellular, component); hep B: hepatitis B; polio: poliomyelitis; Hib: Haemophilus type b.

Recent steps forward on registering HIV/AIDS products where the need is greatest, but mixed picture overall

Some companies have performed well on registering their HIV/AIDS products in countries with a high burden of the disease, but some key products are not registered in the countries where the need is greatest. The ten countries with the highest burden of HIV/AIDS (among adults) are Lesotho, Eswatini, Mozambique, South Africa, Botswana, Equatorial Guinea, Namibia, Zimbabwe, Zambia, and the Central African Republic.

Both emtricitabine/tenofovir alafenamide (Descovy®) from Gilead and dolutegravir (Tivicay PD) from GSK (via its majority-owned business specialising in HIV products, ViiV Healthcare), have recently been filed for registration in seven high disease burden countries. Specifically, dolutegravir has been filed for registration in these countries within two years of being approved by the US FDA.

However, for the remaining HIV/AIDS products in scope, five have all been filed in less than three of the ten countries with the highest burden of disease, while the remaining eight products have not been filed in any of these ten countries.

PRODUCT DELIVERY

What are companies doing to ensure their SRHR products are available and affordable?

Access strategies are ways in which companies can make sure their products reach the people who need them. Companies should put strategies in place for their products to increase availability, affordability and supply in LMICs, ensuring these strategies are tailored for both the product and the country.

Products in scope of this analysis

This Special Report analyses access strategies for 44 products indicated for SRHR-related diseases and health needs, looking at the products that have been sampled from companies' portfolios according to the Index methodology. All the companies in scope have at least one product included in this analysis, with the exception of Boehringer Ingelheim, Merck and Novo Nordisk. Of these products, 17 are analysed as supranationally-procured products. The other 27 are analysed in terms of companies' strategies to ensure access to the product to individual countries.

What is pooled procurement and which companies participate?

Supranational procurement agreements are pooled procurement mechanisms whereby large volumes of health products are purchased by an organisation for supply in multiple countries. This is an important mechanism to ensure a sufficient supply of affordable SRHR-related products are available in LMICs, especially the poorest countries.

Eight of the companies in scope – AbbVie, Bayer, Bristol Myers Squibb, Pfizer, GSK, MSD, Roche and Johnson & Johnson – engage in international agreements for the procurement of SRHR products. Between them, they work with organisations including Gavi, the Vaccine Alliance (Gavi); the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund); UNITAID; Clinton Health Access Initiative (CHAI); and the Pan American Health Organization (PAHO).

Supranational procurement of HPV vaccines to prevent cervical cancer

In 2020, an estimated 90% of global deaths from cervical cancer occurred in LMICs,¹³ where access to preventative products such as the HPV vaccine are limited. In an effort to reduce the number of women dying from this preventable disease, 41 countries in scope have introduced national HPV immunisation programmes. Two companies in scope (GSK and MSD) supply HPV vaccines to countries in scope of the Index through Gavi's pooled procurement mechanism. Programmes such as Gavi's play an important part in reducing deaths from cervical cancer.

It is important that companies consider the access needs of people living in countries that do not qualify for Gavi support. For example, due to the high cost of the vaccine, non-eligible countries may face challenges in budgeting for vaccination programmes. In recognition of this, both GSK and MSD have agreed, with conditions and for a limited timeframe, to continue to support countries that have transitioned from Gavi by providing HPV bivalent vaccine (Cervarix®) and HPV quadrivalent vaccine (Gardasil®), respectively, at the same price they were accessed when supported by Gavi.

GOOD PRACTICE

GSK's supranational procurement strategy for its HPV vaccine

GSK's HPV bivalent vaccine is supplied through supranational agreement via Gavi. GSK applies tiered pricing for this product, based on World Bank income classifications (whether a country is high-, upper-middle, lower-middle or low-income), with countries eligible for Gavi's programme eligible for the lowest price for the vaccine.

GSK has also committed to applying the same terms of the agreement to countries that have transitioned out of the Gavi programme (e.g., if they have moved into a different income classification) and therefore don't receive the lowest cost for vaccines. GSK also applies an equitable pricing strategy in South Africa, a country not eligible for Gavi support, by offering its HPV bivalent vaccine to the Ministry of Health via a tender process. Since South Africa's HPV immunisation programme began in 2014, GSK has won all tenders based on the cost of vaccines.

Access to contraceptives through supranational procurement and pricing strategies

In 2019, it was estimated that of the 1.1 billion women of reproductive age that have a need for family planning, 270 million still had an unmet need for contraception.¹⁴ Access to contraception is important to prevent unwanted pregnancy and pregnancy-related health risks for women living in LMICs. Pregnancy-related health risks disproportionately impact women in LMICs, where an estimated 94% of maternal deaths occurred in 2017.¹⁵

Global access to contraception is increasing, with the United Nations Population Fund (UNFPA), the world's largest supranational procurer of contraceptives, reporting that an additional 60 million women and girls were using modern contraceptives in 2020 compared to 2012 via its supranational agreements and public-private partnerships.

GOOD PRACTICE

Bayer's participation in supranational procurement for Jadelle®

Bayer is the biggest supplier of contraceptives to UNFPA, accounting for 11% of UNFPA procurement in 2021.¹⁶ Bayer supplies its levonorgestrel-releasing implant (Jadelle®), a long-acting reversible contraceptive (LARC) that provides contraception for up to five years. Within the last ten years the annual volume of the levonorgestrel-releasing implant has quadrupled and in total more than 49 million implants have been provided to the world's poorest countries. This is important as LARCs, including implants, can be a safe and cost-effective alternative to short-acting contraceptives.

GOOD PRACTICE

Pfizer's participation in supranational procurement for Sayana Press®

Pfizer supplies subcutaneous depo medroxyprogesterone acetate (Sayana Press®), a LARC providing at least 13 weeks of contraception, through Family Planning 2030 (FP2030). Subcutaneous depo medroxyprogesterone acetate has several characteristics that make it well suited for low-income countries, particularly its potential for self-administration, its length of contraceptive cover, compact and discreet size, and shelf life at room temperature.

Although supranational procurement agreements are important means of providing access in the world's poorest countries, these agreements are often limited to a small group of products for women's health conditions – particularly contraceptives, HIV/AIDS medicines and diagnostics and HPV vaccinations.

NCDs, such as breast and uterine cancer, have so far not been included in supranational procurement agreements. Therefore, to ensure access in LMICs, companies should particularly pursue access strategies – outside of supranational agreements – to ensure their NCD products reach these countries.

Examining access strategies and equitable pricing for SRHR-related products

It is important that companies tailor access strategies to overcome barriers to access that are specific to the country. This means considering challenges presented by weak health and regulatory systems in LMICs. A good access strategy has equitable pricing that considers the ability to pay of different buyers (both public and private) in all contexts (between upper-middle, lower-middle and low-income countries, and also between countries) and additional non-pricing initiatives to maximise the reach of low-income patients.

Lack of access strategies for oncology products, especially in low-income countries

Although the quality of access strategies varies across products and countries, the Index found that in low-income countries, companies consistently do not have access strategies in place for some SRHR products. Weak health systems, lack of regulatory capacity and inadequate funding pose challenges to reaching patients in low-income countries.

This gap in access is particularly pronounced for oncology products, especially breast cancer. The Index analysed access strategies for 14 breast cancer products, of these 11 (78%) did not have an access strategy in any low-income country in scope. Products for HIV/AIDS and hepatitis B are more likely to be covered by access strategies in low-income countries. Of the combined total of six products for these indications that are included in this analysis, five products had an access strategy in at least one low-income country.

Companies could consider non-exclusive voluntary licensing for key breast cancer products

Despite the complexities in accessing markets in low-income countries, companies can think beyond traditional routes to provide access to these patients. One mechanism to achieve this is non-exclusive voluntary licensing, where, under certain terms and conditions, the company agrees to allow sub-licensees to manufacture and sell generic versions of their products in LMICs. Currently, the only non-exclusive voluntary licences addressing the SRHR diseases in scope of this report are for HIV.

The Medicines Patent Pool (MPP) is an intermediary that facilitates licensing agreements between pharmaceutical companies and generic manufacturers, and it has identified three products to treat breast cancer. Where gaps in access for these products exist, voluntary licensing through MPP would lead to substantial public health impact. The products identified include ribociclib (Kisqali®) from Novartis, abemaciclib (Verzenio®) from Eli Lilly and palbociclib (Ibrance®) from Pfizer.

GOOD PRACTICE

Novartis's access strategies for its maternal haemorrhage product

For its product methylergonovine maleate, for maternal haemorrhage, Novartis can demonstrate examples of good access strategies in at least one upper-middle income country (Colombia), a lower-middle income country (India) and a low-income country (Togo).

Although the strategies implemented in Colombia and India are more comprehensive, Novartis does report some efforts to improve affordability in Togo.

In Colombia, the product is included in the national Health Benefit Plan and is offered to patients at no cost. Novartis's price is based on budget impact and prices in external reference countries. In India, in addition to pricing strategies, Novartis manufactures locally and has eliminated promotional investments to decrease cost to the patient.

Togo's national health authority is responsible for setting the price of methylergonovine maleate (Methergine®), and patients pay out of pocket in the private channel. Novartis reports that during price negotiations with the government, local affordability was considered.

Methylergonovine is also included in the list of essential medicines.

PRODUCT DELIVERY

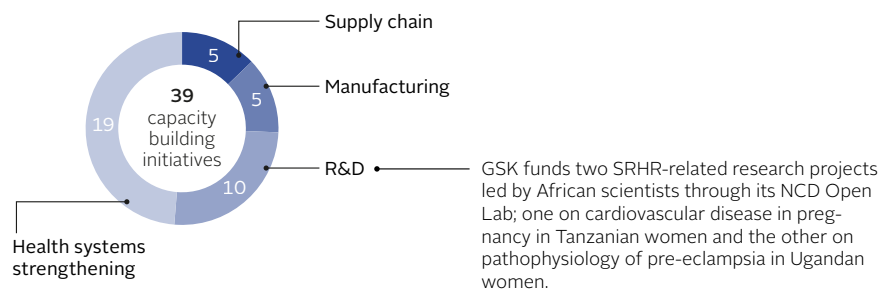
What are companies doing to ensure the uptake of SRHR products and care in LMIC health systems?

In addition to developing and researching new products, capacity building is another way companies can help improve access to medicine and address issues in the availability and accessibility of SRHR products. Health systems, supply chains, and manufacturing capacity within LMICs should be equipped for delivering SRHR treatments to women and girls. Companies can also build R&D capacity in LMICs to develop medicines and vaccines for SRHR-related products.

What kinds of capacity building initiatives are companies involved in for SRHR?

FIGURE 20 Engagement in capacity building for SRHR varies across fields

While companies are engaged in multiple health systems strengthening initiatives for SRHR, fewer examples are seen for supply, manufacturing or R&D capacity building initiatives.



Health systems strengthening to address uptake of SRHR products

Of the capacity building efforts assessed in the Index, health systems strengthening initiatives are the most common way that companies address SRHR-related diseases and health needs, with 11 companies involved in a combined total of 19 initiatives. Through initiatives like MSD for Mothers, Takeda and World Vision's Healthy Village programme, or Roche's involvement with NJIA, companies are addressing health system gaps, such as lack of trained healthcare workers and lack of disease awareness.

MSD for Mothers began in 2011 and has the largest country reach out of all the SRHR-related capacity building initiatives seen in the Index, targeting 31 LMICs in scope of the Index. It is a USD 650 million global initiative that contributes the company's scientific and business expertise and financial resources to address preventable maternal deaths through supporting quality maternity care and access to modern contraception. MSD has worked with more than 150 collaborators and has reached over 18.2 million women globally through its programmes that aim to support safe, high-quality and respectful maternal care.

Notably, 11 of the 19 health systems strengthening initiatives for SRHR are active in a single country. Especially when outcome measurements show impact like reduced maternal mortality or improved patient awareness, companies can now act to scale up their health systems strengthening efforts to reach more women and girls in countries with high disease burden or unmet health needs.

Companies can help address supply chain barriers through capacity building

Fewer examples are seen of companies engaging in supply chain capacity building, despite supply being a major barrier to accessing SRHR products. Although several supply barriers require efforts from governments and other local stakeholders, some companies are performing well in capacity building, by supporting efforts from local and international actors.

Supply chain issues like a lack of trained staff and weak information systems pose a threat to the continuous supply of contraceptives in LMICs. Several agencies

like UNFPA are actively working in LMICs and low-income countries to support supply of contraceptives in addition to other SRHR products. However, such agencies rely on partnerships with pharmaceutical companies, who supply the necessary products and greatly impact product availability, affordability, and uninterrupted supply. Four companies engaged in supply chain capacity building specifically targeting SRHR-related diseases and health needs, three of which report working directly with the UNFPA. For example, Bayer is one of the three suppliers of implants and oral contraceptives for the Reproductive Health Supply Coalition’s (RHSC), Global Family Planning Visibility and Analytics Network (GFP-VAN) and participated in shaping the platform. As of April 2022, the RHSC reported that its efforts to mitigate stockouts averted 2 million pregnancies across 48 countries and provided 373,000 additional CYPs* across 37 countries.

Reaching women and girls through inclusive business models

Inclusive business models are scalable, commercially viable models that provide goods, services and livelihood opportunities to low-income populations. These models are particularly relevant for women and girls, as they are disproportionately impacted by poverty and face additional barriers to access. Several constraints prevent companies from including women and girls as consumers, employees or producers in their value chain, such as gender-based expectations, limited literacy, and lack of rights and agency. Nonetheless, if pharmaceutical companies want to ensure that the entire income pyramid is able to benefit from accessing their medicines, they must engage in inclusive business models that target these groups.

Nine of the twenty companies in scope of the Index show evidence of their engagement in inclusive business models that address SRHR-related diseases and health needs (AstraZeneca, Bayer, Boehringer Ingelheim, Gilead, Johnson & Johnson, MSD, Novartis, Pfizer and Roche), despite 19 companies having products in their portfolio that cover SRHR diseases or health needs. Although half of the SRHR inclusive business models evaluated target maternal health, women’s health needs extend beyond those related to reproduction. Across all disease areas, companies can address women and girls’ unmet access needs using inclusive business models.

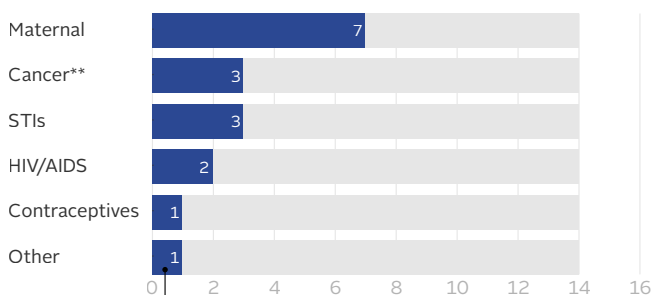
GOOD PRACTICE

In the Philippines, Novartis has an inclusive business model for its breast cancer treatment

In 2021, Novartis launched an inclusive business model to help low-income women in the Philippines access and afford ribociclib (Kryxana®/Kisqali®) for breast cancer treatment. Through research, the company found that patients in the Philippines began treatment but were unable to sustain treatment due to the cost. The company subsequently launched a model where patients pay less for a longer duration of treatment, thus incentivising adherence. Further, to enable implementation of a progressive discounting scheme across different pharmacy partners, Novartis partnered with a technology provider to extend eligibility of patients to the scheme and assist them in areas such as enrolment, eligibility tracking and medicine compliance reminders. In parallel, Novartis is also working with governments to encourage inclusion of ribociclib in the national formulary to support government reimbursement for the product for those that require it.

FIGURE 21 Inclusive business models cover multiple SRHR-related disease areas and health needs

Half of the SRHR-related inclusive business models analysed by the Index are targeted toward addressing maternal health needs.



One of the business models covered by this analysis includes women as employees in the company’s value chain, but does not cover a specific disease area.

*The United States Agency for International Development (USAID) defines Couple-Years of Protection (CYP) as the estimated protection provided by family planning methods during a one-year period, based upon the volume of all

contraceptives sold or distributed free of charge to clients during that period. This includes permanent methods, such as sterilisation, and the lactational amenorrhea method.

**Cervical and breast cancer

NEXT STEPS

What can companies do to ensure women and girls in LMICs have access to the SRHR-related products they need?

R&D investment and clinical trials

Of the SRHR-related diseases and health needs included in this report, cancers, hepatitis B and HIV/AIDS draw the bulk of the R&D focus. The remaining half of the diseases and health needs make up less than 10% of the SRHR pipeline, with some not addressed at all. More R&D investment in these areas is needed, especially to fill product gaps for diseases and health needs that currently remain unaddressed, for example, pre-eclampsia and postpartum haemorrhage. Furthermore, there is an underrepresentation of pregnant women in clinical trials and, where appropriate, companies can make additional efforts to include them in clinical research in line with WHO recommendations.

Supporting access through supranational procurement

Companies' efforts to make their products affordable in LMICs are unbalanced, with areas for improvement, especially in access to SRHR-related non-communicable diseases. Pooled procurement via supranational agreements is focused on HIV medicines and diagnostics, HPV vaccines, and contraceptives. When countries are not eligible, or no longer eligible (due to their income classification changing) to benefit from supranational procurement, companies should develop access strategies for these countries to ensure that women and girls can access medicines at a similar price.

Access strategies for more products, in more countries

For key products in their portfolios, and particularly for non-communicable diseases like ovarian cancer, endometriosis and uterine cancer, for which there is no supranational procurement mechanism, companies must implement country-specific access strategies to ensure equitable access. Access strategies are generally missing in low-income countries, especially for breast cancer, while treatments for HIV/AIDS and hepatitis B are mostly covered by equitable pricing strategies across all income tiers. Companies can take steps to develop access strategies for these products and ensure that they reach women and girls living in low-income countries.

Investment in capacity building and tailoring inclusive business models

Companies have an additional role to play beyond researching and supplying products. Barriers such as lack of awareness, supply chain barriers, and lack of trained health workers also need to be addressed. Higher levels of company engagement in health systems strengthening are needed and efforts can be made to scale up these initiatives to more countries where there are women and girls with unmet access needs. Companies can engage with partners, such as the UNFPA, to build supply chain capacity for SRHR products in specific areas including demand forecasting and improving infrastructure for storage and delivery of medicines.

In addition, several companies have SRHR products in their portfolio, like contraceptives, products indicated for HIV/AIDS, and cancer therapies, that are only accessible through regular business practices that may not be inclusive, meaning that they are not tailored to address the specific needs of women and girls.

REFERENCES

1. United Nations Population Fund. Unfinished Business: The Pursuit of Rights and Choices for All; 2019.
2. Mariani G, Kasznia-Brown J, Paez D, et al. Improving women's health in low-income and middle-income countries. Part I: challenges and priorities. Published online 2017. doi:10.1097/MNM.0000000000000751
3. Vanbenschoten H, Kuganantham H, Larsson EC, et al. Impact of the COVID-19 pandemic on access to and utilisation of services for sexual and reproductive health: a scoping review. *BMJ Glob Health*. 2022;7:9594. doi:10.1136/bmjgh-2022-009594
4. Chapman N, Doubell A, Goldstein M, et al. G-FINDER | Sexual and Reproductive Health Research and Development: Understanding the Spectrum; 2020. Accessed July 5, 2022. <https://www.policycuresresearch.org/g-finder/>
5. United Nations General Assembly. Transforming Our World : The 2030 Agenda for Sustainable Development; 2015.
6. Starrs AM, Ezeh AC, Barker G, et al. Accelerate progress—sexual and reproductive health and rights for all: report of the Guttmacher–Lancet Commission. *The Lancet*. 2018;391(10140):2642–2692. doi:10.1016/S0140-6736(18)30293-9
7. The United Nations Entity for Gender Equality and the Empowerment of Women. Promoting Gender Equality in Sexual, Reproductive, Maternal, Newborn, Child and Adolescent Health: Programming Guide.; 2019.
8. World Health Organization. Maternal mortality. Published 2019. Accessed October 15, 2022. <https://www.who.int/news-room/fact-sheets/detail/maternal-mortality>
9. Smith DD, Phippen JL, Adesomo AA, Rood KM, Landon MB, Costantine MM. Exclusion of Pregnant Women from Clinical Trials during the Coronavirus Disease 2019 Pandemic: A Review of International Registries. *Am J Perinatol*. 2020;37(8):792. doi:10.1055/S-0040-1712103
10. van der Graaf R, van der Zande ISE, den Ruijter HM, et al. Fair inclusion of pregnant women in clinical trials: An integrated scientific and ethical approach. *Trials*. 2018;19(1):1–9. doi:10.1186/S13063-017-2402-9/TABLES/1
11. Avram MJ. Pharmacokinetic studies in pregnancy. *Semin Perinatol*. 2020;44(3):151227. doi:10.1016/J.SEMPERI.2020.151227
12. World Health Organization (WHO), International Maternal Paediatric Adolescent AIDS Clinical Trials Network (IMPAACT), International AIDS Society. Research for Informed: Accelerating the study of New Drugs for HIV in Pregnant and breastfeeding Women.; 2021. Accessed October 10, 2022. https://www.impaactnetwork.org/sites/default/files/inline-files/PW_Call_to_Action_final.pdf
13. Sung H, Ferlay J, Siegel RL, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin*. 2021;71(3):209–249. doi:10.3322/caac.21660
14. Kantorová V, Wheldon MC, Ueffing P, Dasgupta ANZ. Estimating progress towards meeting women's contraceptive needs in 185 countries: A Bayesian hierarchical modelling study. *PLoS Med*. 2020;17(2):e1003026. doi:10.1371/journal.pmed.1003026
15. UNFPA, UNICEF, Organization WH, Group WB, Division the UNP. Trends in Maternal Mortality: 2000 to 2017 | UNFPA - United Nations Population Fund. WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Published online 2019;104. Accessed November 4, 2022. <https://www.unfpa.org/featured-publication/trends-maternal-mortality-2000-2017>
16. United Nations Population Fund. UNFPA Procurement Statistics 2021.; 2021. Accessed November 4, 2022. <https://www.unfpa.org/resources/unfpa-procurement-statistics-2021>

SPECIAL REPORT: PROGRESS ANALYSIS

Is the industry making progress on improving access to medicine?

The 2022 Index report marks the eighth edition of the Access to Medicine Index, which was first published in 2008. For over a decade, the Index has provided insights into how 20 of the world's largest pharmaceutical companies perform on access to medicine in low- and middle-income countries (LMICs). The methodology for the 2022 Index has a high level of continuity with the previous Index, allowing for a detailed longitudinal analysis of where progress has been made – and where it has not.

This Special Report explores the extent to which the industry is making progress on improving access to medicine, and progress towards the UN Sustainable Development Goal 3 (SDG3) for 2030, despite the challenge of the COVID-19 pandemic.

The analysis presented here compares data from the 2022 Access to Medicine Index with data from the 2021 Index, and where possible, previous editions of the Index. Although the methodology was updated with a new robust framework after the publication of the 2018 Index, comparisons have been drawn where viable and meaningful.

GOVERNANCE OF ACCESS

Progress seen at board level as companies increasingly integrate strategies to address access to medicine

This section looks at where there has been a shift from indirect to direct top-level accountability for access to medicine and whether the companies are increasingly embedding an access-to-medicine mindset in their business operations. Additionally, this section considers changes in how companies ensure compliance with codes of conduct and incentivise good ethical conduct by sales agents.

Governance structures and incentives

Since 2018, the number of companies with either a board member or a board-level committee responsible and accountable for access to medicine activities has increased from 11 in 2018, to 12 in 2021, and 16 in 2022, with Eisai, Bristol Myers Squibb, Merck and Sanofi now also providing evidence of direct board-level accountability for access-to-medicine activities.

In 2019, the Foundation published an independent ten-year analysis titled, “Are pharmaceutical companies making progress when it comes to global health?”, which identified a shift from indirect board-level responsibility for access to medicine towards assigning direct responsibility to a named board member. As the data from the 2021 and 2022 Indexes shows, there has been noticeable progress.

In 2021, 13 companies provided evidence of access-related incentives for senior executives, including the CEO, and regional or in-country management. In 2022, one more company, Gilead, provided evidence of incentives for senior management, indicating only a slight improvement in the companies’ top-level incentivisation of access-related targets and goals.

The 2022 Index finds that three companies have newly implemented an access-to-medicine strategy, meaning all 20 companies now have an access-to-medicine strategy in place to expand access to their products for people living in LMICs. These companies are AbbVie, Astellas and Daiichi Sankyo. Previously, these companies had only general commitments to improve access to medicine rather than a clear, intergrated access-to-medicine strategy.

Nineteen of the 20 companies have integrated their access-to-medicine strategy into their overall corporate strategy, with Gilead having a business rationale for its access-to-medicine strategy that is focused on partnerships to enhance access. This is in stark contrast to the 2021 Index, where just 11 companies had integrated strategies.

FIGURE 22 Progress in number of companies with direct board-level responsibility for access to medicine

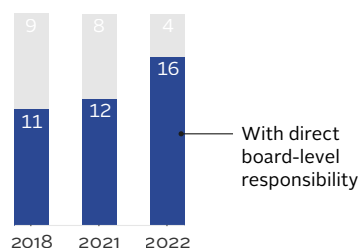


FIGURE 23 Small increase in the number of companies with access incentives for senior management

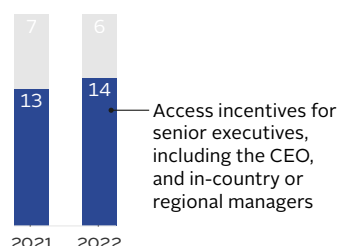


FIGURE 24 Clear signs of progress as all 20 companies now have an access-to-medicine strategy

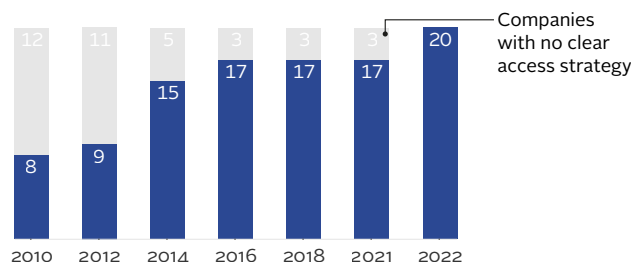
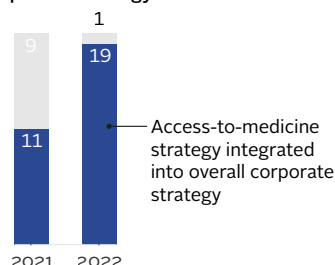


FIGURE 25 Significant increase in number of companies that have integrated their access-to-medicine strategies into their overall corporate strategy



While all pharmaceutical companies included in the analysis have set targets and goals related to their access-to-medicine initiatives, companies vary considerably in terms of the quantity and quality of outcome reporting.

For example, several companies report outcomes using centralised, easy-to-digest dashboards detailing how and when short-, medium- and long-term results were achieved for all activities. Other companies do not have such transparent practices; for example, they may share this information via multiple documents or external websites, or only report on certain products or therapeutic areas, making it difficult to gain a complete picture of the company's activities and hold them accountable.

Ethical marketing and compliance

With respect to risk management of unethical marketing and other practices, the 2022 Index has determined that companies are making strides. AbbVie, Bristol Myers Squibb, Boehringer Ingelheim, Daiichi Sankyo, Gilead and Sanofi newly demonstrate that sales agents' incentives are not based solely on sales volume.

The number of companies decoupling sales agents' rewards from sales targets has steadily increased over time. Compensation for sales representatives is becoming increasingly tied to qualitative performance indicators, such as technical knowledge or compliance adherence.

The Foundation's ten-year progress report, published in 2019, found that all 20 companies had auditing controls in place since the 2016 Index. In the 2022 Index, this remains the case.

In 2018, the Index began analysing whether companies had additional controls in place to ensure compliance with each country's regulatory and anti-corruption laws. This included fraud-specific risk assessments, a continuous monitoring system for compliance and processes to ensure third-party compliance.

Of the five controls measured by the Index in 2021, only eight companies demonstrated evidence of applying all of them. In 2022, five additional companies have implemented all controls, meaning there are 13 companies that have a strong – i.e., comprehensive – internal control framework for ensuring compliance. The five additional companies are Bayer, Bristol Myers Squibb, Eisai, Merck and Pfizer.

FIGURE 26 More companies are increasing transparency about their access-to-medicine activities

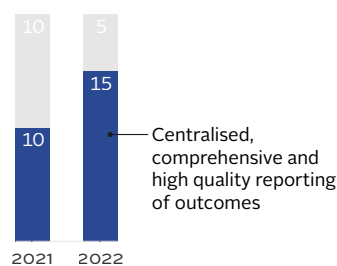


FIGURE 27 Companies are making progress on decoupling agents' rewards from sales targets

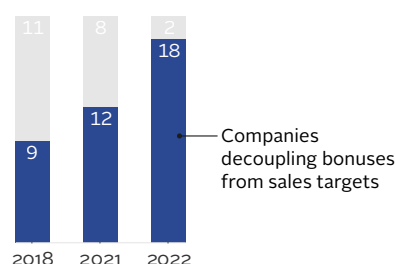


FIGURE 28 Some signs of progress in applying specific compliance controls

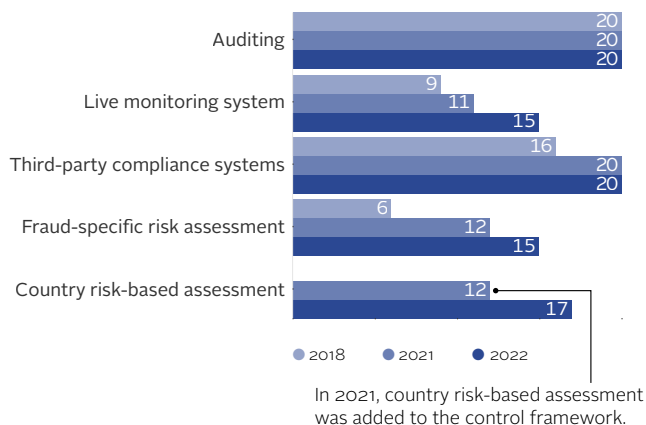
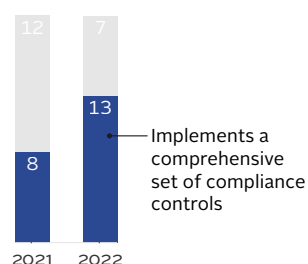


FIGURE 29 Progress in implementing a comprehensive set of compliance controls to prevent corrupt and non-compliant activity



RESEARCH & DEVELOPMENT

Companies make progress in access planning but little change in makeup of R&D pipelines

Breakdown of the pipeline

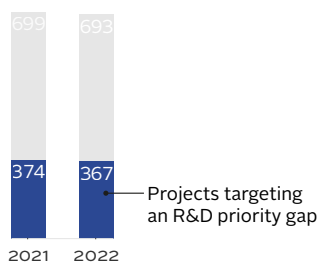
The total number of projects targeting specific disease classifications has remained relatively stable since the 2021 Index, with a slight decrease in the number of R&D projects in the pipeline targeting diseases in scope; 1,060 projects in 2022 compared with 1,073 projects in 2021. A total of 62 products received regulatory approval,* 479 new projects were added to the pipeline and 466 projects were removed during the period of analysis.** Notably, there has been a decrease in the number of projects targeting neglected tropical diseases (NTDs). Despite 20 new NTD projects being added to the pipeline, the total number of NTD projects fell from 89 in the previous Index to 69 in the 2022 Index. The decrease in the number of active projects is mostly a result of some discovery-phase projects being discontinued and some projects leaving the pipeline after successfully reaching product approval and launch.

Among R&D projects to address priority diseases, a small number of diseases dominate the pipeline

Of the 1,060 projects in the pipeline, one third target a disease identified as a priority R&D treatment gap, as defined by global health organisations (see Appendix VI) – a figure consistent with the findings of the previous Index.

However, although there are 64 priority diseases, over half of these projects (202) focus on four priority diseases: coronaviral diseases, HIV/AIDS, malaria, and tuberculosis. Many diseases with urgent requirements for R&D are not being addressed by research-based pharmaceutical companies. This figure remains consistent with the 2021 pipeline, where 199 projects targeted these four diseases. This is a long-term trend that was also identified by the Foundation’s 10-year progress report in 2019, which found that, in general, companies’ R&D activities are concentrated on a few diseases.

FIGURE 32 Limited change in companies’ focus on R&D for priority diseases



*This includes products that received emergency use authorisation or conditional marketing approval during the period of analysis (1 June 2020 - 31 May 2022).

**Period of analysis 1 June 2022 - 31 May 2022

FIGURE 30 HIV/AIDS and COVID-19 draw more R&D attention, number of projects targeting NTDs decreases

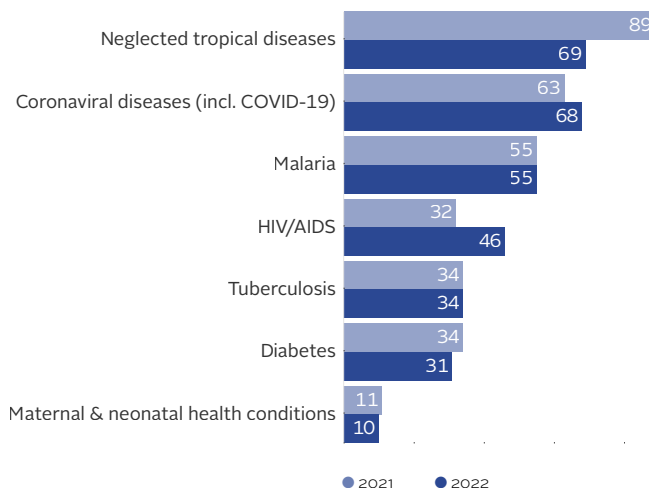


FIGURE 31 R&D activity for NTDs such as leishmaniasis, onchocerciasis and Chagas disease decreases

Neglected tropical disease	2021	2022
Buruli ulcer	0	0
Chagas disease	27	21
Dengue and chikungunya	12	11
Dracunculiasis	0	0
Echinococcosis	0	0
Food-borne trematodiasis	1	0
Human African trypanosomiasis	7	7
Leishmaniasis	28	15
Leprosy	2	1
Lymphatic filariasis	5	1
Mycetoma	1	1
Onchocerciasis	11	4
Rabies	3	3
Scabies and other ectoparasites	0	0
Schistosomiasis	18	16
Snakebite envenoming	0	0
Soil-transmitted helminthiasis	4	3
Taeniasis/cysticercosis	0	0
Trachoma	0	0
Yaws	0	0

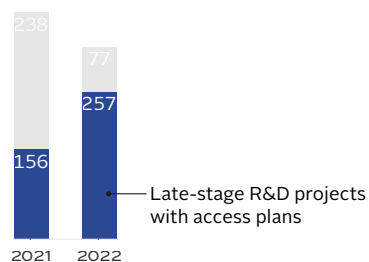
Companies begin to look ahead but with a narrow lens

While the ten-year progress report published by the Foundation in 2019 found that the proportion of late-stage R&D projects with access plans had remained largely unchanged over the previous decade, in 2022 the number of late-stage projects with access plans has increased markedly. In the 2021 Index, 40% of late-stage projects analysed had plans for access in place during the R&D stage. This year, 77% of late-stage projects have access plans in place.

This improvement corroborates a Key Finding from the 2021 Index, which identified an industry shift towards systematic access planning during late-stage R&D so that new products quickly reach the people who need them in LMICs. The significant increase between the 2021 and 2022 Indexes may indicate that companies' commitments to systematically implementing access planning during R&D are now leading to tangible results.

However, an in-depth analysis of the quality and breadth of these plans concludes that the majority of these plans focus on a select number of countries in scope, thus leaving these important product developments out of reach for most. Furthermore, most of these plans focus solely on registering the product in at least one country in scope of the Index with few provisions for affordability to ensure the product will be accessible for all.

FIGURE 33 More late-stage R&D projects have access plans compared to previous years



PRODUCT DELIVERY

Progress in access strategies and voluntary licensing, but overall picture mixed

Each product should have an access strategy to ensure it is widely available and affordable in LMICs. Equitable pricing and non-exclusive voluntary licensing (NEVL) are two important mechanisms that companies can use as part of an access strategy to increase access to a product. Furthermore, patent transparency is an important tool to ensure generic manufacturers can quickly enter the market once the original patents on a health product expire.

This section shows how companies have developed their access strategies since the 2021 Index. It also looks at how companies have progressed in NEVL and patent transparency over past Indexes.

More products now covered by access strategies

Since the previous Index, there has been a significant increase in the number of products in scope that are now covered by an access strategy. Access strategies can include, for example, pricing strategies, non-pricing initiatives (e.g., patient assistance programmes, non-exclusive voluntary licensing, donations) or a combination of pricing strategies with non-pricing initiatives.

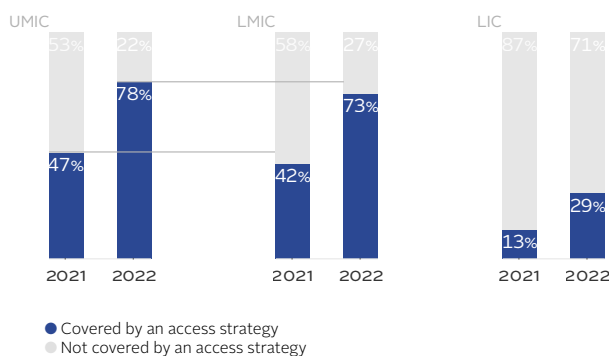
It is important that companies put access strategies in place for both self-administered products and healthcare practitioner (HCP)-administered products. However, as in the 2021 Index, HCP-administered products continue to be covered by fewer access strategies compared to self-administered products in upper-middle income and lower-middle income countries. Access strategies are also far less likely to be used to expand access to products in low-income countries, compared to upper-middle income countries and lower-middle income countries.

Compared with the 2021 Index, data analysed in the 2022 Index shows an increase in the number of companies engaging in supranational agreements.

AstraZeneca now supplies products via supranational agreements, and in countries not eligible for international procurement processes. The company, along with Pfizer, also has access strategies that include the same terms as supranational agreements. As the figure shows, this has slightly increased the proportion of the products in scope that are covered by these access strategies. Data analysed in the 2022 Index shows progress in the percentage of products covered by an access strategy in countries outside supranational agreements. A smaller percentage of products are not covered by access strategies in non-eligible countries.

FIGURE 34 Percentage of products covered by access strategies in upper-middle, lower-middle, and low-income countries

Healthcare practitioner-administered products



Self-administered products

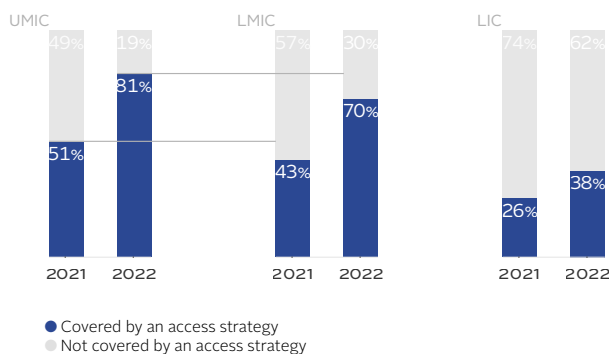
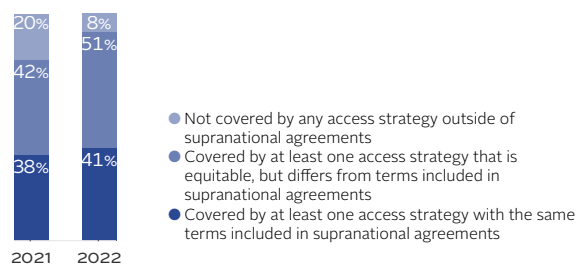


FIGURE 35 Small increase in number of products included in access strategies outside of supranational agreements



Increase in voluntary licensing is mainly related to COVID-19 products

Engaging in NEVLs is one way that research-based pharmaceutical companies can ensure that key healthcare products, or the compounds vital to making those products, reach more people who need them – particularly those living in LMICs. When companies offer NEVLs, this can facilitate the entrance of generic manufacturers to market, making medicines more affordable and accessible.

AstraZeneca, Eli Lilly and Novartis have entered into new licensing agreements since the previous Index. There are now 27 licenced compounds, which include three new NEVLs for COVID-19 treatments and one private voluntary licence for a COVID-19 vaccine (in addition to the COVID-19 product already covered by a licence in the 2021 Index). Although more companies are getting involved in licensing agreements, the transparency, quality and breadth of these licences vary.

Number of companies disclosing patent status for some of their products remains high

When companies publicly disclose patent status data about their products – i.e., sharing information about where patents are filed – this transparency can bring significant benefits in terms of access to medicine. In particular, it provides greater certainty to generic medicine manufacturers and international drug procurers when planning the manufacture and/or supply of generic products, thereby facilitating increased supply and affordability.

Of the 20 companies, 19 publicly disclose information on the status of patents related to at least some of the products in their portfolio, the same number as the 2021 Index. Most of the data is shared through the online database Pat-INFORMED – an initiative coordinated between the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the World Intellectual Property Organization (WIPO) – while a few companies self-publish patent information online.

FIGURE 36 Five products have been newly covered by voluntary licences in the last two years*

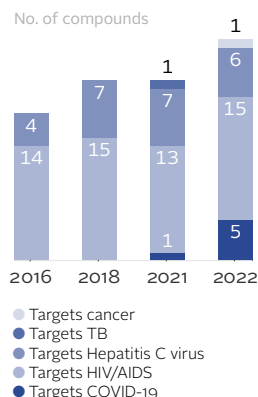
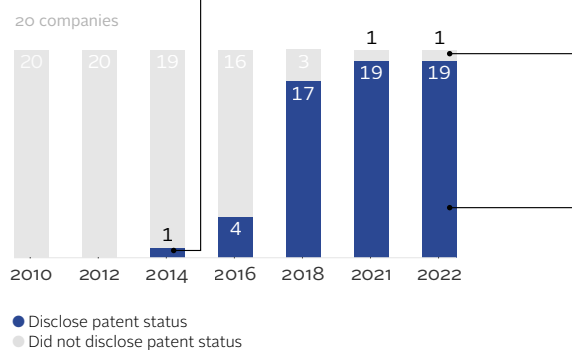


FIGURE 37 Number of companies sharing patent status data for some products in their portfolios

The first company to take this step was Merck, followed in 2016 by AstraZeneca, Gilead and Novo Nordisk.



Boehringer Ingelheim does not publicly disclose the patent status of its products on its website or Pat-INFORMED.

19 companies disclose patent information through the Pat-INFORMED online database, or on their company website. AstraZeneca, Merck and Sanofi lead in patent transparency, by currently sharing the expiry dates of patents on their websites.

* During the period of analysis for this Index: 1 June 2020 - 31 May 2022.

PRODUCT DELIVERY

Progress in capacity building in R&D and manufacturing, but stagnation in health systems strengthening

Capacity building initiatives focused on health systems strengthening, manufacturing, supply chain and R&D represent additional ways in which pharmaceutical companies can improve access to medicine and address issues in health product availability and accessibility (e.g., appropriate prescription, efficient administration).

Overall improvement in proportion of initiatives meeting all Good Practice Standards

For almost all fields of capacity building, improvement has been seen in the percentage of initiatives included that meet all Good Practice Standards (GPS; see Appendix IV); overall, 21 additional initiatives meet all GPS compared with the previous Index. The most significant improvement was seen in R&D capacity building, with an increase of 34 percentage points. Supply and manufacturing had smaller increases of 18 and 26 percentage points, respectively. For R&D capacity building, 11 more initiatives were included compared with the previous Index. In both supply chain and manufacturing capacity building, 13 new initiatives were included for analysis.

However, the number of high-quality capacity building initiatives focused on health systems strengthening has stayed relatively stable. In the 2021 Index, analysis showed that health systems strengthening initiatives were improving in terms of quality and quantity. In the 2022 Index, while seven new initiatives have been included for analysis, only two more initiatives meet all GPS, thereby reducing the overall percentage of health systems strengthening initiatives that meet all GPS.

Progress in outcome measurement focused on R&D capacity building

Measuring and sharing outcomes can provide valuable insights that can improve ongoing projects and inform future activities. Because of this, measuring capacity building outcomes is one of the GPS for manufacturing, supply and R&D capacity building, and publicly disclosing outcomes is a GPS for health systems strengthening. Outcome measurements across capacity building can include changes in patient health outcomes, quantity of donated equipment, evidence of patient reach or decreased stockouts in pharmacies.

Since the last Index, companies have especially done more to measure outcomes of R&D capacity building. Improvement in outcome measurement was also seen in supply chain capacity building initiatives, but no improvement was seen in measuring outcomes of manufacturing capacity building initiatives.

The Index measures whether companies both measure and publicly disclose outcomes of health systems strengthening initiatives. In the 2022 Index, only a marginal improvement in public disclosure of outcomes was seen across health systems strengthening initiatives.

FIGURE 38 More supply, manufacturing and R&D capacity building initiatives meet all Good Practice Standards, but improvements in health systems strengthening initiatives have stagnated

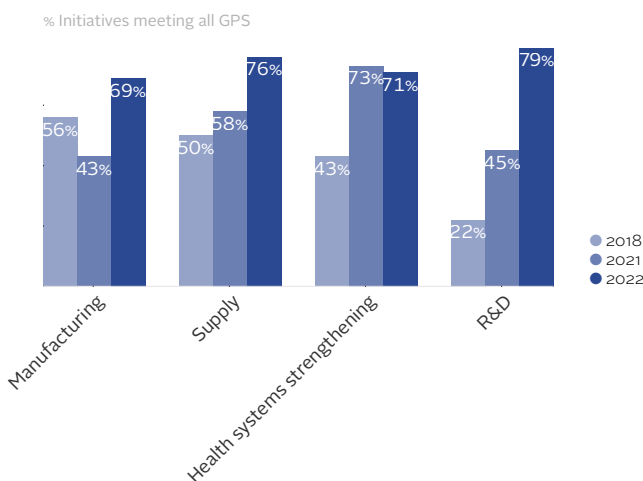


FIGURE 39 Varied progress in measuring outcomes across capacity building fields

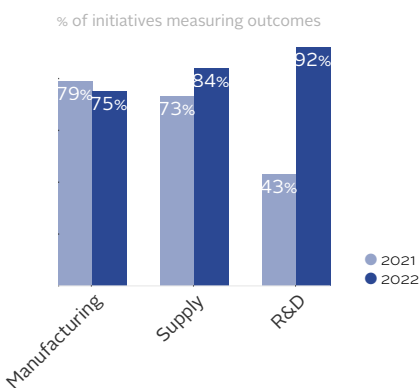
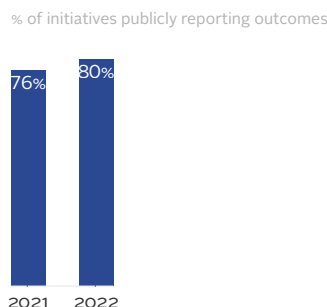


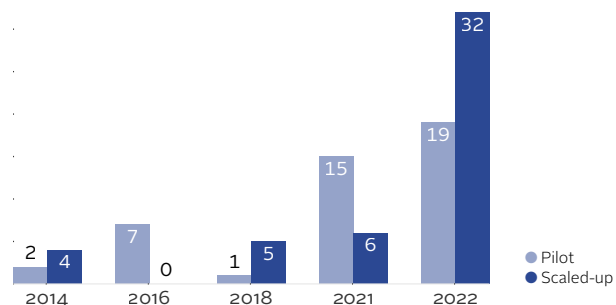
FIGURE 40 Stagnation in public disclosure of outcomes for health systems strengthening



Five-fold increase in scaled-up inclusive business models since 2021 Index

Since 2014, when inclusive business models were first assessed in the Index, ten more companies are engaged in inclusive business models, with 16 companies currently engaged in 51 inclusive business models. This change reflects companies' efforts to address unmet health needs of vulnerable groups who may face additional barriers to access. The number of inclusive business models that have scaled up has increased five-fold since 2021, whereas the number of piloted inclusive business models has stayed relatively consistent. Scale-up can involve expanding to new countries, increasing the number of patients served, or expanding the diseases covered.

FIGURE 41 Use of inclusive business models continues to expand, with an emphasis on scaling up models



Technical Areas

The 2022 Index's analytical framework consists of three Technical Areas: **Governance of Access, Research and Development** and **Product Delivery**.

The following chapters lay out the data collected about the 20 companies in scope – and analyse this information to draw out conclusions.

Each of the following Technical Areas feature:

- An overview of how the Index assesses company performance.
- A ranking of the 20 pharmaceutical companies detailing what separates the best and worst performers.
- Detailed figure-led analyses identifying industry and company strengths, weaknesses, trends and opportunities.

GOVERNANCE OF ACCESS

CONTEXT

As pharmaceutical companies search for new opportunities to increase patient reach in low- and middle-income countries (LMICs), they must ensure that their products are accessible to people at the base of the income pyramid. Improving access to medicine sustainably requires that companies create clear access strategies that focus on the long term and incorporate these into their business strategies, while simultaneously engaging their workforce to adopt an access-to-medicine mindset. Moreover, companies need to conduct business ethically and enforce stringent compliance processes across their operations while additionally demonstrating transparency in reporting their access outcomes.

This technical area looks at how companies plan, integrate, implement and manage objectives related to improving access to medicine in LMICs, as well as their approach to limiting unethical behaviour that, in contrast, would hinder access.

PERFORMANCE INDICATORS

In this Technical Area, the company's performance is assessed against the following indicators:

- Board-level responsibility of an access-to-medicine strategy and incentivisation of senior management and in-country management toward achievement of access-to-medicine goals
- Integration of an access-to-medicine strategy within the overall corporate strategy and across all therapeutic areas in which the company is involved
- Public disclosure and measurement of access-to-medicine activities, including commitments, goals, targets, objectives and outcomes
- Ethical business conduct
- Intellectual property (IP) strategy conducive to facilitating access to medicine in countries in scope of the Index

WHAT BEST PRACTICE LOOKS LIKE

The top-performing companies have an access-to-medicine strategy that extends across all therapeutic areas they are involved in. They have access-related incentives in place for senior managers, including the CEO, and are actively engaged in measuring the progress and outcomes of their access-to-medicine initiatives in LMICs. The best-performing companies also engage in ethical business practices by decoupling financial rewards among sales agents from sales volume targets, and implementing robust frameworks for compliance to mitigate the risk of non-compliance across business operations in LMICs, including third-party collaborators.

INSIGHTS

- All 20 companies assessed have established an access-to-medicine strategy with measurable objectives.
- Most companies have incentives that are not fully linked to sales, with some companies reporting not using sales and marketing representatives at all for some products related to diseases in scope.
- Many companies still do not provide evidence of a comprehensive set of compliance controls for preventing non-compliant activities that may create barriers to access in countries in scope.

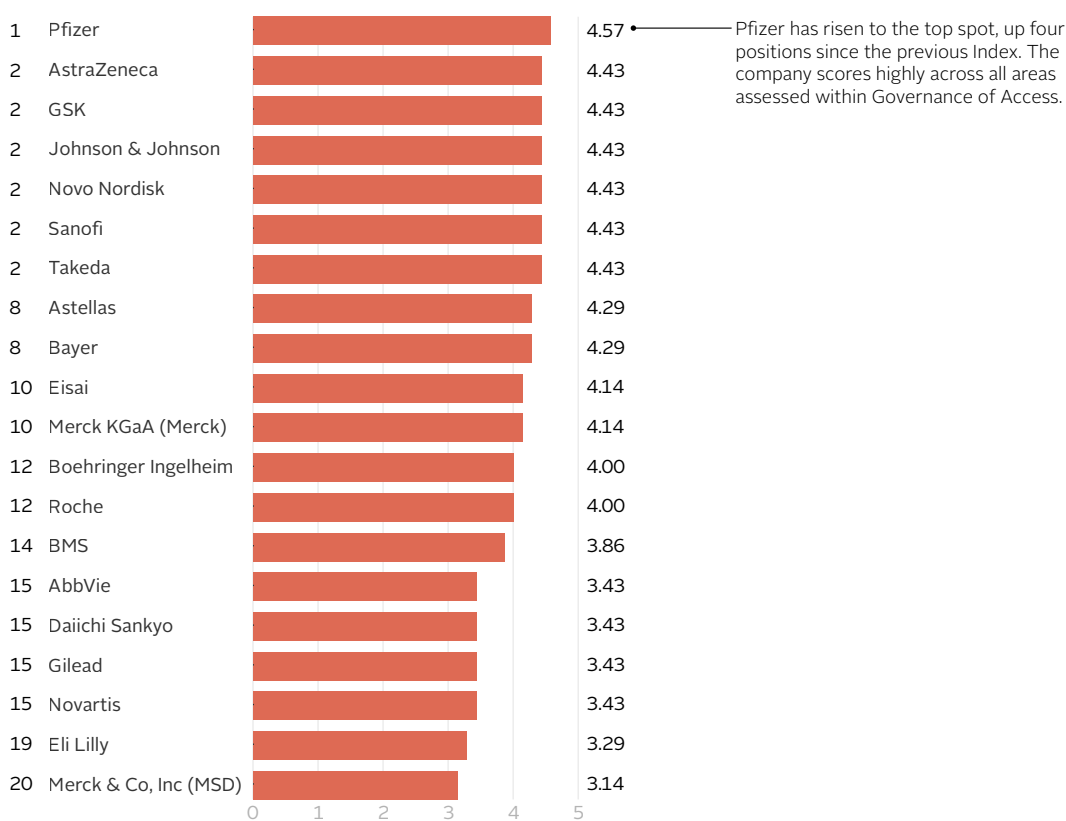
FIND OUT MORE	PAGE
Sub-ranking	58
How do companies prioritise access to medicine?	59

This section features a detailed figure-led analysis identifying industry strengths, weaknesses, trends and opportunities as of the time of writing. For a fine-grained view of individual company activity in this Technical Area, see the Report Cards, page 147.

HOW THE COMPANIES PERFORM

Top-performing companies demonstrate strong responsible business practices

FIGURE 42 Governance of Access Ranking



The top spot is held by Pfizer, with the company scoring highly across all areas assessed within Governance of Access. Pfizer provides evidence of well-established structures of governance and management, with responsibility assigned and incentives offered at the highest level. It takes an optimal approach to ensuring ethical business practices – e.g., in addition to adopting a balanced scorecard approach, sales targets for sales agents are not set at the individual level, and it has a policy to limit transfers of values to healthcare professionals in LMICs. It also has stringent compliance processes across its operations, including with third parties.

The lower-performing companies do not provide evidence of direct board-level responsibility for their access activities, nor do they provide evidence of incentives to achieve access-related goals. Furthermore, they demonstrate only some of the compliance controls analysed by the Index and provide little information related to responsible promotional practices. Novartis is an exception here as a company with a strong compliance programme but a low score in this Index, due to a breach settlement.

GOVERNANCE STRATEGY AND RESPONSIBLE BUSINESS PRACTICES

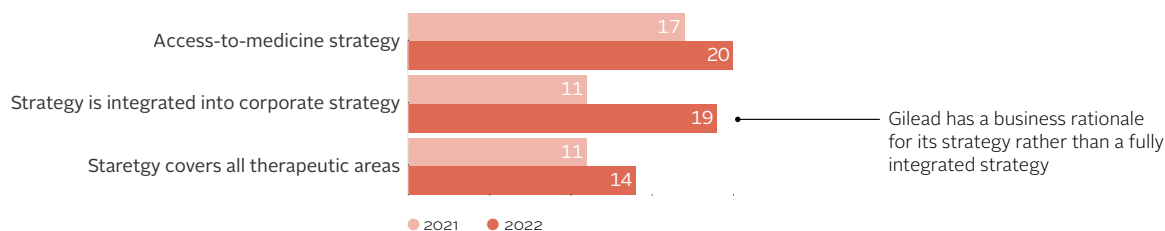
How do companies prioritise access to medicine?

Patients in LMICs shoulder the bulk of the global disease burden, yet essential healthcare products are often entirely unaffordable or unavailable to them. Achieving greater access for these patients requires companies to give LMICs an important place in their business operations.

Implementing clear, long-term strategies

All 20 companies that were assessed have established an access-to-medicine strategy with measurable objectives. Most companies demonstrate best practice by embedding their access-to-medicine strategy within their overall corporate strategy, indicating that access to medicine in LMICs is relevant for long-term growth. Of the 19 companies with integrated strategies, 14 apply access thinking across all therapeutic areas in which they are involved. Gilead provides evidence of a business rationale for its access-to-medicine strategies rather than a fully integrated strategy covering all therapeutic areas.

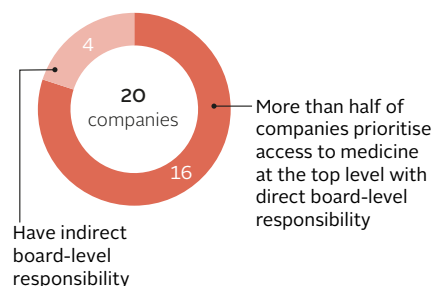
FIGURE 43 Do companies have strong access-to-medicine strategies in place?



Prioritising access to medicine at the top level

Companies that demonstrate best practice in prioritising access to medicine have a board member or a board-level committee that is directly responsible for access initiatives to ensure that access-related objectives are given attention, remain on track and are achieved. In the 2021 Index, 12 companies provided evidence of direct board-level responsibility for their access initiatives. During the period of analysis*, the number of companies with a board-level committee increased to 16 companies. Astellas, Daiichi Sankyo, Eli Lilly and MSD** provide evidence of indirect board-level responsibility, with executive-level committees and executive team members often responsible for access strategies.

FIGURE 44 Is access to medicine a priority at the highest level?



*Period of analysis for the 2022 Index: 1 June 2020 to 31 May 2022
 **Merck & Co., Inc., Rahway, NJ USA

Incentivising action

Access is more likely to be an important goal of an organisation when senior management, and especially the CEO, have key performance indicators specifically linked to access-to-medicine objectives. Ideally, access incentives include a non-financial component and are oriented toward long-term goals, as evidenced by AstraZeneca, Bayer, Daiichi Sankyo, Novartis, Sanofi and Takeda. Companies in scope with no evidence of access incentives for either senior executives, including the CEO or in-country/regional managers include AbbVie, Bristol Myers Squibb, Eli Lilly, MSD and Merck.

Promoting ethical sales practices

Although incentives can encourage employees to work towards achieving access-related goals, bonuses and rewards for sales representatives are commonly linked to sales volume. This can negatively affect access to medicine by increasing the risk of mis-selling or over-selling products. Companies are, however, moving away from such sales incentive structures and taking steps to decouple sales incentives from sales targets, thereby removing the incentive to oversell. This is often done by including qualitative metrics in agents' variable compensation scheme through distinction in practice related to antimicrobial resistance; market uptake for priority products; or safeguards to ensure ethical practices.

In the period of analysis, 18 companies have incentives that are not fully linked to sales volume. However, Pfizer and Sanofi are the only companies demonstrating evidence that sales targets are not set at the individual level, with Sanofi reporting that such targets are set at the national level in countries in scope of the Index; the further incentives are from the individual level, the better, as it can reduce the motivation to engage in unethical practices to achieve targets. Furthermore, some companies report not using sales and marketing representatives at all for some products related to diseases in scope of the Index. For example, Johnson & Johnson does not deploy sales representatives for all products in scope of its Global Public Health organisation, such as HIV medicines.

Publicly disclosing outcomes of access-to-medicine activities

Monitoring and evaluation of access-to-medicine activities are crucial to track and demonstrate progress toward objectives, and the public disclosure of this progress facilitates accountability and transparency. All companies publicly disclose commitments, targets and objectives related to their access-to-medicine initiatives, but they differ in the quality of outcome reporting. Several companies, such as Takeda and Novo Nordisk, report outcomes of all access-related activities directly on their website in a centralised manner (e.g., a company report or outcomes dashboard) as opposed to reporting on only a subset of access-related activities on an external platform. For example, Takeda reports its outcomes within its Access to Medicines progress report, and Novo Nordisk reports outcomes within its Year in Review report. Additionally, outcome reporting occurs regularly (e.g., at least annually) among top-performing companies.

FIGURE 45 Are access-related goals incentivised among senior management?

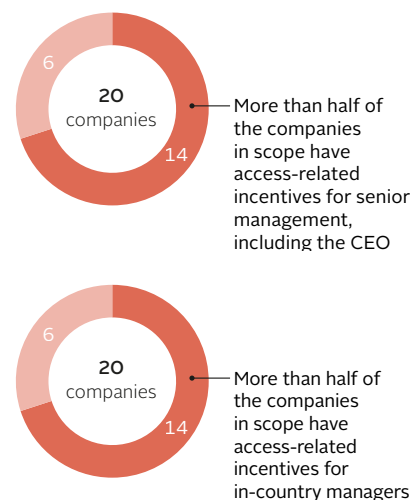


FIGURE 46 Are companies promoting ethical sales practices?

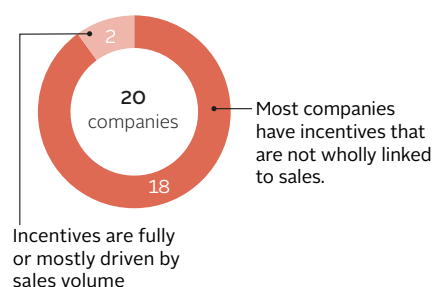
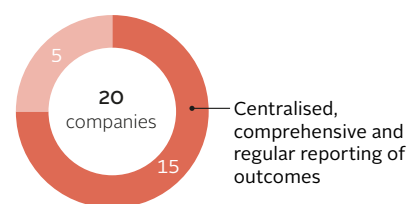


FIGURE 47 How are companies reporting progress on their access-to-medicine activities?



Mitigating non-compliance and corrupt behaviour

Within the health sector, the pharmaceutical industry is argued to be one of the sub-sectors particularly vulnerable to corruption due to the highly complex and multifaceted structure of the sector itself (e.g., multiple actors, high-value products and contracts). This may create multiple points of potential vulnerability related to bribery and other corrupt activities.¹ Therefore, the Index looks for a strong internal framework for ensuring compliance (i.e., processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour among the company's employees and the third parties with which it formally engages). All companies have auditing and third-party compliance mechanisms in place. Compared with the 2021 Index, five additional companies - Bayer, Bristol Myers Squibb, Eisai, Merck and Pfizer - provide evidence of all controls assessed by the Index. Other companies include Astellas, AstraZeneca, GSK, Eli Lilly, Johnson & Johnson, Novo Nordisk, Novartis, Sanofi and Takeda. Bristol Myers Squibb, Eisai, Gilead and Merck newly demonstrate evidence of country risk-based assessments, while Eli Lilly reports that it conducts country risk-based assessments annually in every country/region where there is an Ethics & Compliance Officer present. AbbVie, Bristol Myers Squibb and Merck disclose evidence of fraud-specific risk assessments. Bayer, Bristol Myers Squibb, Merck and Pfizer newly provide evidence of a live-monitoring system.

Have any cases been recently settled that relate to breaches of law or compliance issues?

Cases of breaches are often not exposed publicly in countries in scope of the Index, or they may not be identified by regulatory or law enforcement entities due to weaker capacity to impose measures against unethical marketing or corruption. Still, breaches do occur and may become public knowledge. Therefore, the Index analyses whether companies have been found to be the subject of negative rulings or settled cases regarding breaches of internationally recognised codes of conduct, laws and regulations related to unethical marketing practices, corrupt practices, anti-competitive practices, or misconduct in clinical trials in countries within scope of the Index.

There is evidence that, during the period of analysis, Novartis has agreed to pay to settle charges that a former subsidiary violated the books and records and internal accounting controls provisions of the Foreign Corrupt Practices Act (FCPA) between 2011 and 2014 in Vietnam, which is in scope of the Index.

Conclusions

The 2022 Index is seeing evidence that companies are making progress when it comes to adopting good governance structures and enforcing rigorous standards of behaviour across their operations. This is reflected in the increase in the number of companies with top-level accountability for their access-to-medicine activities and those incentivising senior management to deliver on access-to-medicine goals and enforcing ethical marketing practices.

Yet, in other areas related to responsible business practices, progress is still lagging. Many companies still do not provide evidence of a comprehensive set of compliance controls for preventing non-compliant activities that may create barriers to access in countries in scope of the Index. Furthermore, while all companies perform well in their public reporting of commitments, measurable targets, and objectives for access-related activities, there is room for improvement when it comes to the public disclosure of outcomes related to these activities. This is especially important for transparency and accountability purposes.

REFERENCES

¹ Gurun, N., Gürkaynak, G., & Yildiz, C. (2019, February 6). An Overview of Corruption Risks in the Pharmaceutical Sector | IFLR1000. IFLR1000.

FIGURE 48 How do companies monitor compliance?

Companies	Fraud-specific risk assessment	Third-party compliance systems	Country risk-based assessment	Auditing	Live-monitoring system
Abbvie	●	●	●	●	●
Astellas	●	●	●	●	●
AstraZeneca	●	●	●	●	●
Bayer	●	●	●	●	●
Bristol Myers Squibb	●	●	●	●	●
Boehringer Ingelheim	●	●	●	●	●
Daiichi Sankyo	●	●	●	●	●
Eisai	●	●	●	●	●
Eli Lilly	●	●	●	●	●
Gilead	●	●	●	●	●
GSK	●	●	●	●	●
Johnson & Johnson	●	●	●	●	●
MSD	●	●	●	●	●
Merck	●	●	●	●	●
Novo Nordisk	●	●	●	●	●
Novartis	●	●	●	●	●
Pfizer	●	●	●	●	●
Roche	●	●	●	●	●
Sanofi	●	●	●	●	●
Takeda	●	●	●	●	●
Total	15	20	17	20	15

Thirteen companies in scope demonstrate best practice by applying all compliance controls looked for by the Index

RESEARCH AND DEVELOPMENT

HOW R&D CAN HELP EXPAND ACCESS TO MEDICINE

The Research and Development (R&D) technical area focuses on the products that companies are developing to target diseases in scope of the Index. The Index tracks R&D activity for all diseases in scope, with a particular focus on those which lack treatment options and disproportionately affect people in low- and middle-income countries (LMICs). These so called 'priority diseases' require R&D investment to develop viable treatments. Such product development is referred to as 'priority R&D' by the Index. Companies have the expertise and resources to develop products with the potential to overcome these treatment gaps.

Inequitable access to healthcare products is a universal issue, therefore companies should begin developing individual access plans for each product in the pipeline to ensure that they will be available to those that need them, regardless of where they live. The quality and geographic scope of these R&D access plans are evaluated to assess whether companies are laying the groundwork to make their products available and accessible to people living in LMICs. Outside of their own pipelines, companies can contribute to capacity building by working with local stakeholders during the R&D process. This empowers local researchers to address relevant R&D needs and identifies key access obstacles that may be faced once the products are registered.

The importance of developing new products and initiating plans for access during the R&D stage is increasingly recognised by global health stakeholders. Consequently, in terms of scoring and ranking the companies, this technical area is more heavily weighted than in the previous Index.

PERFORMANCE INDICATORS

The companies' performance in the R&D technical area is assessed against the following criteria:

- **Product development:** The composition of a company's pipeline, including the number and type of projects in development targeting diseases in scope of the Index.
- **R&D investment disclosure:** Transparency of R&D investment data is necessary to highlight gaps in funding for neglected diseases.
- **Planning for access:** Planning ahead to ensure new products can be swiftly made available and accessible in countries in scope. Such plans are referred to as 'access plans.'
- **R&D capacity building:** The quality of initiatives that build local R&D capacity is assessed against the Good Practice Standards framework (see Appendix IV).

WHAT DOES BEST PRACTICE LOOK LIKE?

The best-performing companies have projects in development that address urgent R&D treatment gaps for priority diseases as identified by global health organisations. Top companies systematically plan for access during R&D and have policies to implement project-specific access plans no later than Phase II of clinical trials. Leading companies put these policies into practice and provide evidence of comprehensive plans for every late-stage project in development, i.e., from Phase II onwards. Comprehensive plans consider ways to make the product available in the countries in scope of the Index and ensure it can be supplied continuously at an affordable price. The best plans have a broad geographic scope in order to reach the greatest number of patients.

INSIGHTS

- 1 Slight decrease in the number of R&D projects in the pipeline targeting diseases in scope. 1,060 projects in 2022 compared to 1,073 projects in 2021.
- 2 62 products received regulatory approval and 479 new projects were added to the pipeline during the period of analysis.*
- 3 Over one third of projects in the pipeline target treatment gaps identified as priority R&D.
- 4 All companies improve in planning for access for late-stage R&D projects. However, these plans tend to focus on a core group of upper-middle income countries, with only 15% of plans including a low-income country.

FIND OUT MORE

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Assessing companies' access plans for pipeline projects	70

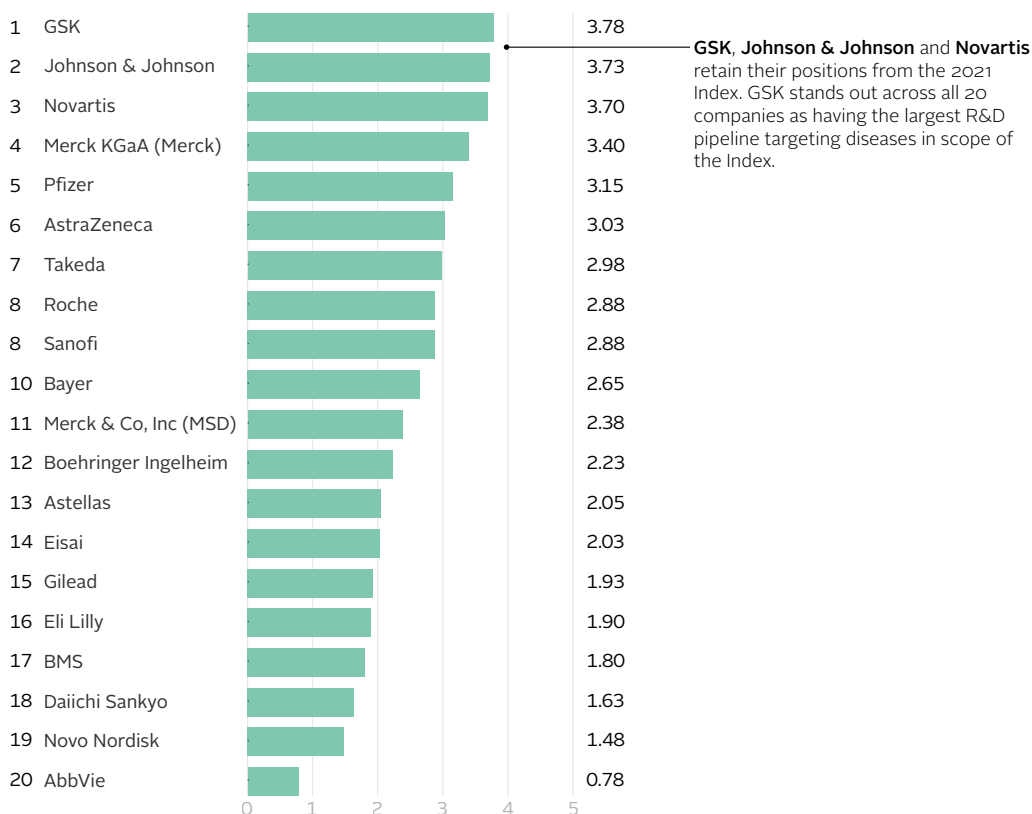
— This section takes an in-depth look at the quality and quantity of companies' access plans during the R&D stage

*This includes products that received emergency use authorisation or conditional marketing approval during the period of analysis (1 June 2020 - 31 May 2022).

HOW THE COMPANIES PERFORM

Marked improvement across the board in R&D

FIGURE 49 Research & Development Ranking



The top spot is retained by GSK, followed closely by Johnson & Johnson and Novartis. Out of all 20 companies, GSK has the largest pipeline targeting diseases in scope of the Index. It also has the largest number of projects in development that target priority diseases such as malaria, tuberculosis and HIV/AIDS.

The top-performing companies score highly across all assessment criteria, including access planning and capacity building. Johnson & Johnson, Novartis, and Merck provide evidence of access planning during the R&D stage for all late-stage projects in this analysis.

Bayer has made progress from its previous ranking in the R&D technical area by introducing a comprehensive policy that systematically plans for access. Furthermore, the company includes the highest number of countries in its access plans on average.

PIPELINE ANALYSIS

Products in the pipeline: are companies addressing R&D priorities?

New health products, including medicines, vaccines and diagnostics, can help those suffering from previously untreatable conditions or enhance health outcomes by improving on existing treatments. However, the development of health products is a lengthy and expensive process. Because they need to conform to high standards of safety and efficacy, most candidates in development targeting unmet healthcare needs never reach the market. As a result, developments for diseases with high burdens in LMICs are often overlooked in favour of products for markets that are more profitable.

To tackle this problem, the global health community has urged that the needs of people living in LMICs should be proactively included in companies' R&D activity. The industry plays a pivotal role in responding to this call. For example, GSK and Novartis have reinforced commitments to invest in R&D for neglected tropical diseases (NTDs).¹

How R&D priorities are identified and defined in this analysis

The World Health Organization (WHO) and Policy Cures Research, an independent R&D-focused policy group, have published lists of the most urgently needed products to incentivise their development. Thirty-nine of the diseases, conditions and pathogens in scope of the 2022 Index are included on these lists, and are considered 'priority diseases' – i.e., particular R&D priorities for global health. The Access to Medicine Index assesses R&D activity for these projects separately from other diseases in scope to highlight companies' efforts in addressing unmet healthcare needs for diseases despite there being little financial incentive to do so. The Index also monitors R&D activity for diseases in scope that fall outside the 'priority disease' categorisation, because these diseases have a high prevalence in LMICs.

When no product is currently available on the market to sufficiently treat, diagnose or prevent a priority disease, or therapeutic efficacy is lacking; this is defined as a 'product gap.' These products may be medicines, vaccines, diagnostics, medical devices or vector control products. Every company, regardless of size or therapeutic focus, can play a role in addressing these gaps. This analysis looks at which of these gaps are being addressed by the 20 companies assessed. Any project in the pipeline that targets a product gap for a priority disease is considered 'priority R&D' by the Index. There are 243 product gaps within scope of the Index. As these priority lists focus primarily on neglected and communicable diseases, the Access to Medicine Index methodology also analyses products for non-communicable diseases (NCDs) that have a clear public health value in LMICs.

FIGURE 50 About a third of projects address a specific priority R&D gap

R&D projects usually start in the discovery phase of development and progress through the pipeline until they are approved for market use.

Note that the 2022 Index does not monitor pre-clinical R&D activity for non-priority diseases.

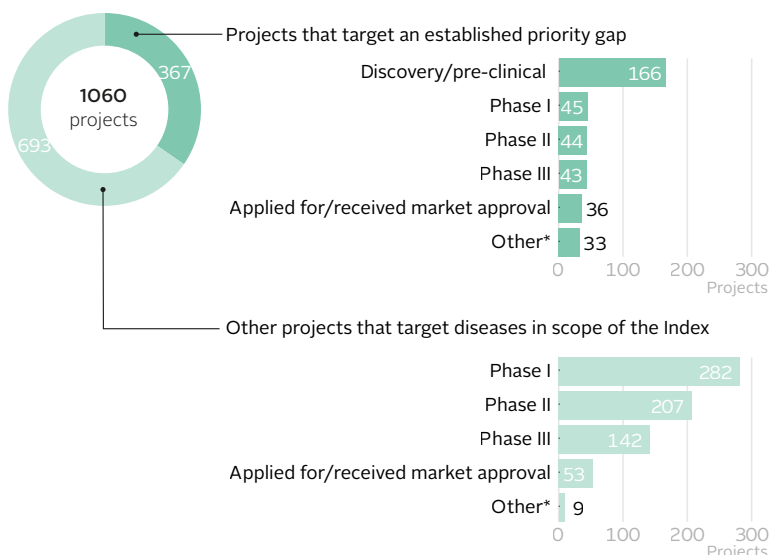


FIGURE: 51 What does each company pipeline look like?

All companies are developing products that target an established R&D priority gap.

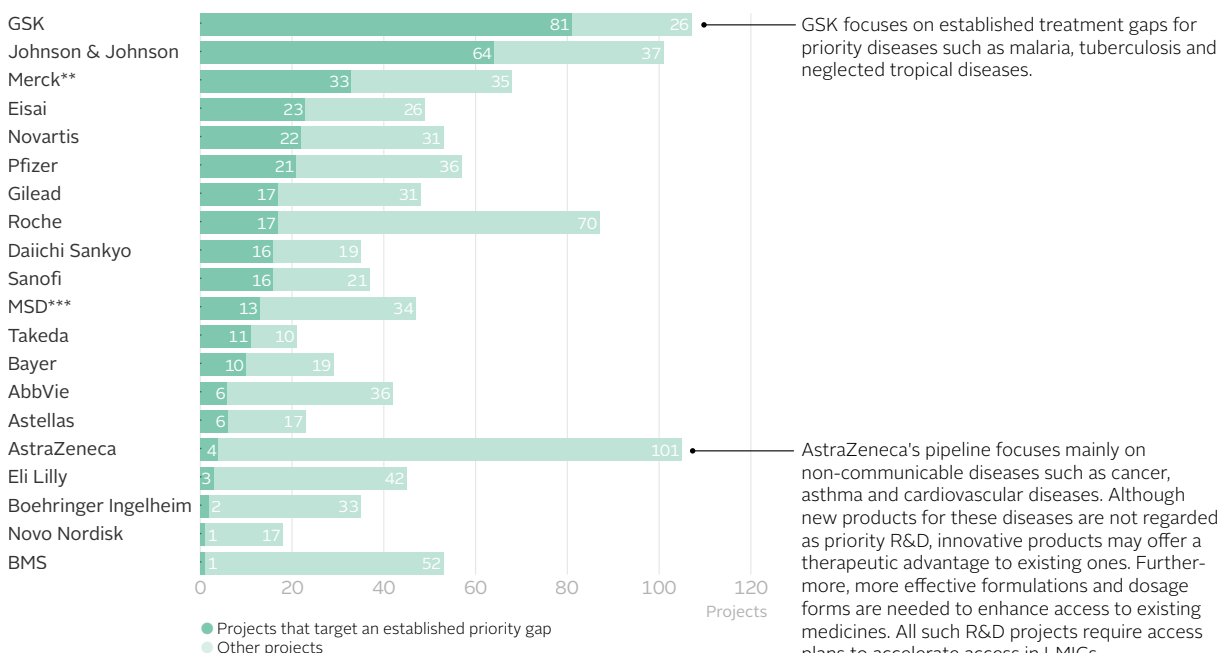
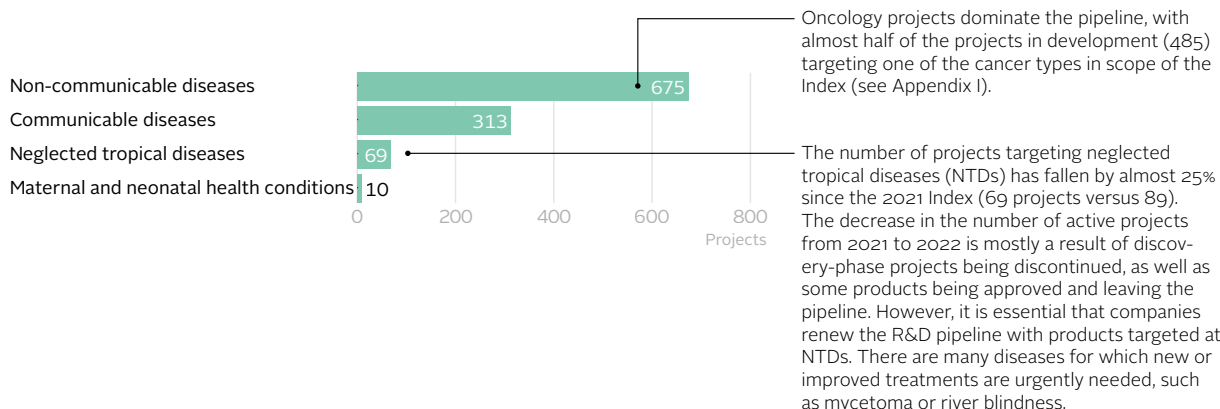


FIGURE: 52 More than half of projects are for non-communicable diseases

This chart shows which diseases are the focus of the 1,060 R&D projects.*

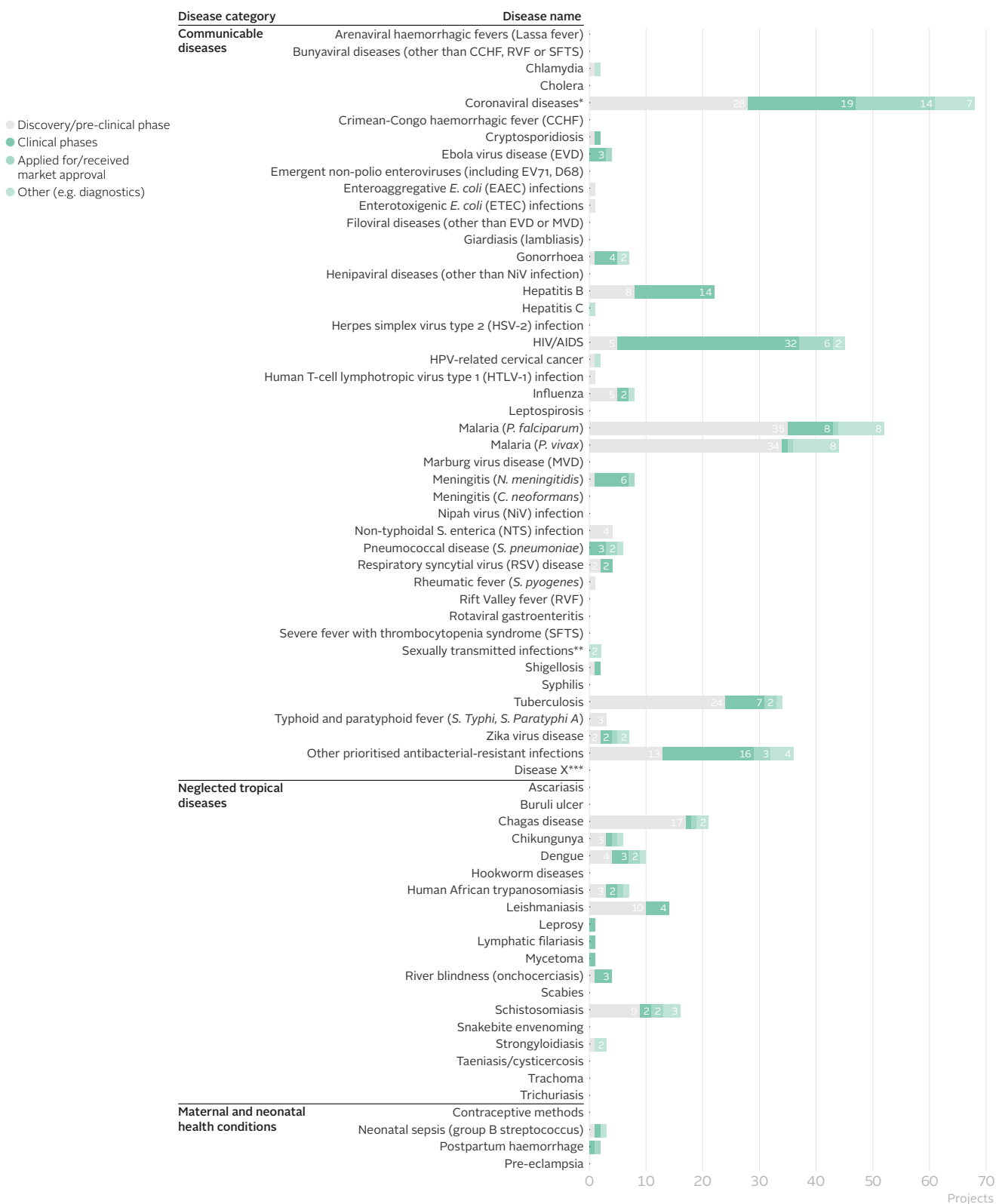


*Other includes projects that are market approved, subject to first global registration, have a technical lifecycle and projects that follow a different development cycle (e.g., diagnostics).

**Merck KGaA (Darmstadt, Germany)
 ***Merck & Co, Inc (Rahway, NJ, USA)
 †The total is the sum of all projects counted. Some projects fall into several disease categories.

FIGURE 53 By disease, how does the priority R&D pipeline break down?

Although all the diseases in this figure have been identified as priority diseases by global health stakeholders, the number of projects in development to address the priority gaps varies according to disease type. There are many projects in development targeting coronaviral diseases, malaria and HIV/AIDS, while other neglected diseases are left behind.



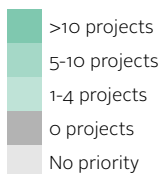
*Including Middle East respiratory syndrome coronavirus (MERS-CoV), Severe acute respiratory syndrome (SARS) and other highly pathogenic coronaviral diseases. There were only developments for COVID-19.

**Other than chlamydia, gonorrhoea, syphilis or HSV-2 or HTLV-1 infections.
 ***Disease X is defined by WHO as a pathogen currently unknown to cause human disease that could cause a serious international epidemic. Priority R&D for this dis-

ease is restricted to platform technologies that enable cross-cutting R&D preparedness that is also relevant for an unknown Disease X. Not included in the remaining gaps.

FIGURE 54 For many diseases, there are no products in development to address treatment gaps

This table shows how many R&D projects the companies are pursuing for each of the priority diseases and conditions in scope of the Index, broken down by the category of product (e.g., whether it is a vaccine or medicine). The 'product gaps' indicated in the table show which products are urgently needed by people living in low- and middle-income countries, as identified by WHO and Policy Cures Research (see Appendix I). R&D gaps include maternal health conditions, such as pre-eclampsia and several sexually transmitted infections (STIs), as well as emerging infectious diseases such as Crimean Congo haemorrhagic fever. The zeroes represent gaps for which no R&D activity could be identified. Of the gaps, 173 of the 243 are unaddressed.



Disease category	Disease name	Medicines	Vaccines (preventive)	Vaccines (therapeutic)	Diagnostics	Microbicides	Vector control products	Devices (for reproductive health only)	Gaps remaining
Communicable diseases	Arenaviral haemorrhagic fevers (Lassa fever)	0	0	0	0				4
	Bunyaviral diseases (other than CCHF, RVF or SFTS)	0	0	0	0		0		5
	Chlamydia	0	1	0	1				1
	Cholera	0	0	0	0				4
	Coronaviral diseases*	42	17	0	3		0		2
	Crimean-Congo haemorrhagic fever (CCHF)	0	0	0	0		0		5
	Cryptosporidiosis	2	0	0	0				3
	Ebola virus disease (EVD)	0	4	0	0		0		4
	Emergent non-polio enteroviruses (including EV71, D68)	0	0	0	0				4
	Enterogastric <i>E. coli</i> (EAGC) infections	0	1	0	0				1
	Enterotoxigenic <i>E. coli</i> (ETEC) infections	0	1	0	0				1
	Filoviral diseases (other than EVD or MVD)	0	0	0	0		0		5
	Giardiasis (lambliaosis)	0	0	0	0				1
	Gonorrhoea	3	2	0	2				1
	Henipaviral diseases (other than NiV infection)	0	0	0	0		0		5
	Hepatitis B	20	0	1	0				1
	Hepatitis C	0	0	0	1				2
	Herpes simplex virus type 2 (HSV-2) infection	0	0	0	0				4
	HIV/AIDS	39	2	2	1	0			1
	HPV-related cervical cancer	0	1	0	1	0		0	4
	Human T-cell lymphotropic virus type 1 (HTLV-1) infection	0	0	1	0				3
	Influenza	0	8	0	0				0
	Leptospirosis	0	0	0	0				1
	Malaria (<i>P. falciparum</i>)	38	3	0	1		5		1
	Malaria (<i>P. vivax</i>)	32	1	0	1		5		1
	Marburg virus disease (MVD)	0	0	0	0		0		5
	Meningitis (<i>N. meningitidis</i>)	0	8	0	0				1
	Meningitis (<i>C. neoformans</i>)	0	0	0	0				2
	Nipah virus (NiV) infection	0	0	0	0		0		5
	Non-typhoidal <i>S. enterica</i> (NTS) infection	0	4	0	0				3
	Pneumococcal disease (<i>S. pneumoniae</i>)	0	6	0	0				1
	Respiratory syncytial virus (RSV) disease	0	3	0	0				0
	Rheumatic fever (<i>S. pyogenes</i>)	0	1	0	0				0
	Rift Valley fever (RVF)	0	0	0	0		0		5
	Rotaviral gastroenteritis	0	0	0	0				1
	Severe fever with thrombocytopenia syndrome (SFTS)	0	0	0	0		0		5
	Sexually transmitted infections**	0	0	0	2				3
	Shigellosis	1	1	0	0				2
	Syphilis	0	0	0	0				4
	Tuberculosis	33	1	0	0				2
	Typhoid and paratyphoid fever (<i>S. Typhi</i> , <i>S. Paratyphi A</i>)	0	3	0	0				3
	Zika virus disease	2	2	0	0		2		2
	Other prioritised antibacterial-resistant infections†	19	14	0	1				-
	Disease X***	0	0	0	0				0
	Neglected tropical diseases	Ascariasis	0	0	0	0			
Buruli ulcer		0	0	0	0				3
Chagas disease		19	0	1	0		1		2
Chikungunya		3	1	0	0		2		2
Dengue		7	1	0	0		2		2
Hookworm diseases		0	0	0	0				2
Human African trypanosomiasis		6	0	0	0		1		3
Leishmaniasis		14	0	0	0				3
Leprosy		1	0	0	0				3
Lymphatic filariasis		1	0	0	0		0		2
Mycetoma		1	0	0	0				1
River blindness (onchocerciasis)		4	0	0	0		0		3
Scabies		0	0	0	0				2
Schistosomiasis		9	0	0	2		0		3
Snakebite envenoming		0	0	0	0				3
Strongyloidiasis		0	0	0	1				2
Taeniasis/cysticercosis		0	0	0	0		0		3
Trachoma		0	0	0	0				2
Trichuriasis		0	0	0	0				1
Maternal and neonatal health conditions		Contraceptive methods	0	0	0	0		0	
	Neonatal sepsis (group B streptococcus)	0	2	0	0				0
	Postpartum haemorrhage	2	0	0	0		0		1
	Pre-eclampsia	0	0	0	0				3

*Including Middle East respiratory syndrome coronavirus (MERS-CoV), Severe acute respiratory syndrome (SARS). There were only developments for COVID-19.

**Other than chlamydia, gonorrhoea, syphilis or HSV-2 or HTLV-1 infections.

***Disease X is defined by WHO as a pathogen currently unknown to cause human disease that could cause a serious interna-

tional epidemic. Priority R&D for this disease is restricted to platform technologies that enable cross-cutting R&D preparedness that is also relevant for an unknown

Disease X. Not included in the remaining gaps.

† The WHO priority pathogen list does not define specific products needed.

Exiting the pipeline: recently approved products

During the period of analysis,* 62 R&D projects successfully reached the end of the pipeline. Companies were then able to launch these new products by filing for registration with a national regulatory authority – the first steps towards making a product available. When a product meets the standards of safety and efficacy set by the regulators, it is deemed 'approved' and can be marketed. Below are examples of products that received regulatory approval with an internationally recognised authority during the period of analysis, as well as details of the specific steps that companies are taking to make these products available and accessible in LMICs.

VACCINE REGIMEN FOR EBOLA

Company: Johnson & Johnson

Description: In 2020, Zabdeno® & Mvabea®,** a two-shot vaccine regimen to prevent Ebola virus disease (Zaire ebolavirus strain), was approved by the European Medicines Agency (EMA). In April 2021, WHO granted pre-qualification status to the regimen.² This is an important step that could accelerate registration in countries with high disease burdens, where an outbreak is likely to occur.

PAEDIATRIC FORMULATION FOR MALARIA

Company: GSK

Description: In 2022, tafenoquine (Kozenis®) received regulatory approval for the prevention of relapse of *Plasmodium vivax* malaria in paediatric populations. Developed in partnership with Medicines for Malaria Venture (MMV), the approval includes a novel 50 mg tablet that can be dispersed in water. This makes administration much easier for children, who are disproportionately affected by the disease.

PAEDIATRIC FORMULATION FOR CHAGAS DISEASE

Company: Bayer

Description: In 2020, nifurtimox (Lampit®) became the first US Food and Drug Administration (FDA)-approved treatment for Chagas disease in children. Nifurtimox has been available for several decades, but Bayer has developed a new paediatric formulation that disperses in water to assist in administration for children.

ORAL TREATMENT FOR SLEEPING SICKNESS

Company: Sanofi

Description: Developed by Sanofi in partnership with Drugs for Neglected Diseases *initiative* (DNDi), fexinidazole was approved during the period of analysis as the first all-oral treatment for both stages of sleeping sickness (human African trypanosomiasis). Sanofi's plan for access includes registration in countries within scope of the Index, submitting the product for WHO prequalification, and a donation programme in partnership with WHO to ensure availability in endemic countries.

Spotlight on R&D for diabetes

Diabetes is a growing problem worldwide with approximately 75% of the 537 million adults with diabetes living in LMICs.³ Yet, access to diabetes products such as insulins and glucometers is often limited in LMICs. For glucose-lowering medicines (including insulin) only half of people in LMICs reported having their treatment needs met.⁴ In LMICs, there are many barriers to accessing products currently available on the market – for example, insulins require continuous cold storage and both insulin and delivery devices such as pens often present affordability challenges. R&D can therefore play an essential role in overcoming these barriers to access for people with diabetes in LMICs. The Access to Medicine Index has identified several promising projects in development with the potential to address the needs of people with diabetes living in LMICs.

Sanofi's biosimilar insulin aspart was approved during the period of analysis. A biosimilar drug is a drug that is highly similar to a biological drug (such as insulin) that is already on the market. Quality-assured biosimilar insulins can stimulate price competition and hold a great deal of as-yet unrealised potential, especially with several patents on long-acting insulins recently expiring.

Novo Nordisk is developing DuraTouch, a low-cost durable pen device for the administration of insulin. Access to an affordable pen device has the potential to improve adherence to insulin regimens, as it is a preferred mode of administration to traditional insulin vials (which require syringes to inject the insulin). The company plans to make this product available in several countries in scope of the Index.

Novo Nordisk received a positive opinion from the EMA to update the storage conditions of two of its human insulin products, insulin human (rDNA) (Actrapid®) and isophane human insulin (rDNA) (Insulatard®). The more flexible storage conditions allow the insulins to be stored outside a refrigerator for up to four weeks before opening (if kept below 30C°) in countries outside the European Union. This has the potential to facilitate insulin distribution and storage in countries in scope of the Index, for example, during humanitarian crises and in areas where access to refrigeration is limited. In August 2022, Novo Nordisk received the first country approval for the new storage conditions in Lebanon, the company plans to pursue national submissions in more than 50 low- and middle-income countries.

Further analysis of the actions that pharmaceutical companies are taking to ensure access to insulin in LMICs and opportunities for expanding access to diabetes care can be found in the Access to Medicine Foundation's October 2022 report.⁵

Conclusions

The Index finds that projects targeting NCDs continue to dominate the pipeline, with almost half of all pipeline projects targeting a type of cancer in scope. The total number of projects in development has remained relatively consistent with the last Index (1,073 in 2021, compared to 1,060 in 2022). There has, however, been a significant drop in the number of projects in development to treat neglected tropical diseases.

367 projects in development target an R&D product gap for a priority disease. These projects primarily focus on coronaviral diseases, HIV/AIDS, malaria and tuberculosis. The number of projects targeting these diseases has remained relatively consistent since the last Index (374 priority projects in 2021). Despite priority diseases comprising one third of the pipeline, several product gaps remain unaddressed. Consequently, there continues to be little to no R&D activity developing products for several debilitating diseases that disproportionately affect people in LMICs.

ACCESS PLANNING

Assessing the quality and quantity of companies’ access plans during the R&D stage

Why should companies begin planning for access during the R&D stage?

Planning for access is important during the research and development (R&D) phase to facilitate timely access to medicines. It is crucial that pharmaceutical companies begin planning during the development phase to overcome potential barriers to access, particularly in low- and middle income countries (LMICs) where, for example, poor supply chain infrastructure or weak regulatory capacity can be obstacles to access. Due to large variations in healthcare systems between countries, this complex task requires country-by-country assessments. This is why companies need to start early on during R&D to ensure that access is accelerated once the new product is registered.

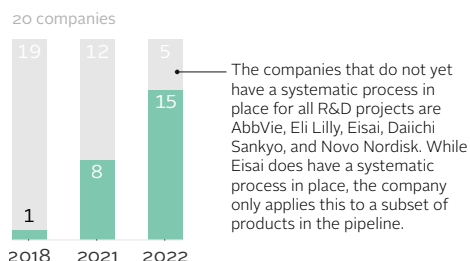
Companies are expected to start establishing access plans for projects that are in Phase II of clinical development and onwards, referred to as 'late-stage candidates'. Pharmaceutical companies need to plan ahead to ensure new products are rapidly accessible and affordable once they become available.

Industry puts policies into practice

The previous Index found a shift within the pharmaceutical industry towards systematic access planning during R&D. In 2021, the Index identified eight companies leading in implementing frameworks for access planning. This year 15 companies now have systematic frameworks to plan for access in LMICs for all R&D projects.

FIGURE 55 Number of companies with processes to systematically address access to medicine for all new products

The number of companies that now have systematic frameworks in place to plan for access in LMICs for all R&D projects has increased in successive editions of the Index.



The number of companies that now plan for access during R&D for every single late-stage project in scope has risen from zero in the previous 2021 Index to six. Johnson & Johnson, Merck, Novartis, and Takeda – four of the eight companies that were highlighted as shifting to more systematic access planning for their R&D projects in the previous Index – have now reported access planning for 100% of all their late-stage R&D projects. Additionally, Astellas and Boehringer Ingelheim also have access plans for all their late-stage R&D projects. This marks the first time any of the companies have reached this milestone and represents a significant improvement.

FIGURE 57 19 of the 20 companies demonstrate evidence of access planning

This figure shows the percentage of late-stage R&D candidates for which each company has access plans.

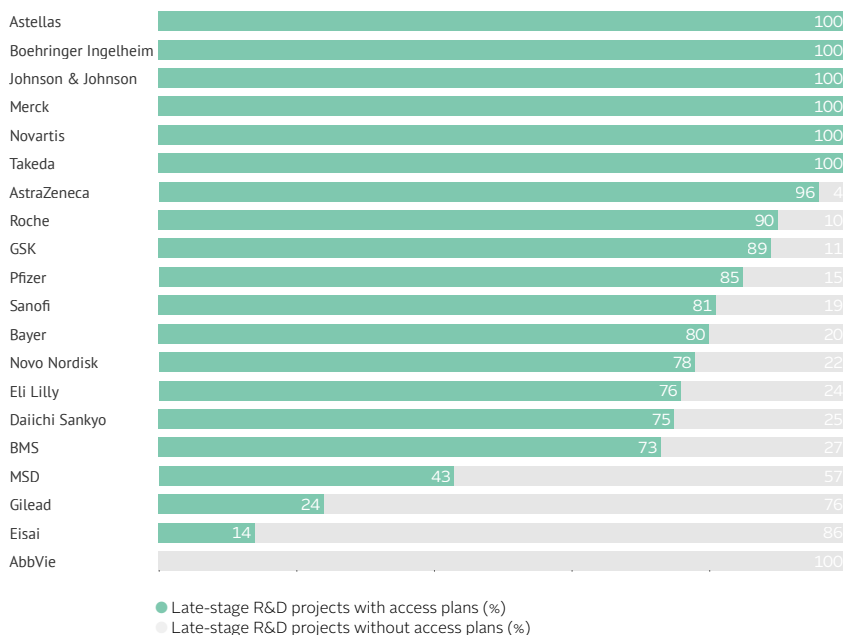


FIGURE 56 Six companies now plan for access for all late-stage projects

In the 2021 Index, no companies had access plans in place for all late-stage R&D projects, so this represents a significant improvement.

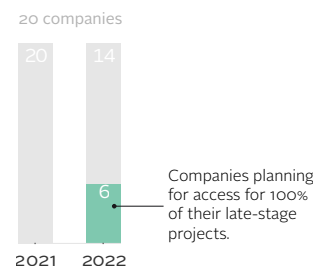
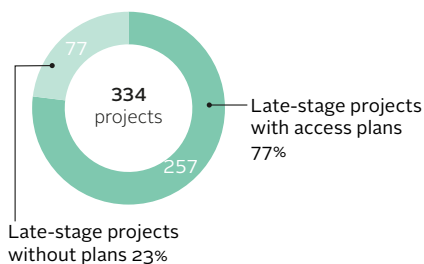


FIGURE 58 One in four projects have no access plans in any countries in scope of the Index

This figure shows the proportion of late-stage projects in the pipeline supported by an access plan for at least one country in scope.



More than three-quarters of late-stage R&D projects (77%) are accompanied by an access plan in at least one country in scope of the Index. This finding is a significant improvement compared to the previous Index, where 40% of late-stage projects were covered by an access plan. Although there is progress in access planning, many products and many countries in scope are not covered by any access plan at all.

Access plans focus on a small number of LMICs, with the poorest countries missing out

Despite an industry-wide improvement in planning for access during the R&D stage, the number of countries included in plans is low. On average, an access plan includes only six of the 108 countries in scope of the Index, and only 38 out of 257 projects (15%) are covered by an access plan that includes at least one low-income country. This gap in access is amplified further for non-communicable diseases (NCDs) where only 5.5% of plans include a low-income country. Donor funding is typically directed towards prioritised communicable diseases, yet the growing burden of NCDs in LMICs means that resources need to be directed towards these diseases during the R&D stage to ensure equitable access. Notably, Bayer's access plans include an average of 26 countries in scope, with 63% of these plans including a low-income country. These access plans target both communicable and NCDs in scope of the Index.

The countries included in access plans often mirror those where clinical trials are being conducted. Predominantly, they are upper-middle income countries or emerging markets such as India, South Africa, China, Mexico, Colombia and Brazil. Carrying out clinical research can be a gateway to providing access to investigative and, in due course, approved medicines for people living in these countries. In general, if the medicine is successful in clinical trials, companies commit to filing for regulatory approval in the countries where the trials have taken place.

To expand the range of countries in which clinical trials take place, Roche has initiated a framework for clinical trials in East Africa. The company is building local research and clinical trial capacity in Uganda and Kenya and is thereby ensuring the inclusion of patients in Africa in clinical trials, focusing initially on oncology.

FIGURE 59 Which countries are included in access plans?

Companies are more likely to plan for access in emerging markets such as Brazil, India, China, Mexico and South Africa. Consequently, the availability of newly-launched products may be limited to these countries. Fewer plans for product launch consider lower-middle income countries and low-income countries.

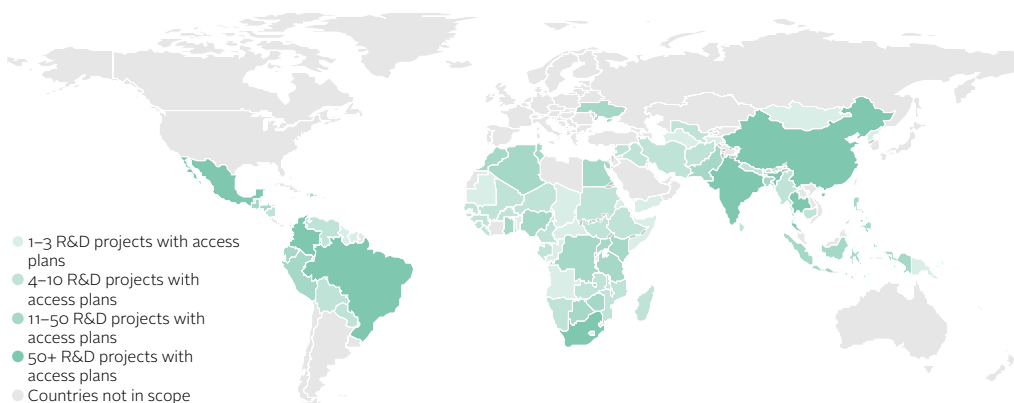
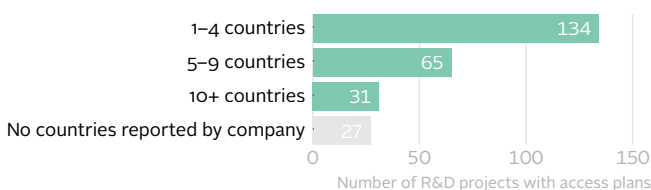


FIGURE 60 Geographic reach of R&D access plans

More than half of access plans include fewer than five countries in scope of the Index.



What are the components of a good access plan for R&D projects?

The Index analyses access plans that are project specific and tailored to the needs of countries in scope. There is no one-size-fits-all approach to access planning, but a comprehensive plan considers availability, affordability and sustainable supply of the product.

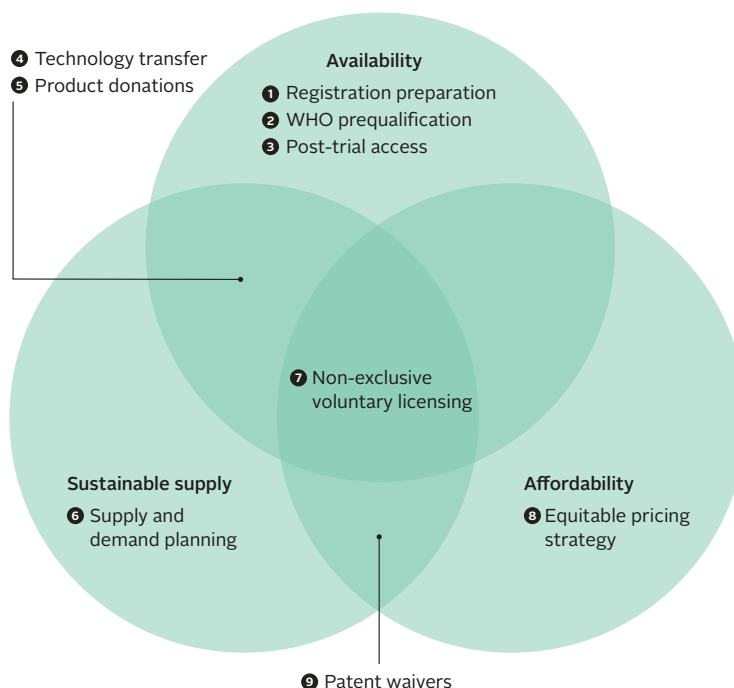
The Index has identified several components that are conducive to access. These are:

- 1 Plans to register the product in many of the countries in scope**
To make a product available, companies must file for registration with the national regulatory agency of the country where they intend to market the product. Once the product receives regulatory approval, it can be marketed in that country. To ensure that the largest unmet medical needs are addressed for each project, companies must consider burden of disease when deciding where to launch the product on the market.
- 2 Plans to apply for WHO prequalification**
Prequalification means WHO has deemed the product to meet acceptable standards of quality, safety and efficacy. This process can accelerate the registration process in LMICs where national regulatory capacity may be lacking.
- 3 Post-trial access guarantees for clinical trial participants**
Once clinical trials have ended, companies can provide continued access to the investigational products that have demonstrated significant benefits.
- 4 Plans to engage in technology transfers or local manufacturing arrangements**
Companies can transfer knowledge on a medicine and its established manufacturing processes to local manufacturers. This ensures that the product is available in sufficient quantities to meet demand locally.

- 5 Plans to make product donations**
Companies can donate products to increase availability in countries within scope of the Index.
- 6 Supply and demand planning**
Companies can plan by forecasting the anticipated quantities of a product required in countries within scope of the Index. This can help to guarantee supply chains and prevent drug shortages.
- 7 Commitments to engage in non-exclusive voluntary licensing agreements**
If a company does not intend to register a product in countries within scope of the Index, it can engage in non-exclusive voluntary licensing. These agreements allow selected manufacturers to produce generic versions of the drug and supply them in countries where the product may otherwise be unavailable.
- 8 Plans to apply equitable pricing strategies**
To ensure accessibility, companies must ensure that products are affordable. Each project should be accompanied by an equitable pricing strategy that considers ability to pay in different countries. As best practice companies should include intra-country differential pricing with special prices for the public sector and/or health insurance; this is especially relevant for upper-middle income countries with large private markets.
- 9 Commitments to future patent waivers**
Companies can waive intellectual property rights for products in LMICs. This enables generic manufacturers to produce the product without the risk of infringing patents.

A comprehensive plan includes several of these ‘access components’ to expedite access to the product while it is still in the R&D stage. Furthermore, the access plan should have a broad geographic scope to maximise the number of patients reached.

FIGURE 61 At the R&D stage, a good access plan includes multiple access components
Access plans must address availability, affordability and sustainable supply. Various combinations of access components can be incorporated to fulfil these requirements.



Many plans include very few 'access components' and are far from comprehensive

Although there has been progress in the proportion of late-stage R&D projects with access plans, the quality of access plans for projects in the pipeline varies widely. To be comprehensive, an access plan must consider several factors to ensure a medicine is available and affordable.

Of the 257 plans analysed, 134 (52%) only contain plans for registration in countries in scope but have no other components to ensure equitable access. Regulatory approval is necessary for a drug to be launched in a particular country but is not sufficient to guarantee patients' access to medicine, unless companies take further steps to make the product available and affordable.

Only 56 plans (22%) contained project-specific strategies that address affordability. Furthermore, only 22 plans (8%) consider the burden of disease when deciding what countries in scope of the Index to launch the product in. There is discrepancy in the quality of access plans for priority diseases compared to those for NCDs. Inclusion of R&D gaps for NCDs on priority lists could stimulate R&D activity and access planning to address these gaps.

Although companies have made headway in planning for access during R&D, there is a lack of evidence to suggest that these plans will result in access to the populations that need them the most. Without tailored plans to ensure affordability and supply in countries in scope of the Index, these products may remain out of reach for many when they are brought to market.

Partnering with access-oriented organisations to improve access planning

R&D projects developed in collaboration with access-oriented organisations such as Wellcome Trust, the Bill and Melinda Gates Foundation and DNDi have more comprehensive access plans than those which aren't. The Index found that these projects consider on average 4.1 access components (compared with 1.9 components for other projects). This means these access plans are more likely to consider a variety of factors to enable access (e.g., availability, affordability and supply). Almost 30% of priority R&D projects are developed in partnership with access-oriented organisations and almost half are in partnership with partners that receive public funding.

FIGURE 62 Which access components do companies use?

In this chart, a green dot indicates that the company has used the access component at least once in any of its access plans. On the other hand, a grey dot indicates that there was no evidence for this.

	Registration preparation	WHO prequalification	Post-trial access	Technology transfer	Product donations	Supply and demand planning	Non-exclusive voluntary licensing	Equitable pricing strategy	Patent waivers
AbbVie	●	●	●	●	●	●	●	●	●
Astellas	●	●	●	●	●	●	●	●	●
AstraZeneca	●	●	●	●	●	●	●	●	●
Bayer	●	●	●	●	●	●	●	●	●
Bristol Myers Squibb	●	●	●	●	●	●	●	●	●
Boehringer Ingelheim	●	●	●	●	●	●	●	●	●
Daiichi Sankyo	●	●	●	●	●	●	●	●	●
Eisai	●	●	●	●	●	●	●	●	●
Eli Lilly	●	●	●	●	●	●	●	●	●
Gilead	●	●	●	●	●	●	●	●	●
GSK	●	●	●	●	●	●	●	●	●
Johnson & Johnson	●	●	●	●	●	●	●	●	●
MSD	●	●	●	●	●	●	●	●	●
Merck	●	●	●	●	●	●	●	●	●
Novo Nordisk	●	●	●	●	●	●	●	●	●
Novartis	●	●	●	●	●	●	●	●	●
Pfizer	●	●	●	●	●	●	●	●	●
Roche	●	●	●	●	●	●	●	●	●
Sanofi	●	●	●	●	●	●	●	●	●
Takeda	●	●	●	●	●	●	●	●	●

Access plans for key R&D projects

Below are some examples of important access plans identified by the Index. These access plans demonstrate how companies are planning to ensure access to their products in LMICs and are tailoring their access plans to the needs of different patient populations.

GSK, MALARIA VACCINE

In 2021, GSK's malaria vaccine RTS,S/ASo1 (Mosquirix™) was recommended by WHO for large-scale implementation and rollout to children living in regions with moderate to high transmission. The recommendation was based on a pilot programme that was supported by GSK and carried out in three countries in scope of the Index: Ghana, Kenya and Malawi. As part of its plans for access GSK has donated the first ten million doses for use in the pilots and publicly committed to a not-for-profit price. It has also submitted a dossier for prequalification to WHO. In parallel, it is building capacity for large-scale sustainable manufacturing of the vaccine and has entered into a technology transfer agreement with Indian manufacturer Bharat BioTech Vaccines.

TAKEDA, DENGUE VACCINE

During the period of analysis,* Takeda began regulatory submissions for its dengue vaccine QDENGGA® (TAK-003). In August 2022 (after the period of analysis concluded), the vaccine received first regulatory approval in Indonesia and subsequently was recommended for approval in the EU and dengue-endemic countries by the Committee for Medicinal Products for Human Use (CHMP) of EMA.⁶ Takeda's access plan for its dengue vaccine focuses primarily on countries with the highest unmet medical need. The company's access plan includes innovative equitable pricing models and plans for sustainable supply.

BAYER, CHRONIC KIDNEY DISEASE ASSOCIATED WITH TYPE 2 DIABETES

In 2021, the FDA approved finerenone (Kerendia®) for the treatment of patients with chronic kidney disease (CKD) associated with type 2 diabetes. Bayer has a comprehensive access plan with a clear objective to address patient access by considering affordability for patients. Multiple measures are being taken by the company to accelerate access, including a comprehensive strategy to gain regulatory approval in a wide range of countries. The plan covers 29 countries in scope of the Index, including low-income countries.

MERCK, SCHISTOSOMIASIS TREATMENT

In partnership with the Pediatric Praziquantel Consortium, Merck is developing arpraziquantel, a potential new treatment option for children under six years old suffering from schistosomiasis.⁷ Merck's access plan considers availability, affordability and supply. Merck intends to apply for WHO prequalification to accelerate regulatory approval in countries within scope of the Index, and has also entered into a contract manufacturing agreement with Universal Corporation Ltd., Nairobi, Kenya for the large-scale production and future provision of the treatment in endemic countries in Africa.

BAYER, VECTOR CONTROL PRODUCT FOR MOSQUITO-BORNE DISEASES

Bayer's Fludora® Co-Max is a vector control product used to control adult mosquitos (*Aedes spp.* and *Culex spp.*). With its dual mode of action (providing benefits in managing pyrethroid- and organophosphate-resistant mosquitoes and in slowing down the development of resistance) it has the potential to prevent mosquito-borne diseases such as Zika and dengue. The product received WHO prequalification during the period of analysis to facilitate faster registration in countries where it is required. Bayer also provides evidence that it plans to register the product in several countries in scope of the Index.

*Period of analysis: 1 June 2020 - 31 May 2022

PFIZER, GROUP B STREPTOCOCCUS VACCINE

Pfizer is developing a group B streptococcus vaccine candidate (PF-o676o8o5) with funding from the Bill and Melinda Gates Foundation (BMGF). The support from BMGF will enable faster and more equitable deployment of the vaccines, particularly in LMICs with high burden of disease, at a sustainable price. Plans for sustainable supply and WHO prequalification are in development should the vaccine be successful in clinical trials.

NOVARTIS, IV FORMULATION FOR SEVERE MALARIA

In partnership with PAMAfrica Consortium funded by EDCTP and Wellcome Trust, Novartis is developing cipargamin (KAE6o9), an IV formulation for the treatment of severe malaria. Although the project is only in Phase II of clinical trials, Novartis provides evidence of a comprehensive plan for access. Clinical trials are ongoing or planned in 12 countries in scope of the Index. Should this candidate be successful in trials, Novartis commits to register the drugs in those countries in line with its post-trial access to medicines policy.

Conclusions

The 2022 Index has identified clear evidence that companies' policies for systematic access planning are actually being implemented, with more companies now establishing access plans for more of their projects in the R&D pipeline. Six companies now have access plans in place for all the late-stage candidates included in this analysis.

For leading companies, the focus must now shift to improving the quality and expanding the geographic reach of plans. The Index finds that companies' access plans only include an average of six of the 108 countries in scope, with certain countries included more often than others. Most plans focus solely on registration, but companies can do more to ensure that their plans consider affordability and sustainable supply. Establishing an access plan is a promising first step, but the quality of that plan is key to determining whether it results in widespread access in LMICs.

In particular, companies must do more to ensure a wider and more diverse range of countries are included in access plans, specifically low-income countries who are currently not included in more than 85% of plans. It is vital that this is planned out during the R&D stage to ensure that innovative products are widely and rapidly available to those that need them most.

REFERENCES

1. Grover N, Rigby J. GSK, Novartis pledge funds for diseases that mostly affect the poor. Published 2022. Accessed July 5, 2022. <https://www.reuters.com/business/health-care-pharmaceuticals/gsk-novartis-pledge-funds-diseases-that-mostly-affect-poor-2022-06-23/>
2. Johnson & Johnson. Johnson & Johnson Ebola Vaccine Regimen Demonstrated Robust and Durable Immune Response in Adults and Children in Data Published in The Lancet Infectious Diseases. Published 2021. Accessed August 24, 2022. <https://www.jnj.com/johnson-johnson-ebola-vaccine-regimen-demonstrated-robust-and-durable-immune-response-in-adults-and-children-in-data-published-in-the-lancet-infectious-diseases>
3. International Diabetes Federation. IDF Diabetes Atlas 10th Edition; 2021.
4. Flood D, Seiglie JA, Dunn M, et al. The state of diabetes treatment coverage in 55 low-income and middle-income countries: a cross-sectional study of nationally representative, individual-level data in 680102 adults. *Lancet Healthy Longev.* 2021;2(6):e340-e351. doi:10.1016/S2666-7568(21)00089-1
5. Martinez C, Romero C, Sánchez Villalobos N. What are pharma companies doing to expand access to insulin - and how can efforts be scaled up? Access to Medicine Foundation. Published October 2022. Accessed November 1, 2022. <https://access-to-medicinefoundation.org/news/drug-makers-that-dominate-the-worlds-insulin-market-must-scale-up-access-efforts-globally>
6. Takeda. New Dengue Vaccine Approved in Indonesia for Use Regardless of Prior Dengue Exposure. Published 2022. Accessed September 7, 2022. <https://www.takeda.com/newsroom/newsreleases/2022/takeda-qdenga-dengue-tetravalent-vaccine-live-attenuated-approved-in-indonesia-for-use-regardless-of-prior-dengue-exposure/>
7. Merck. Merck Announces Positive Phase III Results for Arpraziquantel as Part of its Schistosomiasis Elimination Program. Published 2021. Accessed August 24, 2022. <https://www.merck-group.com/en/news/phase-three-results-for-arpraziquantel-16-11-2021.html>

PRODUCT DELIVERY

CONTEXT

The choices pharmaceutical companies make in delivering their products are a critical factor in ensuring people in need receive access to essential medicines and treatments. The Product Delivery Technical Area assesses a wide range of elements that contribute towards equitable access after a product has been developed. This includes, among others, registration, licensing, equitable pricing, donations, intellectual property sharing and health systems strengthening.

PERFORMANCE INDICATORS

Companies' performance in this Technical Area is assessed against the following indicators:

- Disclosing patent statuses and public commitment not to enforce patents
- Sharing intellectual property (IP) with third parties
- Using non-assert declarations and/or licensing agreements to enable generic medicine manufacturing and supply
- Registering products in countries within scope, highlighting those that face a high burden of disease
- Deploying access strategies for three types of products: supranationally procured, healthcare professional-administered and self-administered
- Engaging in manufacturing and supply chain capacity building initiatives
- Ensuring continuous product supply in low- and middle-income countries (LMICs)
- Engaging in health systems strengthening initiatives
- Piloting and scaling up inclusive business models that reach populations at the base of the income pyramid
- Reporting of substandard and falsified medicines in a timely manner
- Donating products in response to expressed need
- Engaging in structured donation programmes aimed at the elimination, eradication, or control of diseases in scope

WHAT DOES BEST PRACTICE LOOK LIKE?

Best-performing companies register their products in a wide range of LMICs in scope of the Index – in particular those facing the highest burden of disease.

Having equitable access strategies in place is crucial to securing affordability and supply for patients. Top-performing companies achieve this by entering supranational procurement agreements, and/or by implementing pricing models that are based on all relevant payers' ability to pay. Best-performing companies also apply additional non-pricing initiatives to maximise the availability of their products to the most vulnerable patients through, for example, patient assistance programmes and non-exclusive voluntary licensing agreements.

Companies that partner with local manufacturers on projects with clear and measurable goals and objectives, to ensure the sustainability of their efforts in LMICs, stand out across health systems strengthening, manufacturing and supply chain capacity building indicators. Additionally, these companies make efforts to scale-up inclusive business models that address the access needs of underserved populations and work in partnerships to pilot new models where needs are unmet.

INSIGHTS

- 1 Overall industry-wide improvement in access planning and an increase in products covered by an access strategy, but low-income countries remain overlooked.
- 2 Of the 20 companies, 15 have scaled up 32 inclusive business models (IBMs) to reach more countries and more patients at the base of the income pyramid. Some companies are also piloting IBMs offering products for non-communicable diseases.
- 3 Despite an improvement in the number of technology transfers, the geographic scope of capacity building initiatives for manufacturing continues to focus on India, China and Brazil.

FIND OUT MORE

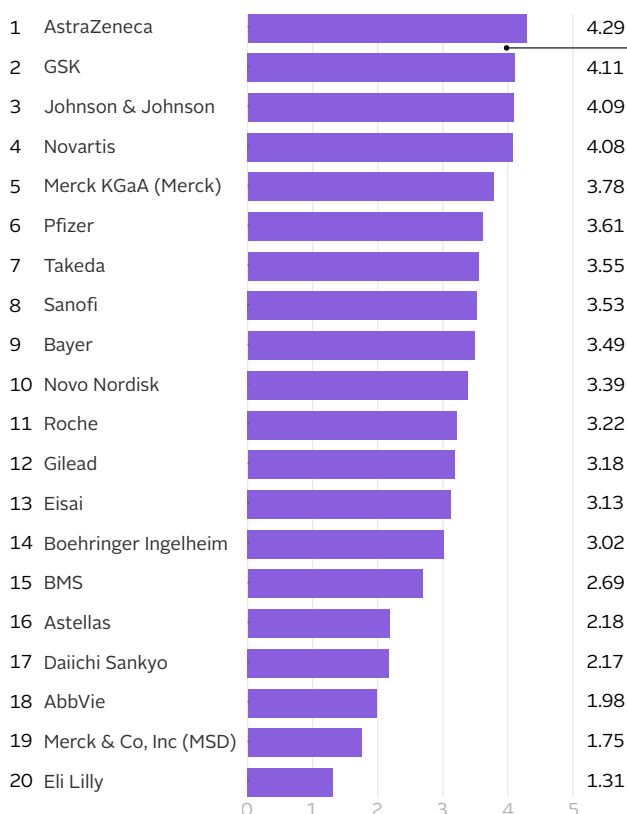
	PAGE
Sub-ranking	78
Portfolio	79
Registration	81
Access Strategies	88
Licensing	99
Product Donations	105
Inclusive Business Models	109
Supply, Quality and Manufacturing	117

The various sections within the Product Delivery Technical Area include detailed, figure-led analyses identifying industry strengths, weaknesses, trends, and opportunities at the time of writing. For a granular view of each company's activities in this area, see company Report Cards.

HOW THE COMPANIES PERFORM

Stand-out performers demonstrate wide-ranging approaches towards equitable access

FIGURE 63 Product Delivery Ranking



AstraZeneca takes the top spot in Product Delivery, leading in its approach to patent transparency and sharing of intellectual property assets. It has made progress by licensing and transferring technology for its COVID-19 vaccine. **GSK** and **Johnson & Johnson** complete the top three, performing well across all assessment criteria, including equitable access strategies. Notably, in 2022, Novartis became the first company to agree to a non-exclusive voluntary licence for a medicine to treat a non-communicable disease.

What separates the best and worst performers?

The top ten companies rank closely in terms of scoring, with various companies in the top ten excelling in different areas, such as intellectual property (IP) management and access approaches for specific products. The best-performing companies demonstrate strong examples of patent transparency, sharing of IP assets and engage in voluntary licensing in tandem with technology transfers. Almost half of these companies also apply equitable access strategies broadly and participate in high-quality capacity initiatives across all fields.

Medium-performing companies tend to have a more varied performance across assessment criteria by, for example, having a less diverse range of equitable access strategies or capacity building initiatives. Companies may perform strongly in some areas but below average in other areas, such as registration, IP management, supply chain and manufacturing capacity building.

The lowest ranked companies employ a minor number – if any – equitable access strategies that cover few products and countries. They perform poorly when it comes to registering their products in low-income countries and countries with a high disease burden. These companies engage in few or no manufacturing and supply chain capacity building initiatives, with some evidence of health systems strengthening initiatives.

PORTFOLIO ANALYSIS

What products do companies have in their portfolios?

The Portfolio Analysis section provides an overview of the products covered in the Product Delivery Technical Area of the 2022 Index, by summarising the product types and disease categories included – and not included – in the companies’ portfolios, and providing the broader context to the analysis that follows. Collating information on all 20 companies’ portfolios also reveals what types of products are most common, and where the gaps are.

The products have been selected for analysis in the 2022 Index based on several inclusion criteria, such as whether they are included on the World Health Organization (WHO) Model List of Essential medicines (EML) or the WHO Essential Diagnostic List (EDL), or – in the case of off-patent products – whether their availability can significantly shape the market (see Appendix I).

Product types and disease coverage

FIGURE 64 What types of products are in the companies’ portfolios?

Most of the products in scope of this analysis are medicines, followed by diagnostics and vaccines.

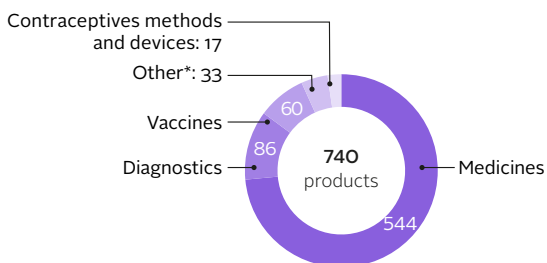
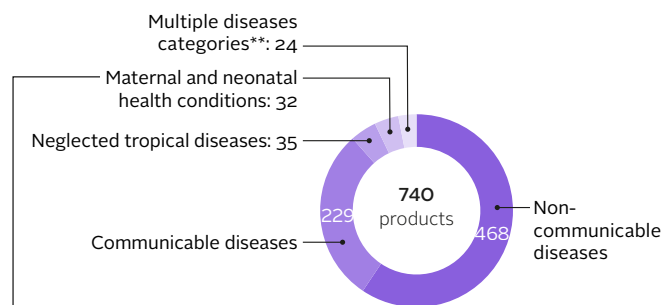


FIGURE 65 What categories of diseases are covered by the products in the companies’ portfolios?

Most of the products are for non-communicable diseases.



There are few products in the companies’ portfolios for maternal and neonatal health conditions. Further analysis is available elsewhere in the Index in the Special Report on women’s sexual and reproductive health.

*Other includes vector control products and platform technologies.

**This refers to products that target diseases in more than one of these categories – for example, Intron® A (MSD) is indicated for chronic hepatitis B and C (communicable diseases) and some cancers (non-communicable diseases).

TABLE 4 What diseases are not covered by products in companies' portfolios?

This table shows the diseases and medical conditions that are not targeted by any of the products in scope of the 2022 Index – collectively across the 20 companies. The Index also finds that this overall picture is unlikely to change in the near future, as only three of these diseases and conditions have active developments in the collective R&D pipeline: river blindness (onchocerciasis), mycetoma and rheumatic fever.

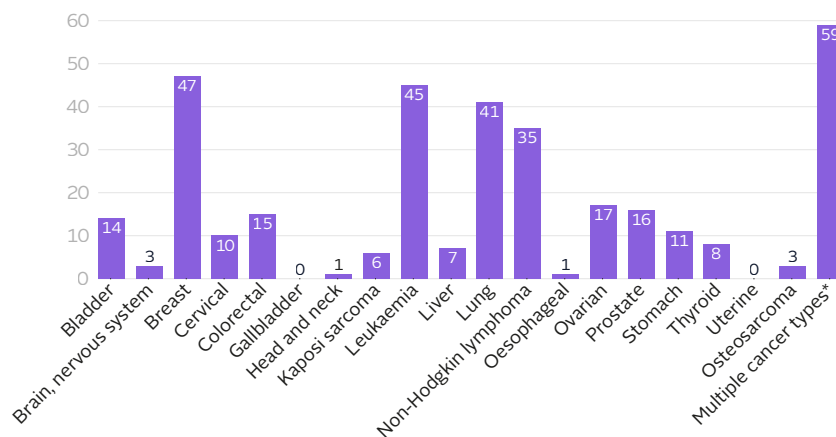
Disease category	Disease, condition or pathogen
Non-communicable diseases	Bipolar affective disorder
Communicable diseases	Arenaviral haemorrhagic fevers (Lassa fever)
	Bunyaviral diseases
	Disease X
	Emergent non-polio enteroviruses
	Henipaviral diseases
	Leptospirosis
	Rheumatic fever
Maternal and neonatal health conditions	Birth asphyxia and birth trauma
	Obstructed labour
Neglected tropical diseases	Buruli ulcer
	Dracunculiasis
	Mycetoma, chromoblastomycosis and other deep mycoses
	River blindness (onchocerciasis)
	Scabies and other ectoparasites
	Snakebite envenoming
	Trachoma
	Yaws

Cancer products are well-represented in company portfolios – but for some cancers more than others

Among the 468 products for non-communicable diseases, 183 are indicated for cancer. Breast cancer is one of the most prevalent cancer types globally, and is targeted by many products in the companies' portfolios. On the other hand, there are no products for gallbladder cancer, and only one for head and neck, uterine and oesophageal cancer, respectively. Osteosarcoma, a type of bone cancer, has been newly added to the list of cancers in scope of the Access to Medicine Index for 2022, and is targeted by three products included in this analysis.

FIGURE 66 How many products are in companies' portfolios for each cancer type?

Cancer products in the portfolio mainly target blood cancer (leukaemia and non-Hodgkin lymphoma), breast cancer and lung cancer. Out of the 183 cancer products, 142 are medicines, 35 are diagnostics, four are vaccines and two are platform technologies – e.g. delivery technologies and devices.



*This category refers to products indicated to treat more than one cancer type.

PRODUCT DELIVERY - REGISTRATION

How do companies perform on registering their products in LMICs?

When a product is ready to be launched, the first step the company can take towards making it available in any given country is filing it for registration with that country's regulatory authorities. Once the product is registered, it can then be marketed and sold.* Registering products in a wide range of countries, including low- and middle-income countries (LMICs), is vital for ensuring access to those products globally.

Regulation of medical products aims to ensure that only high-quality, safe and effective medicines, vaccines and diagnostics are allowed onto the market.¹ If a product gains approval from a national regulatory body recognised as a 'stringent regulatory authority' (SRA) by the World Health Organization (WHO), such as the European Medicines Agency (EMA), this can help streamline and speed up regulatory processes in other countries, including LMICs.²

However, even after SRA approval, local regulatory processes must be completed. In countries with limited regulatory capacity, there can be lengthy regulatory processes, compromising patients' timely access to much-needed safe, effective and quality-assured medical products.³ Among other steps, companies can mitigate these challenges by engaging in a Collaborative Registration Procedure or applying for WHO prequalification, as explored in the following pages.

Which products are in scope of this analysis?

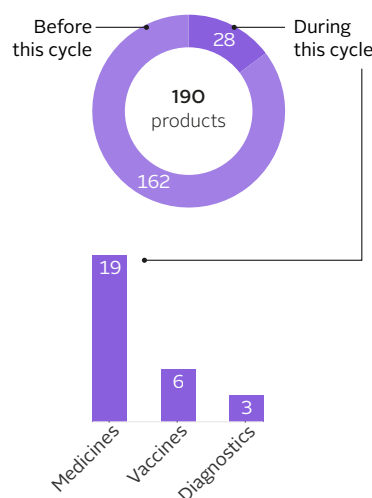
The Index assesses a sample of the 20 companies' most recently-marketed products to gain insight into the companies' registration practices in the 108 LMICs in scope. Companies each submitted up to a maximum of ten recently-launched products to the Index for analysis, resulting in a total of 190 products. The Index looks at the number of LMICs in which the companies have registered these 190 products, as well as aggregating the data to show which countries are most likely to receive submissions for registration – and which are most likely to be overlooked. In particular, this analysis assesses the extent of companies' efforts to register their products in the countries with the highest burden of disease.

For newer products – i.e., those that received their first global regulatory approval in the last five years – the gold standard for a company is to file in as many LMICs as possible, and in at least half of the ten countries with the highest burden of disease (measured according to the global burden of the disease targeted by each specific product). This is particularly important for products that are innovative or superior to those already on the market.

With each company submitting up to ten products, some of the products in scope actually received their first global regulatory approval at least five years ago. For these older products, the Index looks for companies to have filed them for registration in more than 45 LMICs in scope, and in seven or more of the ten countries with a high burden of disease.

FIGURE 67 Products analysed with regards to registration

There are 190 products in scope of this analysis. Of these products, 28 received their first market approval from the European Medical Agency (EMA), US Food and Drug Administration (FDA), Health Canada, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), or another Stringent Regulatory Authority (SRA) during the period of analysis (1 June 2020 to 31 May 2022).



*As part of the registration process, the responsibility to file a product for registration rests with companies. For the purpose of this analysis, products are counted as having been registered in a coun-

try if the company has filed it for registration, even if the approval status is not yet known.

In which countries do pharma companies file their products for registration?

Among the 108 countries in scope, there are particular countries – mainly upper-middle income countries – where products are far more likely to be registered.

While products for non-communicable diseases (NCDs) such as diabetes and cancer are at least filed in some low-income countries, more so than products for communicable diseases, there are low-income countries in which no products have been filed at all. For example, the Access to Medicine Foundation’s October 2022 report on access to insulin in LMICs found that no insulin products in scope of that analysis have been filed in 24 countries – the majority of which are low-income countries.⁴

FIGURE 68 The ten countries in scope where the most products have been filed for registration

The countries in which the highest number of the 190 products are filed are mainly upper-middle income countries, with Brazil topping the list. There are three lower-middle income countries in the top ten, but no low-income countries.

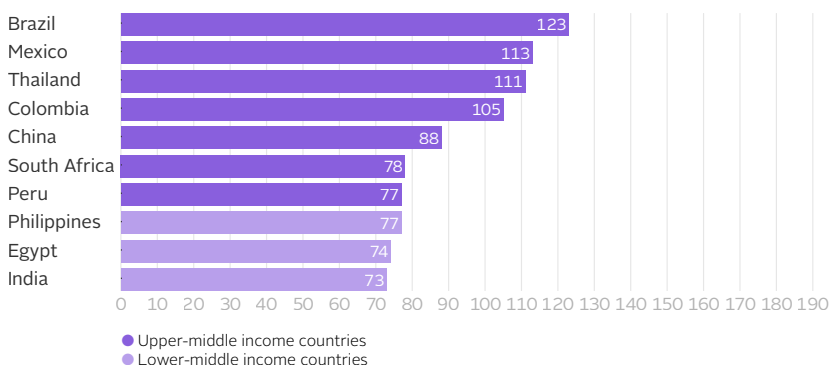
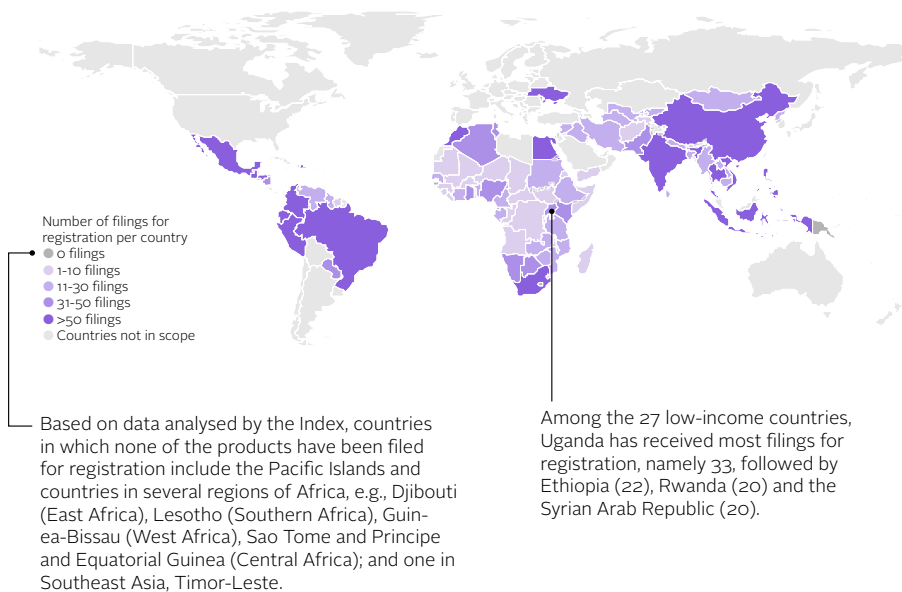


FIGURE 69 Which countries do companies register their products in?*

This map highlights the number of the 190 products in scope that have been filed for registration in each of the 108 LMICs included in the analysis.



* For a subset of companies, the exact registration status of their latest products within LMICs could not be reported as no data was provided/verified by the company or available in the public domain dur-

ing the period of analysis. Registration filings are based on companies’ data submission, there are non-submitting companies such as Eli Lilly and MSD.

Companies rarely file in countries with highest disease burdens

Most products (78%) are registered in less than half of the countries with a high burden of disease, according to the product's main indication (see box, below). Bayer has the highest number of products that meet the milestone of being filed in at least half of these countries.

What does 'burden of disease' mean?

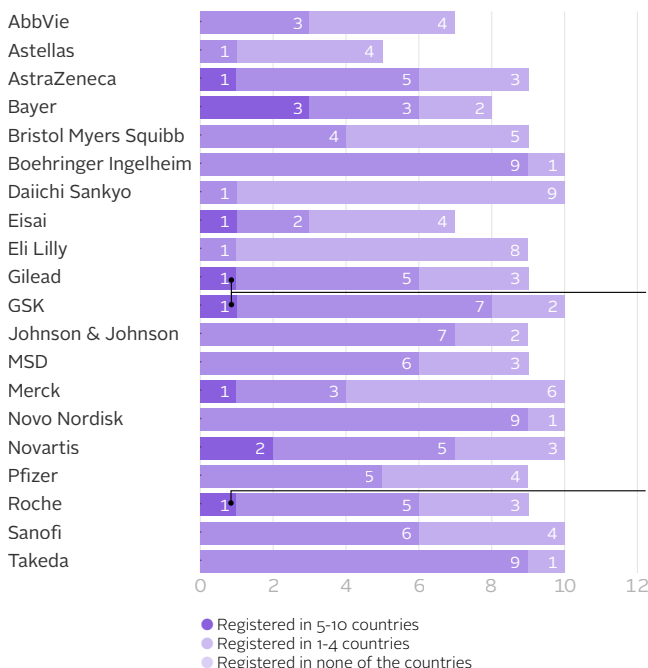
The burden of disease has been measured with the rate of disability-adjusted life years (DALYs), a universal metric that allows comparison between different populations and health conditions across time. One DALY equals one lost year of healthy life, allowing for an estimation of the total number of years lost due to specific causes (such as diseases and injuries).

What is a product's 'indication'?

The disease or condition that a product is targeted towards treating. Some products have more than one indication – e.g., when indicated for multiple different types of cancers. Of the 190 products assessed in this analysis there was data available for the global burden of disease for 179 products, 21 of which have multiple indications. For these 21 products, their main indication was selected by determining for which disease they serve as a first-line treatment in order to measure the global burden of diseases targeted by each specific product.

FIGURE 70 There is considerable variation in how widely each company registers its products in LMICs

Out of the 190 products in scope, this figure analyses the 179 products for which global burden of disease data was available (certain products, such as COVID-19 and contraceptive products, were not assessed in terms of burden of disease). It shows how many have been filed for registration in at least five of the ten countries with the highest burden of disease (measured according to the global burden of the disease targeted by each specific product).**



Two products indicated for HIV/AIDS have been filed in seven of the top ten highest burden countries. Emtricitabine/tenofovir alafenamide (Descovy®) from Gilead, approved in 2016 by the US FDA, has been filed for registration in Botswana, the Central African Republic and Mozambique. Dolutegravir (Tivicay PD) from GSK, approved in 2020 by the US FDA, has been filed for in Namibia, Malawi, Zimbabwe (with high burdens among the paediatric population).

The product most filed in highest burden disease countries according to its indication is Elecsys® Chagas, from Roche, approved in 2020 by the US FDA. This diagnostic, used to identify and screen individuals infected with Trypanozoma cruzi, is included in the WHO Essential Diagnostic List, and has been filed in eight of the top ten high burden disease countries, including Brazil, Colombia and Ecuador.⁵ The product has not been filed for registration in Bolivia or Paraguay.

** All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are acces-

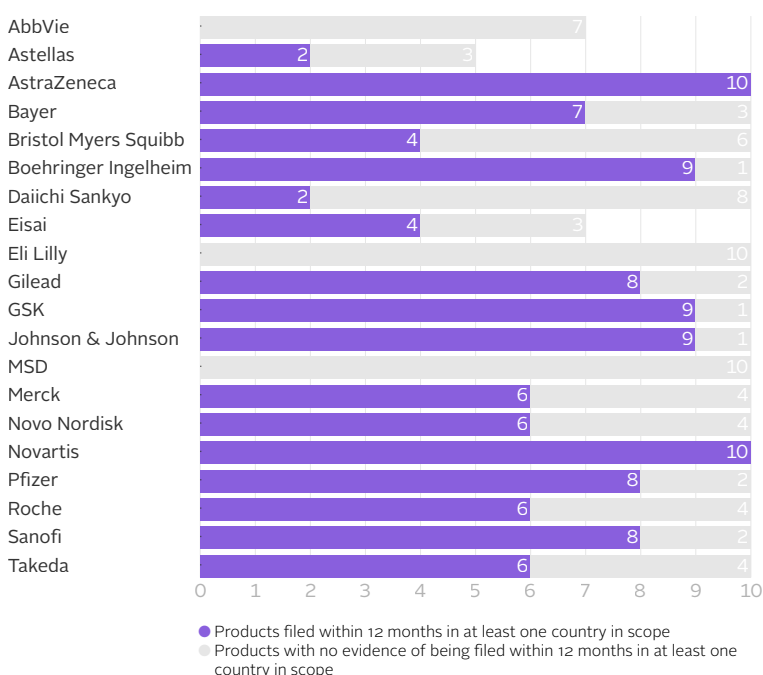
sible through other sources. Eli Lilly and MSD declined to submit data to the 2022 Access to Medicine Index.

How do companies perform on registering products rapidly, and which products do they prioritise?

Rapidly filing new products for registration in LMICs is important to allow and accelerate access to these products. Yet, in LMICs, the registration of newly-launched products typically occurs less frequently and usually later than in higher-income countries where markets are considered to have higher commercial value. Only two companies, AstraZeneca and Novartis, filed all their newer products for registration in at least one LMIC in scope of the Index within 12 months of first global approval. In addition, there are some companies that do not provide any evidence of having rapidly filed any of the products in scope within an LMIC.***

FIGURE 71 How rapidly do companies file their products for registration in LMICs after approval?

Within 12 months after first global approval, only two companies had filed all their products in scope (a maximum of ten products per company) for registration in at least one of the 108 countries in scope.



*** All companies were assessed based on data submitted to the Index in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are acces-

sible through other sources. Eli Lilly and MSD declined to submit data to the 2022 Access to Medicine Index.

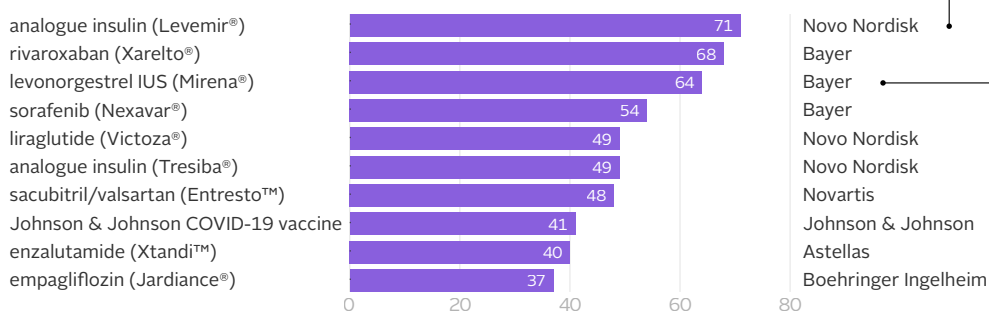
Older products and those for NCDs are more widely filed

Among the products in scope of this analysis – i.e., a maximum of ten of each company’s most recently launched products – the products that are registered in the highest number of the countries in scope are generally those that were launched longest ago. The ten on-patent products that have been most widely filed in LMICs had their first global launch at least seven years ago, with the exception of Johnson & Johnson’s COVID-19 vaccine.

Companies had more time to file those products for registration widely compared to newer products, but it is also vital that new products are widely filed as soon as possible so that patients worldwide can benefit from new treatments.

FIGURE 72 The top ten most widely filed on-patent products are mainly older products targeting non-communicable diseases

These products mostly target non-communicable diseases such as diabetes mellitus, cardiovascular diseases and various cancers.



Novo Nordisk has filed its older analogue insulins relatively widely. For example, insulin detemir [rDNA origin] (Levemir®), globally approved by the EMA in 2004, has been filed in 71 of the 108 LMICs in scope.

Out of the ten products from Bayer analysed by the Index, three have been filed for registration in at least half of the 108 countries in scope. For example, rivaroxaban (Xarelto®), indicated for stroke and ischaemic heart disease, has been filed in 68 countries in scope. It was first approved in 2008, by Health Canada.

How some companies are overcoming registration challenges, and what mechanisms are available

The regulatory approval of medical products in countries with limited regulatory resources can be lengthy, which often compromises patients’ timely access to much-needed safe, effective and quality-assured medicines.⁶ To ensure access to those products, companies must overcome registration challenges, such as lack of mature regulatory systems, unclear local regulatory requirements or lack of capacity for processing registration dossiers due to resource-limited health authorities. Below, several potential solutions for companies to overcome those challenges are highlighted, as well as mechanisms available to them.

Collaborative Registration Procedure

Facilitated regulatory pathways are designed to increase the speed and efficiency of registration in resource-limited settings. The Collaborative Registration Procedure (CRP), for example, helps pharmaceutical companies and other stakeholders ensure faster access to quality-assured, safe and effective medical products to patients in need.⁶

The CRP is developed based on reliance and recognition approaches to accelerate national registrations by providing National Regulatory Authorities (NRAs) with detailed product assessments and inspection reports generated by SRAs, or by WHO through its prequalification procedure. Through collaboration between NRAs, SRAs, the WHO prequalification programme (WHO PQ) and pharmaceutical companies, the CRP facilitates and accelerates the registration of medical products that have received WHO PQ or have been approved by SRAs.

By participating in the CRP, pharmaceutical companies need only submit one product dossier across countries that also participate, avoiding the duplication of both good manufacturing practice inspections and product testing prior to

registration.⁶ The CRP process allows for more efficient post-approval changes, reduces the amount of human and financial resources required, and can shorten the timeline for a product becoming available to populations in need. Furthermore, the process enhances and facilitates collaboration, interactions, and information exchanges between companies, countries and WHO.

WHO prequalification programme

WHO PQ was initiated in 2001 to improve access to safe, effective and affordable quality-assured medicines used by millions of people in LMICs by assessing a range of essential products initially focused on HIV, tuberculosis and malaria, for procurement by UN agencies and the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund).⁷ This programme also aims to support regulatory capacity in LMICs by providing professional development and training for regulators and developing a mechanism to generate assessments of medical products which can significantly reduce the registration time for those products in countries.

WHO PQ assesses medical product dossiers, conducts good manufacturing practice inspections and organises quality control testing of products.⁷ By submitting all their relevant products for WHO PQ, companies can help facilitate UN procurement and promote rapid regulatory uptake by all LMICs. WHO research also shows that participating in prequalification can provide companies with benefits over time, including increased sales or market access and reduced manufacturing costs.⁸

Examples of companies using facilitated tools and mechanisms

Twelve of the 20 companies in scope of the Index now participate in WHO PQ. The entire portfolio of the companies (including products older than the 190 products analysed for registration), includes 35 WHO prequalified products, covering communicable diseases such as HIV/AIDS, hepatitis B and C and coronaviral diseases; NCDs, such as cancer; neglected tropical diseases such as lymphatic filariasis; as well as contraceptives.

Some companies are already making use of the CRP to accelerate the registration of their products in countries, including Johnson & Johnson and ViiV Healthcare (majority owned by GSK), which are actively collaborating with WHO in the African Region (AFRO Region), and have had many products approved through this process. Pfizer and Roche have also made use of CRP in the AFRO region for some of their products.³

Other facilitated pathways available to companies include regional/joint assessments, such as the Joint Assessment Procedure of the Association of Southeast Asian Nations (ASEAN), which currently considers a wide disease scope. GSK also participates in this procedure.⁹

More companies should collaborate closely with NRAs, SRAs and other stakeholders such as WHO, to participate in these facilitated mechanisms, make use of relevant tools, and support strengthening regulatory authorities, with the goal to be able to timely register much-needed medical products in as many relevant countries as possible.

FIGURE 73 More than half of the companies are participating in facilitated pathways to register their products.

Companies can participate in Collaborative Registration Procedures (CRP) with WHO prequalified products or products assessed and/or approved by an SRA. Companies can also participate in regional/joint assessments such as various AFRO Region Joint Assessments and the ASEAN Region Joint Assessment. These facilitated regulatory pathways help to increase access to healthcare products in countries that are often underserved.

	Facilitated regulatory pathways			
	CRP for WHO PQ products	CRP for SRA-approved/assessed products	AFRO Regional Joint Assessments	ASEAN Joint Assessment
AbbVie	●			
Astellas				
AstraZeneca				
Bayer	●			
Bristol Myers Squibb	●			
Boehringer Ingelheim				
Daiichi Sankyo				
Eisai	●			
Eli Lilly				
Gilead	●			
GSK	●	●	●	●
Johnson & Johnson	●	●	●	
MSD	●			
Merck				
Novo Nordisk				
Novartis	●			
Pfizer	●	●	●	
Roche	●	●	●	
Sanofi	●			
Takeda				

Conclusions

Filing for registration is only the first step in a complex regulatory process that will allow for a product to be available on the market in a particular country. Rapidly filing for registration can play a critical role in shortening the amount of time taken to have products reach the hands of patients. More companies need to file their products more widely for registration in LMICs – particularly in low-income countries and in those with a high disease burden. These countries are commonly left out, which means that people living here do not have access to any newly launched and potentially life-saving healthcare products. While these countries often present complex regulatory barriers that make it difficult for companies to register products, there are unique solutions that can help overcome these challenges.

Some companies are already making use of facilitated procedures and tools, including the CRP, to accelerate the registration of their products in LMICs. Companies can also submit all their relevant products for WHO prequalification to facilitate UN procurement and promote rapid regulatory uptake.

Regulation of quality-assured medicines is a shared effort between regulators, manufacturers, procurers, health providers, donors and institutions such as WHO.⁷ Companies must contribute to these endeavors to increase access to medicines, protecting people from health emergencies and providing them with better health and well-being.

REFERENCES

- World Health Organization (WHO). Health products policy and standards. Published 2022. Accessed July 25, 2022. <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/regulations>
- WHO. List of Stringent Regulatory Authorities. Published 2022. Accessed November 1, 2022. <https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>
- WHO. Accelerated Registration of FPPs Approved by SRAs. Published 2022. Accessed July 25, 2022. extranet.who.int/pqweb/medicines/faster-registration-fpps-approved-sras
- Martínez C, Romero C, Sánchez Villalobos N. Published October 6, 2022. Accessed November 9, 2022. <https://accessmedicinefoundation.org/news/drugmakers-that-dominate-the-worlds-insulin-market-must-scale-up-access-efforts-globally>
- WHO. The Selection and Use of Essential in Vitro Diagnostics: Report of the Third Meeting of the WHO Strategic Advisory Group of Experts on in Vitro Diagnostics; 2020. Accessed November 1, 2022. [https://www.icao.int/EURNAT/EUR%20and%20NAT%20Documents/COVID%2019%20Updates-%20CAPSCA%20EUR/02%20February%202021%20COVID19%20Updates/COVID19%20-%202021-02-01%20Updates/WHO%20Essential%20diagnostics%20list%20\(EDL\).pdf](https://www.icao.int/EURNAT/EUR%20and%20NAT%20Documents/COVID%2019%20Updates-%20CAPSCA%20EUR/02%20February%202021%20COVID19%20Updates/COVID19%20-%202021-02-01%20Updates/WHO%20Essential%20diagnostics%20list%20(EDL).pdf)
- Vaz A, Roldão Santos M, Gwaza L, et al. WHO collaborative registration procedure using stringent regulatory authorities' medicine evaluation: reliance in action? *Expert Rev Clin Pharmacol.* 2022;15(1):11-17. doi:10.1080/17512433.2022.2037419
- World Health Organization. Medicines Prequalification. Published 2022. Accessed November 9, 2022. <https://extranet.who.int/pqweb/medicines>
- WHO. Manufacturers. Published 2022. Accessed November 9, 2022. <https://extranet.who.int/pqweb/medicines/information/manufacturers>
- National Pharmaceutical Regulatory Agency (NPRA). ASEAN Joint Assessment Procedure. Published 2020. Accessed November 9, 2022. <https://npra.gov.my/index.php/en/directive-general/1527125-asean-joint-assessment-procedure-for-pharmaceutical-products-public-announcement.html>

ACCESS STRATEGIES

How do companies ensure worldwide access to their products?

In general, companies can use three main access strategies to increase access to medicine:

- **Equitable pricing strategies:** Setting prices within the ability of specific payers to pay, with reference to a range of socioeconomic and demographic factors in the country. Equitable pricing strategies should be supported by additional non-pricing initiatives such as patient assistance programmes, non-exclusive voluntary licensing and health systems strengthening, in order to improve availability and affordability of the healthcare products.
- **Responsible intellectual property (IP) management:** Licensing agreements under pro-access terms and/or pledges not to enforce patents to facilitate generic entry.
- **Product donations:** Identifying populations with no capacity to pay for the new product and donating products as appropriate in collaboration with local partners.

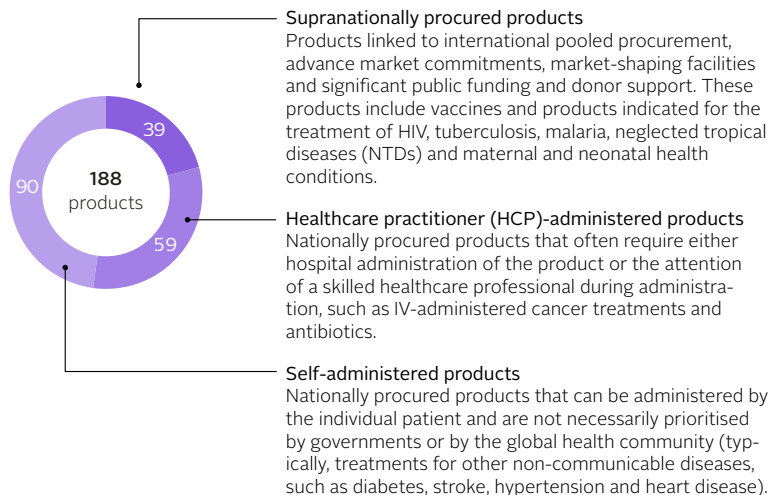
Products assessed by the Index

To see how companies tailor their access strategies to reach a larger proportion of the income pyramid globally, and how they overcome product-specific access barriers when dealing with different products, the Index analyses three different categories of products: supranationally procured, healthcare practitioner-administered, and self-administered.

For each of these three product categories, the Index analysed a sample of a maximum of five products per company, resulting in a total of 188 health products. Overall, this sample consists of a group of products that are considered essential for a well-functioning healthcare system, and for which large companies hold a controlling position regarding access – determined either through patents or their dominance of the market. Of these 188 products, 102 are listed on the World Health Organization Model List of Essential Medicines (EML).

FIGURE 74 Breakdown of products analysed in this section

Across all three areas, there are a total of 160 medicines, 17 vaccines, 6 contraceptive products, 3 diagnostics* and two vector control products.



*All three diagnostics products are from Roche and are included in the analysis of supranationally-procured products.

ACCESS STRATEGIES

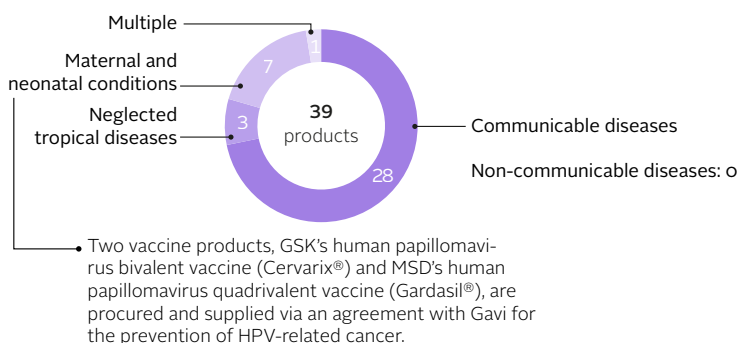
Supranationally-procured products

Supranational procurement agreements between the public and private sectors to secure vaccines and treatments for high-burden infectious diseases, including HIV/AIDS, tuberculosis (TB) and malaria, as well as products for reproductive health, have been demonstrably successful in expanding equitable access and ensuring availability of affordable, quality-assured products that meet countries' needs. These agreements enable the procurement of products at a large volume for multiple low- and middle-income countries (LMICs) and help mitigate supply chain weaknesses and other logistical barriers to securing sufficient supply, in addition to improving affordability for lower-income countries and reducing commercial risks for companies.

The 2022 Index analyses up to five supranationally-procured products per company, i.e., products for which international pooled procurement, advance market commitments, market-shaping facilities and significant public funding and donor support exist. Organisations engaged in supranational procurement include Gavi, the Vaccine Alliance (Gavi), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), the Pan American Health Organization (PAHO) and the United Nations Population Fund (UNFPA).

FIGURE 75 Overview of supranationally procured products in scope

The majority of the 39 products in scope of this analysis target communicable diseases, particularly the infectious diseases HIV/AIDS (10), TB (5) and malaria (4).



Do companies extend the terms of supranational agreements to non-eligible countries?

With selection criteria based on income level, gross national income (GNI) per capita, or World Bank classification, not all LMICs are eligible for all – or any – supranational procurement programmes. Yet, in many countries that are not eligible, including many upper-middle income countries, there is still a high need for a more affordable and reliable supply of these key healthcare products.

For this reason, the Index also assesses whether these companies offer the same terms of access for their products to countries which are not covered by these agreements, or which are not otherwise eligible. To provide an insight into this, companies have been requested to provide one example, per product, of their approach in a non-eligible country.

Companies show best practice when they extend their strategies for these products not only to countries graduating from supranational procurement agreements (e.g., if they have recently moved into a higher World Bank country income classification), but also to those countries and populations that have never met the criteria for inclusion. Companies can either apply the same terms of the agreements or implement strategies with different yet equitable terms, based on the relevant payers' ability to pay.

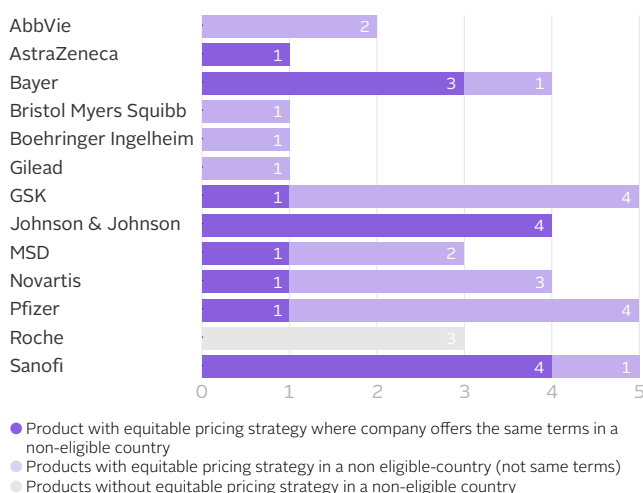
FIGURE 76 How many companies have products under supranational agreements, and do they offer the same terms of access to countries outside these agreements?

Thirteen of the 20 companies supply products via supranational agreements. This figure looks at how many companies offer equitable pricing strategies to at least one country outside of supranational agreements, and – of those – whether they offer the same terms of access to both eligible and non-eligible countries.



FIGURE 77 How do companies facilitate access to products in countries outside of supranational agreements?

In total, 36 of the supranationally-procured products in scope are covered by an access strategy in at least one non-eligible country.



Eight companies extend the same terms of supranational agreements to at least one non-eligible country. These agreements cover a total of 16 products. Based on this sample of products, the companies with the greatest number of products supplied to non-eligible countries under the same terms as through supranational agreements are Johnson & Johnson, Sanofi and Bayer.

Among the companies that extend the same terms of the supranational agreements to non-eligible countries, AstraZeneca, GSK, Johnson & Johnson, MSD and Pfizer have each expanded patient reach for all products in scope of this analysis, compared to the previous Index.

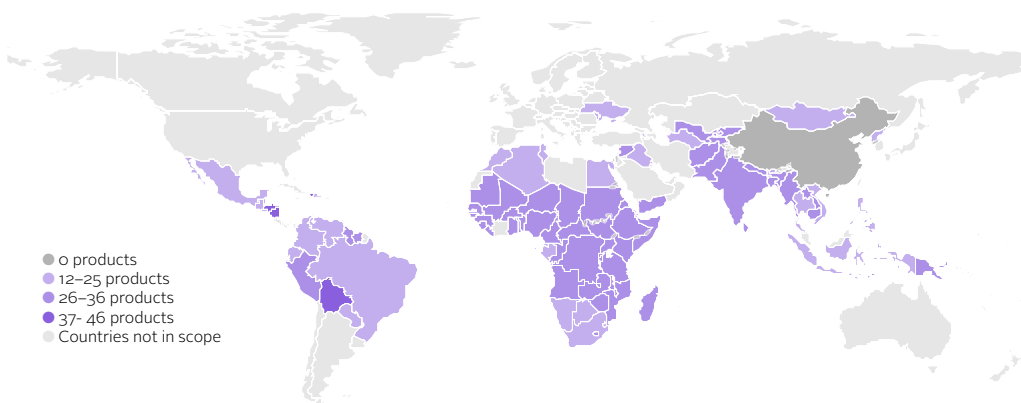
GSK and Pfizer both apply equitable pricing strategies to four out of their five products analysed. GSK, for example, applies pricing models based on the Human Development Index (HDI) that incorporate socioeconomic and demographic factors to reflect people’s individual ability to pay. Additional non-supranational access strategies are discussed in greater detail below.

Among companies applying equitable access strategies, seven are implementing additional non-pricing initiatives to reach more patients in the non-eligible countries

assessed, such as non-assert declarations, technology transfers and non-exclusive voluntary licensing. Bayer, Boehringer Ingelheim and Gilead demonstrate expanded patient reach for all their products in scope of this analysis, while GSK does so for three out of its four products assessed.*

FIGURE 78 Countries covered by supranational procurement agreements

The map shows eligible countries covered by supranational agreements signed between companies in scope and international procurers Gavi, Global Fund Partnership, PAHO, UNFPA, and/or Family Planning 2030 (FP2030). Agreements signed with these procurers cover 30 of the 39 products in scope. For some products, multiple organisations are involved in procurement.



GOOD PRACTICE

For its human rotavirus vaccine, GSK applies the same terms used in its Gavi supranational agreement in a non-Gavi-eligible country (Angola)

GSK supplies its human rotavirus rix4414 strain (live, attenuated) (Rotarix®), for the prevention of rotavirus infection that causes diarrhoeal diseases, supranationally via Gavi. The example submitted to the Index relates to Angola, a country outside the supranational agreement, for which GSK applies the same terms of the agreement. It provides evidence of increased patient reach. Through the GSK price freeze commitment, GSK continues to supply Angola at Gavi prices for 10 years from the date of their graduation from Gavi support.

GOOD PRACTICE

For an antifungal medicine, Gilead uses different terms in non-eligible countries than in its supranational agreements, but employs equitable access strategies

Gilead supplies its antifungal medicine amphotericin b liposome (AmBisome®), which is used to treat both visceral leishmaniasis and cryptococcal meningitis, through multiple supranational procurers. Outside of these agreements, it supplies the medicine at a not-for-profit price in a number of LMICs, specifically the same group of countries that are covered by the company’s voluntary licence for its HIV/AIDS product. For countries that do not qualify for the not-for-profit price, such as Mexico, the company employs tiered pricing, based on a payer’s ability to pay and disease burden. 4,108 patients were reached in Mexico during the period of the analysis.

The scope of supranational procurement has so far been limited to a small number of disease areas, because there is no large-scale donor funding available to procure commodities or to support government procurement more widely – particularly for products that target non-communicable diseases.¹ In the absence of supranational procurement options, companies can instead focus on expanding access to their products by using country-specific access strategies, including equitable pricing strategies and non-pricing initiatives, as explored in the following section.

* Increase in patient reach might be not possible to assess for products that are newly in scope of the Index, or if data was submitted relating to a different country than in previous Indexes.

ACCESS STRATEGIES

Country-specific access strategies for healthcare practitioner-administered and self-administered products

Globally, on average, out-of-pocket spending on medicines accounts for the largest household expenditure: up to 44% in low-income countries, 40% in lower-middle income countries, and 34% in upper-middle income countries, respectively.² The consequence of this spending is that 100 million people are pushed into extreme poverty each year.³

Affordability is one of the main barriers to access to medicine. Companies can increase equitable access to their products across the income pyramid by improving the affordability of their products and tailoring country-specific strategies that consider relevant payers' ability to pay, as well as features of local health systems.

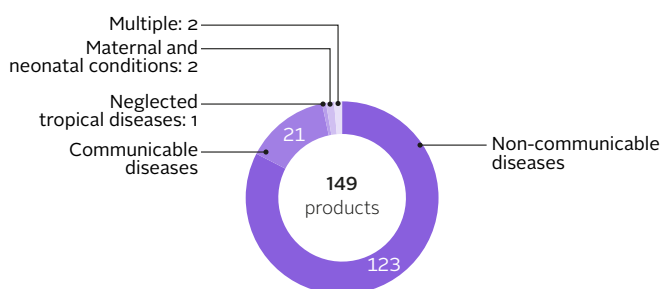
For each product in scope (up to five healthcare practitioner (HCP)-administered and up to five self-administered product per company), the Index assessed examples of the access strategies applied in three countries: one classified as upper-middle income, one lower-middle income, and one low-income, as per the World Bank income group classification.

What does best performance look like, in terms of access strategies?

The best-performing companies demonstrate how their pricing strategies* take the payers' ability to pay into account across different segments of the population (e.g., by considering socioeconomic and demographic factors)** and how non-pricing initiatives (i.e., patient assistance programmes, donations, voluntary licensing) complement those pricing strategies to maximise the numbers of patients reached across the income pyramid.

FIGURE 79 **Products covered by country-specific access strategies**

Products analysed in this section include 59 HCP-administered products and 90 self-administered products. This figure shows which types of diseases they treat.



* Equitable pricing strategies play a significant part in increasing access to medicine. To maximise the availability of key products to those with less income, companies can apply access strategies to these products across LMICs. However,

when setting pricing strategies, companies do not always integrate into their pricing approach a payer's ability to pay for a product.

** The characteristics of a population such as age, sex, income level, education level, employment, etc.

ACCESS STRATEGIES

What strategies do companies use to expand access to their products, and where?

In looking at the access strategies used by companies to expand access to their products, three main types of strategies can be identified:

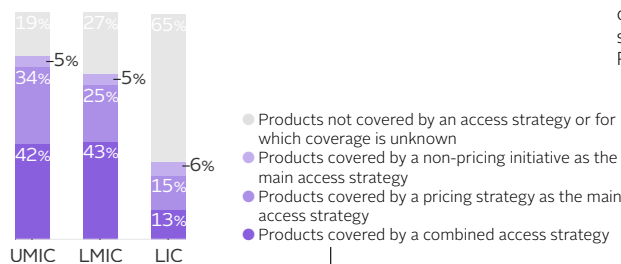
- **Pricing strategy** as the main access strategy;
- **Non-pricing initiative** as the main access strategy;
- **Combined access strategy** including both a pricing strategy and a non-pricing initiative.

Most products included in the analysis are covered by an access strategy with at least one pricing or a non-pricing initiative in at least one upper-middle income country (UMIC) and at least one lower-middle income country (LMIC) among the 108 countries in scope. However, low-income countries are left behind, with most products not covered by any access strategy.

In terms of quality of access and pricing strategies, Novartis, Johnson & Johnson, and GSK are leaders in implementing access strategies that take the payer's ability to pay into account.

FIGURE 80 Where do companies provide access to their products and what types of strategies are applied?

Between upper-middle income, lower-middle income and low-income countries, there is variation in the number and type of access strategies used by companies to expand access to their products.



Among the examples analysed by the Index, Novartis has 11 such strategies, the most out of any of the companies in scope, while GSK, Sanofi and Pfizer follow with 10 each.

Johnson & Johnson, Gilead, AstraZeneca and Novartis lead in applying combined access strategies that consider affordability across their products. Among the examples analysed by the Index, Johnson & Johnson reports 18 such strategies, Gilead 14, and Novartis and AstraZeneca 12 each.

ACCESS STRATEGIES

How many products are covered by access strategies, and where?

FIGURE 81 How many products are being covered by an access strategy?

For each company, a maximum of 10 products (up to five HCP-administered and up to five self-administered products) were selected for analysis. Each company was asked to provide three examples of a country-specific access strategy covering that product – one in an upper-middle income country, one in a lower-middle income country, and one in a low-income country. The figure shows the number of products covered by each access strategy type across all three World Bank country income classifications.

Companies	Upper-middle income countries			
	Combined strategy	Pricing Strategy	Non-pricing initiatives	No access strategy or coverage is unknown
AbbVie	●	●	●	●●●
Astellas	●	●●		●●
AstraZeneca	●●●●●	●●●●●		
Bayer	●●	●●●		●
Bristol Myers Squibb	●●	●●●		
Boehringer Ingelheim	●●●●●	●●		
Daiichi Sankyo	●	●●●	●	●
Eisai	●●	●●		
Eli Lilly				●●●●●●●●●●
Gilead	●●●●		●●	
GSK	●●●●●	●●●		
Johnson & Johnson	●●●●●●●●	●●		
MSD			●	●●●●●●●●●●
Merck	●●●●●	●		●
Novo Nordisk	●●	●●●		
Novartis	●●●●●	●●●●		
Pfizer	●●●●	●●●●●		
Roche	●●●●●		●	●●●
Sanofi*	●●●	●●●●●●		
Takeda	●●	●●●●	●	

Companies	Lower-middle income countries			
	Combined strategy	Pricing Strategy	Non-pricing initiatives	No access strategy or coverage is unknown
AbbVie	●			●●●●●
Astellas	●	●		●●●
AstraZeneca	●●●●●	●●●●		
Bayer	●●●	●●		●
Bristol Myers Squibb	●	●●●	●	
Boehringer Ingelheim	●●●	●●●●		
Daiichi Sankyo				●●●●●●
Eisai	●●●●			
Eli Lilly				●●●●●●●●●●
Gilead	●●●●●		●	
GSK	●●●	●●●●		●
Johnson & Johnson	●●●●●●●●	●●		
MSD				●●●●●●●●●●
Merck		●●●●	●	●●
Novo Nordisk	●●●●		●	
Novartis	●●●●●●●	●●		
Pfizer	●●●●●	●●●	●●	
Roche	●●●●●●			●●●
Sanofi	●●	●●●●●●●		
Takeda	●●●●●		●	●

*Sanofi has one product in scope which is excluded from analysis in the upper-middle income country category.

Companies	Low-income countries			
	Combined strategy	Pricing Strategy	Non-pricing initiatives	No access strategy or coverage is unknown
AbbVie		●	●	●●●●
Astellas	●●			●●●
AstraZeneca	●	●●●		●●●●●●
Bayer	●●			●●●●
Bristol Myers Squibb			●	●●●●
Boehringer Ingelheim		●		●●●●●●
Daiichi Sankyo				●●●●●●
Eisai				●●●●
Eli Lilly				●●●●●●●●
Gilead	●●●●●		●	
GSK	●	●●●		●●●●
Johnson & Johnson	●●	●●●		●●●●●
MSD				●●●●●●●●●●
Merck		●		●●●●●●
Novo Nordisk	●●●	●		●
Novartis		●●●●●	●	●●●
Pfizer		●	●●●●	●●●●●
Roche				●●●●●●●●
Sanofi	●	●●●●		●●●●●
Takeda	●●●		●	●●●

Examples of companies' access strategies across countries with different income levels

AstraZeneca

In Egypt, a lower-middle income country, AstraZeneca's medicine osimertinib (Tagrisso®), used to treat lung cancer, is distributed through both the public and private sectors. Osimertinib (Tagrisso®) is reimbursed in the public sector and the eligible patients (70% of patients) can access it without co-payment. The product is covered by private insurance funds and the number of patients who pay out-of-pocket is limited. AstraZeneca also implemented a patient access programme, for patient support, with education materials and funding for testing.

Pfizer

In Malawi, a low-income country, Pfizer uses a patient assistance programme (PAP) to provide access to apixaban (Eliquis®), a product for stroke prevention. While the product is not yet registered in Malawi, Pfizer uses the PAP to offer the product free of charge to eligible patients.

Pfizer

Pfizer applies tailored pricing strategies for both the public and private market in Mexico for its lung cancer medicine lorlatinib (Lorbrena). In the public sector, lorlatinib's price has been determined based on a formal government HTA (Health Technology Assessment). In the private channel, the price is set by internal and external reference pricing, competitor-based pricing, and private patient affordability considering demographic variables such as monthly income by household.

GSK

GSK considers the ability to pay of the payers in both the public and private sectors to set the price of its asthma and COPD medicine, fluticasone propionate/salmeterol xinafoate (Seretide®). The examples provided are Thailand (an upper-middle income country), Pakistan (a lower-middle income country) and Uganda (a low-income country). In Thailand, although the product is reimbursed in the public sector, the company launched a second brand product (Evolfo) at a reduced price to meet the ability to pay of public hospitals with budget constraints.

More products now covered by access strategies

Since the 2021 Index, 15 companies have demonstrated an increase in the number of products covered by at least one access strategy in an upper-middle income country, and at least one access strategy in a lower-middle income country.

Bristol Myers Squibb demonstrates the largest improvement in both upper-middle and lower-middle income countries. For each of its five products in scope, it now reports access strategies in both upper-middle and lower-middle income countries, a significant change from the 2021 Index which could not identify any access strategies among the company's products included for assessment. In showing the biggest increase, Bristol Myers Squibb is followed by Johnson & Johnson and AstraZeneca. In lower-middle income countries, Johnson & Johnson's access strategies cover six additional products, while AstraZeneca now has strategies for all its 10 products assessed, compared to four out of nine products assessed in 2021.

However, although there is an improvement in the number of products covered by at least one access strategy compared to the 2021 Index, especially in lower-middle income countries, the strategies can now become more robust and comprehensive in order for companies' products to be made available and affordable to more people.

Many products in low-income countries still not covered by access strategies, but progress seen since 2021 Index

Most of the products in scope (97 of 149) are not covered by any access strategy in any low-income country. However, of the 52 access strategies in low-income countries analysed by the Index, 37 of these do consider payers' ability to pay, which is good practice.

While Novartis was the only company with an access strategy for all of its products in scope in low-income countries, the 2022 Index results suggest that more companies are expanding access to their products in the poorest countries. Compared to the 2021 Index, 13 companies demonstrate an increase in the number of products covered by an access strategy in at least one low-income country, with Johnson & Johnson, Gilead and Sanofi leading in this regard. For example, Johnson & Johnson has strategies for five of its 10 products assessed, compared to one of 10 in 2021.

ACCESS STRATEGIES

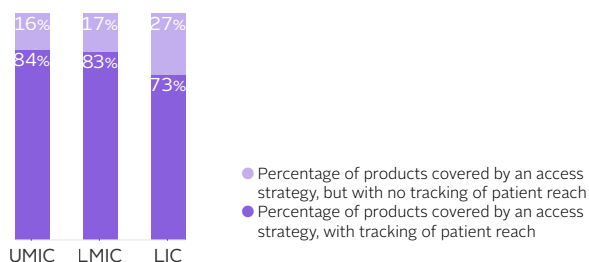
Do companies track how many people they reach with their access strategies?

The Index looked for evidence of patient reach resulting from the access strategies employed by the companies in scope.

In general, companies do provide evidence of patient reach of products covered by access strategies. They do so at a similar level for the examples provided of access strategies used in upper-middle and lower-middle income countries, and at a slightly lower level in the examples they provided for low-income countries.

FIGURE 82 Among products covered by access strategies, for what percentage are companies tracking patient reach?*

For the HCP and self-administered products covered by at least one access strategy, companies report evidence of patient reach across countries in different income classifications (upper-middle, lower-middle, and low-income) for the majority of their products.



Examples of tracking of patient reach

Bayer

In the two years prior to the inclusion of Bayer’s cancer product regorafenib (Stivarga®) on China’s National Reimbursement Drug List (NDRL), patient reach for regorafenib was less than 2,700 patients. After obtaining reimbursement, patient counts rose to 16,000 in 2019, 25,000 in 2020, and 36,000 in 2021. The price reduction and broad reimbursement enabled by the NRDL has improved access to regorafenib.

Novartis

For its cardiovascular product sacubitril/valsartan (Entresto™), Novartis has seen increased patient reach in Mexico after it was included for reimbursement and full access in the public channel. Patient reach was 11,069 in 2019, 18,628 in 2020, and 41,265 in 2021.

* This chart assesses only the products for which access strategies were reported. As only 35% of products in scope are covered by an access strategy in any of the low-income countries in scope, it should be borne in mind that this bar in the figure therefore refers to only a small number of access strategies.

Conclusions

For supranationally-procured products, including many medicines and vaccines targeting communicable diseases, companies are strongly recommended to extend pricing arrangements using the same terms to countries not eligible for such procurements. These are mostly in lower-middle and upper-middle income countries where patients still face barriers to access due to high prices, yet are less likely to benefit from supranational procurement.

For products that are not subject to supranational procurement, companies now have access strategies for more products. However, the quality of the strategies varies across products and income groups. In addition, data suggests that access strategies are not consistently applied for the same product across countries with different income levels, and lack of access to products remain an evident issue in low-income countries.

REFERENCES

1. NCD Alliance. Invest to Protect NCD financing as the foundation for healthy societies and economies. Published 2022. Accessed August 26, 2022. https://ncdalliance.org/sites/default/files/resource_files/NCD%20Financing_ENG.pdf
2. World Health Organization. Global Expenditure on Health: Public Spending on the Rise?; 2021. Accessed October 12, 2022. <https://www.who.int/publications/i/item/9789240041219>
3. World Health Organization. World Bank and WHO: Half the world lacks access to essential health services, 100 million still pushed into extreme poverty because of health expenses. Published December 13, 2017. Accessed October 17, 2022. <https://www.who.int/news/item/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses>

LICENSING

How are companies using voluntary licensing as part of their strategies to expand access?

Pharmaceutical companies can improve access to their patented medicines by granting voluntary licences, so that generic medicine manufacturers in low- and middle-income countries (LMICs) are able to develop generic versions of the product. This can be an effective way of improving the availability and affordability of key products, especially those that are new and innovative, and that might not otherwise be accessible to people living in LMICs.

In particular, companies can engage in non-exclusive voluntary licences (NEVLs), which means the licence is open to multiple manufacturers, often in different countries and regions. The Medicines Patent Pool (MPP) plays a central role in facilitating the agreement of NEVLs. Similarly, companies can opt not to enforce or file for patents, or engage in non-assert declarations in LMICs. These Intellectual Property (IP) strategies can promote access by fostering competition in the market and increasing the manufacturing base.

What is the gold standard for a non-exclusive voluntary licence?

To be most effective, NEVLs should have access considerations at their centre, and should be designed to reach a wide range of patients with a need for the licensed product. Good-quality NEVLs involve coordination and sustained commitment from industry, governments, NGOs and organisations such as the MPP.

However, detailed information about NEVLs is sometimes not publicly available, and access clauses are often not transparent. Some NEVLs are also limited in geographical scope – by being restricted to Least Developed Countries only, for example – which can restrict their impact on expanding access and benefitting global health.

What is a non-assert declaration?

A non-assert declaration is where a rights holder commits not to enforce certain patents in a defined group of countries. This allows a generic version of a patent-protected product to be produced and commercialised in those countries.¹

Medicines Patent Pool

The MPP is a UN-backed international organisation that aims to facilitate the process of voluntary licensing by negotiating licence terms with patent holders and sub-licensing to generic manufacturers on public health-oriented terms and conditions. The MPP covers treatment options for HIV, hepatitis C and tuberculosis, and it has expanded its mandate to work on priority medicines for other disease areas including cancer, cardiovascular diseases, diabetes and COVID-19.²

Licensing through the MPP offers advantages from a global health perspective because the process is more transparent than when licences are issued privately. Licences through MPP also tend to apply to a larger number of territories – meaning fewer limitations on where the generic drugs can be produced and sold – and include several other access-friendly terms.³

LICENSING

More compounds are covered by licences in 2022

The 2022 Index has identified 27 voluntary licences and three non-assert declarations among the companies in scope.* These are 26 NEVLs and one sequence of exclusive voluntary licences, from AstraZeneca. Out of the 20 companies, ten can be identified as engaging in licensing agreements: AbbVie, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Gilead, GSK, Johnson & Johnson, MSD, Novartis and Pfizer.

The three non-assert declarations identified by the Index include lopinavir/ritonavir (Aluvia®/Kaletra®) adult and paediatric licences from AbbVie, as well as non-assert declarations for Darunavir (Prezista®, Prezcoibix®/Rezolsta®, Symtuza®) from Johnson & Johnson.

The 26 NEVLs cover an average of 80 of the 108 countries in scope (a mean of 80; a median of 91). AbbVie's adult lopinavir/ritonavir, indicated for HIV, is the broadest, covering all countries in scope except Ukraine. The reason for this wide scope is that the company gave up its global patent rights in 2020 for lopinavir/ritonavir so that it could be tested as a potential treatment for COVID-19. Ultimately, no benefits were observed with lopinavir/ritonavir treatment for COVID-19. However, AbbVie's non-assert declarations and NEVL now have the potential to help expand access to a key HIV medication in LMICs.

This section explores NEVLs that cover cancer and HIV. NEVLs for COVID-19 products are covered in the Index's COVID-19 Special Report.

Access to cancer medicines

Cancer is a leading cause of death worldwide.⁴ Data from the Global Cancer Observatory shows that in 2020, just over three million new cases of cancer were reported in LMICs, with nearly two million deaths reported. The World Health Organization (WHO) estimates that by 2030, approximately three quarters of all cancer deaths will occur in LMICs.

In addition to the existing burden of communicable diseases in LMICs, the rise in non-communicable diseases (NCDs), such as cancer, has led to a 'double burden of disease' in these countries.⁵ In resource-poor settings, affordable access to cancer medicines can be a major challenge. International collaboration is required to be able to make cancer medicines available, and to guarantee that patients will receive accurate and timely treatment.^{6,7}

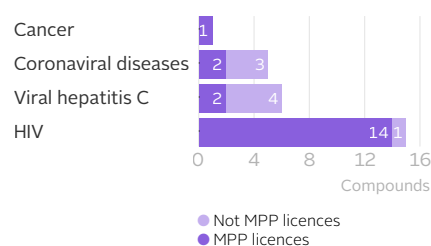
ATOM coalition

The Access to Oncology Medicines (ATOM) Coalition is an innovative collaborative model aiming to increase access to quality-assured essential cancer medicines in low-income and lower-middle income countries in a sustainable manner.

This unprecedented partnership was formed to ensure that specific needs of each country with respect to its cancer burden will be addressed. Countries will receive the support they need to receive essential medicines and diagnostics where they are lacking, as well as training on their use, so that availability becomes

FIGURE 83 27 compounds are covered by licensing agreements by the companies in scope

Licensing agreements for compounds to treat HIV are most common.



*Companies submitted information regarding the patent status of their products, NEVLs and/or non-assert declarations to the Index for analysis. Information available in the public domain was mainly found on the MPP website.² For a sub-

set of companies, details regarding scope or access clauses of NEVLs could not be reported as no data was provided/verified by the company or available in the public domain during the period of analysis. Not all NEVLs were publicly available.

sustainable in the long term. The intent is to not only ensure access to cancer medicines but also follow-up and quality care. Existing organisations will be brought together to create synergy and exchange best practices between partners.⁸

AstraZeneca, Bristol Myers Squibb, Eli Lilly, Gilead, MSD, Novartis, Roche and Sanofi have all committed to collaborating with the ATOM Coalition.⁹

MPP is part of this global partnership as an observer, responsible for negotiating voluntary licences for priority medicines. Licensing for cancer medicines is important to expanding affordable access to these essential medicines in LMICs.¹⁰ Good quality licensing agreements for oncology products will enable generic versions to be available in LMICs pending regulatory approval.⁴

Coalition to Accelerate Access to Long-Acting PrEP

HIV pre-exposure prophylaxis (PrEP) is the use of prescription medication as a means of preventing HIV infection. Oral PrEP was approved in 2012 and was shown to be safe and effective in HIV prevention. The Coalition to Accelerate Access to Long-Acting PrEP advocates for an accelerated, equitable, sustainable and collaborative approach to make longer-acting PrEP options equitably and quickly accessible. The coalition is convened by Unitaid, WHO, Joint United Nations Programme on HIV/AIDS (UNAIDS), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and US President's Emergency Plan for AIDS Relief (PEPFAR), with global advocacy for HIV prevention (AVAC) as the Secretariat, and works with leading donors and agencies to develop strategies to identify and overcome access challenges for new PrEP options, such as long-acting injectable options.¹⁴

GOOD PRACTICE

Novartis, first NEVL for a cancer compound

Novartis has entered into a non-exclusive voluntary licensing (NEVL) agreement with the MPP for its on-patent blood cancer medicine nilotinib (Tasigna®), allowing for production by generic medicine manufacturers.* This is a significant milestone, as it is the first cancer compound to be added to the patent pool, as well as the first-ever drug for an NCD to be added.¹¹ It also sets a precedent for other companies to engage in NEVLs for products covering cancer and other NCDs.

Nilotinib is used for chronic myeloid leukaemia in both children and adults. Due to its cardiovascular side effects, patients need to be carefully assessed before it is administered and must be periodically monitored.^{11, 12} The primary patent for nilotinib expires in 2023, with secondary patents expiring later.¹³ The MPP will sub-license nilotinib so that a generic version can be manufactured and supplied in the licenced territory, subject to local regulatory authorisation. All royalties that would have been received by Novartis will be reinvested back into the ATOM coalition.

GOOD PRACTICE

ViiV Healthcare, HIV licensing agreement for CAB-LA PrEP

Cabotegravir (CAB) long-acting (LA) (Apretude) from ViiV Healthcare, the global HIV company majority-owned by GSK, is an extended-release formulation of CAB and in 2021 became the first long-acting injectable option approved for HIV PrEP. This extended dosing regimen is convenient and overcomes potential administration challenges in LMICs, as one injection every two months can be more convenient than oral medication that needs to be taken daily.

In July 2022, ViiV Healthcare announced a voluntary licensing agreement with MPP for CAB-LA PrEP, which will allow selected generic manufacturers to develop, manufacture and supply generic versions of the product in 87 countries in scope of the Index.^{15, 16, 17} While this voluntary licence has not been assessed or included in the scope of the 2022 Index, as it was announced after the period of analysis had ended, it is highlighted here as a notable development that will be especially significant for women of reproductive age in sub-Saharan Africa who are disproportionately affected by HIV; the disease is the leading cause of death in women and girls between the ages of 15 and 49 in this region.^{18,19}

*Novartis announced that it would enter into the NEVL in May 2022, during the period of analysis of the Index (1 June 2020 – 31 May 2022). While the agreement was officially signed in October 2022, after the period of analysis had

ended, the NEVL meets the inclusion criteria to be in scope of the 2022 Index.

LICENSING

Greater transparency needed from companies on patent status and policies

Several criteria are assessed when analysing licensing and patent policies from companies. Apart from engaging in NEVLs, companies can publicly and clearly share information regarding patent status, patent information, and where patents will be filed or enforced.^{20, 21} This can give greater certainty to international drug procurers and generic medicine manufacturers when planning to manufacture and/or supply generic products.

Nineteen of the 20 companies publicly share data about their products' patent status. Seventeen of them do so via the Pat-INFORMED platform, a publicly available resource where patent holders can voluntarily provide information about the patent status of their product. Companies can, however, go further, or share information via other platforms or websites in order to make patent information more accessible in the public domain. The gold standard is that each company publicly discloses the patent status for all its products in its portfolio that are in scope of the Index. This information is transparent and updated; it includes the jurisdiction, publication number, publication date, filing date, grant date, grant number, and expiration date of each patent. As expiry dates cannot be shared in Pat-INFORMED, or if the platform is not used by the company, information about expiry dates should be shared publicly elsewhere, e.g., on the company's website.

Companies can also support the expansion of access to medicine by making a public commitment not to enforce or file patents, or to abandon existing patents, in a wide range of LMICs – and being transparent about this policy. A majority of the companies (17) publicly commit not to enforce or file patents in LMICs. However, only five make the commitment not to enforce patents for all their products in a broad range of countries in scope of the Index.

FIGURE 84 For less than 40% of the on-patent products in companies' portfolios, information about patent expiry dates is publicly available

Among the companies in scope, an overall figure of 740 products are included for analysis in the Index. Of these, 323 are on-patent and 292 off-patent. For the remaining 125, information about patent status is not available, or is non-applicable (e.g., for biological products). Even among products known to be on-patent, expiry dates are not easily found in the public domain.

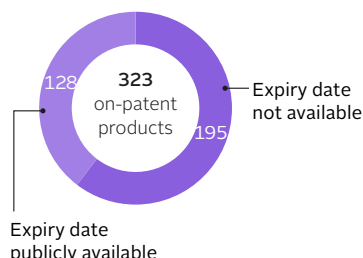
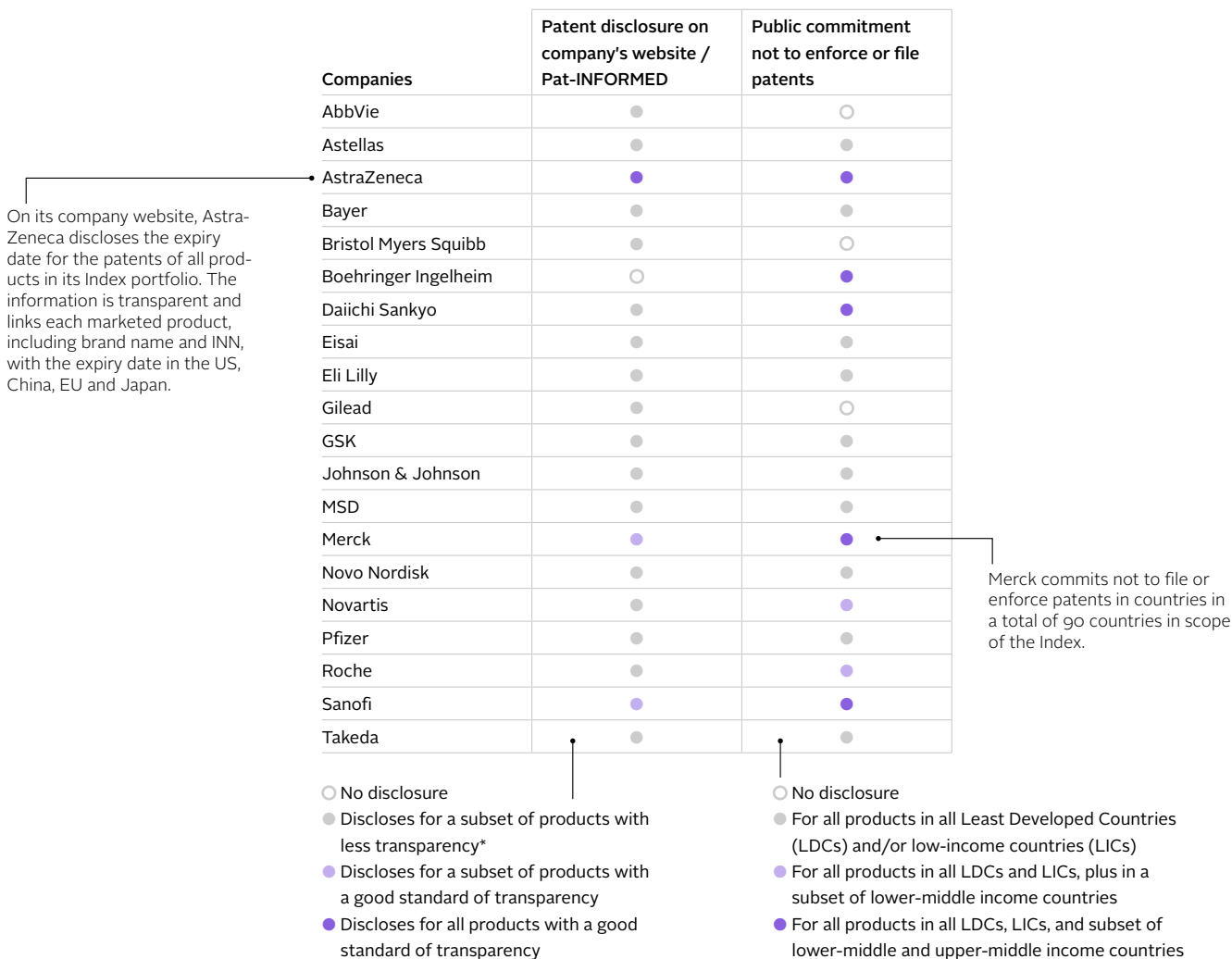


FIGURE 85 **How do companies perform in patent policies?**

This table shows companies' performance on patent disclosure (via either Pat-INFORMED or the company's website), and what public commitments it has made not to force or file patents in LMICs. AstraZeneca, Merck and Sanofi are more transparent in this area compared to their peers, while Boehringer Ingelheim does not publicly disclose patent information about its on-patent products.



Conclusions

While the majority of the licensing agreements analysed in the 2022 Index cover a wide range of countries in scope, many of these agreements exclude upper middle-income countries. Further, companies do not always make information on their non-exclusive voluntary licences (NEVLs) publicly available. Transparency in licensing agreements and patent policies is essential, as it helps facilitate procurement agencies' decision-making regarding product supply, and enables generic medicine manufacturers to identify designated LMICs in which they can develop and supply generic versions of medicines.

Companies now need to engage in more NEVLs to cover more products – particularly for non-communicable diseases – across a wider range of countries. In addition, when entering future NEVLs, companies also need to consider technology transfers and access-oriented clauses in order to help accelerate the subsequent product delivery, uptake and sustainable supply in LMICs.

*The standard of transparency is compared to the standard set out by the US FDA's Orange Book where patent data includes at least the patent number, jurisdiction and expiry date.

REFERENCES

- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). Voluntary licenses and non-assert declarations. Published July 28, 2010. Accessed August 31, 2022. <https://www.ifpma.org/resource-centre/voluntary-licenses-and-non-assert-declarations/>
- Medicines Patent Pool. Licences. Published 2022. Accessed July 20, 2022. <https://medicinespatentpool.org/progress-achievements/licences>
- Shadlen KC. Accelerating pooled licensing of medicines to enhance global production and equitable access. *The Lancet*. 2022;400(10352):632-634. doi:10.1016/S0140-6736(22)01013-3
- Oomen, Karin P Q; Karuranga, Suvi; Iyer, Jayasree K. Improving Access to Cancer Care: A First Analysis of Pharmaceutical Company Actions in Low- and Middle-Income Countries; 2017. Accessed August 31, 2022. <https://accessmedicinefoundation.org/publications/improving-access-to-cancer-care-a-first-analysis-of-pharmaceutical-company-actions-in-low-and-middle-income-countries>
- Pramesh CS, Badwe RA, Bhoo-Pathy N, et al. Priorities for cancer research in low- and middle-income countries: a global perspective. *Nat Med*. 2022;28(4):649-657. doi:10.1038/s41591-022-01738-x
- Robertson J, Barr R, Shulman LN, Forte GB, Magrini N. Essential medicines for cancer: WHO recommendations and national priorities. *Bull World Health Organ*. 2016;94(10):735-742. doi:10.2471/BLT.15.163998
- Union for International Cancer Control (UICC). UICC - who we work with. Published July 26, 2022. Accessed August 31, 2022. <https://www.uicc.org/who-we-work/networks/access-oncology-medicines-atom-coalition#3>
- UICC. Improving access to and use of essential life-saving cancer medicines in LLMICs. Published May 30, 2022. Accessed August 31, 2022. <https://www.uicc.org/news/improving-access-and-use-essential-life-saving-cancer-medicines-llmics>
- UICC. ATOM Coalition Partners. Published July 26, 2022. Accessed August 31, 2022. <https://www.uicc.org/who-we-work/networks/access-oncology-medicines-atom-coalition#partners>
- Medicines Patent Pool. MPP joins ATOM, a new global coalition to increase access to and the use of essential cancer medicines in low and lower middle-income countries. Published May 20, 2022. Accessed August 31, 2022. <https://medicinespatentpool.org/news-publications-post/mpp-joins-atom-a-new-global-coalition-to-increase-access-to-and-the-use-of-essential-cancer-medicines-in-low-and-lower-middle-income-countries>
- Novartis. Boosting access to cancer care where it's needed most. Published May 24, 2022. Accessed August 31, 2022. <https://www.novartis.com/stories/boosting-access-cancer-care-where-its-needed-most>
- Novartis. INDICATIONS for TASIGNA® (nilotinib) Capsules. Published 2022. Accessed August 31, 2022. <https://www.hcp.novartis.com/products/tasigna/ph-cml/#important-safety-info>
- Burrone. Bulletin of the World Health Organization. 2019;97:575-577. doi:http://dx.doi.org/10.2471/BLT.18.229179
- Global Advocacy for HIV Prevention. Coalition to Accelerate Access to Long-Acting PrEP. Published July 2022. Accessed November 9, 2022. <https://www.avac.org/resource/coalition-accelerate-access-long-acting-prep>
- Medicines Patent Pool. MPP, ViiV Healthcare CAB-LA for PrEP. Published May 27, 2022. Accessed October 13, 2022. <https://medicinespatentpool.org/news-publications-post/medicines-patent-pool-viiv-healthcare-enter-negotiations-over-voluntary-licensing-of-cabotegravir-long-acting-for-hiv-pre-exposure-prophylaxis>
- Medicines Patent Pool. ViiV Healthcare and MPP sign NEVL. Published July 28, 2022. Accessed October 13, 2022. <https://medicinespatentpool.org/news-publications-post/viiv-healthcare-and-the-medicines-patent-pool-sign-new-voluntary-licensing-agreement-to-expand-access-to-innovative-long-acting-hiv-prevention-medicine>
- Medicines Patent Pool. Cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP). Published July 2022. Accessed October 13, 2022. <https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep>
- ViiV Healthcare. ViiV Healthcare cabotegravir LA for PrEP. Published March 2022. Accessed October 13, 2022. <https://viivhealthcare.com/hiv-news-and-media/news/company-statements/viiv-healthcare-statement-on-voluntary-license/#1>
- Institute for Health Metrics and Evaluation. GBD Compare. Published 2022. Accessed October 13, 2022. <https://vizhub.healthdata.org/gbd-compare/>
- Medicines Patent Pool (MPP). MedsPal. Published online 2022. Accessed November 10, 2022. <https://www.medspal.org/?page=1>
- WIPO. Pat-INFORMED. Published online 2022. Accessed November 10, 2022. <https://www.wipo.int/patinformed/>

PRODUCT DONATIONS

Are companies donating medicines responsibly based on expressed need?

Long-term donation programmes are implemented by pharmaceutical companies as a clear, defined long-term strategy to control, eliminate or eradicate a disease, ad hoc donations are a short-term gift of medical products made in response to an expressed need. Ad hoc donations can be made based on the explicit request of a country but can also be made during emergency situations, such as conflicts and natural disasters. Pharmaceutical companies can provide ad hoc donations in several ways. For example, they can preposition key medicines in distribution partners' warehouses for later donation or respond directly to requests for medicines made by stakeholders, such as governments and humanitarian aid organisations.

Ad hoc donations can be valuable in filling gaps in health systems and providing access to life-saving products in times of crisis. In Tigray Ethiopia, ad hoc donations have been made to supplement the weakened health infrastructure caused by the recent conflict.¹ For example, in August 2021 the Novo Nordisk Foundation supported humanitarian aid efforts in Ethiopia by donating 92,000 human insulin vials through a request from the Danish Red Cross. In the recent war in Ukraine, pharmaceutical companies have donated over 22 million doses of essential medicines as of March 2022.² Examples are seen of companies making efforts to ensure donations reach the country despite the supply chain disruption caused by the ongoing war.

At the same time, when medicine donations are poorly executed, they can cause harm to recipient countries through, for example, high disposal costs for expired products. Research has shown that up to 70% of donated medicines and medical products are not used as they are not functional, appropriate or staff lack training in administering/using the products.³ Despite several companies having donation policies in place, recent crises like the COVID-19 pandemic have shown that ad hoc donation efforts can present opportunities for malpractice, such as offloading unwanted or nearly expired medicines. According to the Africa Centres for Disease Control and Prevention, during the pandemic, 2.8 million doses of vaccines had expired on the continent of Africa as of early 2022, most of these being donated products.⁴ Although this is only a small percentage of the total vaccines received, the number is likely to be underestimated due to lack of information about doses supplied to low- and middle-income countries (LMICs) through donations.

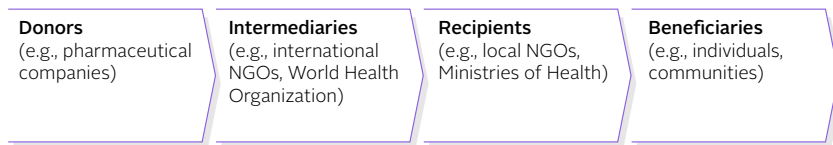
When making ad hoc donations it is important that companies take steps to ensure that these donations are held to the quality standards of the updated 2010 World Health Organization (WHO) Guidelines for Medical Donations.⁵ While ensuring proper distribution of such donations can be met with several logistical barriers – given the varied stakeholders involved in the supply chain – these barriers emphasise the importance of company involvement in the full process of medical donations, from needs assessments to last-mile distribution. This includes collaborating with recipients to ensure that medicines reach the final user – the patient.

Ad hoc donations

A gift of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on the explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

FIGURE 86 Main stakeholders in medical donation supply chain

This streamlined diagram shows the stakeholders involved in the supply of medical donations. Several other stakeholders can be involved before a donation reaches a beneficiary, such as customs controls and local third-party logistics providers in recipient countries. Furthermore, these stakeholders are based in multiple countries and have varying regulatory requirements, further complicating the supply chain. This complexity can make tracing donations to the end user difficult, especially during emergency situations when administrative systems can become disrupted and at a higher risk for corruption.



What makes a good donation policy?

The Index measures whether pharmaceutical companies have policies in place to deploy ad hoc donations in response to expressed need. These donation policies should be set up in such a way that the provided products benefit the recipient to the maximum extent possible, meaning that unsolicited medicine donations are discouraged. Donations should be made in accordance with the government policies and administrative arrangements of the recipient country. Further, donated products should be listed on the national list of essential medicines, or on the WHO Model List of Essential Medicines (EML). A plan should be made for effective coordination and collaboration between the donor and recipient, and this plan should be agreed upon by both parties. Provisions should be made to uphold the quality of medicine donations, and these quality standards should at minimum be the same as what is expected in the donor country. Companies are also expected to take responsibility for donations reaching their intended user and when working with partners.

What ad hoc donation policies do companies have in place?

All 20 companies analysed in the 2022 Index have a donation policy for ad hoc requests for medicine donations. Nine companies publicly specify their alignment with WHO Guidelines for Medicine Donations, including compliance with country requirements and requirements for securing and storing medicines in the recipient country. An additional four companies shared their alignment with WHO Guidelines with the Access to Medicine Foundation but do not have a publicly available statement. For the remaining seven companies, there is no evidence to suggest that the donations made align with WHO Guidelines.

Examples of companies that publicly disclose their commitments to upholding the quality of their product donations

GSK

As a global healthcare company, GSK recognises a responsibility to make product donations in the form of ongoing humanitarian assistance and/or as emergency support when natural disasters hit.

We are committed to ensuring that our donation programmes are managed in a responsible way, are needs-based and should not disrupt or undermine healthcare provision in recipient countries.

GSK donations are, therefore, made in accordance with an established framework of legal obligations and internal processes, and in line with WHO Guidelines on Product Donations.

AbbVie

AbbVie supports targeted product donations that build and advance health system capacity, access and infrastructure.

We are committed to ensuring that our donations to charitable, philanthropic partners are responsibly managed, meet important healthcare needs, and sustain the healthcare system capabilities in recipient countries.

AbbVie adheres to a strict Global Product Donations Policy, which aligns with WHO Guidelines for Medicine Donations. AbbVie is an active member of the Partnership for Quality Medical Donations (PQMD).

Sanofi

The Sanofi Espoir Foundation, in charge of coordinating and validating all medicine and vaccine donations for humanitarian purposes from Sanofi's organisations worldwide, has established a set of guidelines modelled on those used in WHO, setting stringent criteria to evaluate each donation request submitted to the Group's subsidiaries. These criteria include an on-the-ground needs assessment, the evaluation of the medical skills of the applicant organisation, the adequacy of the drugs with the disease profile in the recipient country, an expiry date of at least 12 months upon arrival in the country, the presence of notices and labels written in an understandable language, and the availability of storage in a secure location with an access limited to authorized people.

TABLE 5 Examples of company donations during the Ukraine crisis

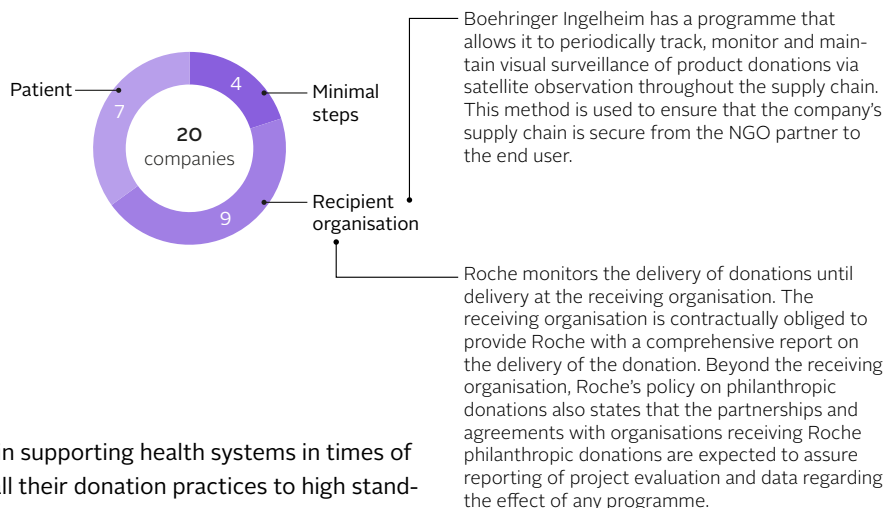
This table does not include financial donations or medical equipment donations. The information presented in this table is not an exhaustive list of all donations made by pharmaceutical companies and is instead based on company data submissions to the 2022 Index.

Company	Partner(s)	Product(s)	Date of first donation
AstraZeneca	Direct Relief Ukraine	budesonide* (Pulmicort®); dapagliflozin** (Forxiga®); budesonide/formoterol* (Symbicort®); ticagrelor (Brilinta®); fulvestrant (Faslodex®); olaparib (Lynparza®); goserelin** (Zoladex®)	14 March 2022
Bayer	Ukrainian Ministry of Health	moxifloxacin* (Avelox®) IV and tablets; ciprofloxacin*	1 March 2022
Boehringer Ingelheim	Direct Relief	ipratropium bromide* (Atrovent® HFA) inhalation aerosol; telmisartan* (Micardis®) oral tablets three dosages; telmisartan/hydrochlorothiazide* (Micardis Plus®) oral tablets three doses; tiotropium* (Spiriva® Respimat®) inhaler two doses; tiotropium* (Spiriva®) inhalation powder capsules	Q1 2022
	Polish Ministry of Health	tiotropium /olodaterol (Yanimo®)	Q1 2022
Daiichi Sankyo	Americares	olmesartan (Benicar®)	Before 31 May 2022
	Portuguese Pharmaceutical Industry Association (Apifarma)	metoprolol** 100 mg film-coated tablets; metoprolol** 200 mg prolonged-release tablets	Before 31 May 2022
	Belgian Pharmaceutical Industry Association (Pharma.be)	diclofenac sodium (Motifene®)	Before 31 May 2022
GSK	Ukrainian Ministry of Health	amoxicillin clavulanate* (Augmentin®); ceftazidime*(Fortum®); cefuroxime* (Zinacef™/Zinnat®); salbutamol*; paracetamol*(Panadol)	8 March 2022
Novo Nordisk	Ukrainian Ministry of Health	insulin human (rDna)*(Actrapid® HM); insulin human (rDna)* (Actrapid® FLEXPEN); insulin aspart (l-arginine)* NovoRapid® FlexPen®; glucagon*(GlucaGen®HypoKit)	March 2022
Novartis	Ukrainian Ministry of Health	108 different antibiotics and painkillers from the Sandoz portfolio	March 2022
Roche	Multiple (unnamed)	ceftriaxone* (Rocephin®)	2 March 2022

Monitoring the delivery of donations

Nine out of 20 companies show evidence of taking steps to ensure that the donated products reach the recipient organisation (e.g., local non-governmental organisations). Only seven companies show evidence of tracking donations until reached by the end user, being the patient. The remaining four companies take minimal steps to track their donations to the patient. Some approaches to monitor donations until the end-user include periodic field visits and distribution reports, in addition to other receipt and utilisation feedback. Other methods used include using online tools and platforms to track allocation. These kinds of online tracking tools can be valuable in increasing transparency and helping diagnose supply issues early on.

FIGURE 87 Less than half of companies demonstrate evidence of monitoring donations until reached by the end-user being the patient



Conclusions

Given the critical role of ad hoc donations in supporting health systems in times of need, it is important that companies hold all their donation practices to high standards, so that quality medicines reach those in need, in a timely manner. Data from the 2022 Index shows that just under half of companies in scope publicly share their commitments to engage in ad hoc donations that comply with WHO guidelines. More companies can publicly commit to adhere to these standards to hold themselves, and their partners, accountable for quality and timely donations. Index data also shows that less than half of companies show evidence of taking clear steps to ensure that donations reach patients at the last mile. More effort is needed in this area to monitor both distribution and use. This includes not only tracking donations until they reach district-level medical stores but also ensuring that the medicines are able to be utilised by the patients that need them.

While ad hoc donations can be a temporary solution to addressing public health needs in critical times, these donations should not be used in place of sustainable access strategies such as technology transfers, health systems strengthening initiatives and equitable pricing strategies.

REFERENCES

- 1 Devi S. Humanitarian access deal for Tigray. *The Lancet*. 2020;396(10266):1871. doi:10.1016/S0140-6736(20)32669-6
- 2 European Federation of Pharmaceutical Industries and Associations (EFPIA). Pharmaceutical industry response to the war in Ukraine. Published March 10, 2022. Accessed August 30, 2022. <https://www.efpia.eu/news-events/the-efpia-view/efpia-news-pharmaceutical-industry-response-to-the-war-in-ukraine/>
- 3 McDonald S, Fabbri A, Parker L, Williams J, Bero L. Medical donations are not always free: an assessment of compliance of medicine and medical device donations with World Health Organization guidelines (2009–2017). *Int Health*. 2019;11(5):379-402. doi:10.1093/inthealth/ihz004
- 4 Winning A. Africa calls for donated vaccines with shelf life of 3 to 6 months | Reuters. Published January 20, 2020. Accessed June 20, 2022. <https://www.reuters.com/world/africa/africa-cdc-says-it-plans-talk-merck-about-covid-pill-2022-01-20/>
- 5 World Health Organization. Guidelines for Medicine Donations, Revised 2010. 3rd ed.; 2010. Accessed June 17, 2022. <https://www.who.int/publications/i/item/9789241501989>

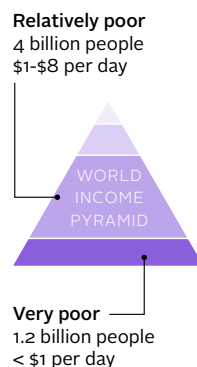
INCLUSIVE BUSINESS MODELS

Are companies engaging in inclusive business models to reach underserved populations?

The World Bank's International Finance Corporation estimates that 76% of the world's population is living at the base of the income pyramid (BoP), including 4 billion people (61% of the world population) living on USD 1-8 per day, and 1.2 billion people (15% of the world population) living on less than USD 1 per day.¹ While these figures are concerning, they likely under-represent the true number of people who live in poverty, without access to basic goods, services, and opportunities. Certain vulnerable groups such as children/youth, indigenous people, migrants and women face additional barriers to access due to factors like stigma and economic constraints.

Globally, individuals at the BoP spend more than half of their household income on pharmaceuticals, often purchased from pharmacies without a prescription, instead of hospitals or clinics, as these facilities are often less accessible.² When individuals living at the BoP cannot afford to pay for healthcare, treatment may be delayed until conditions worsen, which can lead to higher costs of treatment down the line.

Pharmaceutical companies are often reluctant to conduct business in BoP communities despite the combined high purchasing power of the population as a whole and the high individual household expenditure on health. This may be caused by various overlapping factors, including low profit margins, low levels of health-seeking behaviour and a lack of market information, logistics infrastructure and qualified healthcare personnel. Although a variety of these factors may be missing in some communities, pharmaceutical companies can leverage existing assets in BoP communities and develop inclusive business solutions to address barriers and ensure people living at the BoP have access to quality and affordable medicines.



Defining inclusive business models

The United Nations Development Programme (UNDP) defined inclusive business models in its 2008 report *Creating Value for All - Strategies for Doing Business with the Poor*: "Inclusive business models include the poor on the demand side as clients and customers, and on the supply side as employees, producers and business owners at various points in the value chain. They build bridges between business and the poor for mutual benefit. The benefits from inclusive business models go beyond immediate profits and higher incomes. For business, they include driving innovations, building markets and strengthening supply chains. For the poor, they include higher productivity, sustainable earnings and greater empowerment."³

What are inclusive business models in the context of access to medicine?

The Index assesses inclusive business models that address access-to-medicine barriers that prevent BoP communities from attaining adequate healthcare. It is important that these models include clear plans or evidence of financial sustainability and allow business operations to continue and develop. Models should be revenue-generating or revenue neutral, thus creating value for both BoP communities and businesses. In that sense, inclusive business models are not a company social responsibility programme or a charity, but instead are an additional way of doing business.

What are the inclusive business models in scope of this analysis?

In 2022, a total of 51 inclusive business models were included for analysis out of 62 models identified and assessed based on company data submissions and information from the public domain. The remaining 11 initiatives were excluded from analysis as they did not serve the BoP or other vulnerable groups, or were considered, for example, philanthropic capacity building initiatives or pricing strategies such as patient assistance programmes that are not inherently financially sustainable.

Overall, 15 companies have scaled up a combined total of 32 inclusive business models (e.g., to more disease areas or more countries), which is five times as many models as the previous Index.

FIGURE 88 More companies are scaling up existing inclusive business models than piloting new models

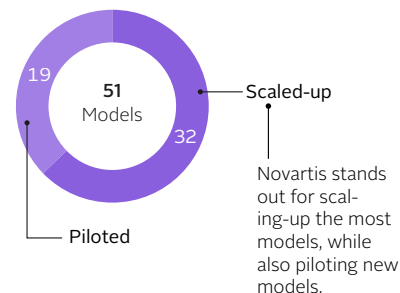
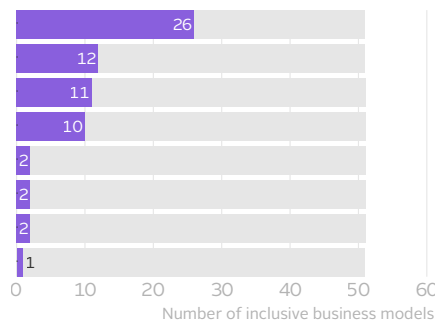


FIGURE 89 Few inclusive business models in the Index serve specific vulnerable groups that are highly represented within the BoP

According to data analysed by the Index, 26 of the 51* inclusive business models in scope serve individuals living at the BoP. Few models serve specific vulnerable groups, such as women, children/youth and rural communities.

- Base of the income pyramid
- Women
- Children/youth
- Rural communities
- People living with HIV
- People living with with physical disabilities
- Older adults
- Indigenous populations



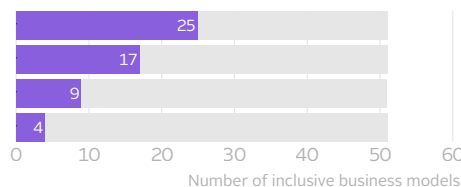
Nearly half of inclusive business models cover non-communicable diseases (NCDs)

Inclusive business models covering NCDs are prevalent, while models aiming to address health needs that disproportionately impact BoP populations, such as neglected tropical diseases (NTDs), are lacking. Models should not be driven by the potential to produce earnings, but by the potential to achieve positive patient outcomes, particularly for low-income populations. This means that in addition to NCDs like cancer or Alzheimer’s disease, companies should engage in inclusive business models that address diseases that disproportionately impact low-income populations, such as NTDs.

FIGURE 90 Nearly half of inclusive business models cover non-communicable diseases

Caption: Almost half of the 51* inclusive business models cover NCDs, followed by communicable diseases, maternal and neonatal health conditions, and NTDs. Five models are not shown in the figure as the exact disease/condition was not specified.

- Non-communicable diseases
- Communicable diseases
- Maternal and neonatal health conditions
- Neglected tropical diseases



* Inclusive business models can cover more than one vulnerable group/disease category. Therefore the sum of models across all groups/categories exceeds 51.

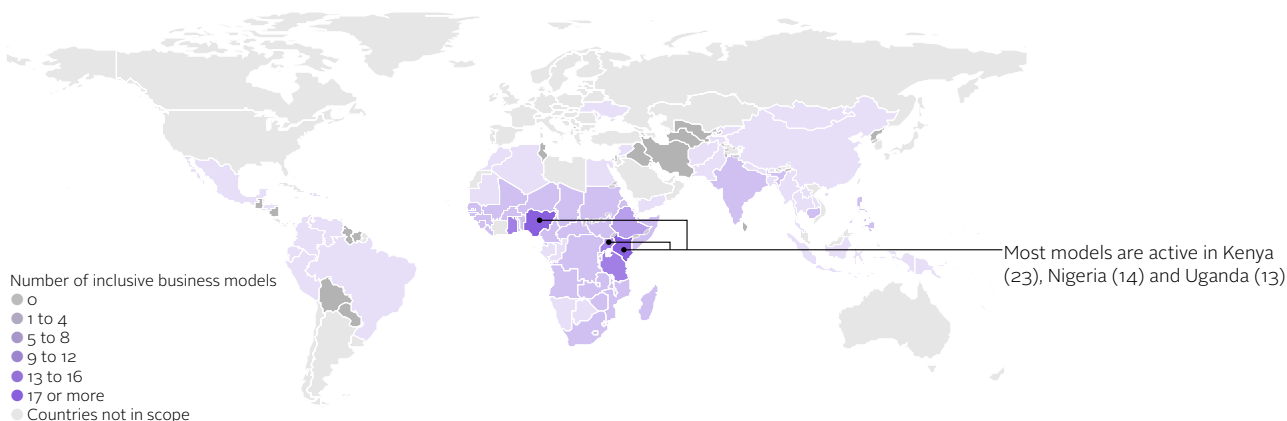
Inclusive business models are highly concentrated in sub-Saharan Africa

Inclusive business models assessed in the Index are highly concentrated in sub-Saharan Africa, particularly Kenya (23), Nigeria (14) and Uganda (13). Some models were active in South Asia (particularly in India, with five models) as well as a few countries in East Asia (Cambodia and Vietnam with four models and the Philippines with five). Kenya, Uganda, Ghana and Nigeria had the highest number of models launched during the period of analysis (four each), with Kenya and Nigeria having most scale-ups within the analysis period (19 and 10, respectively).

These countries may have multiple inclusive business models active, as they present companies with factors which facilitate business development, such as government disease prioritisation, existing infrastructure, or non-governmental organisation (NGO) activity.

FIGURE 91 Most models are concentrated in Kenya, Nigeria and Uganda

There are 51* inclusive business models in scope of the 2022 Index. Collectively, these models cover 85 (79%) of the 108 countries in scope. However, most models are concentrated in a selection of countries in sub-Saharan Africa.



* Inclusive business models active in more than one country are represented more than once in this map. Therefore, the sum of models across all countries exceeds 51.

INCLUSIVE BUSINESS MODELS

How are companies reaching low-income markets using new inclusive business models?

Traditional business planning in high-income countries often includes sufficient market data and resources that can be used to plan a business model. In LMICs, piloting inclusive business models can be more challenging, as companies face barriers such as lack of market data, lack of government reimbursement, and lack of infrastructure. Companies must account for these barriers when piloting new inclusive business models in LMICs by taking time to develop and be adaptable.

Novo Nordisk, Pfizer and Sanofi launch new models

During the period of analysis, Novo Nordisk, Pfizer and Sanofi launched initiatives that aim to address access constraints to products in the companies' portfolios. These models have the potential to address access constraints at the BoP, however, limited evidence was shown of plans for outcome measurements that capture change in affordability and availability of medicines.

Pfizer, An Accord for a Healthier World

In 2022, Pfizer launched its An Accord for a Healthier World which aims to provide all its patented medicines and vaccines at not-for-profit prices to 45 lower-income countries. Pfizer also reports that as new medicines and vaccines are launched, they will be added to the Accord Portfolio on a not-for-profit basis. A variety of patent-protected medicines and vaccines are made available through the Accord that helps treat, prevent and manage a variety of diseases, such as infectious diseases including COVID-19, pneumonia, and meningitis, certain cancers including advanced kidney cancer and types of leukaemia and breast cancer, and both inflammatory and rare diseases. Pfizer is currently working with Accord partners to identify mechanisms to reduce the length of time it takes for these products to reach countries covered by the Accord. In five countries, including Rwanda, Ghana, Uganda, Senegal and Malawi, Pfizer is working with healthcare officials to identify areas where Accord partners can address factors like limited diagnostic capacity, supply chain efficiency and healthcare worker education.

Sanofi, Global Health Unit

In 2021, Sanofi launched its Global Health Unit, which will continue to expand the company's work with local governments, stakeholders, intergovernmental agencies and NGOs to increase access to its medicines. Sanofi plans for this unit's remit to cover 40 LMICs, seeking to improve access to 30 medicines for both communicable and non-communicable diseases (NCDs), most of which are listed on the World Health Organization (WHO) Model List of Essential Medicines (EML). Through the Global Health Unit, Sanofi has shared a commitment to expand access to analogue insulins, aiming to reach 300,000 insulin-dependent patients by 2030, which is in comparison to its 2021 reach of 15,000 patients. Sanofi also aims for the unit to be self-financed by charging patients just enough to cover the cost of treatment. This will be implemented through the sale of products under a new brand (Impact®) at a lower price. The unit also aims to strengthen health systems by establishing an impact fund to support start-up companies and other innovators involved in the development of sustainable healthcare in the 40 LMICs within the unit's remit. Outcome measurements include the number of patients provided with Impact® brand medicines and the number of beneficiaries reached by programmes, for example patients diagnosed or healthcare practitioners (HCPs) trained.

Novo Nordisk, iCARE

Novo Nordisk is now expanding its strategies through a comprehensive approach to access in LMICs. The iCARE initiative was launched in 2021 as a business-integrated model aimed at improving access to diabetes treatment in 49 countries in sub-Saharan Africa, through four areas of work (Capacity, Affordability, Reach and Empowerment). The initiative aims to substantially increase the number of people with diabetes accessing insulin in sub-Saharan Africa (with the exception of South Africa) by 2025. iCARE has been launched in seven pilot countries so far, Ethiopia, Ghana, Côte d'Ivoire, Kenya, Nigeria, Sudan and Tanzania. The initiative targets challenges such as affordability barriers impeding access to care for vulnerable patients, procurement and supply chains (including last-mile distribution) barriers, mark-ups, inadequate forecasting, health-care practitioners' capacity, knowledge gaps in diabetes management, and patient education. Outcome measurements are conducted across the four work areas: capacity (e.g. number of HCPs trained), affordability (e.g. number of patients receiving insulin through the programme), reach (e.g. number of new distributors onboarded in at least two countries), and empowerment (e.g. number of patients reached through the patient support programme).

INCLUSIVE BUSINESS MODELS

How are companies measuring impact and scaling inclusive business models?

Several companies have scaled up inclusive business models during the analysis period, while taking some steps to measure impact on factors like availability and affordability. While some companies take steps to measure both business performance and social value, this is not a common practice that companies take across all business models. Although there is no universally accepted impact measurement framework for assessing the social and business value of inclusive business models, some companies demonstrate evidence that can be used to inform further discussion on effective impact measurements. A good outcome measurement for an inclusive business model captures short and long-term patient reach and patient outcomes in a way that identifies value to BoP populations.

AbbVie expands the Access to Care Program to more facilities

AbbVie's Access to Care (ATC) Program, launched in 2002 through Abbott and now through AbbVie, facilitates access to the company's HIV medication in LMICs. Through ATC, AbbVie also builds HIV treatment capacity, knowledge and clinical skills through peer-to-peer initiatives for healthcare workers in fifteen African countries such as South Africa and Zambia.

Scale-up: AbbVie reports that it has expanded this initiative to more facilities in countries where the programme was active during the analysis period.

Outcomes: AbbVie reports that it measures both countries and patients served, including an additional breakdown of children served. The company also measures population health outcomes like percentage reduction in mortality, reflected by WHO findings. Related to the direct impact of ATC, AbbVie measures the increase in numbers of patients able to afford care. The total number of HIV patients serviced by the ATC program over the past five years increased from 266 million in 2017 to 421 million in 2021.

Pfizer supports the scale-up of an inclusive clinic

Through the Pfizer Foundation's Global Health Innovation Grants (GHIG) programme, the company supported the scale-up of Jacaranda Health. Jacaranda Health is an inclusive clinic that partners with governments to deploy affordable and scalable solutions to decrease maternal deaths and increase access to maternal health services through Universal Health Coverage (UHC). Jacaranda Health works in government hospitals, where the majority of underserved mothers and babies in Kenya receive care.

Scale-up: To scale-up this initiative, the Pfizer Foundation supported the implementation of artificial intelligence detection and referral for pregnancy danger signs into a digital health platform and expanded pregnancy danger sign detection.

Outcomes: To track trends and lessons learned in inclusive business models for low-resource settings, Pfizer partners with Innovations in Healthcare (IiH) hosted by Duke University. This partner leads programme evaluation for GHIG models like Jacaranda Health, providing guidance to individual grantees and identifying learnings from across the entire cohort of grantees to help inform the Pfizer Foundation's investment strategy. In 2022, Jacaranda Health has reported several outcomes, including that 85% of pregnant women flagged with a danger sign via the digital health platform now go to a hospital.

Novartis continues to scale up its long-running model

The Novartis Healthy Family programmes, launched in 2007, are social business models that build local and sustainable healthcare capabilities for populations at the BoP through country-tailored programmes. This is the longest-running model since the Index began collecting data on inclusive business models in 2014. The programmes are operational in India (Arogya Parivar), Kenya (Familia Nawiri), Uganda (Familia Nawiri) and Vietnam (Kung Kong Khoe). They address social issues that impact access to healthcare, such as education, infrastructure and distribution. The social activities are independent from commercial operations but are financed through the sale of a selection of Novartis products.

Scale-up: Programmes within the four countries have expanded. In India, for example, the programmes are expanding into ophthalmology through a network of partnerships including with Aravind Eye Care System, one of the largest providers of eye care in the world. Since 2021, the programme has reached additional areas in Vietnam, including three provinces and three states. Novartis has also started community engagement discussions in Mexico to explore the feasibility of programme implementation.

Outcomes: According to the Novartis in Society Integrated Report 2021, since 2007, the combined outreach for all projects across the four countries has delivered health education to more than 75 million people. Novartis reports on several outputs in its 10-year report such as revenues generated, country presence, and number of health education meetings. The report also outlines barriers the company faced in measuring outcomes, such as the inability to practically and scientifically prove social impact. Novartis now reports that it measures outcomes, including the number of patients filling prescriptions, at what prices, and how many are returning regularly.

Novartis builds in outcome measurement as a core element of its model covering NCDs

Novartis Access[®], launched in 2015, offers a portfolio of on- and off-patent medicines addressing key noncommunicable diseases (NCDs), including cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer. The Novartis Access portfolio is offered as a basket to governments, NGOs and other institutional customers in lower-income countries at a price of USD 1 per treatment, per month. To manage their chronic condition long-term and depending on public subsidy levels, patients in participating countries may either receive Novartis Access medicines free of charge or be able to purchase them at a low price. The model is offered to underserved patient populations who are not covered by national or private mechanisms in ten countries (e.g. Ethiopia, Kenya, Nigeria, Pakistan, Rwanda, Tanzania, Uganda, Venezuela, Vietnam and Mongolia).

Scale-up: Since 2020, the portfolio of products offered has been expanded in Vietnam and Pakistan. Novartis has also signed an agreement with the Mongolian government to launch Novartis Access[®] in the country. Novartis reported that baseline assessments to inform country expansions were underway in both Laos and Cambodia.

Outcomes: Based on learnings from outcome measurements of Novartis Healthy Family, the company worked to build monitoring and evaluation as a core element of Novartis Access[®]. Local teams who manage the programme in each country define and measure predetermined outcomes through local implementing partners. These KPIs (e.g., total patients reached versus patients reached through access approaches) are tracked via local progress reports with updated and consolidated data reported in the Novartis in Society reports.

MSD supports the expansion of an inclusive business model to address maternal health

M-TIBA is a mobile platform launched by PharmAccess, Safaricom and CarePay, that allows people to save, borrow, and share money for healthcare at low costs.

Scale up: In Kenya and Tanzania, MSD is supporting the expansion of M-TIBA to include maternal health services through MomCare, which is a new platform that links patients, providers, and payers to improve the financing and delivery of maternity care. The digital platform helps families create 'health wallets' to save mobile money and pay for health services from affiliated providers. It also offers 'bonuses' to providers who successfully deliver the full continuum of quality maternity care to patients.

Outcomes: Through data collection, M-TIBA provides insights in healthcare needs and costs. In 2021, partners reported that in Kenya, data from the first participating cohort to the ninth, showed that the percentage of 'good' patient journeys increased from 40% to 76%. Several other outcomes were reported, such as utilisation of contraceptives and family planning counselling. As of late 2020, over 20,000 women are connected via MomCare in Kenya and Tanzania.

Conclusions

Analysis of inclusive business models from companies in scope of the Index suggests that companies are scaling up existing models, but piloting relatively few. While scale-ups can help broaden the patients reached with these models, it is important that companies tailor their models to specifically reach even the lowest tiers of the income pyramid. When scaling up, attention should be paid to measuring the value to BoP populations. When rigorous measurements and transparent reporting show that an inclusive business model is successful in improving access to healthcare and allows modest profit for the company, further investments can be made to scale up.

Based on the sample that was assessed by the Index, companies' inclusive business models are highly concentrated in a few countries in sub-Saharan Africa. In addition to engaging in inclusive business models in these countries, companies have an opportunity to pilot new models that serve access needs of people in additional countries, even when existing infrastructure is yet to be established. When piloting new models, companies should consider the unique health needs of the populations they plan to serve, which may include targeting additional disease categories, such as NTDs or maternal health.

Three inclusive business models from Novo Nordisk, Pfizer and Sanofi were launched during the analysis period that show particular potential for improving access to medicines for underserved populations living in LMICs. However, clear steps are needed to measure and report patient reach, especially measuring the value brought to patients at the BoP and other vulnerable groups. More companies can launch models like these, to improve access to their portfolios, and engage in more financially sustainable ways of reaching underserved populations, where other business models may fall short.

REFERENCES

1. Business Call to Action United Nations Global Compact. *Implementing Inclusive Business Models: How Businesses Can Work with Low-Income Communities*; 2015. Accessed June 21, 2022. <https://www.unglobalcompact.org/library/3161>
2. Hammond AL, Kramer William J, Katz RS, Tran JT, Walker C. *The Next 4 Billion: Market Size and Business Strategy at the Base of the Pyramid*; 2007.
3. United Nations Development Programme. *Creating Value for All: Strategies for Doing Business with the Poor*; 2008.

SUPPLY, QUALITY AND MANUFACTURING

How do companies help safeguard the supply and quality of their products?

The importance of strengthening supply chains to ensure access in LMICs

Supply chains in low- and middle-income countries (LMICs) are often very complex, involving multiple stakeholders along the value chain from manufacturing to import, wholesale and retail, with several auxiliary roles involved at each level.^{1,2} In LMICs challenges in demand forecasting due to lack of data, lack of trained supply chain staff and unexpected manufacturing disturbances (e.g., due to natural disasters or contaminations) can impede the continuous supply of medicines. When supply chains function poorly, communities are burdened with increased costs, circulation of substandard and falsified medicines and frequent stockouts.

The impact and lessons of COVID-19

Recent global crises, such as the COVID-19 pandemic, have brought the impact of supply disruption on global health security to the fore. The 2021 Index highlighted efforts made by companies in the wake of the pandemic to augment supply, prevent shortages, and ensure availability of essential medicines in LMICs. The Index found that companies had taken steps to ensure continuous supply during the pandemic, such as building cold chain capacity and moving buffer stocks closer to regions where they would be deployed. Although COVID-19 emphasised how crucial continuous pharmaceutical supply chains are, momentum must not be lost.

It is important that lessons learned from the pandemic be harnessed to strengthen supply chains so that they are better able to handle future disruptions. Companies have a responsibility to strengthen their own supply chains to ensure continuous supply of high-quality products, while paving the way for smoother supply of products outside their own portfolio.

What can companies do to build capacity for manufacturing safe and effective medicines in LMICs?

Manufacturing is the first step in the pharmaceutical supply chain, making it a pivotal moment to ensure the supply of safe and effective medicines to LMICs. The Index assesses what companies are doing to build capacity of third-party manufacturers to improve supply and prepare for future production needs in the LMICs in scope.

The manufacturing capacity building initiatives assessed in the 2022 Index are concentrated in India, China and Brazil. While continuing to build manufacturing capacity in these countries can help with regional supply, more efforts are needed to improve manufacturing capacity in regions, such as sub-Saharan Africa, that rely heavily on imported pharmaceutical goods.

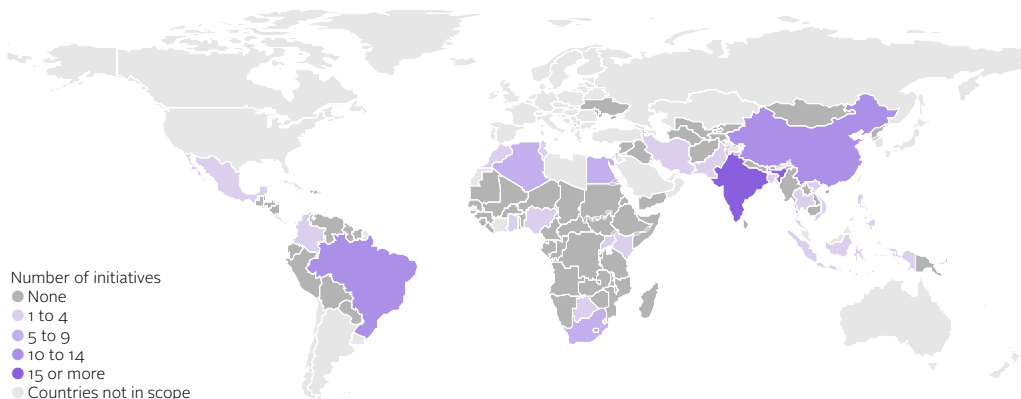
Supply chain

A supply chain is a system of organisations, people, and activities that support the movement of a product or service from supplier to customer by facilitating the flow of material, information, and financial resources. The core functions of a supply chain are carried out in three phases: manufacturing, procurement, and distribution.^{1,2}

FIGURE 92 Manufacturing capacity building is concentrated in India, China and Brazil

China and Brazil

India, China and Brazil are covered by 20, 13 and 12 of 55* initiatives, respectively.



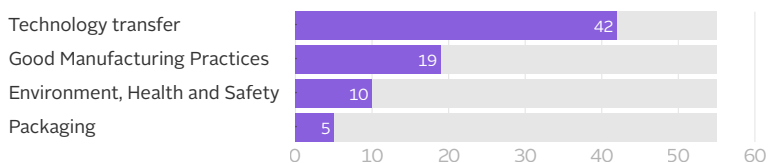
GOOD MANUFACTURING PRACTICE

Company: Pfizer

Description: Starting in 2019, Pfizer External Supply Operating Unit hired dedicated teams of colleagues based in emerging markets, including in Egypt, to work proactively with local contract manufacturing organisation (CMO) partners to improve compliance with quality, environment, health and safety (EHS) standards. The overall goal of this initiative is to ensure supply to patients in Egypt, including for medicines that the government has mandated in-country manufacturing for. These teams provide oversight and support to Pfizer’s local partners and are comprised of experts in operations, quality, supply chains, procurement and EHS. Pfizer measures outcomes (e.g., technical transfer timelines, number of repeat quality audit findings), shares them with CMOs and works with them to continuously improve. For example, for CMOs in Egypt that produce antibiotics, Pfizer has evaluated the performance of the CMO with respect to the Anti-Microbial Resistance (AMR) Industry Alliance and responsible manufacturing framework. Currently Pfizer is assessing sourcing even more products from CMOs in Egypt as well as other Africa Middle East territories.

FIGURE 93 How are companies engaging in manufacturing capacity building?*

Almost all of the manufacturing capacity building examples seen in the Index are technology transfers. Fewer initiatives involve upskilling local manufacturers to be able to achieve Good Manufacturing Practices (GMP). Even fewer than 20% of initiatives involve improving Environmental, Health and Safety (EHS) Standards or increasing packaging and/or labelling capacity of third-party manufacturers.



*Initiatives that are active in more than one country are counted more than once in this figure. Therefore, the total number of initiatives shown in this map exceeds 55.

**Initiatives that cover more than one type of activity are included more than once in this figure. This means that the sum of all initiatives exceeds 55.

Majority of companies involved in technology transfers to build manufacturing capacity in LMICs

Out of the 55 manufacturing capacity building initiatives analysed in this Index, technology transfers are the most common form of manufacturing capacity building that companies are involved in, accounting for 42 initiatives. Technology transfers can shorten supply chains and improve regional availability of medicines, by localising production closer to where products will be distributed.

Pharmaceutical companies may initiate a technology transfer for several reasons. Companies often outsource production to CMOs in LMICs to supply their respective regions.

Technology transfers can also be made in combination with exclusive or non-exclusive voluntary licence agreements that can allow one or multiple local manufacturers to enter the market, potentially lowering prices. Companies can also transfer technology to manufacturers in LMICs where they have issued a non-assert declaration. Non-assert declarations are pledges by rights holders not to enforce patents in certain territories or under certain conditions, allowing a generic version of a patented medicine to be produced. Index data shows that less than a third of companies' technology transfers are part of licensing agreements or non-assert declarations.

Gilead stands out due to its efforts to provide licensing partners with a technology transfer of manufacturing processes for active pharmaceutical ingredients, as well as finished products for HIV, hepatitis C and more recently the COVID-19 antiviral medication remdesivir (Veklury®). Recently, AstraZeneca licensed its COVID-19 vaccine to multiple manufacturers in LMICs in combination with technology transfer packages.

Contract manufacturing organisations (CMOs)

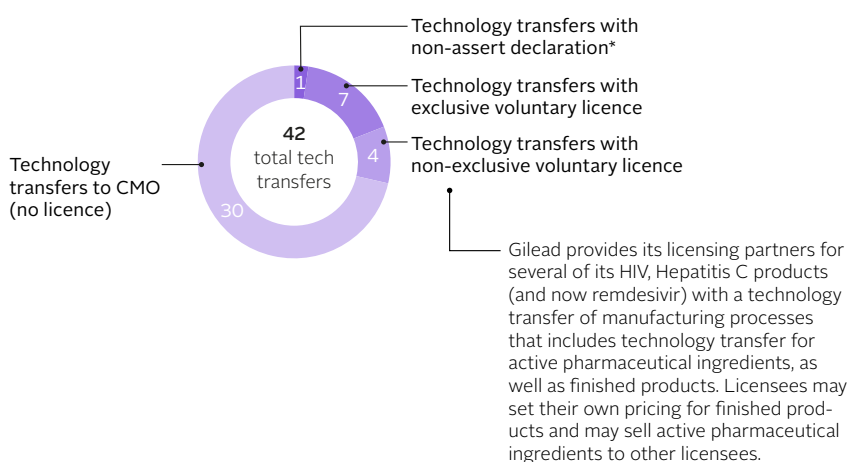
CMOs in the pharmaceutical industry are companies that work with pharmaceutical companies on a contract basis to perform drug manufacturing and/or development services from pre-formulation to commercial development. By outsourcing production, pharmaceutical companies can increase manufacturing capacity and allow the company to focus resources on drug discovery or marketing.

Technology transfers

Technology transfer for drug manufacturing is the process of transferring documentation and professional expertise (e.g., know-how and associated data) to another site capable of reproducing the process. Most transfers take place over a period of several years where ongoing support and training is provided to the local manufacturer. Often skills are built in areas that can be applied broadly to the manufacturer beyond the product being transferred, for example, processes for ensuring GMP and safety.

FIGURE 94 Most technology transfers are not conducted in combination with licensing agreements

Most companies' technology transfer initiatives are carried out via contracting agreements that do not include a licence to market the finished product. The remaining examples include exclusive licences, or non-exclusive voluntary licences where multiple generic manufacturers can manufacture the drug. One technology transfer is conducted in combination with a non-assert declaration.*



*Non-assert declarations are pledges by rights holders not to enforce patents in certain territories or under certain conditions, allowing a generic version of a patented medicine to be produced.

Transferring technology to enable local manufacturing can have multiple benefits, from improving regional availability to lowering the cost of medicines to the patient. However, there are some barriers to localisation that may deter companies from extending their supplier base beyond a select few manufacturers with existing expertise. For example, transferring technology to a manufacturer in a country lacking regulatory capacity for GMP inspection and enforcement could delay or prevent project completion.

While these barriers may make localisation more difficult in some countries, there are several LMICs, such as Nigeria, where governments are working to improve the domestic pharmaceutical sector through mechanisms like policy intervention and investment. Companies can work with governments to localise production in order to continue to reach those markets.

CASE STUDY: SANOFI

Responding to government calls for local manufacturing through capacity building

Since 2015, Sanofi has been working with May & Baker Nigeria Plc. to produce some of its products, including the antibiotic metronidazole (Flagyl®). May & Baker is one of the approximately 180 approved local manufacturers inspected by the Nigerian Agency for Food and Drug Administration and Control (NAFDAC). In Nigeria a new government regulation stipulates that as of 1 May 2019, a newly registered imported product is given a maximum period of ten years (five years of initial registration plus another five years of renewal registration) to migrate to local production or be refused sales in Nigeria.³ This legislation requires local manufacturers to meet the often strict Good Manufacturing Practices (GMP) requirements required by originator companies to be able to manufacture. In response to this new legislation, Sanofi proactively trained May & Baker on hygiene and on-site safety provisions. To be able to transfer technology for two of its products, Sanofi also built capacity for reading and analysis of analytical meters, process validation, production of validation batches and protocols, as well as reporting for pharmaceutical products. The insights gained by May & Baker through these trainings can be applied to all pharmaceutical products produced by the company.

Most companies now demonstrate best practice on combatting substandard and falsified products

Pharmaceutical companies can help combat the issue of substandard and falsified products by:

- Implementing policies or procedures for reporting substandard and falsified products to national regulatory authorities and/or World Health Organization (WHO) Rapid Alert, especially when local regulatory systems are weak or compromised;
- Ensuring that reporting takes place in a timely manner (i.e., within ten working days) to minimise the harm to public health;
- Establishing a policy or procedure that stipulates a faster reporting timeframe when laboratory analysis is not required and visual inspection is sufficient to confirm falsification.

In the 2021 Index, only six companies demonstrated best practice by implementing all three of these criteria: Astellas, AstraZeneca, Eisai, GSK, Novartis and Takeda.

In the 2022 Index, two more companies newly demonstrate best practice: Roche and Johnson & Johnson. For Daiichi Sankyo, the situation differs among subsidiaries regarding policies and procedures for reporting confirmed cases of substandard and falsified medicines to health authorities, and with regard to timely reporting. Six other companies provide evidence of a policy that ensures timely reporting of cases of substandard and falsified cases, although they do not provide evidence of shortened timelines for reporting these cases that do not require laboratory analysis for confirmation. These companies are Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Merck, Novo Nordisk and Sanofi.

WHO defines substandard products as those that are authorised but fail to meet its quality standards or specifications, and it defines falsified products as those that deliberately or fraudulently misrepresent their identity, composition or source.

FIGURE 95 How many companies demonstrate best practice on combatting substandard and falsified products?

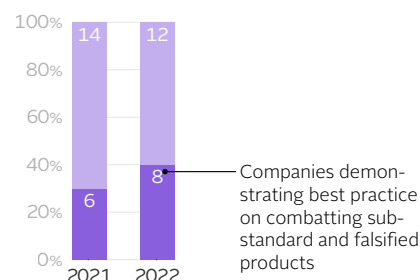


FIGURE 96 The majority of companies have a policy for reporting substandard and falsified products

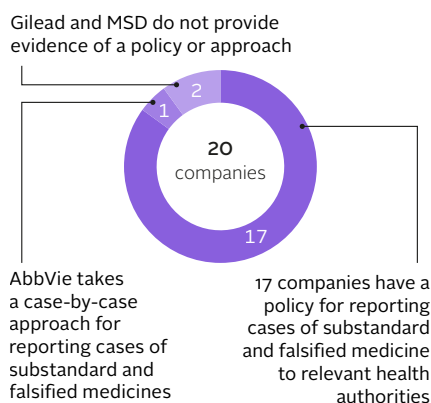
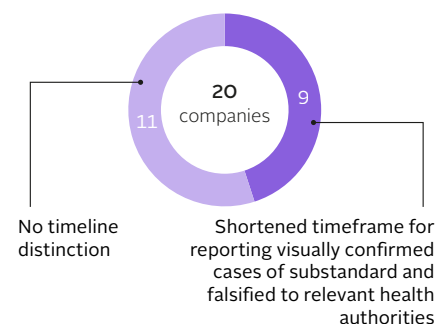


FIGURE 97 Most companies commit to reporting cases of substandard and falsified products within ten days



FIGURE 98 Nine companies have a policy that stipulates a faster reporting timeframe when visual inspection is sufficient to confirm falsification



What steps can companies take to ensure continuous supply of medicines in LMICs?

Beyond supporting manufacturers in LMICs to manufacture high-quality products, companies also have a responsibility to ensure that medicines in their own portfolios reach the people who need them. Furthermore, companies' ability to invest resources into building resilient supply chains allows them to pave the way for the supply of products outside of their portfolio through mechanisms like knowledge sharing.

Communicating with stakeholders about issues impacting the supply chain

Collaboration with local manufacturers, distributors and logistics providers is necessary in order to identify bottlenecks and improve capacity for appropriate supply chain and manufacturing management. Below are some examples of how companies are communicating and collaborating with stakeholders to mitigate supply interruptions:

- Dedicating local logistics teams from within the company to serve as a mediator between the company's central inventory management and local stakeholders (e.g., governments, purchasers, hospitals) to communicate demand and supply of products;
- Developing user-friendly portals to simplify communication between distributors and suppliers;
- Implementing clearly defined notification procedures for stockouts to communicate with local authorities;
- Holding pre-emptive meetings with managers from local manufacturing sites and other stakeholders involved in supply to collaborate and plan early on for issues that may impact supply; or
- Holding regularly scheduled (e.g., monthly) meetings with governments to discuss in-country requirements and demand fluctuations.

Ensuring resilience in the Active Pharmaceutical Ingredient supply market

Supply chains come under threat when manufacturers rely on a small number of Active Pharmaceutical Ingredient (API) suppliers. When the sole supplier of these ingredients is compromised (e.g., through regional conflict or contamination issues), bottlenecks are created and supply of essential products is delayed. Even relying on a diverse range of suppliers within one country may pose a threat to supply chain stability. Companies can deploy several strategies to mitigate the risk of API shortages.

FIGURE 99 Most companies combine dual API sourcing and buffer stocks to mitigate supply risks

The most reported approach to mitigating API supply risks was combining multiple API suppliers with a buffer stock of API. MSD does not show evidence of a strategy to mitigate API shortages.

Multiple API suppliers	In-house APIs	API buffer stocks	Number of companies
●		●	6
●			4
●	●		3
	●		3
●	●	●	2
	●	●	1

Takeda has teams that evaluate demand development across the organisation and assess new API suppliers where needed to ensure business continuity. Takeda also holds appropriate levels of stock of API and excipients at several manufacturing sites within its supply chains, including when there are unforeseen supply disruptions at prior levels of internal or external manufacturing.

The importance of keeping buffer stocks of finished products

Nineteen of the 20 companies have strategies for managing buffer stocks. In addition to managing buffer stocks of APIs, companies can also keep buffer stocks of finished products in local or regional distribution centres. By working with customers and other stakeholders to understand demand, companies can build in a safety margin to ensure that medicines are available when demand surges. Keeping safety stocks in different regions where they will be distributed can be more impactful for ensuring continuous supply than holding safety stocks at company warehouses in only a few corners of the world.

Examples of buffer stock policies and their use

Novartis

With the introduction of a rapid response platform, Novartis uses dynamic safety stocks which are flexible and can be increased or decreased depending on the need (e.g., for products with low shelf-life, new products with unstable demand). Novartis used this buffer stock strategy with sacubitril/valsartan (Entresto™) in the Philippines. When it launched in the Philippines in 2016, Novartis operated with an increased safety stock of eight weeks.

There were three reasons why Novartis decided to have a higher safety stock: (1) Unstable demand – there was uncertainty in how healthcare practitioners and patients would react to the medicine. Novartis anticipated a potential increase in demand, because of feedback from other country organisations which launched ahead of the Philippines; (2) Shelf-life is 36 months; (3) Minimum order quantity coverage was up to three months.

Sanofi

Sanofi's inventory policy sets target levels for each subsidiary of the company. Inventory levels are set for active ingredients, semi-finished, and finished products, for all products the company supplies. Decisions about inventory levels are based on factors like where the product is considered vital, the complexity of the manufacturing process and the number of sources for the raw materials used to manufacture the final product.

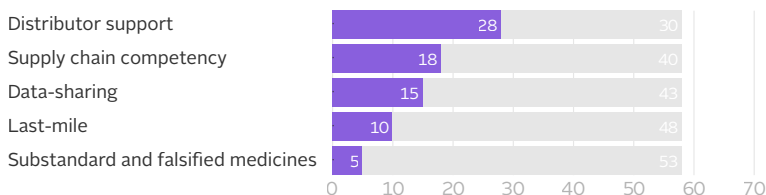
Strengthening supply chains in LMICs

Pharmaceutical companies can act as facilitators in guiding supply chain reform to improve supply of products to those who need them in LMICs. AstraZeneca, GSK, Johnson & Johnson, Novartis and Takeda stand out in terms of sharing the maximum number of capacity building initiatives possible, all meeting all Good Practice Standards (see Appendix IV). These initiatives have clearly-defined and measurable goals/objectives, aim for sustainability or have long-term aims, and measure outcomes.

In working with distributors to supply their own products, pharmaceutical companies can build capacity for further supply of other products through training on various supply topics (e.g., documentation, cold-chain transports, Good Distribution Practices, demand forecasting). Besides distributors, companies can also build capacity of other stakeholders, such as university students interested in working in the field of supply chain management, or supply chain stakeholders in a country's Ministry of Health. Furthermore, pharmaceutical companies can build capacity in detecting substandard and falsified medicines. This can include preventing circulation of falsified versions of their own medicines, as well as sensitising stakeholders about detection of these dangerous alternatives circulating the market. Companies can also support last-mile delivery, and overall data collection and management to improve supply.

FIGURE 100 Few initiatives focus on detecting substandard and falsified medicines outside a company's own supply chain

Out of the 58* supply chain capacity building initiatives assessed, about half include distributor support. The least common form of capacity building seen is supporting the detection of substandard and falsified medicines in the supply chain.



BUILDING CAPACITY OF SUPPLIERS TO SUPPORT RESPONSIBLE SUPPLY CHAIN PRACTICES

Initiative: Pharmaceutical Supply Chain Initiative (PSCI)

Companies involved: AbbVie, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Gilead, GSK, Johnson & Johnson, Eli Lilly, Merck, MSD, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi, Takeda

Description: The PSCI is a non-profit business membership organisation formed in 2006 that aims to bring together members to define, establish and promote responsible supply chain practices, human rights, environmental sustainability and responsible business. The PSCI created a set of principles for supply practices related to ethics, labour, health & safety, environment and management systems. All PSCI members are expected to support and incorporate the principles into their key supplier documents and agreements. In addition to the principles, the PSCI also includes a supplier collaborative auditing programme and builds capacity of suppliers involved. Several companies report adopting PSCI principles into their supply chain frameworks. AbbVie, for example, reports that through PSCI-based sustainability audits, the percentage of suppliers that have a programme and goals in place to reduce waste generation increased from 77% in 2019 to 86% in 2021.

SUPPLY CHAIN COMPETENCY BUILDING

Initiative: People Who Deliver Strategic Training Executive Programme (STEP 2.0)

Companies involved: GSK, Johnson & Johnson, MSD

Description: The STEP 2.0 programme was launched in 2016 by People Who Deliver, a global coalition hosted by the UN Children's Fund (UNICEF), and includes Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), United States Agency for International Development (USAID) and the International Federation of Pharmaceutical Wholesalers (IFPW). It is an evolution of the STEP programme, launched in 2016, to address a lack of supply chain skills and a need for improved leadership skills at the middle management, senior leader/executive level, whether it is at a central medical store or Head of Procurement at the Ministry of Health. STEP 2.0 provides healthcare personnel with the non-technical leadership training, skills, and competencies that are engrained in private sector supply chain managers so that immunisation managers can effectively fulfil their roles. The initiative is focused on helping to solve critical gaps in supply chain competencies related to project and people management, problem solving skills, communication skills and professional development. Pharmaceutical company partners such as GSK, Johnson & Johnson and MSD have supported this initiative through delivering leadership classes to supply chain leaders, utilising their supply chain expertise.

*Initiatives may include more than one activity and in this case are counted more than once in this figure. Therefore, the sum of initiatives exceeds 58.

SUBSTANDARD AND FALSIFIED MEDICINES

Initiative: Fight the Fakes

Companies involved: All companies

Description: At the end of 2020, a new multi-stakeholder non-profit association was launched that aims to raise awareness about the dangers of substandard and falsified medicines. GSK has been involved with this initiative since its inception but formally became a member in 2021. Fight the Fakes Alliance and its members work collectively to tackle the growing global burden of substandard and falsified medicines to safeguard public health and strengthen health systems. GSK supports the Fight the Fakes awareness campaigns by training customs, law enforcement and regulatory authorities and wholesalers, giving them the tools to detect suspected falsified medicines. GSK reported that the training reached over 2,000 individuals in China, Colombia, El Salvador, Guatemala, Mexico, Peru, Philippines, and Vietnam, as well as other countries outside the scope of the Index.

DISTRIBUTOR SUPPORT/DATA SHARING

Initiative: Neglected tropical disease (NTD) Supply Chain Forum

Companies involved: Eisai, GSK, Johnson & Johnson, Merck, MSD, Pfizer

Description: The NTD Supply Chain Forum is a public-private partnership that was established in 2012 to serve as the platform for engagement for NTD supply chain experts from WHO, pharmaceutical companies, non-governmental organisations, donor organisations, ministries of health, and logistics providers. Its mission is to support endemic countries in the control/elimination of NTDs by strengthening supply chains to improve access to drugs and diagnostics.

DATA SHARING

Initiative: Strengthening Pandemic Response and Preparedness and Health Supply Chains with the World Food Programme (WFP)

Company involved: Takeda

Description: Takeda's five-year project with the WFP aims to develop an approach to strengthening supply chains that deal with inventory inefficiencies, reactive supply chain processes and low data quality and availability. A key component of this project is to help the WFP update its information systems to be able to efficiently organise the transport and storage for its partners for essential health supplies throughout the world and track near real-time all the way to the last-mile recipients. The newly developed Control Tower information system consists of three interfaces tailored to the needs of the different stakeholders involved in the execution of partner supply requests. The initiative includes several other digital tools that were developed to gather data via crowd-sourced updates (e.g., population density, location of health facilities) or facilitate planning and Key Performance Indicator measurement of health partners.

Conclusions

Companies are taking steps to ensure continuous supply of their products in LMICs through actions such as holding buffer stocks of finished products, diversifying API sourcing, and communicating with stakeholders in the supply chain about potential supply risks. While companies generally perform well in taking steps to ensure continuous supply of their own products, their performance varies in terms of building capacity for manufacturing and supply through third parties in LMICs.

Since the COVID-19 pandemic, companies have increased their engagement in manufacturing capacity building, specifically through technology transfer agreements for COVID-19 vaccines and medicines. However, efforts are still focused on emerging markets (i.e., India, China, Brazil). The pandemic has shown that relying on a select few manufacturers leaves countries vulnerable to vaccine nationalism, export bans, and shortages. This extends beyond COVID-19 vaccines, to other life-saving medicines and diagnostics for other diseases. Companies should seek out partnerships with manufacturers in LMICs to localise production, improve regional availability and build manufacturing capacity for current and future supply of products in LMICs.

While building manufacturing capacity in LMICs is important for long-term global health security, this alone is not enough to ensure a rapid and effective response to future public health emergencies. Distribution through effective supply chains is a crucial step in ensuring continuous supply, and companies have a role to play in this area. Pharmaceutical companies' expertise in supply chain practices can be instrumental outside of the supply of their own products, however, a quarter of companies perform below average in terms of building supply chain capacity. Companies can work in partnerships to build capacity of third-party supply chain stakeholders, in areas like data sharing, last mile support, and mitigating the circulation of sub-standard and falsified medicines.

REFERENCES

1. Yadav P. Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform. *Health Syst Reform*. 2015;1(2):142-154. doi:10.4161/23288604.2014.968005
2. Pisa M, McCurdy D, Chalkidou K, et al. Improving Global Health Supply Chains through Traceability; 2019. Accessed October 31, 2022. <https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf>
3. Fatokun O. Fostering local production of essential medicines in Nigeria. *Bull World Health Organ*. 2020;98(7):507. doi:10.2471/BLT.19.249508

Best Practices

Best Practices are shared to accelerate adoption of similar practices by other companies, and to help raise the overall level of standard practice to achieve greater access to medicine. Each Best Practice has been shown to meet at least some of the following criteria:

- Proven effectiveness
- Sustainability
- Replicability
- Alignment with external standards / stakeholder expectations

The 2022 Access to Medicine Index has identified 19 Best Practices across the Technical Areas analysed. There are three Best Practices in Governance of Access, six in Research & Development, and ten in Product Delivery. Some of these focus on a single company, while other Best Practices draw on examples from several companies.

Six companies promote and reward the effective delivery of access initiatives at top levels

ASTRAZENECA, GSK, JOHNSON & JOHNSON, NOVARTIS, PFIZER, TAKEDA

Location: Global

Focus: n/a

Action: Incentivising top-level managers with financial and non-financial rewards to achieve access targets and objectives, establishing senior-level responsibility

Aim: To reinforce governance of access through incentive structures

When responsibility for access strategies lies directly with a company's board of directors, this helps to ensure top-level accountability for access, prioritisation of goals and keeping targets on track. GSK, Novartis, Pfizer and Takeda remain leaders in this area, as in the previous Index, and they are now joined by AstraZeneca and Johnson & Johnson. All six companies maintain access as a pillar of their business operations, make board-level committees responsible for access strategies and deploy financial and non-financial short- and long-term incentives, for the CEO, relevant senior executives, and in-country and regional management. The companies also disclose how access aligns with overall strategy.

GSK announced in 2021 that of its six new Environmental, Social, and Governance (ESG) focal areas, two will be access/global health and health security. As part of the assessment for achieving operational business objectives, GSK uses area-specific metrics to measure success in delivery for all executive directors. GSK plans to increase accountability through a leadership bonus plan that considers the achievement of strategic/operational business objectives per area.

Takeda has developed a corporate philosophy dashboard to outline access KPIs for its Executive Team. For senior executives and in-country managers in two units (growth and emerging markets), it uses financial and non-financial incentives to promote access strategies. It also reports that it has increased the weighting for access-related incentives for senior managers and country managers from five to ten percent and has formed an Access Excellence Committee to monitor and evaluate access planning and metrics in accordance with Takeda's Access Framework.

Pfizer continues to commit to holding leadership accountable for societal and environmental impact. Having examined how best to link compensation with ESG performance, Pfizer's compensation committee adopted the ESG scorecard, which took effect in 2022. The company says this will help determine funding for its annual short-term incentive plan and strengthen its commitment to ESG initiatives. Globally, implementation of the scorecard will cover approximately

30,000 staff, including senior leaders.

Novartis continues to perform well in this area through embedding its Access Principles (APs) into governance structures. Its five-year roadmap for ESG strategy and activities includes key priorities to accelerate AP commitments. A performance management process applied worldwide and with short- and long-term incentives helps to foster a high-performance culture. Targets align with ESG strategic priorities including access, and mid- to long-term targets include implementing access strategies for all new medicines, tiered pricing for launches in pharmaceuticals and oncology business units, and reduction of the time lag between launches in high- and lower-income countries.

AstraZeneca's Access to Healthcare strategy sets goals for equitable access, affordability and pricing and health system resilience, and uses financial and non-financial rewards to incentivise the CEO, some senior executives and in-country/regional managers to achieve these goals.

Johnson & Johnson's overarching business strategy includes an access-to-medicine strategy embedded in its global public health (GPH) unit. Access and GPH are strategic priorities and executive committee members (including the CEO) are evaluated for performance on these. Its Health for Humanity Goals 2025 provide KPIs with outcomes rewarded via short- and long-term incentives for senior management. The company also incentivises leaders to achieve access goals through award programmes, continued learning, rotational development programmes, secondments, employee engagement and empowerment programmes and volunteering opportunities.

More companies need incentives linked to access

Some companies do not yet incentivise access to medicine or offer incentives to only a subset of staff. Increasingly, the industry standard is to incentivise all top-level managers to perform for the long-term with access in mind. The Index looks for companies to link incentives more closely to access-related metrics.

To quantify the outcomes of their access programmes, two companies use partnerships to measure impact and share knowledge of best practice

GILEAD AND TAKEDA

Location: Low- and middle-income countries

Action: Establishing partnerships to support monitoring and evaluation of access activities

Aim: To determine whether access programmes are successful and identify best practices

Access programmes funded by the private sector are increasing in number and scope. Even so, research shows that outcomes are not always evaluated effectively. When activities lack proper monitoring and evaluation, it can be difficult to demonstrate if they made an impact or were successful. As companies work to improve access to medicine, it is important to ensure activities remain effective. Reliable measures are especially needed in low- and middle-income countries where most access programmes operate, and outcomes may lack certainty.

Several companies have partnerships to help them measure outcomes for access programmes. Gilead and Takeda go further with partnerships that are increasing their abilities to share knowledge and improve best practice globally. Both companies aim to evaluate access programmes objectively, with a focus on impact and quality of outcomes. For example, this could include evaluating the impact training has on a community, as opposed to quantity and output of activities (i.e., the total number of people trained).

Gilead asked Boston University (BU) to evaluate its access programme for tenofovir disoproxil fumarate (Viread®), with a view of expanding this to other treatments. Within the latest period of the Index analysis, BU's report highlighted benefits and areas for improvement, finding that voluntary licensing had resulted in "the steepest increases in availability of medicines to patients in need".¹ Gilead has since expanded its voluntary licensing programme to include other HIV therapies and hepatitis C treatments. Following publication of the BU's report, in 2021-2022 two sets of Gilead employees (from its Global Patient Solutions unit and cross-functional partners) attended training sessions by BU researchers in monitoring and evaluation for access activities. Through this partnership, Gilead is identifying best practices and finding ways to incorporate them into ongoing partnership activities.

Takeda leads in its recognition that while more companies are funding access programmes, many are finding it difficult

to determine "what works". In 2019, it began working with Innovations in Healthcare (IiH), a non-profit founded by Duke Medicine, McKinsey & Company and the World Economic Forum, to develop its Access to Health Impact framework. This framework, launched in 2021 and recognised by the Index, can be used to independently measure health system contexts, therapeutic areas and patient experiences.

Takeda has now made its associated guidebook and data collection template available for public use. These enable the design, measuring and evaluation of progress and outcomes for global health programmes sponsored by the private sector. The framework provides metrics to support live adaptations for real-time developments, with the goal of ensuring access programmes have the intended impact and can optimise and maximise resources. Takeda aims to implement the framework across health sectors, and in collaboration with IiH is using the methodology and framework to evaluate outcomes for its flagship Takeda Blueprint for Innovative Healthcare Access, in Meru county, Kenya.

Sharing best practice through collaborations

For companies, there may be challenges in extracting data from access programmes to check whether interventions are working. Partnerships established by Gilead and Takeda show that collaboration can enable more efficient collection of data and be used to evaluate future efforts, even generating tools with wider application. Partnerships can also help to ensure that evaluative work contributes to sharing best practice. The Index looks for companies to engage with relevant and local stakeholders, including universities, to consider local needs and improve access to medicine.

¹ Wirtz V J, Ray M, Rockers P, Laing R. Evaluation of the Gilead Access Program. 2020.

Three companies have changed their business models to tackle access barriers and reach more people with their products

GSK, PFIZER AND SANOFI

Location: Global

Action: Creating new models to offer pipeline and portfolio products in low- and middle-income countries (LMICs) at affordable prices

Aim: To increase the availability and affordability of medicines and vaccines among poorer populations

Several companies have access strategies that cover some or all products and portfolios. However, the 2022 Index finds that many countries do not benefit from these strategies, with low-income countries consistently overlooked. Three companies lead in evolving strategies to cover a broad range of treatments in LMICs, helping to ensure patients have access to essential and life-saving medicines at affordable prices.

Of Sanofi's four strategic pillars, two (Affordable Access and Vulnerable Communities) prioritise access. In April 2021 Sanofi unveiled its new strategy with the creation of Sanofi Global Health (GHU), a non-profit unit dedicated to increasing access to essential medicines in the poorest countries. Through GHU, the Impact® brand was launched, which is a new brand of standard-of-care medicines for non-profit distribution to at-risk populations. Impact®, which includes insulin and glibenclamide amongst others, will allow Sanofi to distribute 30 of its medicines to 40 lower-income countries, addressing conditions including diabetes, cancer, malaria, tuberculosis and cardiovascular disease. GHU has also established a global health impact fund to support start-up companies and innovators to deliver scalable, sustainable health solutions in underserved regions. The aim is to provide access to a broad portfolio of medicines, covering a range of therapeutic areas, in many countries while also strengthening local health systems and funding local support programmes and businesses.

GSK announced in June 2021 that it wanted to positively impact more than 2.5 billion lives over the next ten years, including 1.3 billion people in LMICs. Having spun off its consumer healthcare business, 'New GSK' covers infectious diseases, HIV, oncology and immunology, aims to lead in Environmental, Social, and Governance (ESG) and focuses on six areas including pricing/access and global health.

A dedicated global health group, established in August 2021, now reports to the company's chief global health officer. This measures success in health impacts, such as patient reach and progression in developing medicines and vaccines

targeting priority neglected diseases and infectious diseases in lower-income countries. GSK has since announced a 10-year investment of GBP 1 billion to accelerate R&D in infectious diseases that disproportionately affect lower-income countries. Separately ViiV Healthcare, which is majority-owned by GSK, created a global health and access forum to focus on governance for access-related discussions across its portfolio.

Pfizer announced An Accord for a Healthier World in May 2022. The initiative aims to create sustainable, equitable access to high-quality healthcare for up to 1.2 billion people. Pfizer commits to providing all 23 of its patent-protected medicines and vaccines (and future products) to 45 low- and lower-middle-income countries on a not-for-profit basis, to treat and prevent diseases such as COVID-19, pneumonia, meningitis, cancer and inflammatory and rare diseases. Five countries (Ghana, Malawi, Rwanda, Senegal and Uganda) quickly joined the Accord, and Rwanda received its first shipment of 1,500 treatment courses in August 2022.

Pfizer commits to fostering collaborations to address factors that limit access, including diagnosis, education and infrastructure. For example, Pfizer and Rwanda's Ministry of Health are providing healthcare workers with professional education and training. Pfizer is also exploring partnerships to support Rwandan medical specialists and diagnostic enhancements, and to establish a telemedicine consultation platform to connect healthcare professionals in Rwanda with global experts.

Increasing access through a widened scope

People at the base of the income pyramid are frequently overlooked for access to medicine. Sometimes companies focus on only a narrow range of countries (e.g., upper-middle income countries) and/or products (e.g., those targeting communicable diseases). Companies can address this by widening their scope while increasing specificity, considering how to help the world's most vulnerable populations by examining all relevant means to make essential medicines more available and affordable.

RESEARCH & DEVELOPMENT – ACCESS PLANNING

Bayer's systematic planning policy helps it develop quality access plans to make products available swiftly and widely

BAYER

Location: Low- and middle-income countries

Focus: R&D pipeline projects for communicable and non-communicable diseases (NCDs)

Action: Implementing a systematic policy to develop access plans and having access plans in place that include many countries in scope of the Index

Aim: To make all successful products available soon after launch

Pharmaceutical companies need to plan ahead to ensure that new products, once launched, are quickly accessible and affordable for people in low- and middle-income countries (LMICs).

Bayer introduced a new systematic access planning policy in 2021. It now commits to develop access plans for all its pipeline candidates (both in-house and collaborative) and aims to register new products in LMICs within 12 months of first global launch. Bayer's structured access planning process begins during Phase I of clinical trials, and specific access plans are created during Phase II. The new policy also aims to address barriers to access and opportunities for inclusion of LMICs in access planning during the R&D stage.

The 2022 Index has identified six companies that now have access plans in place for all late-stage R&D projects. However, Bayer leads in its geographic scope, applying its process to a wide number of countries in scope of the Index and seeking to register candidates in a large number of LMICs, rather than focus on a small cohort of emerging markets. For the late-stage candidates analysed, Bayer had eight access plans that included, on average, 26 countries in scope of the Index (compared to the industry average of six countries). Of these, 63% include at least one low-income country (far above the industry average of 15%).

Bayer performs well in access planning for both communicable and non-communicable diseases (NCDs), providing evidence of a tailored approach for each R&D project. In general, for all companies, access plans for R&D projects targeting communicable diseases are more comprehensive than those for NCDs. This is because R&D projects for communicable diseases are often donor-funded and created in partnership with access-oriented organisations to facilitate widespread access.

Bayer leads in access planning for late-stage R&D pipeline products for NCDs, demonstrating best practice not just in the quality of plans overall, but for the breadth of countries in which it plans to register products – a necessary first step for access.

For example, for finerenone (Kerendia®), developed for patients with chronic kidney disease associated with type 2 diabetes, it has a comprehensive plan across 29 countries in scope (including low-income countries) and a strategy to gain regulatory approval in a wide range of countries. It has multiple innovative measures and a clear objective to increase access by considering affordability for patients.

For vericiguat (Verquvo®), developed with MSD to treat patients with heart failure, Bayer has an access plan covering 24 countries in scope including several low-income countries. This also considers innovative pricing strategies to ensure affordability.

Next steps

As the industry shifts toward systematic access planning during R&D, more companies are mainstreaming and integrating access planning in their pipelines. Bayer demonstrates best practice through planning for accelerated access in a large number of countries in scope and leading in access planning for NCDs.

RESEARCH & DEVELOPMENT – REGULATORY APPROVALS

Four companies lead in securing regulatory approvals for medicines in their R&D pipelines to treat diseases that disproportionately affect people in LMICs

BAYER GSK, JOHNSON & JOHNSON, SANOFI

Location: n/a

Focus: Neglected tropical diseases (NTDs) and other infectious diseases

Action: Securing regulatory approval for medicines at the end of the R&D pipeline to treat diseases that disproportionately affect people in LMICs

Aim: To improve access to effective treatment for NTDs and other infectious diseases

Often, there is little financial incentive for companies to develop products for NTDs and other infectious diseases, which have a disproportionate burden in LMICs. While the 2022 Index finds an overall decrease in R&D activity focused on such diseases, some companies are continuing to invest R&D resources in targeting neglected diseases, leading to positive R&D outcomes. The 2022 Index has identified four companies (Bayer, GSK, Johnson & Johnson and Sanofi) that have secured approval for six important treatments shown in clinical trials to be safe and effective. Each new product received approval from a stringent regulatory authority, and addresses a gap identified as priority areas for R&D. Each product is covered by a multi-faceted access plan.

Bayer gained Food Drug and Administration approval for paediatric nifurtimox (Lampit®), for Chagas disease in children, in August 2020. Nifurtimox is currently registered for adults and children in several Latin American countries, and the company is working to expand registration to additional endemic high disease-burden countries. Bayer's Fludora Co-Max (a space-spray vector control product, effective for combatting Aedes mosquito-borne viruses such as dengue, Zika and Chikungunya) was prequalified by the World Health Organization (WHO) in October 2020. Bayer launched it the following month and has received regulatory approvals in Côte d'Ivoire, Vietnam and Mexico. It has also been filed for registration in India, Indonesia, Iraq, the Philippines and Brazil.

GSK (through ViiV Healthcare) gained FDA approval in June 2020 for its paediatric label extension and formulation of dolutegravir (Tivicay PD), used to treat HIV/AIDS. This was supported by a robust access plan that included use of an equitable pricing strategy, non-exclusive royalty-free voluntary licensing, a partnership with The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network, WHO prequalification and WHO Collaborative Procedure for Accelerated Registration.

GSK has also developed a new paediatric formulation for

tafenoquine (Krintafel/Kozenis), which was first approved in adults in 2018. In March 2022, in partnership with Medicines for Malaria Venture, GSK secured marketing approval from the Therapeutic Goods Administration (TGA) for a novel, 50 mg dispersible tablet that facilitates administration in children, it also submitted it to Brazil's regulatory authority in November 2021 and plans further regulatory submissions in malaria-endemic countries.

Johnson & Johnson gained approval for its two-shot Ebola vaccine regimen (Zabdeno® and Mvabea®) from the European Medicines Agency (EMA) in 2020. Its access plan includes WHO prequalification, strengthening of health systems and capacity building initiatives through its vaccination monitoring platform Vxnaid™, and product donations. This approval represents significant progress in efforts to prevent the spread of Ebola.

Sanofi's fexinadazole, which treats *T.b. gambiense* human African trypanosomiasis (sleeping sickness), secured FDA approval in July 2021. The company, which partners with WHO and the Drugs for Neglected Diseases initiative, plans to submit the product for WHO prequalification and to work with WHO to manage administration through a donation programme. It will also apply to the EMA for an extension of indications to treat a variation of the disease (*T.b. rhodiense*) in endemic countries in sub-Saharan Africa.

Further R&D investment needed to close gaps

In securing regulatory approval for products that are needed, these four companies can be credited for their achievements and for exemplifying action and investment. R&D remains a top priority for the creation of effective treatments for many diseases, such as leishmaniasis and lymphatic filariasis, and new formulations and/or vaccines (such as microneedle patches for measles and rubella). More companies can now act to address these R&D needs.

RESEARCH & DEVELOPMENT – CAPACITY BUILDING

By validating conditions for flexible storage, Novo Nordisk aims to reduce the burden of diabetes management and increase access to insulin products

NOVO NORDISK

Location: More than 50 low- and middle-income countries

Focus: Diabetes

Action: Re-evaluating the thermal stability of human insulin products and gaining regulatory approval to revise guidance and create safe conditions for flexible storage

Aim: To reduce the burden of diabetes management and the need for continuous cold storage

Diabetes is a growing problem worldwide, but especially in low- and middle-income countries (LMICs) where around three-quarters of the 527 million adults with diabetes live. As a result, access to insulin is an increasingly urgent global health priority. Current estimates show insulin is needed by more than 72 million people, yet only about half of those who depend on the life-saving treatment have access to it. Novo Nordisk demonstrates best practice with a proactive approach to increasing access to reliable insulin products.

Addressing thermostability as a barrier to access

Standard guidance is that human insulin products must be kept cool from the moment of manufacture until the product enters use. Insulin can lose effectiveness when exposed to high temperatures, so regulatory guidance requires unopened products to be stored in a refrigerator (at 2–8°C). When infrastructure for refrigerated storage or supply chain refrigeration is unavailable or unaffordable, strict storage conditions restrict access to insulin for people with diabetes. This is particularly the case in LMICs, and in situations of humanitarian emergency and/or environments with challenging temperature conditions.

In 2021, a joint study from Médecins Sans Frontières and the University of Geneva suggested such insulins could be stored safely without refrigeration for up to four weeks. To meet the requests of these humanitarian actors, Novo Nordisk reassessed the thermal stability of its short- and intermediate-acting products insulin human (rDNA) (Actrapid®) and isophane human insulin (rDNA) (Insulatard®), both of which have been authorised in the EU since 2002 and are widely used in LMICs. Novo Nordisk used its data to seek a label extension and obtain a positive opinion from the European Medicines Agency. It has since updated storage guidance, which now states that its insulins can now be stored in environments of up to 30°C without refrigeration for four weeks before opening.

National submissions by Novo Nordisk to revise storage guidance in more than 50 LMICs are ongoing. The company

also initiated engagements with humanitarian actors to support future use on the ground. In September 2022, insulin human (rDNA) (Actrapid®) and isophane human insulin (rDNA) (Insulatard®) became the first human insulins to be prequalified by the World Health Organization (WHO). According to WHO, the storage guideline update will greatly facilitate the use of products where access to refrigeration is limited. Novo Nordisk is also supporting WHO's Global Diabetes Compact by addressing thermostability as a barrier to access.

Where Novo Nordisk leads, other companies can follow. They could, for example, look at how adaptive R&D might remove barriers for the storage and administration of their products.

RESEARCH & DEVELOPMENT – ACCESS PLANNING

Six companies stand out in access planning for late-stage R&D projects, with two companies leading

ASTELLAS, BOEHRINGER INGELHEIM, JOHNSON & JOHNSON, MERCK, NOVARTIS, TAKEDA

Location: Low- and middle-income countries (LMICs)

Focus: Access planning during the R&D stage

Action: Planning for access for every single late-stage R&D project in scope

Aim: To create access plans for all late-stage pipeline candidates (from Phase II onwards) to ensure new products are made swiftly available in LMICs

Companies need to plan for access during R&D to ensure products, once launched, are made available in LMICs. Access plans help to identify and address barriers to ensure companies can make products available without delay. By disclosing evidence of access planning, companies increase their accountability by allowing the Index to track commitments to register products and reach patients.

Previously, no company had access plans for all late-stage projects. In 2022, six companies have reached the milestone of having access plans for all R&D late-stage projects in scope.

Astellas, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis and Takeda now demonstrate best practice by implementing access planning for all late-stage R&D projects from Phase II of clinical trials, including planning for access to the product in at least one country in scope of the Index. Other companies, including GSK and Sanofi are not far behind, with plans for most R&D projects.

A first step in access planning is the commitment to registering products in LMICs to ensure they can be made available. Companies must also consider other factors, including ensuring products have sustainable supply chains and are affordable. Takeda and Novartis currently lead in the quality of their access plans.

Takeda, which has a relatively small pipeline compared to the other companies in scope, was recognised in the 2021 Index for a strong project-specific access plan for its dengue vaccine, including a global strategy for filing for registration and a global distribution network. Since then, Takeda has strengthened this access plan as the project has progressed through the pipeline.

Takeda takes a structured approach that considers all elements as early as pre-Phase II. For late-stage candidates, including for non-communicable diseases (NCDs) such as epilepsy and cancer, it takes a systematic approach by considering multiple factors: registration, non-exclusive voluntary

licensing, patent waivers, equitable pricing, sufficiency of supply, WHO prequalification, product donations, access through clinical trials and expanded access programmes.

Novartis also excels in the quality of its access plans and, especially, in creating comprehensive plans early in clinical development. It implements plans systematically and gets the process underway for all innovative drug projects by Phase II. In addition, individual access plans include many components specific to a project, for example equitable pricing strategies that are tailored to different markets and plans to use local partnerships to strengthen health systems.

Action needed to increase the quality and depth of access plans

Many companies have developed detailed access plans for R&D projects targeting infectious diseases such as tuberculosis, malaria and HIV, in partnership with access-oriented organisations such as the Drugs for Neglected Diseases *initiative* or Medicines for Malaria Venture. By comparison, projects targeting NCDs, lacking such support are less likely to be covered by comprehensive access plans. Yet, as the Index's analysis of the companies' R&D efforts shows, projects targeting NCDs – especially cancers – dominate the pipeline.

To ensure these products reach the people who need them in LMICs, companies can look to increase the quality and expand the geographic reach of access plans for R&D candidates targeting NCDs. Furthermore, while innovative cancer treatments may require high levels of health practitioner expertise for administration, companies can address with health systems strengthening and capacity building initiatives.

All companies can also make improvements in the geographic scope, quality and depth of their access plans. On average, access plans cover just six of the 108 countries in scope, and most companies focus on registering products in countries where they conduct clinical trials, usually a small cohort of emerging markets such as in Brazil, China, India, Mexico, Thailand and Colombia.

RESEARCH & DEVELOPMENT – CAPACITY BUILDING

GSK and Novartis build R&D capacity to map the human genome across Africa and improve treatments via GRADIANT

GSK, NOVARTIS

Location: Burkina Faso, Mali, South Africa

Focus: Malaria, tuberculosis

Action: Building R&D capacity by supporting local scientists in different African regions through fellowships and grants to support independent research, including funding for the study of genetic diversity and impacts on response to therapeutic products

As few pharmacogenomic data have been collected from people living in Africa, those used to develop medicines come mostly from outside the continent. Genomics differ both between and within continents, so this may affect the efficacy of individuals' response to treatment – and thus, possibly, also for major diseases with a high burden in African countries, such as malaria and tuberculosis. More genomic data is needed to improve the process of drug development and improve our understanding of efficacy and tolerability of current treatments.

Africa Genomic Research Approach for Diversity and Optimising Therapeutics (GRADIANT)

GSK and Novartis address this need through GRADIANT, an initiative established in 2018 as a consortium to support high-quality scientific research that investigates links in genetic diversity across different regions in Africa. Three funding mechanisms are used to support local scientists in different African regions to help build R&D capacity: fellowships in academic institutions to collect and analyse data on determinants of drug response; support for hypothesis-driven research focused on understanding genetic regional variation in drug response; and a seed fund for projects to explore new research goals arising from the first two. GSK and Novartis have jointly committed GBP 2.8 million to fund this over five years, and actively support its projects.

Opportunities to further research into malaria and tuberculosis

In 2021, GRADIANT asked African researchers to submit research proposals on the relevance of diversity when treating malaria and tuberculosis. It will give priority to research that aims to collect data from under-represented regions in Africa and improve the scientific robustness of inconsistent data. Proposals from Burkina Faso, Mali and South Africa were chosen, and researchers and institutions are now being funded to build knowledge, publish/present on scientific fora and develop a public genomic dataset to further the

Aim: For local researchers to build knowledge and R&D capacity, to publish and present on scientific forums and to develop a database that will be publicly available

understanding of medicine efficacy and toxicity in African regions. Annotated genetic variants, for example, could inform ongoing and future research on malaria and tuberculosis, and show how genetic factors affect responses to treatment. Researchers and institutions will initiate and lead research, owning data from studies but ensuring its availability to the public via a database.

GSK and Novartis oversee the initiative via a joint steering committee. Their partner, the South African Medical Research Council, joins them on an administrative steering committee. Both committees meet regularly, dividing roles, strategic decision-making and consultation. Other partners include local universities and public research institutions, and scientific reviewers (both local and international experts) who will provide input to ensure quality. GRADIANT will also help build scientific infrastructure and publish its outcomes.

Paving the way for tailored treatments in low- and middle-income countries (LMICs)

Clearly, genetics have an impact on how medicines work in individuals. By funding the creation of an open dataset to highlight how continental differences may influence therapeutic outcomes, GSK and Novartis make a valuable step to increase understanding. The ambitions and possible impacts of GRADIANT stand out: it sets long-term goals to obtain a dataset which has the potential for widespread benefit. Filling this gap could help many people in LMICs affected by malaria and tuberculosis, and if expanded to include other diseases the project could help many more.

The Index encourages companies with resources and knowledge to build capacity in LMICs to follow suit. Training, educating and clinical trials in LMICs remain important for access, but initiatives such as GRADIANT (and its creation of new datasets) may pave the way for tailored treatments, increase positive impacts in low-resource settings, and help open new markets.

RESEARCH & DEVELOPMENT – CAPACITY BUILDING

Takeda is supporting researchers in LMICs to build local R&D capacity for clinical trials and adapt treatments to meet on-the-ground needs

TAKEDA

Location: India, Kenya, Nigeria, Vietnam**Focus:** Expansion of R&D capacity**Action:** Supporting local researchers in low- and middle-income countries (LMICs) in a variety of ways to build R&D capacity, including for clinical trials**Aim:** To address local health concerns and increase capacity by empowering and supporting local researchers to adapt and repurpose existing treatments and technologies

In many LMICs, there is a significant need to expand capacity for clinical research, but researchers often struggle to get funding to advance their ideas. At the same time, those familiar with local health needs may see ways to repurpose therapeutic products that are already available. Building R&D capacity through this initiative can offer the potential to make big impacts while reducing reliance on new R&D and expensive, hard-to-obtain medicines.

Takeda demonstrates best practice with ReGRoW (Repurposing Grants for the Rest of the World), which provides scientists and clinicians with grants of up to USD 50,000 dollars to investigate repurposing approved therapies to treat diseases in their communities. ReGRoW aims to expand funding for clinical research in LMICs, address local health concerns and lower development costs through use of therapies known to be safe and effective. Founded in 2018 and now part of Takeda's global health strategy, the initiative is governed and funded by its Centre for Health Equity and Patient Affairs and run in partnership with the NGO Cures Within Reach (CWR) and local research institutions.

CWR selects research proposals through a two-stage review process supported by ReGRoW's science advisory board. Takeda then reviews and approves these, and both parties make agreements with local stakeholders, ensuring local needs are addressed. Takeda R&D employees support project teams with research training, virtual monthly meetings, mentoring, emails and phone calls. On-site visits are carried out twice a year.

ReGRoW's global reach

In 2020, ReGRoW funded three trials selected from more than 30 submissions from 12 LMICs across four continents. Trials focused on a rare paediatric liver disease in Vietnam, tuberculosis in Nigeria and snakebite envenoming in Kenya. A project team for the latter built on work from the UK's Liverpool School of Tropical Medicine to run a Phase I clinical trial,¹ which looked at repurposing unithiol (used for heavy

metal poisoning) to treat bites. Previously tested only in white European men, doses were assessed in 64 Kenyan volunteers with a goal to develop a 'snakebite pill'.

Three further trials were funded in 2021, including in India for chronic pancreatitis, and in Nigeria for both triple negative breast cancer and paediatric chronic ear infections. In 2022, ReGRoW has opened a new round of submissions. Its partner research institutions will measure outcomes, and CWR will report on outcomes for patients, clinical adoption of repurposed therapies, data presented or published in top scientific journals, securing of follow-on funding and the planning, start or completion of follow-on clinical trials.

ReGRoW demonstrates good practice, as it aligns activities with local needs in LMICs, trains local researchers and funds equipment. It also addresses gaps in clinical trial capacity and education/training and uses quantitative and qualitative assessments by multiple parties. Takeda has earmarked additional funding to support capacity building and patient care beyond the existing programme and to allow local partners to retain talent and capacity.

With its drive to repurpose existing therapies, ReGRoW is both innovative and sustainable. Other companies should look to invest in similar initiatives. When researchers in LMICs are facilitated to identify needs locally and supported to take ownership of their research and capacity, there is great potential to improve access to medicine.

¹ L.-O. Albuлесcu et al. Preclinical validation of a repurposed metal chelator as an early-intervention therapeutic for hemotoxic snakebite. *Science Translational Medicine*. Vol. 12, May 6, 2020. doi: 10.1126/scitranslmed.aay8314.

PRODUCT DELIVERY – EQUITABLE ACCESS STRATEGIES

Bayer applies a variety of methods to reach different population segments and provide access

BAYER

Location: Afghanistan, Bangladesh, Benin, Bolivia, Brazil, Chad, Colombia, Cote d'Ivoire, Cambodia, China, Democratic Republic of Congo, Dominican Republic, Egypt, Ethiopia, Ghana, Guatemala, Kenya, Madagascar, Nigeria, Paraguay, Rwanda, Senegal, Tanzania, Togo, Uganda, Venezuela, Zambia, Zimbabwe

An estimated 200 million women in LMICs who want to avoid pregnancy currently are not using safe and effective means of contraception.¹ Being able to prevent or control the timing of conception and pregnancy can help women and girls to determine their own path in life, strengthen women's role in society, and create many positive impacts across communities.

Bayer demonstrates best practice through its holistic approach. The company aims to provide modern contraception to 100 million women in LMICs by 2030 by expanding access to its levonorgestrel-releasing intrauterine devices (IUDs) (Mirena® and LNG-IUS). Intrauterine devices (IUDs) are an effective, long acting and reversible contraceptive option, that is well suited to family planning programmes in LMICs. Clinical trials have found IUDs to be more effective at preventing pregnancy than pills, patches or rings, and hormonal IUDs such as Bayer's last for up to five years and are cost-effective.² IUDs also require less maintenance than contraceptive pills or injections and depend less heavily on supply chains, although they do require insertion from trained healthcare practitioners.

Bayer leads with its strategy to meet demand using various means for access in different contexts, even in the same country. Since 2021, Bayer has developed a multi-faceted strategy that covers both public and private markets and tailors this according to country circumstance using donation programmes, supranational agreements, engagement with local authorities and procurement via domestic tenders. Bayer also supports capacity building activities through training initiatives such as virtual training modules, demonstration products and counselling material.

Bayer works with the non-profit Population Council through a joint initiative, International Contraceptive Access (ICA) foundation, to provide its levonorgestrel-releasing intrauterine system LNG IUS via a wide-ranging donation programme. LNG IUS is similar to Mirena®, but is exclusively produced for the programme and is only distributed in resource-poor settings. By 2022, ICA had donated 184,000 LNG IUS

Focus: Reproductive health

Action: Implementing a multilayer holistic approach which uses different strategies to improve access to contraceptives in public and private markets

Aim: To expand access to contraception in low- and middle-income countries (LMICs)

systems in 39 countries, including 20 countries in scope of the Index.

Bayer also uses supranational agreements. Working with the international procurers United Nations Population Fund (UNFPA) and the US Agency for International Development (USAID), it negotiates supply agreements to expand access to contraceptives at affordable prices in eligible countries, considering a country's ability to pay. In 2021, both UNFPA and USAID added IUD levonorgestrel-releasing Mirena® to their commodity procurement catalogues, which will make it available for widespread procurement through regular commodity procurement channels.³

In some countries, IUD levonorgestrel-releasing Mirena® is available only in the private market. To expand sustainable access, Bayer supplies IUD levonorgestrel-releasing Mirena® to branches of the social marketing organisation DKT International to countries in scope, including Benin, Côte d'Ivoire, Ethiopia, Senegal, Tanzania, Togo and Uganda, using a price point that reflects local socioeconomic status and health system maturity. The company is also involved in joint capacity building initiatives.

Bayer's commitment to reach 100 million women depends on a long-term supportive supply security strategy to increase manufacturing. It belongs to the Hormonal IUD Access Group (HIAG) and, based on its estimates for demand, plans to expand manufacturing from a sole site in Finland to a second in Costa Rica, where it will invest USD 200 million.

Next steps

To ensure women in more LMICs have access to affordable contraception, Bayer could commit to extending the same price offered to supranational procurers to non-eligible countries or implement pricing strategies that consider relevant payers' ability to pay such as country-tiered pricing. Other companies could follow Bayer's example by developing strategies that are more layered and holistic, combining and applying different modes to reach more people.

1 United Nations Population Fund. (2021). *Family Planning*. <https://www.unfpa.org/family-planning#readmore-expand>

2 Ali, M., Folz, R. & Farron, M. Expanding choice and access in contraception: an assessment of intrauterine contraception policies in low and middle-income countries. *BMC Public Health* 19,

3 Population Council. (2021). Mirena® added to UNFPA and USAID Product Catalogs. <https://www.popcouncil.org/news/lng-ius-added-to-unfa-and-usaid-product-catalogs>

Novartis is maximising patient reach by tailoring its strategies according to the ability of countries and individuals to pay for medicine

NOVARTIS

Location: Egypt, Ethiopia, India, Mexico, the Philippines, Rwanda, South Africa, Thailand, Uganda

Focus: Cardiovascular disease, cancer and migraine

Action: Creating access strategies including the consideration of relevant payers' ability to pay, and product and market characteristics

Aim: To maximise patient reach across the income pyramid in countries

Equitable pricing strategies play a significant part in increasing access to medicine. To maximise the availability of key products to those with less income, companies are expected to apply access strategies to these products across LMICs. However, when setting pricing strategies, companies do not always integrate into their pricing approach a payer's ability to pay for a product.

Novartis uses additional layers of strategy to increase patient reach. To address affordability in low- and middle-income countries, the company has launched emerging market brands (EMBs), which are generally priced significantly lower than the original brands. Novartis continues to lead by tailoring its strategies for several products in countries in different income classifications (upper-middle income, lower-middle income and low-income). Here, the Index highlights the company's approach for three products.

Regarding Novartis's heart failure treatment sacubitril/valsartan (Entresto®), all three examples submitted by the company for analysis in the 2022 Index are high-quality strategies that address affordability. In Mexico, working with the main national institutional payers, including the largest Latin American health payer IMSS, it has expanded access to hospitals with different specialities and types of services, and increased patient reach more than a hundredfold. In India's self-pay private market, it launched an EMB and has partnered with two local companies (Lupin and Cipla) to expand access and launch co-marketed local EMBs (Azmarada and Cidmus). India now has three brands of the same product at three prices: Novartis's Vymada sacubitril/valsartan (Entresto®) EMB has reached 250,000 patients while Azmarada and Cidmus have (between them) been used to reach an additional 92,000 people. In Ethiopia, the company has applied additional flexibility on price for its EMB (Uperio) to patients paying out-of-pocket in the private sector.

Novartis has strong access strategies for ribociclib (Kisqali®), a medicine to treat breast cancer. For example, it demonstrates best practice in South Africa, using a novel combination to increase access: it has launched an EMB branded

as Kryxana (available for 20% less than the private price for hospitals on a buy-out basis) and offers financial assistance via the Access to Innovative Care Foundation by covering up to 25% of co-payment costs for patients paying out of pocket or via insurance. This solution bridges a gap while Novartis works with public health bodies and practitioners to get ribociclib included in standard treatment guidelines. In India, it applies an innovative strategy to supply this via an EMB for the private market, reducing price and capping payment for patients during treatment. Novartis will launch ribociclib (Kryxana) in low-income African countries including Ethiopia, Rwanda and Uganda in 2023, and is working closely on this with ministries of health and the Clinton Health Access Initiative (CHAI).

For erenumab (Aimovig®), which treats migraine, the company uses a strategy in Thailand that keeps pricing flat across doses and provides certain doses to patients free of charge in the period of analysis, patient reach increased from 213 to 260. In Egypt, where patient reach has grown from 164 to 272, Novartis uses equitable pricing and offers the same price in private and public markets. It also has a support programme for patients paying out of pocket and with low-premium insurance, and a micro-finance scheme. In Ethiopia, the EMB brand Pasurta will soon be launched at a price lower than the global originator. Novartis expects 50 patients will receive treatment in 2022, with reach growing to around 500 by 2026.

Next steps

Novartis stands out for its creative approach to maximising patient reach. As well as applying tiered pricing strategies for several products, it uses EMBs and other non-pricing initiatives such as payment caps, microfinance and patient assistance programmes. It could now tailor these programmes further and consider using questionnaires and assessment by third-party vendors to assess affordability. Novartis could also provide more data on how it updates information about all relevant payers' ability to pay and could disclose how it will keep prices affordable in a climate of rising inflation and production costs.

PRODUCT DELIVERY – EQUITABLE ACCESS STRATEGIES

Three companies stand out with strong equitable access strategies across different country income classifications

GSK (THROUGH ViiV HEALTHCARE), PFIZER, TAKEDA

Location: • Colombia, India, Uganda (GSK)
 • Mexico, India, Uganda (Pfizer)
 • Philippines, Rwanda, Thailand (Takeda)

Focus: Products indicated for cancer and HIV/AIDS

Action: Applying access strategies that consider ability to pay across upper-middle, lower-middle and low-income countries

Aim: To reach additional patients across the income pyramid and in differing economies

Establishing equitable pricing strategies is only one part of the equation in product delivery. Strategies need to be more comprehensive, both for companies and patients, to ensure maximum reach across the income pyramid. GSK, Pfizer and Takeda demonstrate best practice by addressing accessibility and affordability in their access strategies, showing evidence of tailoring their access strategies to meet the needs of countries in different income brackets.

GSK (via its majority-owned business specialising in HIV products, ViiV Healthcare), demonstrates a comprehensive approach to expanding access to its HIV product abacavir, dolutegravir and lamivudine (ALD) (Triumeq®). Its access strategies include tailored equitable pricing strategies, voluntary licensing accompanied by technology transfers, and health systems strengthening initiatives.

In Colombia (an upper-middle income country) and India (a lower-middle income country), ViiV Healthcare commits to applying a flexible pricing approach that factors in gross national income and public health need. Prices are then refined based on local affordability, domestic healthcare system funding, purchasing patterns and volumes, and accessibility for those living with HIV/AIDS. In Uganda (a low-income country), ViiV Healthcare provides extensive support for health systems strengthening activities through its Positive Action programme. ViiV Healthcare uses voluntary licences, enabling generic medicine manufacturers to develop, manufacture and market dolutegravir and dolutegravir-based fixed dose combinations, including abacavir, dolutegravir and lamivudine (ALD). For example, ViiV Healthcare does not currently supply ALD in India, but partners with two India-based generic medicine manufacturers (Mylan Laboratories Ltd and Aurobindo Pharma) that hold voluntary licences to expedite development of more affordable paediatric dispersible formulations of ALD.

Pfizer uses high-quality access strategies to expand access to palbociclib (Ibrance®), used to treat breast cancer. In Mexico (an upper-middle income country), compared to the previous Index, Pfizer has increased patient reach by

continuing with strategies including tiered discounts in the private market, based on co-payment. In India (a lower-middle income country), in 2021 Pfizer introduced a differential approach in a new patient assistance programme, using questionnaires and independent evaluation to assess affordability. In Uganda (a low-income country), its compassionate use programme allows it to make the product available to patients before the product has entered the market.

Takeda was recognised in the 2021 Index for its access strategy for its non-Hodgkin's lymphoma treatment brentuximab vedotin (Adcetris®) in Thailand (an upper-middle income country). Takeda provides evidence of growth in patient reach and uses a third-party organisation to provide data that enables it to tailor prices for individual patients. In the Philippines (a lower-middle income country), where it maintains a patient assistance programme (PAP), it also works with the government to secure funding for medicines and support for diagnostic testing. In addition, it has collaborated with the Philippine Cancer Society to provide financial aid to patients. In Rwanda (a low-income country), once the product is registered, it plans to use inter-country pricing, a PAP and a third-party organisation for evaluative data. Here, it demonstrates best practice by providing patient forecasts to help anticipate demand for the product.

Next steps

The best comprehensive access strategies reflect the needs of a particular country for a specific product. Differentiation is key to increasing affordability, and companies should seek to understand all barriers to access and in each case allow tailoring for affordability. GSK stands out in this area. Pfizer and Takeda deserve credit for increasing patient reach since the last Index. Other companies have yet to follow suit, and all three that lead still have room to improve. All companies should look to apply comprehensive high-quality strategies with consistency, increasing patient reach and widening both their geographic and product scope.

PRODUCT DELIVERY – LICENSING

Novartis sets a precedent by agreeing non-exclusive voluntary licence for a cancer compound

NOVARTIS

Location: Low- and middle-income countries (LMICs)

Focus: Nilotinib (Tasigna®)

Action: Signing a non-exclusive voluntary licensing agreement for a cancer medicine with Medicines Patent Pool (MPP)

Aim: To facilitate production by generic medicine manufacturers of nilotinib

There is a clear need for better access to cancer treatment. It is estimated that by 2030 approximately three quarters of all deaths caused by cancer will occur in LMICs.¹ This is despite the fact that many cancers are now treatable, provided local healthcare systems can swiftly identify disease and effective treatment is made available and affordable.

While national governments are mainly responsible for establishing cancer care systems, pharmaceutical companies can do more to increase access to quality-assured medicines in LMICs, such as those for cancer. One way is to choose to licence them through MPP, which works with patent holders and sublicensees (manufacturers) to facilitate voluntary licensing on public health-oriented terms and conditions, for example by widening the geographic scope of licences and making provision for access clauses.

Engaging with MPP helps companies be more transparent and can also improve the quality of licensing agreements. In assessing the quality of a voluntary licence, the Index considers multiple factors such as whether a licence is agreed before approval for launch or later in the product's lifecycle, or whether it includes restrictions, such as restrictions on manufacturers making active pharmaceutical ingredients or compounds, and on supply in countries where patents are infringed. Companies are also assessed on whether they provide the option for technology transfer – an important element for licensing, but not yet sufficiently common.

Novartis demonstrates best practice by licensing its cancer compound nilotinib via MPP as part of the Access to Oncology Medicines (ATOM) Coalition. In May 2022, it was the first company to join ATOM, a global initiative to improve access to essential cancer medicines in low- and lower-middle income countries and increase diagnosis and care capacity. Through this, it is granting MPP a “freedom to operate licence” for sublicensing to generic medicine manufacturers to make and distribute its medicine in designated countries, currently the licence covers 44 countries, 43 of which are in scope of the Index. It will reinvest royalties into ATOM.

Novartis sets a precedent in licensing an innovative, on-patent cancer medicine via MPP. The primary patent for nilotinib expires in 2023 but secondary patents continue. The medicine is also the first non-communicable disease (NCD) product to be licenced in this way. The company deserves credit for its achievement and efforts, facilitated by MPP, to create new pathways for the licensing of medicines for non-communicable diseases.

Extending NEVLs to reach more people

Novartis' voluntary licence for nilotinib is a promising step. The Index looks for companies to extend this approach to other products – or the compounds required to make those products – especially those for cancer and other NCDs which are currently unaffordable to many people living in LMICs.

¹ Pramesh C, Badwe R, Bhoo-Pathy N, et al. Priorities for cancer research in low- and middle-income countries: a global perspective, *Nat Med*; 2022. <https://doi.org/10.1038/s41591-022-01738-x>

Three companies build local capacity through voluntary licences and technology transfers to manufacturers

BRISTOL MYERS SQUIBB, GILEAD, GSK (THROUGH ViiV HEALTHCARE)

Location: Brazil, China, Egypt, India, Pakistan, South Africa

Focus: Infectious diseases (HIV, hepatitis C, COVID-19)

Action: Voluntarily licensing products to manufacturers in low- and middle-income countries (LMICs) in combination with a technology transfer

Increasingly, companies are widening access to their products through non-exclusive voluntary licensing (NEVL). NEVLs have the potential to improve access, as if there is uptake of the licence from generic medicine manufacturers, supply and affordability can increase as generic versions enter the market.

When companies choose to engage in technology transfers with licensees, they can improve and speed up regional availability of medicines, while building manufacturing capacity that can be used for the future production of medicines. Bristol Myers Squibb, Gilead and GSK (via its majority-owned business specialising in HIV products, ViiV Healthcare) stand out for voluntarily licensing some of their products, while also supporting local manufacturers to build technical capacity through technology transfers.

Expanding accessibility through NEVLs

Gilead leads in this area, working since 2006 to voluntarily license almost all its on-patent products in scope of the Index, including carrying out extensive technology transfers to generic manufacturers. The company has NEVLs covering its hepatitis C and HIV treatments, which include ten products. For example, its voluntary licence for its HIV medicine tenofovir disoproxil fumarate (TDF) includes technology transfer agreements with generic manufacturers.

In 2020, the company agreed to a new NEVL for remdesivir (Veklury®), a medication for COVID-19. It now licenses or sub-licenses medicines to more than 25 third-party manufacturers in LMICs. Gilead reports that it initiates technology transfer ahead of regulatory approval and provides ongoing assistance to support product safety and stability after the technology transfer is complete. It also partners with Medicines Patent Pool (MPP) for licences for TDF, tenofovir alafenamide, bictegravir, cobicistat, elvitegravir and emtricitabine, all of which are compounds for products targeting HIV.

Outcomes are measured by external stakeholders including governments, generic manufacturers, the World Health Organization (WHO), donors, clinicians, medical providers and patients. Reported short-term outcomes of the approach include quality assurance and market registration.

Aim: To build manufacturing capacity and increase affordability of products, improving access to treatments for infectious diseases in LMICs

Medium- and long-term outcomes include the inclusion of TDF in treatment guidelines and data on the procurement of generic TDF.¹ A 2019 study² evaluated how NEVLs for hepatitis C medicines from Gilead and from Bristol Myers Squibb affected access to treatment. Importantly, this looked at patient reach, and found that NEVLs were associated with a significant increase in numbers of people accessing treatment.

Bristol Myers Squibb also works with MPP and both it and ViiV Healthcare combine NEVLs with technology transfers and partner to build capacity. In 2011 Bristol Myers Squibb began the technology transfer for its product atazanavir (Reyataz®), transferring manufacture and distribution to Farmanguinhos, a technical-scientific unit of Fundação Oswaldo Cruz (Fiocruz) and to Nortec Quimica, a local manufacturer of active pharmaceutical ingredients.

ViiV Healthcare has four NEVLs in place with the MPP for HIV products. Beginning in May 2017, **GSK** (through ViiV Healthcare) has partnered with the Clinton Health Access Initiative to establish two public-private partnerships for supply and use in LMICs. Each partnership works with two generic manufacturers with paediatric voluntary licences to expedite the development and market entry of more affordable generic child-friendly formulations of dolutegravir and the fixed-dose combination product abacavir/lamivudine/dolutegravir.

More local partnerships needed to drive progress

When considering whether and how to license their products to manufacturers in LMICs, companies should consider the local and regional availability of their medicines as well as future manufacturing capacity.

Currently, only a few examples of NEVLs in the Index are supported by technology transfer packages, and most activity centres on COVID-19, hepatitis and HIV/AIDS. The Index encourages companies to consider how to combine these measures and apply the approach across multiple therapeutic areas. Companies also need to be fully compliant and transparent about their commitments and are encouraged to partner with other stakeholders.

AstraZeneca facilitates the affordable supply of its medicines and vaccines by publishing information about its patents

ASTRAZENECA

Location: Global

Focus: All products in the company's portfolio

Action: Annually disclosing the patent status for all 32 products in its portfolio, including biological products

Aim: To promote access to medicine by being transparent about its intellectual property information and where it enforces patents

The transparent management of intellectual property, including information about where patents are filed and enforced, can facilitate the affordable supply of medicines by supporting market entry by generic medicine manufacturers and informing decision-making by international procurers. For example, clear and reliable information that a pharmaceutical company will not enforce its patents in a particular country can provide a signal to generic medicine manufacturers in that country that they can begin the process of making a generic version of the product.

Companies demonstrate best practice when they publish the status of all their patents, including biological products. Although disclosure of information on biological products is often complex as multiple patents may be attached, it is also an important step in addressing barriers to access.

Many companies use Pat-INFORMED (Patent Information Initiative for Medicines), a World Intellectual Property Organization (WIPO) database. Of the 20 companies in scope of the Index, 19 publish information about their patents. Boehringer Ingelheim is the only company in scope that does not disclose patent status anywhere. Many companies use the database on Pat-INFORMED to share information about the status of their patents, which is an encouraging first step but does not represent full disclosure. On their own websites, companies can provide more product-specific details, for example disclosing the numbers and expiry dates of each of their patents.

The Index looks at different sources for disclosure of patent status (whether a product is on- or off-patent), including the FDA (US), Health Canada, CIPC (South Africa) and MedsPaL (see Appendix I). Of all companies in scope, **AstraZeneca** demonstrates best practice. It is the only one to publish patent status and information on its website for all of its 32 products in scope for analysis. This includes biological products, such as the two vaccines in scope. Following quality standards for transparency, AstraZeneca publishes annual

information including numbers, brand names and nature, expiry dates (including the platform technology expiry date for vaccines) and jurisdiction. On its website, it discloses patent status in the US, China, EU and Japan.

Increased access through a decrease of patent enforcement

AstraZeneca's transparency, particularly about biological products such as vaccines, sets a benchmark. If more companies increase the quantity and quality of patent disclosures, this will facilitate opportunities for manufacturers to launch generic versions of the products, expand the market and ultimately increase the availability of products.

To improve access, companies can combine transparency in disclosure with a commitment not to enforce patents in LMICs. AstraZeneca commits not to file for patents in 80 countries, and three other companies disclose a list of countries where they do not file for or enforce patents (Boehringer Ingelheim in 61, Merck in 90 and Sanofi in 71). Companies can also consider how to measure outcomes and develop metrics to track, for example, how patent disclosures for specific products can increase patient reach.

PRODUCT DELIVERY – PRODUCT ACCESS

Eleven companies share IP assets through agreements that could speed up the development of NTD products

ABBVIE, BAYER, DAIICHI SANKYO, EISAI, GSK, JOHNSON & JOHNSON, MERCK, MSD, PFIZER, NOVARTIS, TAKEDA

Location: Global

Focus: Neglected tropical diseases (NTDs)

Action: Sharing intellectual property (IP) with third-party researchers at public research institutions or drug discovery initiatives

Aim: To accelerate the development of products for NTDs

Pharmaceutical companies hold a wide array of intellectual property (IP) assets that are valuable to product development, from unpublished clinical trial data to libraries of target-specific compounds. While some companies are resistant to sharing IP, others take a more open approach to promote access, often resulting in innovations that benefit low- and middle-income countries (LMICs).

The 2022 Index has found that the number of R&D projects targeting NTDs has fallen since the last iteration of the Index, even though there are many NTDs for which new or improved treatments are urgently needed, such as mycetoma and river blindness. Choosing to share IP assets with third-party researchers is one way that companies can help to accelerate R&D for under-researched diseases such as NTDs, even if they lack active projects in the R&D pipeline. By sharing IP assets, pharmaceutical companies are also helping to accelerate R&D for new products, averting duplication of efforts and enabling researchers to continue the work companies have started.

IP sharing: filling gaps in pipelines

In 2009, **Bayer** and **Sanofi** shared assets with the Drugs for Neglected Diseases *initiative* (DNDi) and Médecins Sans Frontières to develop a better treatment for sleeping sickness (human African trypanosomiasis) and Chagas disease. The resulting product, fexinidazole, received a positive response by the European Medicines Agency in 2019 to replace a complex and toxic medication that killed around 5% of people it treated. When companies are open with IP assets, they can accelerate R&D and help introduce life-saving products in LMICs.

In 2022, eleven companies (**AbbVie, Bayer, Daiichi Sankyo, Eisai, GSK, Johnson & Johnson, Merck, MSD, Pfizer, Novartis** and **Takeda**) stand out for engaging in recent IP-sharing agreements made with third-party researchers for the development of new products for NTDs. Companies share their IP through partners such as DNDi and BIO Ventures for Global Health/World Intellectual Property Organization

(BVGH/WIPO) and/or through open libraries of compounds. Companies help facilitate access to resulting innovations in various ways, such as encouraging the publication of findings, committing to lowering costs, or generally through granting royalty-free licences to the IP assets shared.

Merck leads, with the most examples of new IP sharing agreements that target NTDs. It partners with BVGH/WIPO to share IP and has also done so through its Open Global Health Library, a platform through which researchers can apply for compounds directly and receive additional information like compound structures after results are shared.

More R&D needed for under-researched diseases

The Index now looks for more companies to contribute to accelerate R&D efforts for under-researched diseases, including NTDs. Companies can engage in new IP-sharing agreements that have access clauses enabling resulting innovations to be accessible in LMICs through mechanisms such as granting royalty-free access to IP assets they have provided or encouraging publication of research results.

By taking its cervical cancer programme online and testing for effectiveness, Roche avoided interruptions in access to care due to COVID-19

ROCHE

Location: Tanzania, India, Uganda

Focus: Cervical cancer

Action: Taking an existing programme (NJIA) online to ensure activities continued during COVID-19 pandemic-related disruptions, and monitoring its effectiveness

Aim: To strengthen health systems by increasing awareness of cervical cancer and access to screening and treatment

When the COVID-19 pandemic disrupted travel and access activities, Roche took a proactive approach to prevent interruptions by launching an online version of NJIA, its leadership development programme to prevent cervical cancer.

The 2021 Index recognised this initiative for best practise, in which Roche partners with Pepal and others to target resource-limited settings and strengthen prevention services. Founded in Tanzania in 2015, it was soon expanded to India and Uganda. It uses a four-level model to train leaders through self-evaluation, peer and line-manager surveys, and tests pre- and post-participation in an immersion week. Through multi-stakeholder multinational partnerships, NJIA has so far invested more than 28,000 hours in leadership development, and tested 60+ innovations.

In 2021, despite COVID-19 pandemic disruptions, NJIA widened its geographic scope to include three new regions in Tanzania. It also launched an online version of the training programme (iNJIA) and invited 57 partners (government health professionals and NGO staff) to take part virtually alongside 48 participants from Roche. Nearly all those involved reported being engaged and inspired by the virtual experience, with most Roche participants saying that learning could be leveraged.

Through iNJIA, Roche provides a sustainable solution which, if regular in-person activities are disrupted, can allow stakeholders to be involved online with in-person workshops. It has measured and reported on the outcomes of this digital adaptation. Separately, Roche also launched a website to consolidate and make available tools and innovations used by governments, NGOs and health charities to reduce the incidence of cervical cancer in low-resource settings.

While COVID-19 lockdowns and surges caused some companies to cease or delay health systems strengthening activities, others worked to scale up initiatives and develop online tools. Roche stands out for its proactive measures to adapt, avoid interruption and ensure its programme remained productive.

Outcome measuring needed to extend offline successes

Any company that is developing or shifting to the use of online tools needs to consider how to measure outcomes to test whether these tools can replicate or improve upon the impacts of offline models.

Offline, for example, NJIA measures how its interventions strengthen the capacity of frontline health leaders and compares changes in behaviours and knowledge to help improve measures. Roche can now look at how to extend offline successes online by leveraging engagement and/or extending measurement to include pre- and post-survey learning or understanding of screening elements.

PRODUCT DELIVERY – HEALTH SYSTEMS STRENGTHENING

Novo Nordisk's CDiC expands access to diabetes care for young people and children in 22 countries in scope of the Index

NOVO NORDISK, ROCHE

Location: Sub-Saharan Africa, South Asia and East Asia

Focus: Children and young people aged under 25 with type 1 diabetes

Action: Using partnerships to strengthen health systems and address their sustainability in low- and middle-income countries (LMICs)

Aim: To integrate type 1 diabetes care for children and young people into health systems in LMICs

Cases of diabetes are surging worldwide, but many patients who require insulin do not have access to a reliable and affordable supply. Of an estimated 1.2 million young people around the world with type 1 diabetes, those in low-resource settings are less likely to have adequate access to healthcare including diagnosis and life-saving insulin. Novo Nordisk, which leads the global insulin market, holding almost half of the share of the total insulin market globally in 2021, demonstrates best practice through its efforts to make provision of supplies for diabetes care more sustainable. Roche also demonstrates best practice for its supporting role in this initiative.

Changing Diabetes in Children Programme

Novo Nordisk established Changing Diabetes in Children (CDiC) in 2009 to improve access to care for children with type 1 diabetes in LMICs. Operating in 22 countries in scope of the Index, it collaborates with governments, local partners and others to raise public awareness of diabetes, strengthen healthcare capacity and increase access to human insulin through the donation of these products and other necessary commodities. Roche is also a partner in CDiC and provides commodities such as glucometers and test strips to young people enrolled in the programme. CDiC has already reached 34,000 young people in low-resource settings and aims to reach 100,000 by 2030. Since the last Index, it has expanded its geographic footprint to eight new countries.

Novo Nordisk has taken steps to address aspects of the programme's sustainability through partnerships with stakeholders like local governments and the World Diabetes Foundation. Through these partnerships Novo Nordisk is working to support integration of type 1 diabetes care for young people into national non-communicable disease responses of partnering governments. The company is also piloting a non-donation model in Ghana, Indonesia and Peru, where health insurance schemes are available that reimburse human insulin for young people with type 1 diabetes.¹

Novo Nordisk has also taken steps to measure and publicly

disclose outcomes of its work through CDiC. The company commissioned a third-party review by University College London to assess the programme in Bangladesh and Kenya and analyse the path for insulin provision and healthcare infrastructure for diagnosis and treatment.¹ In their report, researchers found indirect costs remained a substantial barrier to care and reliance on external funding and delivery in a high-turnover staffing environment created vulnerabilities for long-term sustainability. By commissioning a third-party review, Novo Nordisk demonstrates its transparent approach to measuring impact and seeking insight into future steps that need to be taken to improve the CDiC programme and promote its long-term sustainability.

Strengthening local health systems through partnerships

As companies work to achieve sustainability and integrate activities in local systems, they can find great value through partnership. The Index expects companies to continue working with international and local partners to find ways to develop sustainable models and strengthen health systems locally, and to expand this approach. This could include strengthening data registry systems, which are used by countries for purposes including diabetes surveillance, clinical management, and supporting cost estimations. It could also include incorporating long-term strategies that improve forecasting and supply. Companies should ensure that they monitor and publicly disclose the outcomes of their programmes, in order to gather valuable insights and improve future strategies for expanding access.

¹ Palmer T, Jennings H, Shannon G, et al. Improving access to diabetes care for children: An evaluation of the changing diabetes in children project in Kenya and Bangladesh. *Pediatr Diabetes*. 2021. doi:10.1111/pedi.13277

Four companies are scaling up inclusive business models to help improve the affordability of medicine, especially for non-communicable diseases

ASTRAZENECA, NOVARTIS, ROCHE, TAKEDA

Location: Sub-Saharan Africa

Focus: Non-communicable diseases (NCDs) including sickle cell disease, cancer, hypertension and diabetes

Action: Scaling inclusive business models to increase access to medicines for low-income populations

Aim: To improve the affordability and availability of medicines that treat NCDs

The burden of NCDs is rising in low- and middle-income countries (LMICs), yet appropriate healthcare remains unavailable and unaffordable to many people living in these countries.

Inclusive business models focus on individuals at the base of the income pyramid (BoP) and can contribute to the future affordability and availability of care. These models build bridges between businesses and vulnerable populations for mutual benefit, which can go beyond immediate profits and higher incomes.

AstraZeneca, Novartis, Roche and Takeda demonstrate evidence of scaling up inclusive business models within their programmes to directly address the need for affordable NCD medicines among BoP populations. All feature partnerships with a wide range of stakeholders including governments, institutions, academic partners, and NGOs. Roche and Takeda also partner in the Blueprint for Innovative Healthcare Access.

AstraZeneca began its Healthy Heart Africa (HHA) initiative in 2014. Aiming to reach 10 million people across Africa by 2025, it commits to tackle the increasing burden of cardiovascular disease with low-cost branded antihypertensive medicines, made available to BoP populations. HHA also provides mentorship, equipment and training to healthcare workers and since 2014 has conducted more than 13.5 million screenings, identifying 2.4 million people with elevated blood pressure. It has trained 7,500 healthcare workers in hypertension and initiated the set-up of more than 750 treatment facilities.

Novartis aims to extend the lives of people with sickle cell disease (SCD) in sub-Saharan Africa, through its Africa SCD programme. It will work with governments to accelerate access to affordable hydroxyurea (HU) treatment and develop a paediatric formulation. Other aims are to strengthen the development pipeline and local clinical trial capability, deploy a digital health app for patients allowing for monitoring and evaluation, and leverage data and insights for intensified advocacy and policy work. So far, it has delivered more than 20,000 HU treatments.

Roche set up the Nigerian Cancer Health Fund in 2017, aiming to help the 84% of the Nigerian population living at the BoP afford treatment for breast, colorectal and prostate cancer. The model generates and shares data with the government on the disease burden through a consortium with other pharmaceutical companies, diagnostics companies and private insurance companies. The model mobilises government support, for instance through including the use of digital wallets for patients to pay for treatment. It also measures the number of patients treated, their survival rates, and their quality of life.

Takeda launched Blueprint for Innovative Healthcare Access in partnership with local and regional partners in 2019. Initially piloted in Kenya, the initiative has expanded to other LMICs including Rwanda, Tanzania, Uganda and Nigeria. In these five countries, partners work to enhance local standards of care, increase disease awareness and improve supply chains. The initiative also provides access to medicines and healthcare products. Takeda addresses affordability barriers by establishing a revolving pharmacy fund, providing financial support and guidance, enrolling patients onto local healthcare insurance provisions, and through patient assistance programmes. By the end of 2021, the initiative has already screened over 200,000 people for diabetes, hypertension and cancers and has referred over 12,000 for healthcare.

Establishing inclusive business models to bring benefits for underserved populations

Inclusive business models can be effective in bringing critical products and services to populations who are often overlooked in normal business operations. Where their products are needed to address high burdens of disease, more companies can develop scalable, financially sustainable inclusive business models to address the unmet needs those at the BoP. When companies expand these models, scale-up should be based on impact evaluations that include factors such as patient reach and health outcomes.

Company Report Cards

The 2022 Access to Medicine Index includes a set of 20 company Report Cards that provide detailed overviews of each company's performance. Companies are different in the way they operate, where they operate, and in their portfolio of investigational and marketed products, all of which can have implications for access. Each Report Card includes a summary of the company's strengths and weaknesses, drivers behind changes in its ranking, as well as any best and innovative practices.

The Report Cards are divided into six sections:

PERFORMANCE

Explanation of the company's position in the 2022 Index and a summary of its access-to-medicine performance. Performance is broken down into Technical Areas. It describes the key drivers behind any movement, and the main areas where the company scores well or poorly compared to peers.

CHANGES SINCE 2021

Update on where the company's access-to-medicine performance has changed most notably since the 2021 Index. It includes new or expanded commitments, strategies, activities and programmes.

OPPORTUNITIES

Tailored opportunities for the company to improve access to medicine, taking account of its R&D pipeline, product portfolio, current equitable pricing strategies and approach to IP management, among other factors.

SALES & OPERATIONS

General description of the company's operations, recent mergers & acquisitions, revenue per region and geographical reach.

PIPELINE & PORTFOLIO SUMMARY

Analysis of the company's pipeline of R&D projects as well as portfolio of marketed products that fall within the scope of the Index. This section looks at the size and focus of the company's pipeline and portfolio, whether the company has products that are considered first-line or are on the WHO Model List of Essential Medicines and whether it is conducting priority R&D and planning for access during development.

PERFORMANCE BY TECHNICAL AREA

Overview of the company's performance in each Technical Area measured by the Index. The Report Card performance points have been structured to be comparable between companies, while still describing the company's individual programmes, initiatives and approach.

RANK	SCORE
19	1.84
17 (2021)*	

AbbVie Inc

Stock exchange: NYSE • Ticker: ABBV • HQ: North Chicago, Illinois, USA • Employees: ~50,000

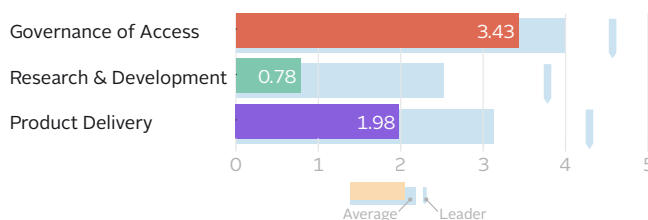
PERFORMANCE IN THE 2022 INDEX

19th place. AbbVie is in the lower ranks across all Technical Areas. It engages in R&D for neglected tropical diseases but lacks access plans for R&D projects in the pipeline. It engages in non-exclusive voluntary licensing but has a comparatively poor performance in capacity building.

Governance of Access: 15th place. AbbVie performs below average in this area. It has an access-to-medicine strategy, but only has some compliance controls in place to mitigate the risk of non-compliance in countries in scope of the Index. It discloses the outcomes of only a subset of its access-to-medicine activities.

Research & Development: 20th place. AbbVie performs poorly in this area. AbbVie has a small-sized priority pipeline compared to its peers. The company does not have a framework in place for systematic access planning and does not have access plans for any of its late-stage pipeline candidates. It does not engage in R&D capacity building.

How score was achieved



Product Delivery: 18th place. AbbVie performs poorly in this area. The company has an average performance in its approach to inclusive business models and supplying products through supranational procurers. However, its performance with regard to healthcare practitioner- and self-administered products is below average. The company engages in non-exclusive voluntary licensing for two compounds, enabling generic supply in 79 countries. AbbVie engages in health systems strengthening initiatives but doesn't publicly disclose outcomes for most of these.

OPPORTUNITIES FOR ABBVIE

Develop access-related incentives for senior management. AbbVie has an access-to-medicine strategy, the Global Integrated Access Strategy (IAS), which serves as the foundation and starting point for regional (area level) and country (affiliate level) access strategies. Financial and non-financial incentives, oriented toward long-term goals, for the CEO and in-country managers can be linked to this strategy.

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. AbbVie can develop a formal access planning framework and accordingly apply access plans considering availability, affordability and sustainable supply for all its projects, no later than Phase II. For example, it can disclose access plans for flubentolisin, an investigational treatment for river blindness being developed in collaboration with DNDi.

Expand access to its hepatitis C product, glecaprevir/pibrentasvir (Mavyret®), through equitable pricing and/or increased non-exclusive voluntary licensing. AbbVie can increase patient reach for glecaprevir/pibrentasvir, indicated for the treatment of chronic hepatitis C infection. It can expand its existing voluntary licence for this product to countries with a high burden of this disease such as the Republic of Moldova, Mongolia and Uzbekistan, or increase access by applying an equitable pricing strategy in these countries.

AbbVie can expand access to innovative medicines for cancer and women's health products. The company can implement equitable access strategies and expand registration of products such as elagolix (Orilissa®) for endometriosis. AbbVie can file for registration in countries where the disease burden of endometriosis is the highest such as Algeria, Mongolia and Papua New Guinea.

CHANGES SINCE THE 2021 INDEX

- Established an ESG council to further strategic, enterprise-aligned delivery on AbbVie's ESG Framework which includes global patient access and affordability as a key material driver.
- Newly established access strategy, the Global Integrated Strategy, covering all therapeutic areas.
- Developed an Executive Council on Neglected Diseases that coordinates across the company to contribute innovative technologies, diverse compounds for screening, and scientific expertise to partners to help address neglected tropical diseases.
- Announced a research collaboration with Scripps Research to develop antiviral treatments for COVID-19.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.
*In the 2021 Index, dense ranking was used. In the 2022 Index, standard

competitive ranking is used. Therefore, a direct comparison with AbbVie's previous rank is not possible.

SALES AND OPERATIONS

Business segments: Pharmaceutical sciences
Therapeutic areas: Aesthetics, eye care, gastroenterology, immunology, neuroscience, oncology, virology, women's health and other specialty areas.

Product categories: Pharmaceuticals

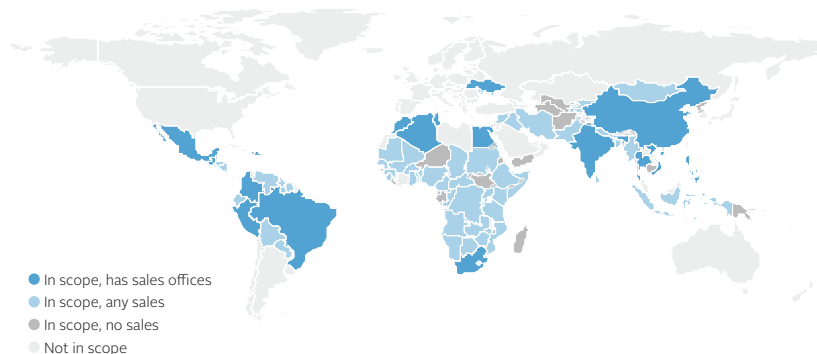
M&A news: AbbVie acquired Syndesi Therapeutics in March 2022 for USD 130 million upfront payment.

AbbVie's products are sold in 81 out of 108 countries in scope of the Index. AbbVie has sales offices in 17 countries, and sells via suppliers and/or pooled procurement in an additional 64 countries.

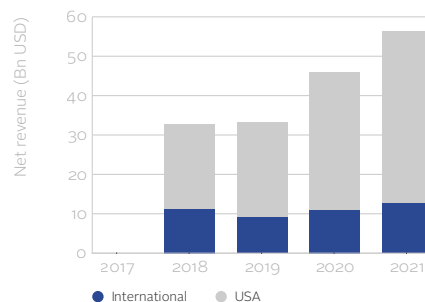
Net revenue by segment (2021) – in USD

Pharmaceutical sciences	56.20 bn
Total	56.20 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

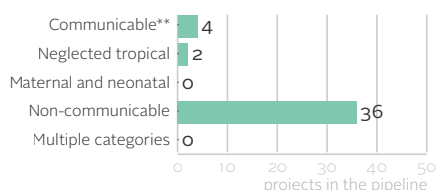
PIPELINE for diseases in scope

AbbVie has a total of 42 R&D projects in scope with six of these projects targeting a priority disease. The other 36 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (two projects). Of the projects targeting other diseases in scope, the focus is on oncology (31). Nine R&D projects are in late-stage development that target either a priority disease (2) or address a public health need in LMICs (7).^{*} Evidence of access planning was not reported for any of these projects.

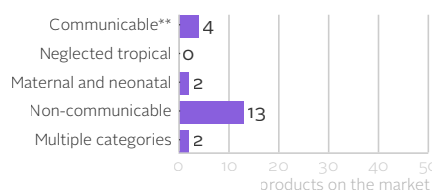
PORTFOLIO as selected for analysis by the Index

AbbVie has 19 medicines in scope, 14 of which are on patent and two contraceptive methods. 37% of the medicines (7) are on the WHO EML. The off-patent medicines target mainly non-communicable diseases (NCDs) such as hypertensive heart disease (2), cancer (1) and endometriosis (1). Furthermore, there is one off-patent medicine for preterm birth complications. The on-patent medicines mainly target NCDs, such as mental health conditions (5) and cancer (2) and communicable diseases such as HIV/AIDS (2), and hepatitis C (2). In addition, one product is for endometriosis, one for migraine and other products target preterm birth complications.

42 projects in the pipeline



21 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	2	0	2	1	1	0	0	6
Addresses needs of LMICs*			8	3	4	0	0	15
Other projects in scope			13	6	2	0	0	21

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	3	11			14
off patent	4	1			5
Vaccines	0	0			0
Contraceptives	1	1			2
Diagnostics				0	0
Other [‡]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

AbbVie Inc

GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. AbbVie performs strongly. It has an access strategy, the Global Integrated Access Strategy (IAS), which serves as the foundation and starting point for product specific strategies at the regional (area) and country (affiliate) level. The IAS covers all of the therapeutic areas in which the company is involved, including Immunology and Oncology and Specialty. The highest responsibility for access lies directly with the board, with its Public Policy committee responsible for corporate responsibility aspects, including access.

Provides evidence of financial access-related incentives at the executive level. AbbVie performs average in this area. It demonstrates evidence of having access-related incentives for senior executives under its key material driver of Patient Affordability and Accessibility within its ESG framework.

Publicly discloses outcomes of a subset of its access-to-medicine activities. AbbVie performs well in transparency regarding access

activities. It discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. For example, the company publicly shares how it contributes to the achievement of the UN SDG3 targets. It shares the outcomes of its access-to-medicine activities for only a subset of initiatives, although it does so in a centralised manner within its ESG Action Report.

Performs above average in responsible promotional practices. AbbVie's sales agents are not incentivised solely on sales volume targets. It does not publicly disclose information related to transfers of values to healthcare professionals (HCPs) in countries in scope of the Index (e.g. payments for attending events or promotional activities) unless required by local regulations, nor does it disclose a policy limiting such transfers, but it does have global, international, and local policies for engaging with HCPs.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. AbbVie has an average performance, demonstrating evidence

of some components looked for by the Index: audits (both internal and external) and formal processes to ensure third-party compliance with company standards. However, AbbVie does not disclose to the Index whether there is fraud-specific risk assessment done in countries in scope of the Index. Additionally, there is no evidence of a continuous monitoring system of activities or country-based assessments. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health. AbbVie does not publicly share any support of the Doha Declaration on TRIPS and Public Health. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, AbbVie, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 20

SCORE 0.78

No structured process for access planning reported. AbbVie does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to its peers. AbbVie has six projects, including two late-stage candidates in its pipeline that target a priority product gap. The priority pipeline focuses on various diseases, including HIV/AIDS, onchocerciasis and tuberculosis. AbbVie did not disclose evidence of access plans for any late-stage projects.

Many projects address a public health need in LMICs.* The company does not disclose evidence of access plans for any of the late-stage projects. In this analysis, AbbVie has seven late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules. Most target cancer. AbbVie did not disclose evidence of access plans for any of the late-stage projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, AbbVie does disclose fully disaggregated R&D investment data to Policy Cures Research.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. AbbVie's performance is below average in this area.

PRODUCT DELIVERY

RANK 18

SCORE 1.98

No public commitment not to enforce patents in countries in scope. AbbVie does not have a public policy that sets out its approach to filing for or enforcing patents in LMICs.

Publicly discloses information on patent status. Like most of its peers, AbbVie publicly discloses the patent statuses for small molecules in scope

via the Pat-INFORMED database. AbbVie discloses patent information such as grant number and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. AbbVie does not report on any new IP-sharing agreements with public

research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

Uses licensing and non-assert declarations to enable generic supply. AbbVie has non-exclusive voluntary licensing agreements in place for two compounds. Its licence for glecaprevir/pibrentasvir (Mavyret®), a treatment for hepatitis C, encompasses 79 countries within the scope of the Index, including 54 middle income countries.

Filed to register new products in one country in scope on average. AbbVie did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among new products, glecaprevir/pibrentasvir (Mavyret™), for viral hepatitis C, has been filed in two countries within the scope of the Index. Among old products with the same indication, its most widely filed is ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira®), filed in 13 countries relevant to the Index, including high burden countries such as Republic of Moldova and Ukraine. None of AbbVie's products considered for analysis are filed for registration in LICs.

Has access strategies for its supranationally procured products in scope. AbbVie performs above average in securing access for products procured supranationally. For the two products assessed in this category, lopinavir/ritonavir (Aluvia®/Kaletra) and ritonavir (Norvir®), AbbVie has procurement agreements with the Global Fund. The price agreed is disclosed and publicly available. The company applies pricing strategies that consider relevant payers' ability to pay in Algeria, a non-eligible Global Fund country, and it provides evidence of patient reach for both the products.

Has access strategies for only one health-care practitioner administered product in scope of this analysis. AbbVie has a below average performance in this area. For one of the three products assessed, the company provides evidence of access strategies in UMIC and LIC country examples. It makes efforts to reach additional patients through donations and has initiatives to strengthen the healthcare systems. For example, AbbVie applies a cost-plus pricing strategy for beractant (Survanta®) in Uganda that is aligned across sub-Saharan Africa. The company provides education through expert training and peer-to-peer mentorship, as well as through

a call-to-action stakeholder's meeting to elevate neonatology to treat neonates at three key Ugandan hospitals. Patient reach is not available.

Has few access strategies for self-administered products for some countries in scope of this analysis. AbbVie has a below average performance in this area. For one of the three products assessed, evidence of an access strategy in countries of all assessed income levels (UMIC, LMIC, LIC) was found publicly. For example, the non-exclusive voluntary license with the Medicines Patent Pool (MPP) for glecaprevir/pibrentasvir (Mavyret®) is still active. Patient reach evidence is not disclosed.

No manufacturing capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. AbbVie's performance is below average in this area.

No supply chain capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. AbbVie's performance is below average in this area.

None of the five health systems strengthening initiatives included meets all Good Practice Standards. AbbVie's performance is below average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In the Partnership with Baylor College of Medicine International Pediatric AIDS Initiative (BIPAI), AbbVie aims to reduce mortality, increase adherence and decrease rate of patients lost to follow up among children and families affected by HIV/AIDS in Romania and Malawi. This initiative meets all GPS.

Has engaged in scaling up one inclusive business model (IBM) but has not shown evidence of its involvement in piloting any new IBMs that meet all inclusion criteria. AbbVie performs average in the use of IBMs aimed at meet-

ing the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Access to Care Program facilitates the availability of the company's HIV medications in LMICs in addition to providing continuing medical education in 15 African countries to increase treatment capacity, knowledge and clinical skills.

Shows average performance in terms of ensuring continuous supply of medicines in LMICs. AbbVie has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, manages a buffer stock of relevant products, and works with several active pharmaceutical ingredient suppliers. However, there is no evidence that the company transfers technology to local manufacturers or is involved in supply chain capacity building initiatives that meet inclusion criteria for evaluation.

Has a case-by-case approach for reporting substandard and falsified (SF) medicines in countries in scope of the Index. AbbVie demonstrates evidence of reporting SF medicines to relevant regulatory authorities and the WHO, on a case-by-case basis. It does not disclose evidence, publicly or to the Index, that it requires reporting to occur within the timeframe of ten days looked for by the Index, nor does it provide evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. AbbVie has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows some evidence of monitoring the delivery of donations.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis. However, AbbVie is engaged in other structured donation programmes such as the programme whereby it has been donating beractant (Survanta®) for infant respiratory distress syndrome to six countries in scope of the Index since 2015 through Direct Relief.

RANK	SCORE
16	2.46
14 (2021)*	

Astellas Pharma Inc

Stock exchange: TSE • Ticker: 4503 • HQ: Tokyo, Japan • Employees: 14,522

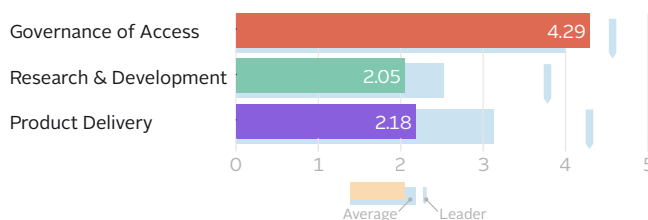
PERFORMANCE IN THE 2022 INDEX

16th place. Astellas performs below average, with a weak performance in Product Delivery, where it has a comparatively poor performance for its equitable access strategies. However, it has strengthened its R&D access planning processes.

Governance of Access: 8th place. Astellas performs well in this area. It has an access-to-medicine strategy that is integrated within the overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, but the responsibility of its access-to-medicine strategy lies indirectly with the board.

Research & Development: 13th place. Astellas has a below average performance in this area. It has a structured access planning process in place and applies this to all late-stage pipeline candidates. However, it has a small-sized priority R&D pipeline compared to peers and does not engage in R&D capacity building.

How score was achieved



Product Delivery: 16th place. Astellas performs below average in this area. It applies access strategies for two of its products in some countries in scope of the Index. The company newly engages in a high-quality supply chain capacity building initiative but lacks engagement in other areas such as manufacturing capacity building and inclusive business models.

OPPORTUNITIES FOR ASTELLAS

Establish direct board-level responsibility for access to medicine. Astellas has an access-to-medicine strategy. The Sustainability Advisory Panel, responsible for this strategy, reports to the CEO. Instead, the CEO can become a member of the Sustainability Advisory Panel, putting the responsibility for the access-to-medicine strategy at the board level.

Expand the geographic coverage of access plans to include more lower-middle and low-income countries. Astellas has access plans in place for all late-stage candidates. For example, it has access plans in place for zolbetuximab (IMAB362), indicated for oesophageal cancer, in six countries in scope of the Index. These are all upper-middle income countries. Astellas can increase the number of countries in scope of the Index included in R&D access plans and specifically focus on low- and lower-middle income countries with the highest burden of disease, such as Mongolia, Malawi and Zimbabwe.

Expand access to innovative medicines for non-communicable diseases. The company can increase affordability and supply through equitable access strategies and/or non-exclusive voluntary licensing to products such as gilteritinib (Xospata®) for leukaemia and ipragliflozin (Suglat®) for diabetes. These products can further be filed for registration in countries within the scope of the Index, especially where the burden of disease is the highest, such as Ethiopia and Bolivia for gilteritinib and Guyana, Sri Lanka and Suriname for ipragliflozin.

CHANGES SINCE THE 2021 INDEX

- Launched Corporate Strategic Plan in 2021 with Access to Health, including the implementation of its access-to-medicine strategy, as part of its sustainability strategic goal.
- The Astellas Global Health Foundation awarded a three-year grant to the Academic Model Providing Access to Healthcare (AMPATH) for a programme that will provide 400,000 people in Kenya with access to mental health programmes.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.
*In the 2021 Index, dense ranking was used. In the 2022 Index, standard

competitive ranking is used. Therefore, a direct comparison with Astellas' previous rank is not possible.

SALES AND OPERATIONS

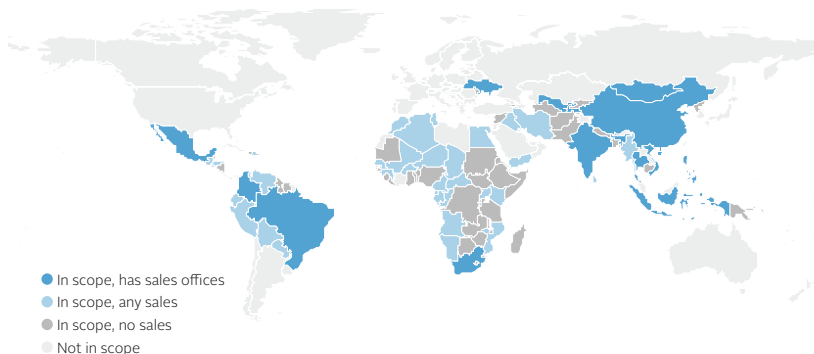
Business segments: Pharmaceutical
Therapeutic areas: Immunology, oncology and urology.
Product categories: Innovative medicines
M&A news: Astellas acquired its own shares and cancelled its treasury stock in March 2022 for JPY 29.4 billion.

Astellas' products are sold in 49 out of 108 countries in scope of the Index. Astellas has sales offices in 14 countries, and sells via suppliers and/or pooled procurement in an additional 35 countries.

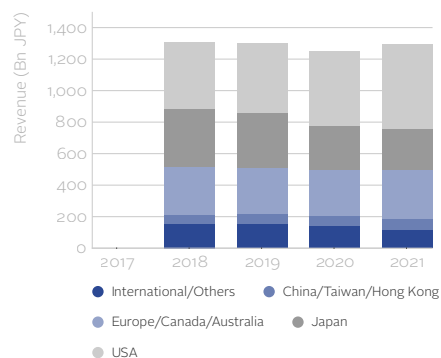
Revenue by segment (2021) – in JPY

Pharmaceutical	1,323.00 bn
Total	1,323.00 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

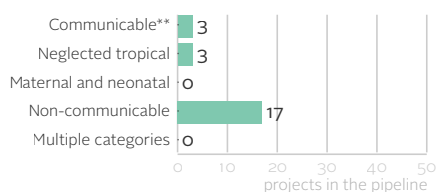
PIPELINE for diseases in scope

Astellas has a total of 23 R&D projects in scope, with six projects targeting a priority disease. The other 17 R&D projects target other diseases in scope. Projects targeting priority diseases include schistosomiasis, Chagas disease and leishmaniasis. Of projects targeting other diseases in scope, the focus is oncology (14 projects). Four R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (3).^{*} Evidence of access planning was in place for 100% of these projects.

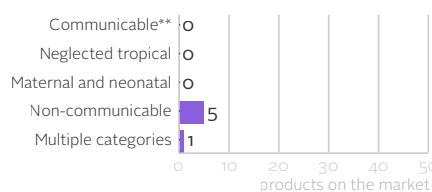
PORTFOLIO as selected for analysis by the Index

Astellas has six medicines in scope, four of which are on patent. 50% of these medicines (3) are on the WHO EML. The off-patent medicines target cancer (1) and HIV/AIDS (1). The on-patent medicines target cancer (3) and diabetes mellitus (1).

23 projects in the pipeline



6 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	4	1	0	0	1	0	0	6
Addresses needs of LMICs [*]			1	1	1	1	0	4
Other projects in scope			9	2	1	1	0	13

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	3			4
off patent	2	0			2
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

Astellas Pharma Inc

GOVERNANCE OF ACCESS

RANK 8

SCORE 4.29

Has an access-to-medicine strategy with measurable objectives, integrated with the overall corporate strategy. Astellas performs strongly. It has an access strategy integrated across the company business as one of its strategic goals in its Corporate Strategic Plan. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, with the Sustainability Advisory Panel overseeing social activities, including access.

Provides evidence of financial access-related incentives at the executive level. Astellas performs well. It incentivises some senior executives to perform on certain access-related factors with financial rewards. The CEO also has access-related incentives linked to its remuneration plan.

Publicly discloses outcomes of its access-to-medicine activities. Astellas performs strongly in transparency of access activities. It publicly discloses commitments on improving social sustainability, measurable goals, objectives, and targets for improving access to medicine in countries in scope of the Index, towards reduc-

ing premature deaths from non-communicable diseases by 2030. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities, including its response to COVID-19, in a centralised manner within its Access Accelerated initiative Year 4 Report.

Performs above average in responsible promotional practices. Astellas' sales agents are not solely incentivised on sales volume targets. The company, however, sets sales incentives at the individual level for agents. Astellas does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g., payments for attending events or promotional activities) unless required by local regulations, but it has a policy and guidance limiting such transfers at the global level, including in countries in scope of the Index.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Astellas performs strongly, demonstrating evidence of all components looked for by the Index:

fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Astellas publicly shares support of the Doha Declaration on TRIPS and Public Health with regard to the Least Developed Countries. However, it expresses reservations on the use of compulsory licensing and states that it does not believe IP protection is a primary factor in limiting access to health. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Astellas, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 13

SCORE 2.05

Access planning processes encompass all projects in the pipeline. Astellas has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index.

A small-sized priority R&D pipeline compared to its peers. Astellas has six projects, including one late-stage candidate in its pipeline that targets a priority product gap. The company focuses on various priority areas, including schistosomiasis, Chagas disease and leishmaniasis. Astellas has an access plan in place for its late-stage candidate targeting a priority product gap. This plan is for the development of paediatric praziquan-

tel in partnership with the Pediatric Praziquantel Consortium.

Some projects address a public health need in LMICs,* with 100% (3/3) of late-stage candidates covered by access plans. In this analysis, Astellas has three late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope of the Index and/or are first-in-class molecules. Most target cancer. Astellas provides evidence of access plans for all three late-stage candidates.

These plans focus mainly on registration preparation in countries in scope.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Astellas does not disclose disaggregated R&D investment data to global health organisations.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Astellas' performance is below average in this area.

PRODUCT DELIVERY

RANK 16

SCORE 2.18

Publicly commits not to enforce patents in countries in scope. Astellas publicly pledges to neither file for nor enforce patents in Least Developed Countries and LICs.

Publicly discloses information on patent status. Like most of its peers, Astellas publicly discloses

the patent statuses for small molecules in scope via the Pat-INFORMED database. Astellas discloses patent information such as filing date, grant number, grant date and jurisdiction.

Is an average-performing company in terms of sharing intellectual property (IP) assets with

third-party researchers. Astellas engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

current Index cycle and meet all inclusion criteria for evaluation.

No use of licensing agreements. Astellas does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register new products in two countries in scope on average. Astellas did not disclose evidence of filing for registration any of its new products in any of the top ten high burden countries. Among old products, its most widely filed is enzalutamide (Xtandi™), for prostate cancer, filed in 40 countries in scope of the Index. The product reaching most LICs is micafungin (Mycamine®), used in HIV/AIDS complications, filed in six of the 27 LICs within scope of the Index.

Astellas is not eligible for assessment of supra-nationally procured products.

Has access strategies for some of the health-care-practitioner-administered products in scope of this analysis. Astellas performs below average in this area. For one of the two products assessed, the company provides evidence of pricing strategies considering some affordability factors for all assessed income levels (UMIC, LMIC, LIC). For example, Astellas applies a pricing strategy that considers relevant payers' ability to pay for micafungin (Mycamine®) in a UMIC. Patient reach is available for one product only in a UMIC.

Has access strategies for some of its self-administered products for some countries in scope for this analysis. Astellas performs below average in this area. For one of the three products assessed, the company provides examples of access strategies which consider affordability factors in countries of all assessed income levels (UMIC, LMIC, LIC). For example, Astellas applies a pricing strategy that considers relevant payers' ability to pay for enzalutamide (Xtandi™) in

the UMIC example provided. Evidence of patient reach is available for two products in UMICs.

No manufacturing capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Astellas' performance is below average in this area.

The one supply chain capacity building initiative included for analysis meets all Good Practice Standards. Astellas' performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. The Astellas Global Health Foundation partners with Academic Model Providing Access to Healthcare (AMPATH) to build ancillary support services including pharmaceutical supply chains, electronic health records and medical supplies to deliver mental health services in Kenya. This initiative meets all GPS.

One of the four health systems strengthening initiatives included meets all Good Practice Standards. Astellas' performance is below average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all GPS than what is average for this indicator. The Astellas Global Health Foundation awarded a grant to the END Fund which works to deliver neglected tropical disease (NTD) treatments through mass drug administration mechanisms designed to control and eliminate NTDs in the Democratic Republic of Congo. This initiative meets all GPS.

Has no inclusive business models that meet all inclusion criteria. There is no evidence that Astellas has engaged in the piloting or scale-up of any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved

populations) in LMICs. Astellas performs below average in this area.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Although there is no evidence of technology transfer initiatives that meet inclusion criteria for evaluation, Astellas does have a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, has a dual active pharmaceutical ingredient sourcing strategy for some products and is involved in supply chain capacity building initiatives. The company manages a buffer stock of relevant products in countries with Astellas warehouses and otherwise works to ensure that third parties have relevant stocks.

Has a policy for reporting substandard and falsified medicines in countries in scope of the Index in less than ten days. Astellas has a policy for reporting falsified medicines within ten days to national health authorities and the WHO, but applies a separate process to substandard medicines. It provides evidence of shortened time frames for reporting for cases which only require visual inspection by experts to be confirmed and are not contingent upon laboratory analysis.

Donates in response to expressed need and monitors delivery. Astellas has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Has no long-term donation programmes for neglected tropical diseases (NTDs) or malaria that are eligible for analysis under this indicator. Astellas is not engaged in any structured donation programmes for NTDs or malaria where elimination, eradication or control goals are possible and that are eligible for analysis under this indicator.

RANK	SCORE
3	3.93
7 (2021)	

AstraZeneca plc

Stock exchange: LSE • Ticker: AZN • HQ: Cambridge, United Kingdom • Employees: 83,100

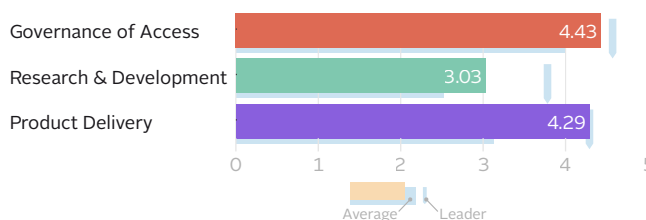
PERFORMANCE IN THE 2022 INDEX

3rd place. AstraZeneca ranks among the top three companies in the Index. The company performs well in all three Technical Areas, particularly in its approach to patent transparency and sharing of intellectual property assets. It has strengthened its performance in R&D access planning, as well as manufacturing and supply chain capacity building.

Governance of Access: 2nd place. AstraZeneca has a strong performance in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. It also incentivises its senior executives, the CEO and in-country and regional managers to perform on access-to-medicine goals.

Research & Development: 6th place. AstraZeneca performs well in this area. It has a structured access planning process in place and applies this to nearly all late-stage candidates. Although its priority pipeline is small compared to its peers, it has the largest pipeline for non-communicable diseases of

How score was achieved



the companies. Furthermore, it performs well in R&D capacity building.

Product Delivery: 1st place. AstraZeneca leads in this area. In all product categories, it applies tailored access strategies across different country income classifications. It also excels in its approach to access strategies for supranationally procured products. The company has shared the highest number of intellectual property assets to third-party researchers. Furthermore, the company has piloted both new and scaled-up existing inclusive business models and it engages in many high-quality capacity building initiatives across all fields.

OPPORTUNITIES FOR ASTRAZENECA

Improve the quality and geographic coverage of access plans. AstraZeneca has project-specific access plans in place for almost all late-stage R&D candidates. These plans focus mostly on registration in the emerging markets of Brazil, India and China. In its plans, the company can include more access components such as equitable pricing and licensing. Furthermore, it can expand the geographic coverage of these plans to focus more on low-income countries. For example, the access plan for nirsevimab, indicated for the prevention of respiratory syncytial virus, can be expanded to include more than five countries in scope of the Index.

Bring equitable pricing initiatives to scale. Through the Healthy Heart Africa (HHA) initiative, the company identifies different levels of ability to pay and affordability in markets to inform its pricing model. AstraZeneca can consider expanding the pricing model of HHA to other countries in sub-Saharan Africa that are not part of the programme yet, such as those with the highest burden of hypertensive disease, including the Central African Republic. The company can apply the HHA model to cover more therapeutic areas such as diabetes and oncology.

Expand access to its diabetes medicine, dapagliflozin (Farxiga/Forxiga®), through non-exclusive voluntary licensing and/or equitable pricing. The company has an access strategy for dapagliflozin across upper-middle income countries, lower-middle income countries and low-income countries, including one of the countries with the highest burden of disease for diabetes. AstraZeneca can provide evidence of implementing access strategies in other countries with high burdens of disease such as Sri Lanka, Kiribati and Micronesia for example via equitable pricing and/or non-exclusive voluntary licensing agreements.

Expand access to cancer products such as osimertinib (Tagrisso®), through equitable pricing and/or non-exclusive voluntary licensing. The company has equitable access strategies in place in UMICs and LMICs. The company can provide evidence of expanding access to the product in LICs and countries where the burden of the disease is highest, such as China, Armenia and Thailand.

CHANGES SINCE THE 2021 INDEX

- Created a dedicated vaccines and immune therapies unit for COVID-19 vaccine and antibody treatments and the existing portfolio for respiratory viral disease.
- Initiated two global training programmes — Parexcel and UNIFY — to expand the pool of under-represented principal investigators and clinical research coordinators.
- Supplied more than two billion doses of COVID-19 vaccine (Vaxzevria) to LMICs at not-for-profit through private licensing agreements.
- Supplied its COVID-19 vaccine (Vaxzevria) through the COVAX facility.
- Initiated new partnerships with the UK Royal Academy of Engineering to strengthen healthcare innovation across Africa.
- Expanded the Healthy Heart Africa (HHA) programme to Senegal, Côte d'Ivoire, Rwanda and Nigeria. This initiative aims to improve access to end-to-end hypertension management and was recently expanded to more therapeutic areas such as diabetes.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

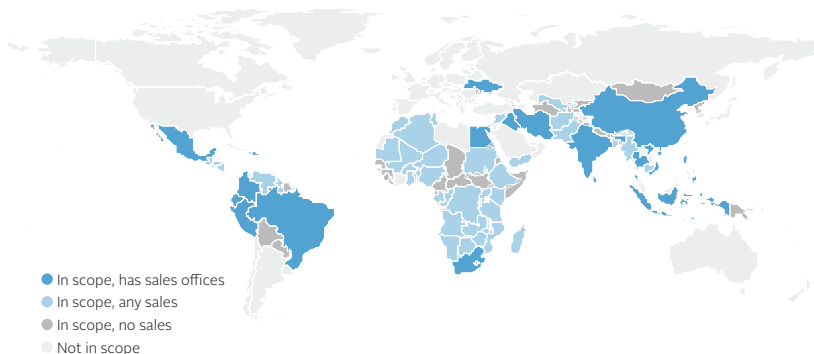
Business segments: Pharmaceutical
Therapeutic areas: Biopharmaceuticals (including cardiovascular, immunology, metabolism, renal and respiratory), oncology and rare diseases.
Product categories: Innovative medicines and vaccines.
M&A news: AstraZeneca acquired Alexion Pharmaceuticals in July 2021 for USD 13.3 billion.

AstraZeneca's products are sold in 62 out of 108 countries in scope of the Index. AstraZeneca has sales offices in 19 countries, and sells via suppliers and/or pooled procurement in an additional 43 countries.

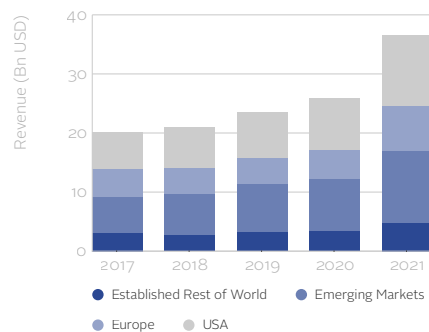
Revenue by segment (2021) – in USD

Pharmaceutical	37.42 bn
Total	37.42 bn

Sales in countries in scope



Sales by geographic region

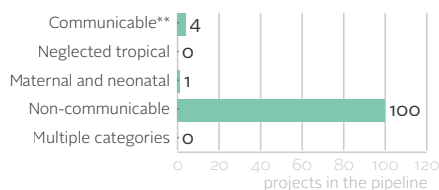


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

AstraZeneca has a total of 105 R&D projects in scope with four of these projects targeting priority diseases. The other 101 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on COVID-19 (three projects). Of the projects targeting other diseases, the focus is on oncology (62). Twenty-five R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (22).^{*} Evidence of access planning was in place for 96% of these projects: three targeting a priority disease and 21 addressing a public health need in LMICs.

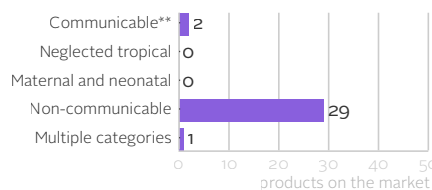
105 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

AstraZeneca has 30 medicines in scope, 25 of which are on patent, and two vaccines. 22% of these medicines and vaccines (7) are on the WHO EML. The off-patent medicines target mainly non-communicable diseases (NCDs) such as hypertensive heart disease (2), asthma (2) and cancer (1). The on-patent medicines also mainly target NCDs, such as diabetes mellitus (8), cancer (8), and different respiratory diseases (7). In addition, the portfolio includes a COVID-19 vaccine and an influenza vaccine.

32 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	0	2	0	2	0	4
Addresses needs of LMICs*			5	13	5	4	0	27
Other projects in scope			24	34	13	3	0	74

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	3	22			25
off patent	3	2			5
Vaccines	1	1			2
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

AstraZeneca plc

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. AstraZeneca performs strongly. It has an access to healthcare strategy integrated within its core business, beyond philanthropy. The strategy covers all therapeutic areas the company is involved in. The highest responsibility for access lies directly with the board, with a dedicated board of directors member responsible for sustainability, including access to healthcare.

Provides evidence of financial and non-financial access-related incentives at the executive level.

AstraZeneca performs strongly. It incentivises select senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards and the CEO has access-related incentives linked to its ESG performance. For example, AstraZeneca's "Contribution to society KPI" measures progress on annual and long-term targets and includes "Access to healthcare" as one of three pillars of sustainability.

Publicly discloses outcomes of its access-to-medicine activities.

AstraZeneca performs strongly in transparency of access activities. It publicly discloses commitments, measurable

goals, objectives and 2025 targets for improving access to healthcare in countries in scope. It facilitates accountability and transparency by consistently sharing the outcomes of its access to healthcare programmes, including its Healthy Heart Africa and Healthy Lung initiatives, in a centralised manner within its ESG Report.

Performs above average in responsible promotional practices.

AstraZeneca's sales agents are not solely incentivised on sales volume targets. The company, however, does not disclose the level at which sales incentives are set. AstraZeneca does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities) unless required by local regulations, but has policies on third party engagement, which can limit compensation and govern contributions and other items to healthcare professionals under certain circumstances.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

AstraZeneca performs strongly, demonstrating evidence of all components looked for by

the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties, including contract language and training on the AstraZeneca Code of Ethics. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health.

AstraZeneca publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, namely on the use of compulsory licensing. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, AstraZeneca, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 6

SCORE 3.03

Access planning processes encompass all projects in the pipeline.

AstraZeneca has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, AstraZeneca begins developing access plans for R&D projects in Phase II/III of clinical development.

A small-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (3/3) of the late-stage candidates analysed.

AstraZeneca has four projects, including three late-stage candidates in its pipeline, that target a priority product gap. These focus mostly on coronaviral diseases. Of AstraZeneca's three late-stage candidates targeting a priority product gap, all have evidence of access plans. These include commitments to register in countries in scope of the Index. Furthermore, the plan for the COVID-19 vaccine (Vaxzevria) includes manufacturing, procurement and distribution agreements with

CEPI and Gavi and a licensing agreement with Serum Institute of India (SII) to supply one billion doses for LMICs.

Many projects address a public health need in LMICs,* with 95% (21/22) of late-stage projects covered by access plans.

In this analysis, AstraZeneca has 22 late-stage R&D projects in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. These projects target several diseases including cancer and kidney diseases. AstraZeneca provides evidence of access plans for 21 of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Publicly discloses disaggregated R&D investment data by phase of development.

However,

AstraZeneca does not disclose disaggregated R&D investment data to global health organisations.

Three of the five R&D capacity building initiatives included meet all Good Practice Standards.

AstraZeneca's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, AstraZeneca's collaboration with the Cancer Research and Clinical Trials Centre (CRCTC) builds R&D oncology capacity in Vietnam through treatment development, medical research and continuous medical education. This initiative meets all GPS.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 1

SCORE 4.29

Public commitment not to enforce patents in countries in scope. AstraZeneca publicly pledges to neither file for nor enforce patents in a subset of Index countries. This commitment applies to 80 countries in scope of the Index, of which all Least Developed Countries and LICs in scope, and a subset of LMICs and UMICs. In sub-Saharan Africa, all countries are part of the commitment beside Ghana, Kenya, Nigeria and South Africa. The policy covers all products in the scope of the Index and publicly discloses the list of countries.

Publicly discloses detailed information on patent status. AstraZeneca publicly discloses on its website information relating to the status of its patents for all products in its Index portfolio. This includes brand name, nature of the patent, patent number, expiry date and jurisdiction.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. AstraZeneca engaged in 14 new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current period of analysis that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing agreements to enable generic supply. AstraZeneca has private, voluntary licensing agreements in place for one product, its COVID-19 vaccine (Vaxzevria). Details of these agreements are not publicly available.

Filed to register new products in ten countries in scope on average. AstraZeneca filed two out of nine newer products in a subset of high burden disease countries. Among new products, its most widely filed is acalabrutinib (Calquence®), indicated for leukaemia, filed in 23 countries in scope of the Index, including Ecuador and Ukraine among the top ten high burden disease. Durvalumab (Imfinzi®) has been registered in 22 countries within the scope of the Index, five of which are high-burden countries (China, Republic of Moldova, Thailand, Ukraine and Vietnam). None of its products assessed are filed for registration in any LIC.

Has access strategies for its supranationally procured product in scope of this analysis. AstraZeneca leads in securing access for its product procured supranationally. For the product assessed in this category, the COVID-19 vaccine (Vaxzevria), it demonstrates access strategies both in countries eligible for supply from such procurers and in countries that procured the vaccine outside the supranational agreement. The company provides evidence of an additional access strategy to increase patient reach. Evidence of patient reach is available.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. AstraZeneca performs above average in this area compared to other companies. For all five products assessed, the company provides examples of access strategies which consider affordability in UMICs and LMICs. It makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay and additional financing mechanisms. For example, AstraZeneca set a direct distribution system for healthcare centres in Uganda to ensure supply stability and price reduction of goserelin acetate (Zoladex®). Evidence of an increase in patient reach in Uganda is provided.

Has access strategies for the majority of its self-administered products for countries in scope of this analysis. AstraZeneca has an above average performance in this area. For three of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). It makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay and patient assistance programmes. For example, AstraZeneca has secured public reimbursement of osimertinib (Tagrisso®) in Egypt, where patient reach has increased.

All five manufacturing capacity building initiatives included for analysis meet all Good Practice Standards. AstraZeneca is a leader in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, AstraZeneca has conducted a full technology transfer to Siam Biosciences for its COVID-19 vaccine (Vaxzevria).

All five supply chain capacity building initiatives included for analysis meet all Good Practice Standards. AstraZeneca is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, in the United for Health Partnership with the Egyptian Government, AstraZeneca provides support and education to governmental pharmacists through a structured programme that involves supply chain management training and scholarships.

Four of the five health systems strengthening initiatives included meet all Good Practice Standards. AstraZeneca's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, AstraZeneca's new initiative PUMUA aims to build capacity for asthma care in Africa through infra-

structure, awareness programmes and training of stakeholders along the patient journey.

Has engaged in scaling up two and piloting two inclusive business models. AstraZeneca performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. As part of the One Young World Lead2030 programme, AstraZeneca has awarded funding to BIVE, a model that facilitates access to timely, high quality and affordable private health-care services for more than 19,000 Colombian people, the majority being low-income coffee farmers.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. AstraZeneca is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. AstraZeneca has a policy for reporting SF medicines to national health authorities within five days. It provides evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed and aims to report within three working days when packaging is sufficient to assess the case.

Donates in response to expressed need and monitors delivery. AstraZeneca has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, AstraZeneca is engaged in another structured donation programme: the Cambodia Breast Cancer Initiative whereby it has been donating anastrozole (Arimidex®) and fulvestrant (Faslodex®) to Cambodia since 2008.

RANK	SCORE
9	3.36
13 (2021)	

Bayer AG

Stock exchange: XFRA • Ticker: BAYN • HQ: Leverkusen, Germany • Employees: 99,637

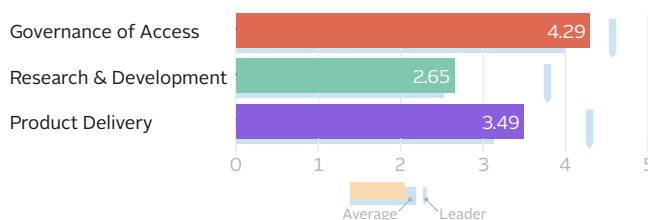
PERFORMANCE IN THE 2022 INDEX

9th place. Bayer ranks among the top ten companies of the Index. It performs strongly in access strategies for healthcare practitioner-administered products. The company has also strengthened its performance in inclusive business models and in access planning during R&D.

Governance of Access: 8th place. Bayer performs well in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy, although the strategy covers only some of its therapeutic areas. It incentivises senior executives and in-country and regional managers to perform on access-to-medicine goals and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 10th place. Bayer's performance is average in this area. It now has a structured access planning process in place and applies this to most late-stage pipeline candidates. Although it has a small-sized priority R&D pipeline, its access plans include the most countries in scope of

How score was achieved



the Index compared to its peers. However, the company's performance in R&D capacity building is below average.

Product Delivery: 9th place. Bayer has an above average performance. The company has comprehensive access strategies for some of its products but lacks access strategy examples in low-income countries for its self-administered products. Bayer has also both scaled-up and piloted inclusive business models and performs well in supply chain capacity building.

OPPORTUNITIES FOR BAYER

Ensure all late-stage R&D projects have comprehensive access plans. Bayer has introduced a structured process for access planning beginning in Phase II of clinical development. It has access plans in place for 80% of late-stage candidates analysed. The company can expand its access plans to all R&D projects from Phase II onwards.

Expand access to on-patent cancer products in lower-middle and low-income countries, such as darolutamide (Nubeqa®). Bayer has access strategies in UMICs for darolutamide, indicated for prostate cancer and listed on the WHO Model List of Essential Medicines. The company can provide evidence of expanding access to the product via equitable access strategies and registration in lower-middle income countries, low-income countries and countries with a high burden of disease such as Guyana and Suriname. In addition, the company can expand access to sorafenib (Nexavar®), indicated for thyroid and liver cancer, via equitable access strategies and registration in LICs and in countries with a high burden of disease such as Bolivia, Guinea and Gambia.

Expand technology transfer initiatives for reproductive health commodities to additional countries. Bayer has previously transferred technology for its hormonal contraceptive products to manufacturers in LMICs such as Algeria and Morocco. Bayer can expand the geographic scope of these technology transfers to build manufacturing capacity and improve regional availability in countries or regions with specific access gaps.

CHANGES SINCE THE 2021 INDEX

- Established an ESG committee in January 2022 at the supervisory board level.
- Invests over EUR 400 million to construct a production site for contraceptives in Costa Rica and expand a production site in Finland, both of which will supply to LMICs.
- Introduced a structured framework to include access planning in the development process early on for all its pipeline projects (both in-house and collaborative).
- Received first approval for nifurtimox (Lampit®) indicated for paediatric Chagas disease.
- Began to report disaggregated R&D investment data to Policy Cures Research.
- Opened two new hubs in Pakistan and the Philippines for The Challenge Initiative (TCI), a platform that enables governments to scale up family planning approaches for the urban poor.
- Extended its commitment with the World Health Organization (WHO) for an additional five years to accelerate control and elimination of neglected tropical diseases including the donation of medicines for treatment of chagas disease and African trypanosomiasis (sleeping sickness), estimated at USD 8 million.
- Donated over USD 3.8 million in products to the UNFPA as well as USD 1 million for logistical supply chain support during the COVID-19 pandemic.
- Received WHO Prequalification (PQ) (RH100) for levonorgestrel-releasing intrauterine system (Mirena®). All contraceptive products sold under supranational programmes have now received WHO PQ.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Consumer health, crop science and pharmaceutical.

Therapeutic areas: Cardiology, oncology, ophthalmology, radiology and women's health.

Product categories: Innovative medicines.

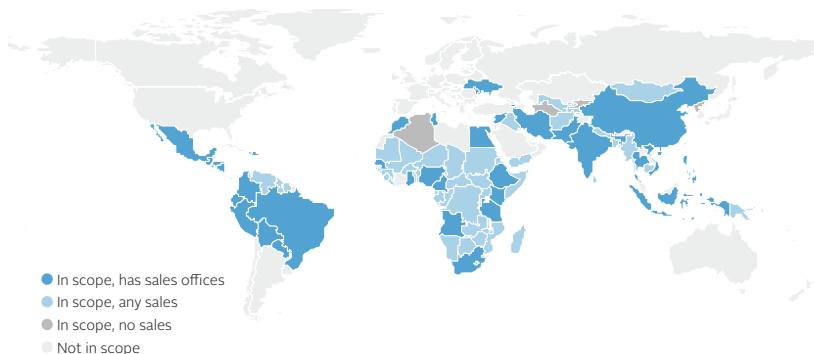
M&A news: Bayer acquired Vividion Therapeutics in August 2021 for USD 1.5 billion.

Bayer's products are sold in 95 out of 108 countries in scope of the Index. Bayer has sales offices in 38 countries, and sells via suppliers and/or pooled procurement in an additional 57 countries.

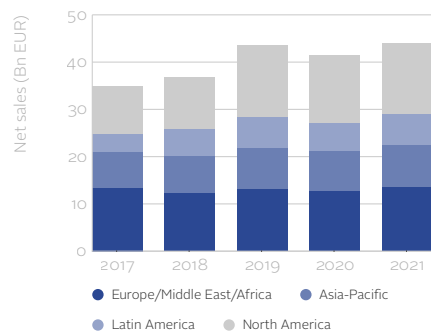
Net sales by segment (2021) – in EUR

Crop science	20.21 bn
Pharmaceutical	18.35 bn
Consumer health	5.29 bn
Total	43.85 bn

Sales in countries in scope



Sales by geographic region



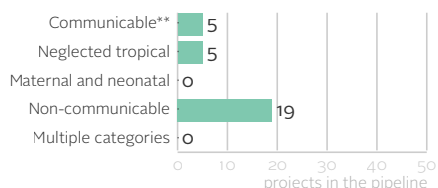
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Bayer has a total of 29 R&D projects in scope with ten of these projects targeting priority diseases. The other 19 R&D projects target other diseases in scope. Six projects concern vector control products. Of the projects targeting priority diseases, the focus is on malaria (three projects). Of the projects targeting other diseases, the focus is on kidney diseases (4) and oncology (10).

Ten R&D projects are in late-stage development that target either a priority disease (4) or address a public health need in LMICs (6).^{*} Evidence of access planning was in place for 80% of these projects: four targeting a priority disease and four addressing a public health need in LMICs.

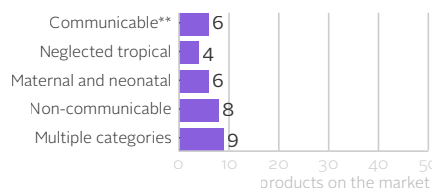
29 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Bayer has 13 medicines in scope and seven contraceptive methods and devices. Of the medicines, eight are on patent. Of the 20 medicines and contraceptive products, 55% (11) are on the WHO EML. In addition, the company markets 13 vector control products. The off-patent medicines target mainly women health, these include contraceptive methods (5) and target neglected tropical diseases, such as human African trypanosomiasis (3). The on-patent medicines mainly target non-communicable diseases such as cancer (5) and kidney diseases (2). The vector control products target communicable diseases such as dengue and chikungunya (8) and malaria (12).

33 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	2	0	0	1	1	2	4	10
Addresses needs of LMICs*			4	2	0	4	0	10
Other projects in scope			3	3	2	1	0	9

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	6			8
off patent	5	0			5
Vaccines	0	0			0
Contraceptives	4	3			7
Diagnostics			0		0
Other [‡]				13	13

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

Bayer AG

GOVERNANCE OF ACCESS

RANK 8

SCORE 4.29

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. Bayer performs strongly. It has an access strategy aiming at increasing the societal impact of its business activities. The strategy covers most therapeutic areas in which the company is involved, mainly focusing on women's health and access to contraceptives. The highest responsibility for access lies directly with the board, with the Chief Sustainability Officer. Furthermore, in 2022 Bayer established an ESG committee at supervisory board level to oversee access-related goals.

Provides evidence of financial and non-financial access-related incentives at the executive level. Bayer performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to sustainability goals.

Publicly discloses outcomes of its access-to-medicine activities. Bayer performs strongly in transparency of access activities. It

publicly discloses its commitments, measurable goals, objectives and targets for sustainability and improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Patient Access Charter and ESG Report.

Performs above average in responsible promotional practices. Bayer's sales agents are not solely incentivised on sales volume targets. However, Bayer sets sales incentives at the individual level for agents. The company does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities) unless required by law, but it does have a Fair Market Value policy to facilitate appropriate transfers.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Bayer performs strongly, demonstrating evi-

dence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Bayer publicly shares support of intellectual property rights in line with the TRIPS Agreement, while highlighting a need for appropriate measures in place for the development of innovative products. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Bayer, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 10

SCORE 2.65

Access planning processes encompass all projects in the pipeline. Bayer has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. Bayer begins developing access plans for R&D projects no later than Phase II of clinical development.

A small-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (4/4) of the late-stage candidates analysed. Bayer has ten projects, including four late-stage candidates, in its pipeline that target a priority product gap. These focus on various disease areas including malaria, Chagas disease, Zika, dengue and chikungunya. Of Bayer's four late-stage candidates targeting a priority product gap, all have evidence of access plans. These plans range from registration to a partnership with the Drugs for Neglected Diseases *initiative* (DNDi). A

notable example is the development of paediatric nifurtimox (Lampit®) to treat Chagas disease. Registration in additional endemic high disease-burden countries is planned for this project.

Some projects address a public health need in LMICs,* with 67% (4/6) of late-stage projects covered by access plans. In this analysis, Bayer has six late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. The projects mainly focus on cancer and kidney diseases. Bayer provides evidence of access plans for four of these projects. These access plans mainly focus on plans for registration in countries in scope and the development of an equitable pricing strategy.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, Bayer does disclose fully disaggregated R&D investment data to Policy Cures Research.

Two R&D capacity building initiatives included for evaluation. Neither initiative included for analysis meet all Good Practice Standards. Bayer's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. Bayer builds R&D capacity in Vietnam, by providing technical assistance to PATH in developing an affordable and sustainable COVID-19 vaccine.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 9

SCORE 3.49

Public commitment not to enforce patents in countries in scope. Bayer publicly pledges to neither file for nor enforce patents. This commitment applies in LICs only, for all its products in scope of the Index.

Publicly discloses information on patent status. Like most of its peers, Bayer discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Bayer discloses patent information such as filing date, grant number, grant date and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Bayer does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Bayer does not engage in voluntary licensing for products in scope of the Index.

Filed to register new products in six countries in scope on average. Bayer did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely registered is rivaroxaban (Xarelto®), an antithrombotic medicine for several indications, including prevention of stroke. It has been filed in 68 countries within scope of the Index, including 12 LICs. Bayer has filed rivaroxaban and sorafenib (Nexavar), indicated for liver and thyroid cancer, in more than half of the top ten high burden countries. sorafenib has been filed in Ecuador, Ethiopia, Honduras, Mongolia, Thailand and Vietnam.

Has access strategies for all its supranationally procured products in scope of this analysis. Bayer has an average performance in securing access for products procured supranationally. For three of the four products assessed in this category, the company demonstrates that it applies the same pricing strategies both in UNFPA countries eligible for supply from such procurers and in at least one country not eligible. The company provides evidence of patient reach, reporting that between 24 and 25 million women received access to modern contraception annually during the reporting period.

Has access strategies for the healthcare practitioner-administered product in scope of this analysis. Bayer performs above average in this area. For the product assessed, levonorgestrel-releasing intrauterine system (Mirena®/LNG-IUS), the company provides examples of access strat-

egies in countries of all assessed income levels (UMIC, LMIC, LIC). It also makes efforts to reach additional patients through donations, supranational agreements and tenders. For example, in Brazil, Bayer has donated this product through the International Contraceptive Access (ICA) Foundation. In Egypt, Bayer reached an agreement with the Ministry of Health to include the contraceptive in the government's Family Planning sector, and it will be provided for free to patients that cannot afford the contraceptive price while strengthening the health system via healthcare practitioner training and awareness campaigns. Bayer provides evidence of an increase in patient reach.

Has access strategies for its self-administered products for some countries in scope for this analysis. Bayer performs below average in this area. For three of the five products assessed, the company provides evidence of pricing strategies considering payers' ability to pay in UMIC and LMIC country examples. Bayer was able to secure rivaroxaban (Xarelto®) full reimbursement in Colombia in January 2022. In addition, it introduced a new patient programme that offers the first treatment cycle free of charge and supports patients in obtaining reimbursement coverage. Evidence that about 500 patients have been included in the programme since December 2021 is provided.

One of the three manufacturing capacity building initiatives included meets all Good Practice Standards. Bayer's performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For the initiative that met all GPS, since 2019, Bayer has built manufacturing capacity of its partners by making it mandatory for all contract manufacturing organisation sites to be audited according to the industry-wide Pharmaceutical Supply Chain Initiative (PSCI) standards.

All three supply chain capacity building initiatives included for analysis meet all Good Practice Standards. Bayer's performance is above average in this area. The number of initiatives meeting all inclusion criteria is average, but more initiatives meet all GPS than what is average for this indicator. For example, Bayer is a partner in the PSCI where it helps suppliers meet PSCI standards in several LMICs including India, China, Kenya and Nigeria.

Three of the four health systems strengthening initiatives included meet all Good Practice Standards. Bayer's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all GPS for this indicator. For example, Bayer is a partner in The Challenge Initiative (TCI) — a platform that enables govern-

ments in countries in scope of the Index to scale up high-impact family planning approaches for the urban poor. This initiative meets all GPS.

Has engaged in scaling up three and piloting two inclusive business models. Bayer performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Through the Bayer Foundation's Women Empowerment Award, Bayer annually awards EUR 25,000 to scale the social enterprises of five female entrepreneurs across sub-Saharan Africa. An example from this cycle is Whispa health, a platform that connects users to local medical centres, with the aim to be Africa's preferred sexual and reproductive health access provider.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Bayer is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, has established multi-source networks for active pharmaceutical ingredients in addition to in-house production and is involved in supply chain capacity building initiatives. The company also manages a buffer stock of relevant products based on local medical needs assessments that inform supply risk management.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Bayer has a policy for reporting SF medicines to national health authorities within seven days for the most severe risk category. It does not provide evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Bayer has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria. In one programme, Bayer publicly commits to controlling Chagas disease in endemic countries in Latin America as well as eliminating human African trypanosomiasis in endemic countries in Africa. The company publicly commits to donating nifurtimox (Lampit®) and suramin (Germanin®) for as long as needed until goals are reached.

RANK	SCORE
13	2.93
12 (2021)	

Boehringer Ingelheim

Stock exchange: N/A • HQ: Ingelheim am Rhein, Germany • Employees: 52,391

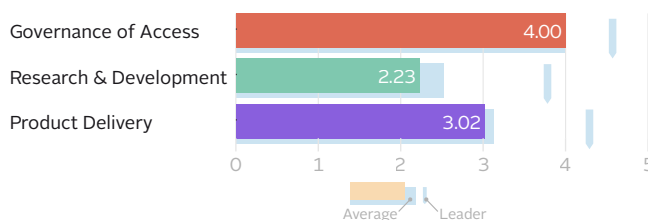
PERFORMANCE IN THE 2022 INDEX

13th place. Boehringer Ingelheim is a middle-performing company. The company has an average performance in Governance of Access and Research and Development but performs below average in Product Delivery. Boehringer Ingelheim has improved its R&D access planning framework but does not publicly disclose the patent status of its products via Pat-INFORMED.

Governance of Access: 12th place. Boehringer Ingelheim has an average performance in this area. It has a clear access-to-medicine strategy and discloses outcomes of its access-to-medicine activities, but it lacks a continuous system to monitor activities as part of its compliance framework for countries in scope of the Index.

Research & Development: 12th place. Boehringer Ingelheim has an average performance in this area. It has introduced a structured access planning framework and applies this to all late-stage pipeline candidates. However, the company has a

How score was achieved



small-sized priority pipeline and has an average performance in R&D capacity building.

Product Delivery: 14th place. Boehringer Ingelheim has a below average performance in this area. The company has access strategies for all its products but lacks examples in low-income countries. It builds capacity in supply chains, manufacturing and health systems, though some initiatives lack evidence of certain quality standards such as public disclosure of outcomes. The company shares intellectual property assets with third party researchers but does not publicly disclose the patent status of its products via Pat-INFORMED.

OPPORTUNITIES FOR BOEHRINGER INGELHEIM

Improve the quality of access plans for late-stage R&D projects. Boehringer Ingelheim has introduced a new policy to systemically plan for access before Phase II of clinical development and has plans in place for all late-stage candidates analysed. For non-communicable diseases the company's access plans focus mostly on registration in countries in scope of the Index. For example, for projects such as iclepertin (BI 425809) for schizophrenia and BI 456906 for diabetes, Boehringer Ingelheim can include more access components such as equitable pricing and licensing in its plans.

Improve transparency of the patent status of its products. Boehringer Ingelheim publicly commits to not file for or enforce patents in 61 countries within the scope of the Index, including all Least Developed Countries and low-income countries and a subset of lower-middle income countries and upper-middle income countries. The company can disclose detailed patent information publicly, either on its website or via Pat-INFORMED, including for its biological products.

Improve access to products on the WHO Model List of Essential Medicines (EML). Boehringer Ingelheim engages in equitable pricing for some of its products. The company has seven products on the WHO EML. The company can further expand access to these products, such as dabigatran (Pradaxa®), for prevention of stroke, and afatinib dimaleate (Giotrif®/Gilotrif®), for lung cancer, via equitable pricing in LICs. Boehringer Ingelheim can engage in non-exclusive voluntary licencing for patented medicines for type 2 diabetes mellitus, such as empagliflozin (Jardiance®).

CHANGES SINCE THE 2021 INDEX

- Newly demonstrates access-related incentives for senior-level executives.
- Created a Vulnerability Framework with input from different organisations to ensure that its access-to-medicine strategies are reaching all vulnerable populations.
- Newly demonstrates evidence that sales incentives are decoupled from sales volume targets.
- Improved access planning during R&D by broadening its framework and implementing it to its entire pipeline, as well as ensuring that all access planning begins in pre-clinical development.
- Established an office in Kenya to serve some of the most vulnerable communities in sub-Saharan Africa and exploring equitable access initiatives in the region.
- Committed (together with Boehringer Ingelheim Stiftung) EUR 150 million into antibiotic R&D of which EUR 40 million is already invested in the Antimicrobial Resistance (AMR) Action Fund, joint venture Aurobac and invested in five biotech companies.
- Created the investment vehicle Boehringer Ingelheim Social Engagement, endowed with EUR 50 million to provide financing for impact to social businesses in vulnerable communities, as an extension of Making More Health.
- Launched the new cervical cancer screening initiative Together Women Can in partnership with AMPATH in Kenya.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Animal health, biopharmaceutical contract manufacturing, human pharmaceutical and other sales.

Therapeutic areas: Cardiometabolic diseases, cancer immunology, central nervous system diseases, immunology, oncology and respiratory diseases.

Product categories: Animal health, biosimilars and innovative medicines.

M&A news: Boehringer Ingelheim signed an option to acquire Trutino Biosciences in June 2022.

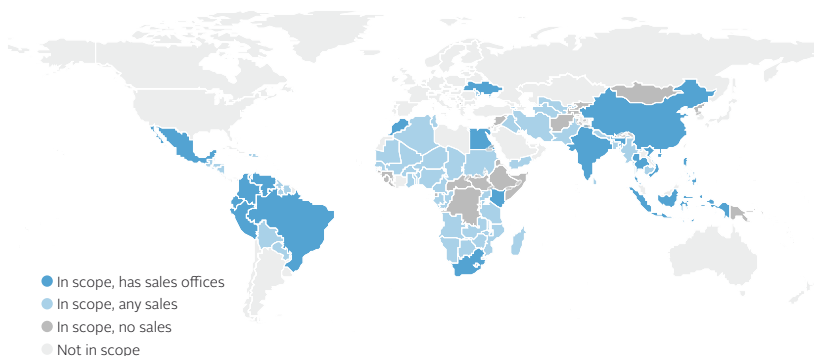
Boehringer Ingelheim's products are sold in 71 out of 108 countries in scope of the Index.

Boehringer Ingelheim has sales offices in 17 countries, and sells via suppliers and/or pooled procurement in an additional 54 countries.

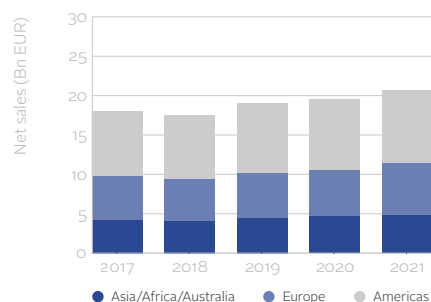
Net sales by segment (2021) – in EUR

Human pharmaceutical	15.29 bn
Animal health	4.30 bn
Biopharmaceutical contract manufacturing	0.92 bn
Other sales	0.03 bn
Discontinued operations	0.08 bn
Total	20.62 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

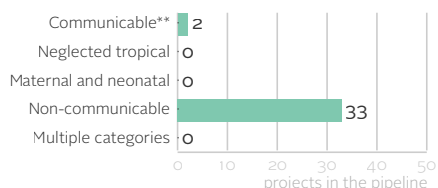
PIPELINE for diseases in scope

Boehringer Ingelheim has a total of 35 R&D projects in scope with two of these projects targeting priority diseases. Thirty-three R&D projects target other diseases in scope. Of the projects targeting other diseases, the focus is on oncology (19), kidney diseases (6), neurology (3), COPD (2), diabetes (1) and heart disease (1). Eight R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (7).^{*} Evidence of access planning was in place for 100% of these projects.

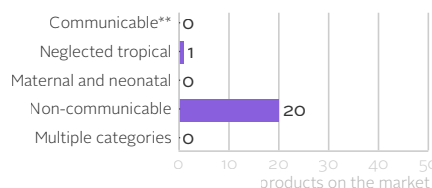
PORTFOLIO as selected for analysis by the Index

Boehringer Ingelheim has 20 medicines in scope, 15 of which are on patent. 60% of these medicines (11) are on the WHO EML. In addition, the company markets one vector control product. The off-patent medicines target mainly non-communicable diseases (NCDs) such as chronic obstructive pulmonary disease and asthma (2), ischaemic heart disease and stroke (2) and diabetes mellitus (1). The on-patent medicines also target the same NCDs as well as hypertensive heart disease (3) and cancer (1).

35 projects in the pipeline



21 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	1	0	0	1	0	0	0	2
Addresses needs of LMICs*			9	3	3	1	0	16
Other projects in scope			16	1	0	0	0	17

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	7	8			15
off patent	4	1			5
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other [‡]				1	1

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

Boehringer Ingelheim

GOVERNANCE OF ACCESS

RANK 12

SCORE 4.00

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Boehringer Ingelheim performs strongly. It has an Access to Healthcare Approach, part of its "Sustainable Development – For Generations" framework, which includes both human and animal health. The strategy covers all therapeutic areas in which the company is involved, namely non-communicable diseases (NCDs). The highest responsibility for access lies directly with the board.

Provides evidence of financial or non-financial access-related incentives at the executive level. Boehringer Ingelheim performs above average. It demonstrates evidence of access-related incentives for senior executives and in-country managers.

Publicly discloses outcomes of its access-to-medicine activities. Boehringer Ingelheim performs above average in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in coun-

tries in scope of the Index. It shares the outcomes of its access-to-medicine activities in a centralised manner directly on its website and within its annual report.

Performs above average in responsible promotional practices. Boehringer Ingelheim's sales agents are not solely incentivised on sales volume targets. However, the company sets incentives based on sales targets at the individual level for agents. It publicly discloses information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g., payments for attending events or promotional activities) according to law and industry association and has global and local policies governing such transfers to ensure compliance with the applicable regulations.

Has compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Boehringer Ingelheim demonstrates evidence of the following components assessed by the Index: fraud-specific risk assessment, audits (both internal and exter-

nal) covering third parties and in all countries where it operates, country risk-based assessments and formal processes to ensure third-party compliance with company standards. It does not, however demonstrate adequate evidence of a continuous system to monitor activities. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Boehringer Ingelheim publicly shares support of the Doha Declaration on TRIPS and Public Health. It views the Declaration as a mechanism offering more juridical certainty to countries which may intend to use the system. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Boehringer Ingelheim, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 12

SCORE 2.23

Access planning processes encompass all projects in the pipeline. Boehringer Ingelheim has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. Boehringer Ingelheim begins developing access plans for R&D projects before Phase II of clinical development.

A small-sized priority R&D pipeline compared to peers. Boehringer Ingelheim has two projects, including one late-stage candidate in its pipeline that target a priority product gap. This project is supported by an access plan.

Many projects address a public health need in LMICs,* with 100% (7/7) of late-stage candi-

dates covered by access plans. In this analysis, Boehringer Ingelheim has seven projects in late-stage development, that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope of the Index and/or are first-in-class molecules. The projects mainly focus on cancer and kidney diseases. Boehringer Ingelheim provides evidence of access plans for all seven late-stage projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Boehringer

Ingelheim does not disclose disaggregated R&D investment data to global health organisations.

One R&D capacity building initiative included for analysis meets all Good Practice Standards. Boehringer Ingelheim's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. Boehringer Ingelheim's Research Beyond Borders (RBB) initiative enables 30 research collaborations with universities and research organisations in countries in scope of the Index to advance drug discovery in areas of high unmet medical need.

PRODUCT DELIVERY

RANK 14

SCORE 3.02

Public commitment not to enforce patents in countries in scope. Boehringer Ingelheim publicly commits to not file for or enforce patents. This commitment applies to 61 countries within the scope of the Index, of which all Least Developed

Countries and LICs in scope of the Index and a subset of LMICs and UMICs.

Does not publicly disclose information on patent statuses on their website. Unlike all its

peers, Boehringer Ingelheim does not disclose the patent status of its products for diseases in scope of the Index on their website nor in Pat-INFORMED.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Boehringer Ingelheim engaged in three new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company also has existing agreements of this nature in place that were established before the current Index cycle.

No use of licensing agreements. Boehringer Ingelheim does not engage in voluntary licensing for products in scope of the Index.

No evidence of new products in scope. Boehringer Ingelheim did not disclose evidence of filing for registration any new products. Among old products, its most widely filed product, empagliflozin (Jardiance®), mainly used in individuals with type 2 diabetes, has been filed for registration in 37 countries in scope of the Index, three among the highest disease burden (Guyana, Sri Lanka and Mexico). Uganda and Yemen are the low-income countries where Boehringer Ingelheim has registered its products analysed under this indicator.

Has access strategies for its supranationally procured product in scope for this analysis. Boehringer Ingelheim has an average performance in securing access for its product procured supranationally. Boehringer Ingelheim supplies its rabies vaccine (Rabisin®), through PAHO, and it shared evidence of access strategies in countries not eligible to benefit from such procurement. The company provides evidence of an increase in animal vaccinations reach over the last two years.

Has few access strategies for its healthcare practitioner-administered products in scope of this analysis. Boehringer Ingelheim performs below average in this area. It provides evidence of access strategies in UMICs and LMICs, but no evidence for LICs for the two products analysed. It makes efforts to reach additional patients using pricing strategies that consider the payer's ability to pay and by entering into collaboration with a public-private partnership. For example, Boehringer Ingelheim has entered into collaboration with The Defeat-NCD Partnership to improve access and affordability to its quality assured medicines across low resource countries. Practically, institutions are now able to procure these medicines through The Defeat-NCD Partnership's Essential NCD Supplies Facilities.

Has access strategies for some of its self-administered products for some countries in scope of this analysis. Boehringer Ingelheim has an average performance in this area. The company provides examples of access strategies in UMICs and LMICs for the five products assessed. It makes efforts to reach additional patients using pricing strategies that consider payers' ability to pay and additional access strategies. The company is able to provide evidence of patient reach for three products in UMIC and LMIC country examples provided.

One of the three manufacturing capacity building initiatives included meets all Good Practice Standards. Boehringer Ingelheim's performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In the initiative that meets all GPS, the company co-develops, and teaches, a comprehensive course on quality drug manufacturing in collaboration with the East China University of Science and Technology, Fudan University and the Shanghai Pharmaceutical School.

One of the three supply chain capacity building initiatives included meets all Good Practice Standards. Boehringer Ingelheim's performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all GPS than what is average for this indicator. Healthy Entrepreneurs manages a fully integrated end-to-end supply chain through training community health entrepreneurs on health and business in addition to how to educate and advise its customers.

Two of the four health systems strengthening initiatives included meet all Good Practice Standards. Boehringer Ingelheim's performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all GPS than what is average for this indicator. For example, the Pakistan-Rabies-Free Campaign is a health systems strengthening initiative done in collaboration with the Indus Hospital in Karachi that aims to involve communities in mass rabies vaccination campaigns and ultimately reduce the incidence of rabies in Pakistan. This initiative meets all GPS.

Has engaged in scaling up three and piloting two inclusive business models. Boehringer Ingelheim performs above average in the use of

inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Healthy Entrepreneurs social start-up trains over 8,000 entrepreneurs to enable them to sell healthcare products in remote villages and reaches more than 10 million individuals on a yearly basis.

Has an average performance in ensuring continuous supply of medicines in LMICs. Boehringer Ingelheim is involved in supply chain capacity building initiatives in LMICs. The company also has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, manages a buffer stock of relevant products and is involved in technology transfer initiatives. The company works with multiple active pharmaceutical ingredient suppliers for some products and otherwise keeps buffer stocks to mitigate supply risks.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Boehringer Ingelheim has a policy for reporting SF medicines to national regulatory authorities within seven days. It discloses to the Index, but not publicly, whether it has quicker reporting time frames for cases that only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Boehringer Ingelheim has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Boehringer Ingelheim is publicly committed to supporting the goal of zero human dog-mediated rabies deaths by 2030: it includes donating the rabies vaccine (Rabisin®) in six countries in scope of the Index.

RANK	SCORE
15	2.60
19 (2021)*	

Bristol Myers Squibb

Stock exchange: NYSC • Ticker: BMJ • HQ: New York, United States • Employees: 32,200

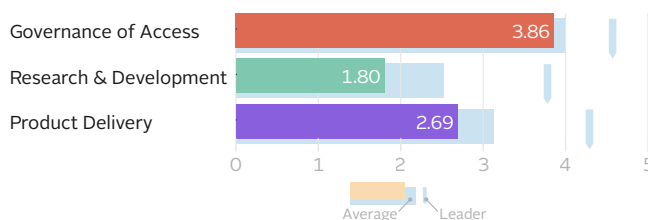
PERFORMANCE IN THE 2022 INDEX

15th place. Bristol Myers Squibb performs below average in two of three Technical Areas. The company has performed below average for access strategies, yet it performs strongly in health systems strengthening. It has improved in access planning in R&D but has a small-sized priority pipeline.

Governance of Access: 14th place. Bristol Myers Squibb has an average performance in this area. It has an access-to-medicine strategy integrated within the overall corporate strategy. It provides evidence of financial and non-financial access-related incentives at the executive level but does not disclose whether in-country managers or the CEO are also incentivised toward access goals.

Research & Development: 17th place. Bristol Myers Squibb performs poorly in this area. The company has a structured access planning process in place, but it does not apply this to all late-stage candidates. The company has an average performance in R&D capacity building.

How score was achieved



Product Delivery: 15th place. Bristol Myers Squibb has a below average performance in this area. The company has strengthened its performance in manufacturing capacity building by participating in technology transfers, yet its performance in equitable access strategies is below average for certain products. It engages in high quality health systems strengthening initiatives but lacks involvement in supply chain capacity building. The company has non-exclusive voluntary licensing agreements in place for two compounds to enable generic supply in LMICs.

OPPORTUNITIES FOR BRISTOL MYERS SQUIBB

Develop access-related incentives for senior management. Bristol Myers Squibb has an access strategy linked to sustainability goals, which includes all therapeutic areas in which the company is involved. Financial and non-financial incentives for the CEO and in-country managers can be tied to the achievement of the sustainability goals under their access strategy. The incentives can also be oriented toward long-term goals.

Ensure all late-stage R&D projects have comprehensive access plans. Bristol Myers Squibb can develop access plans for all projects from Phase II of clinical development. The company has plans in place for 73% of late-stage projects. These plans primarily consist of commitments to registering products in countries where clinical trials for that product have been conducted. Access plans for nivolumab (Opdivo®) and pomalidomide (Pomalyst®), indicated for multiple cancer types, can also include additional access components such as equitable pricing.

Improve access to on-patent cancer drugs on WHO Model List of Essential Medicines (EML). Bristol Myers Squibb has four on-patent products on the WHO EML, including dasatinib (Sprycel®), a product indicated for imatinib-resistant chronic myeloid leukaemia. The company provides access to dasatinib in at least one upper-middle income country via an equitable pricing strategy and to low-income countries and lower-middle income countries via the Max Foundation donation programme. Bristol Myers Squibb can expand access to the product via registration, equitable pricing and non-exclusive voluntary licensing agreements in more countries, especially those where the burden of disease is the highest, such as Afghanistan, Haiti and Ethiopia.

CHANGES SINCE THE 2021 INDEX

- Launched the first ever Global Access Report, which highlights Bristol Myers Squibb' efforts and progress towards advancing access to healthcare and health equity globally.
- Newly demonstrates evidence that sales agent incentives are decoupled from sales volume targets.
- Introduced a structured framework to include access planning in all its pipeline projects.
- Started a new capacity building initiative with multiple partners to support sustainable and effective administration of innovative therapies for the treatment of cancer in LMICs.
- Newly licensed the >4000-member library to Medicines for Malaria Venture (MMV) in addition to donating USD 1 million to support the missions of both MMV and Drugs for Neglected Diseases *initiative* (DNDi).
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.
- Acquired a global exclusive license to develop, manufacture and commercialise Rockefeller's novel monoclonal antibody duo treatment against COVID-19.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.
*In the 2021 Index, dense ranking was used. In the 2022 Index, standard

competitive ranking is used. Therefore, a direct comparison with Bristol Myers Squibb's previous rank is not possible.

SALES AND OPERATIONS

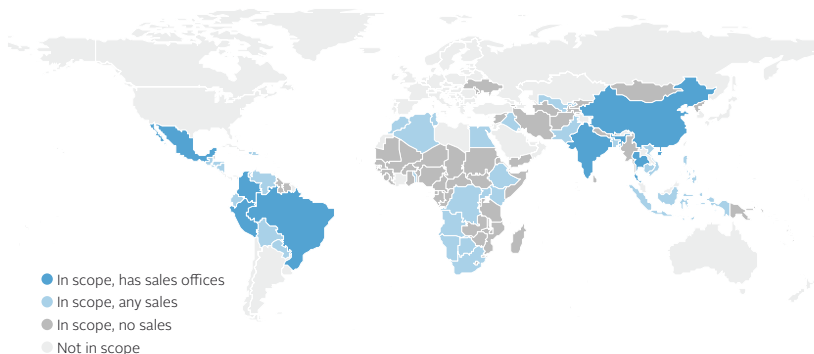
Business segments: Pharmaceutical.
Therapeutic areas: Cardiovascular disease, fibrotic disease, haematology, immunology and oncology.
Product categories: Innovative medicines.
M&A news: Bristol Myers Squibb acquired Turning Point Therapeutics in June 2022 for USD 76.00 per share.

Bristol Myers Squibb's products are sold in **38 out of 108 countries in scope of the Index**. Bristol Myers Squibb has sales offices in 7 countries, and sells via suppliers and/or pooled procurement in an additional 31 countries.

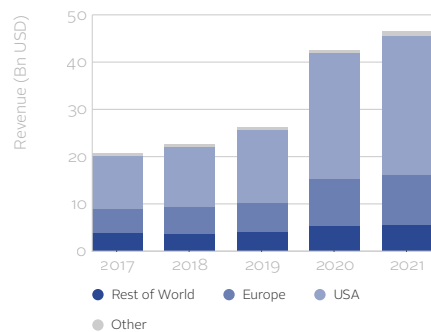
Revenue by segment (2021) – in USD

Pharmaceutical	46.39 bn
Total	46.39 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

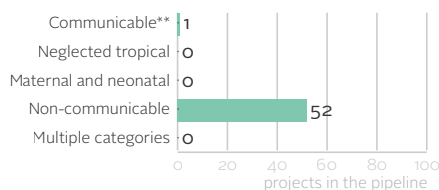
PIPELINE for diseases in scope

Bristol Myers Squibb has a total of 53 R&D projects in scope with one project targeting a priority disease. This project targets COVID-19. The other 52 R&D projects target other diseases in scope. These projects mainly focus on oncology (47 projects). Eleven R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (10)* Evidence of access planning was in place for 73% of these projects: none targeting a priority disease and eight addressing a public health need in LMICs.

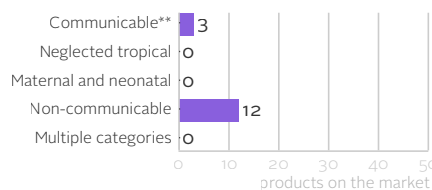
PORTFOLIO as selected for analysis by the Index

Bristol Myers Squibb has 15 medicines in scope, 12 of which are on patent. 33% of these medicines (5) are on the WHO EML. The off-patent medicines target mainly non-communicable diseases such as cancer (2) and thalassaemia (1). The on-patent medicines mainly target cancer (9), HIV/AIDS (2) and viral hepatitis C (1).

53 projects in the pipeline



15 products as selected for analysis by the Index*



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	0	1	0	0	0	1
Addresses needs of LMICs*			4	3	5	2	0	14
Other projects in scope			25	10	2	1	0	38

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	4	8			12
off patent	1	2			3
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other†				0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
 ‡Other includes vector control products.

Bristol Myers Squibb

GOVERNANCE OF ACCESS

RANK 14

SCORE 3.86

Has an access-to-medicine strategy with measurable objectives. Bristol Myers Squibb performs strongly. Its strategy is fully integrated within the overall corporate strategy and covers all of the therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, with the Board Chair and CEO responsible for final decisions regarding the development of each product's access strategy and programs.

Provides evidence of financial and non-financial access-related incentives at the executive level.

Bristol Myers Squibb performs below average. It incentivises its senior executives to take action on access to medicine with financial and non-financial rewards. It does not disclose, however, whether in-country managers or the CEO are also incentivised toward access goals.

Publicly discloses outcomes its access-to-medicine activities.

Bristol Myers Squibb performs strongly in transparency of access activities. It publicly discloses commitments, measura-

ble goals, objectives and sustainability targets, including enhancing patient access to medicines. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Global Access Report.

Performs above average in responsible promotional practices. Bristol Myers Squibb's sales agents are not solely incentivised on sales volume. However, the level at which sales targets are set varies at the individual, team, business unit, national and global level, as well as by therapeutic area. It publicly discloses information related to transfers of value to healthcare professionals in countries in scope of the Index (e.g., payments for attending events or promotional activities) in accordance with laws and regulations.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

Bristol Myers Squibb performs strongly, demonstrating evidence of all components looked for by

the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure compliance with company standards by third parties. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health.

Bristol Myers Squibb does not publicly share any support of the Doha Declaration on TRIPS and Public Health. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Bristol Myers Squibb, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 17

SCORE 1.80

Access planning processes encompass all projects in the pipeline.

Bristol Myers Squibb has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. The phase at which access planning begins depends on the product.

A small-sized priority R&D pipeline compared to its peers, with no access plans in place.

Bristol Myers Squibb has one late-stage candidate in its pipeline that targets a priority product gap. This is the clinical development of abatacept (Orencia®) to treat COVID-19. Bristol Myers Squibb did not submit evidence of an access plan for this project.

Some projects address a public health need in LMICs,* with 80% (8/10) of late-stage projects covered by access plans.

In this analysis,

Bristol Myers Squibb has ten late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. Most target cancer. These plans primarily relate to Bristol Myers Squibb's commitment to register in the countries where it is carrying out clinical trials. Therefore, plans for registration in countries within scope of the Index apply to eight pipeline projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.

Bristol Myers Squibb does not disclose disaggregated R&D investment data to global health organisations.

One R&D capacity building initiative included for analysis meets all Good Practice Standards.

Bristol Myers Squibb's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. Bristol Myers Squibb supports the sustainable and effective administration of innovative therapies for the treatment of cancer in LMICs through its Innovative Cancer Medicines (ICM) partnership with the Parker Institute for Cancer Immunotherapy and the Clinton Health Access Initiative.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 15

SCORE 2.69

No public commitment not to enforce patents in countries in scope. Bristol Myers Squibb does not have a public commitment not to file or enforce patents in LMICs. Bristol Myers Squibb commits to ensure that its patents do not prevent inexpensive HIV/AIDS therapy in resource-constrained countries and regions such as sub-Saharan Africa and India.

Publicly discloses information on patent status. Like most of its peers, Bristol Myers Squibb discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Bristol Myers Squibb discloses this information also in other websites regarding a subset of products.

Is an average-performing company in terms of sharing intellectual property (IP) assets with third-party researchers. Bristol Myers Squibb engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. Bristol Myers Squibb has non-exclusive voluntary licensing agreements in place for two compounds (for the diseases in scope). Its broadest licence, for atazanavir sulfate (Reyataz®), encompasses 97 countries within the scope of the Index, including 71 middle-income countries.

Filed to register new products in four countries in scope on average. Bristol Myers Squibb did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely filed is lenalidomide (Revlimid), for non-Hodgkin lymphoma, filed for registration in 20 countries in scope of the Index, including three high burden countries (Bolivia, Ecuador and Peru). Eight out of its ten products analysed have been filed for registration in one LIC.

Has access strategies for its supranationally procured product in scope for this analysis. Bristol Myers Squibb has an average performance in securing access for its product procured supranationally. The company demonstrates strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, it provides atazanavir sulfate (Reyataz®) at a not-for-profit price through a supranational agreement with The Global Fund. Bristol Myers Squibb has also signed a non-voluntary licensing agreement with the Medicine Patent Pool (MPP) to facilitate access to 97 countries in scope of the Index, including Algeria, a

country non-eligible to benefit from The Global Fund supranational procurement agreement. The company provides evidence of patient reach, reporting that through the MPP license, 2.1 million patients per year were reached.

Has few access strategies for its health-care practitioner-administered products in scope of this analysis. Bristol Myers Squibb performs below average in this area. It provides evidence of access strategies in UMICs and LMICs for three products assessed. For example, in China, it ensured the inclusion of two cancer drugs nivolumab (Opdivo®) and ipilimumab (Yervoy®) on private insurance lists. To maximise patient reach, Bristol Myers Squibb works with a charity organisation, Cancer Foundation of China, to implement a patient assistance programme whereby Bristol Myers Squibb shares the medicines' costs with the patient. Evidence of an increase in patient reach through these approaches is available.

Has few access strategies for its self-administered products for some countries in scope of this analysis. Bristol Myers Squibb performs below average in this area. It provides evidence of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the two products assessed, dasatinib (Sprycel®), an oncology medicine. Bristol Myers Squibb demonstrated to consider relevant payers' ability to pay by securing public reimbursement of dasatinib and lenalidomide (Revlimid®) in Mexico and Morocco respectively, where public coverage is approximately 83% and 30% of the population. Evidence that demonstrates patient reach through these approaches is available.

The one manufacturing capacity building initiative included for analysis meets all Good Practice Standards. Bristol Myers Squibb's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. From 2011 until February 2022, the company was involved in a technology transfer agreement to expand access to atazanavir sulfate (Reyataz®) in Brazil.

No supply chain capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Bristol Myers Squibb's performance is below average in this area.

All five health systems strengthening initiatives included for analysis meet all Good Practice Standards. Bristol Myers Squibb is one

of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, the company collaborates with University Research Co. (URC) on the Multinational Lung Cancer Control Program — a lung cancer programme implemented in seven countries to improve access to early diagnosis by addressing barriers to care.

Has no inclusive business models that meet all inclusion criteria. There is no evidence that Bristol Myers Squibb has engaged in the piloting or scale-up of any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Bristol Myers Squibb performs below average in this area.

Shows average performance in terms of ensuring continuous supply of medicines in LMICs. Bristol Myers Squibb manages a buffer stock of relevant products, is involved in technology transfers to local manufacturers in LMICs, and shows evidence of working with stakeholders to communicate issues that may impact the supply chain. The company does not show evidence of efforts to work with multiple active pharmaceutical ingredient suppliers or engage in supply chain capacity building initiatives that meet inclusion criteria for evaluation.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Bristol Myers Squibb has a policy for reporting SF medicines to relevant health authorities within the timeframe of ten days looked for by the Index. There is no evidence found publicly of a shortened timeframe for reporting cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Bristol Myers Squibb has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows some evidence of monitoring the delivery of donations.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, the company is engaged in another structured donation programme: the Max Access Solutions programme where it donates dasatinib (Sprycel®) for leukaemia to 29 countries since 2017.

RANK	SCORE
17	2.20
16 (2021)*	

Daiichi Sankyo Co, Ltd

Stock exchange: TSE • Ticker: 4568 • HQ: Tokyo, Japan • Employees: 16,033

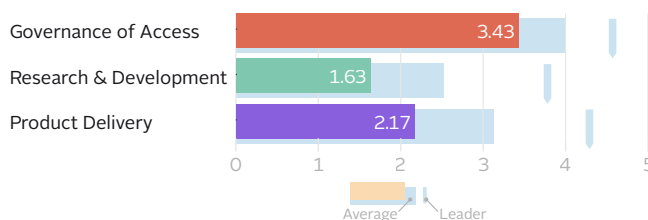
PERFORMANCE IN THE 2022 INDEX

17th place. Daiichi Sankyo is in the lower ranks across all Technical Areas. It has a weak performance in responsible promotional practices and implementation of compliance controls. Furthermore, the company lacks access strategies for the majority of its products assessed. However, it performs well in health systems strengthening.

Governance of Access: 15th place. Daiichi Sankyo performs below average in this area. It has an integrated access-to-medicine strategy, but it provides very little information related to responsible promotional practices and lacks some compliance controls, namely a continuous system to monitor activities, fraud-specific risk assessment and a country risk-based assessment to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 18th place. Daiichi Sankyo performs poorly in this area. It has a general access planning process in place and applies this to a subset of pipeline projects. The company has an average-sized priority pipeline and has

How score was achieved



access plans in place for most late-stage candidates. However, it does not engage in R&D capacity building.

Product Delivery: 17th place. Daiichi Sankyo performs poorly in this area. The company has a strong commitment not to enforce or file patents in the majority of the countries in scope (including low- and lower-middle income countries). It applies a few access strategies, yet only in upper-middle income countries. It has shown evidence of technology transfer initiatives and high-quality health systems strengthening initiatives yet does not engage in supply chain capacity building.

OPPORTUNITIES FOR DAIICHI SANKYO

Ensure that governance structures do not vary across subsidiaries. Daiichi Sankyo's current governance structures related to responsible promotional practices and substandard and falsified medicines vary by subsidiary. It can ensure that such governance structures apply across all subsidiaries. This includes its approach to decoupling of sales targets from sales volume, policies that address responsible interactions with and appropriate payments to healthcare professionals and policies that address the timely reporting of confirmed cases of substandard and falsified medicines to health authorities.

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. Daiichi Sankyo can continue to improve access planning by developing a structured access planning framework. The company has access plans in place for 75% of late-stage R&D projects. It can apply access plans to all projects in the pipeline from Phase II onwards.

Improve access to patented cardiovascular products on the WHO Model List of Essential Medicines (EML). Daiichi Sankyo has two patented products on the WHO EML, edoxaban (Lixiana®), indicated for ischaemic heart disease and stroke, and amlodipine/olmesartan medoxomil (Azor®/Sevikar®), for hypertensive heart disease. The company has an equitable access strategy for edoxaban that covers UMICs. Daiichi Sankyo can further expand access to both this product and to amlodipine/olmesartan medoxomil via registration, equitable pricing and/or non-exclusive voluntary licensing in lower-income countries and high burden countries such as the Republic of Moldova.

CHANGES SINCE THE 2021 INDEX

- Appointed a Head of Access to Healthcare who is responsible for improving access to healthcare and addressing and resolving issues related to access.
- Incorporated improving access to healthcare as a materiality in its current mid-term plan.
- Established an Emerging and Re-emerging Infectious Diseases Research Special Team (EReDS) to address emerging and re-emerging infectious diseases.
- Participated in the AMR Action Fund, which was established to support the clinical development of new antimicrobial agents and to achieve a sustainable antimicrobial market, with a total contribution of USD 20 million.
- Implemented a general access planning framework for a subset of its R&D pipeline.
- Launched two new initiatives in Nepal and Zimbabwe to address breast and cervical cancer care and awareness.
- Signed a joint research agreement and will share its compound libraries with the non-profit public-private partnership Medicines for Malaria Venture (MMV) to screen compounds against new *Plasmodium* biological targets.
- Signed a joint research agreement with the non-profit public-private partnership Drugs for Neglected Diseases initiative (DNDi) to screen compounds against *Trypanosoma cruzi*. Daiichi Sankyo provided a library of 35,000 compounds.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.
*In the 2021 Index, dense ranking was used. In the 2022 Index, standard

competitive ranking is used. Therefore, a direct comparison with Daiichi Sankyo's previous rank is not possible.

SALES AND OPERATIONS

Business segments: Healthcare (OTC) products, prescription drugs and other.

Therapeutic areas: Cell therapy, central nervous system diseases, oncology, rare diseases, vaccines and other disease areas.

Product categories: Consumer health products, generic drugs, innovative medicines and vaccines.

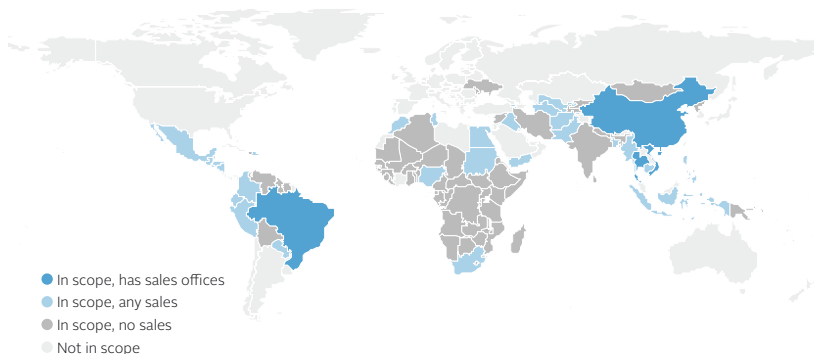
M&A news: None since May 2020.

Daiichi Sankyo's products are sold in 35 out of 108 countries in scope of the Index. Daiichi Sankyo has sales offices in four countries, and sells via suppliers and/or pooled procurement in an additional 31 countries.

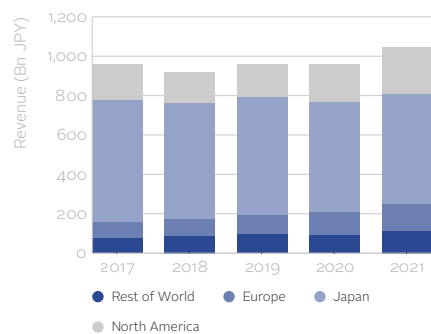
Revenue by segment (2021) – in JPY

Prescription drugs	977.98 bn
Healthcare (OTC) products	64.70 bn
Other	2.20 bn
Total	1,044.89 bn

Sales in countries in scope



Sales by geographic region



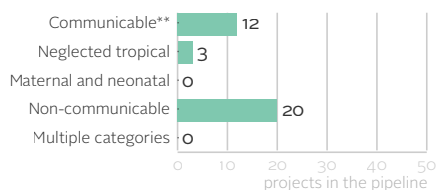
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Daiichi Sankyo has a total of 35 R&D projects in scope with 16 of these projects targeting priority diseases. The other 19 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on lower respiratory infections (three projects), Chagas disease (2), malaria (2) and tuberculosis (2). Of the projects targeting other diseases, the focus is on oncology (15).

Four R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (3).^{*} Evidence of access planning was in place for 75% of these projects: one targeting a priority disease and two addressing a public health need in LMICs.

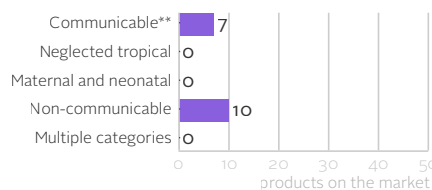
35 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Daiichi Sankyo has 12 medicines in scope, nine of which are on patent. 33% of these medicines (4) are on the WHO EML. In addition, the company markets three diagnostics and two vaccines. The off-patent medicines target mainly non-communicable diseases (NCDs) such as hypertensive heart disease (1) and ischaemic heart disease (1), and a communicable disease, lower respiratory infections (1). The on-patent medicines mainly target NCDs, such as hypertensive heart disease (3), ischaemic heart disease (2) and cancer (2). Daiichi Sankyo's preventative vaccines target tetanus and pertussis. The diagnostics in scope are for tuberculosis (3).

17 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	11	3	0	0	1	0	1	16
Addresses needs of LMICs [*]			3	2	1	0	0	6
Other projects in scope			4	5	3	1	0	13

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	7			9
off patent	2	1			3
Vaccines	2	0			2
Contraceptives	0	0			0
Diagnostics			3		3
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. ^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Daiichi Sankyo Co, Ltd

GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Daiichi Sankyo performs well. Its strategy is focused on expanding medical access to oncology products, with a key theme of the strategy being "how to deliver oncology products around the world". The strategy covers some of the therapeutic areas the company is involved in, but mainly focuses on oncology products. The highest responsibility for access is indirectly with the board, with its Global Management Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Daiichi Sankyo performs well. It incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards, as part of its CSR goals. The CEO also has access-related incentives.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Daiichi Sankyo

performs average in transparency of access activities. It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope of the Index, namely with its capacity building initiatives. It shares the outputs of a subset of its capacity building initiatives, although it does so in a centralised manner directly on its website.

Performs below average in responsible promotional practices. Daiichi Sankyo's policies governing promotional practices vary by subsidiary. It does not publicly disclose whether sales agents are solely incentivised on sales volume targets and not other targets, nor the level at which sales incentives are set. It does not disclose whether it shares information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), nor does it disclose a policy limiting such transfers.

Has some compliance controls to ensure that

governance efforts are not undermined by non-compliant or corrupt activities. Daiichi Sankyo performs below average, demonstrating evidence of some components looked for by the Index: audits and formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of a continuous system to monitor activities, fraud-specific risk assessment or country risk-based assessment. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Daiichi Sankyo publicly shares a general statement on the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, stating that the use of compulsory licensing should be carefully exercised. As a member of the industry association, Daiichi Sankyo, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 18

SCORE 1.63

Access planning processes encompass some projects in the pipeline. Daiichi Sankyo has a general process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects for diseases in scope of the Index.

An average-sized priority R&D pipeline compared to peers, with an access plan in place for its late-stage candidate. Daiichi Sankyo has 16 projects, including one late-stage candidate, in its pipeline that target a priority product gap. These projects target several diseases. Daiichi Sankyo's late-stage candidate is supported by an access plan.

Some projects address a public health need in LMICs,* with 67% (2/3) of late-stage candidates covered by access plans. In this analysis, Daiichi Sankyo has three late-stage R&D projects in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules. Most target cancer. Daiichi Sankyo provides evidence of access plans for two of these projects.

Does not publicly disclose R&D investment data disaggregated by disease category, prod-

uct type or phase of development. However, Daiichi Sankyo does disclose fully disaggregated R&D investment data to Policy Cures Research.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Daiichi Sankyo's performance is below average in this area.

PRODUCT DELIVERY

RANK 17

SCORE 2.17

Public commitment not to enforce patents in countries in scope. Daiichi Sankyo publicly commits to neither file for nor enforce patents. This commitment applies in sub-Saharan African countries (with the exception of South Africa), Least Developed Countries and LICs, and in a subset of LMICs and UMICs.

Publicly discloses information on patent status. Like most of its peers, Daiichi Sankyo publicly discloses the patent statuses for small mole-

cules in scope via the Pat-INFORMED database. It discloses patent information such as filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Daiichi Sankyo engaged in three new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The

company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Daiichi Sankyo does not engage in voluntary licensing for products in scope of the Index.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

Filed to register one new product in one country in scope. Daiichi Sankyo did not disclose evidence of filing for registration any of its new products in any of the top ten high burden countries. Its most widely filed product, edoxaban (Lixiana®) indicated for stroke prevention among other uses as an anticoagulant, has been filed for registration in 12 countries within the scope of the Index, including three high burden disease countries (China, Indonesia and Vietnam). None of its eligible products are filed for registration in LICs.

Daiichi Sankyo is not eligible for assessment of supranationally procured products.

Has an access strategy for a country in scope of the analysis for its healthcare-practitioner-administered products. Daiichi Sankyo performs below average in this area. The company provides data on access strategies for the cancer drug trastuzumab deruxtecan (ENHERTU®) applied in two UMICs. Evidence of patient reach is not available.

Has few access strategies for its self-administered products for some countries in scope for this analysis. Daiichi Sankyo performs below average in this area. The company provides examples of access strategies in UMICs for four of the five products assessed, including efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, the company secured national reimbursement of one product and provides evidence of meeting national payer price expectations. Patient reach is provided for two access strategies in UMIC countries, but the company does not provide examples in LMICs or LICs for any of the products.

One of the two manufacturing capacity building initiatives included meets all Good Practice Standards. Daiichi Sankyo's performance is average in this area. The number of initiatives meeting

all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In the initiative that meets all GPS, which was active from 2002 until 2020, the company worked to strengthen Vietnam's capacity to produce vaccines through the POLYVAC project.

No supply chain capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Daiichi Sankyo's performance is below average in this area.

All three health systems strengthening initiatives included for analysis meet all Good Practice Standards. Daiichi Sankyo's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average but an average number of initiatives meet all GPS for this indicator. For example, through the company's new initiative in Nepal, Daiichi Sankyo expands screening services and improves resident knowledge about breast and cervical cancers through screening camps and public awareness activities. This initiative meets all GPS.

Has no inclusive business models that meet all inclusion criteria. There is no evidence that Daiichi Sankyo has engaged in the piloting or scale-up of any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Daiichi Sankyo performs below average in this area.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Daiichi Sankyo does not show evidence of its involvement in supply chain capacity building initiatives meeting inclusion criteria for evaluation.

However, the company does have a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and transfers technology to local manufacturers in LMICs.

Has procedures in place for reporting substandard and falsified (SF) medicines for several countries in scope of the Index in less than ten days. Daiichi Sankyo provides evidence of reporting SF medicines to relevant national health authorities within five days depending on the region. The company reports aiming at reporting within three days if the case presents a serious risk. Depending on the subsidiary, it provides evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Daiichi Sankyo has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows some evidence of monitoring the delivery of donations.

Has no long-term donation programmes for neglected tropical diseases (NTDs) or malaria that are eligible for analysis under this indicator. Daiichi Sankyo is not engaged in any structured donation programmes for NTDs or malaria where elimination, eradication or control goals are possible and that are eligible for analysis under this indicator.

RANK	SCORE
12	2.95
11 (2021)	

Eisai Co, Ltd

Stock exchange: TSE • Ticker: ESALY • HQ: Tokyo, Japan • Employees: ~10,000

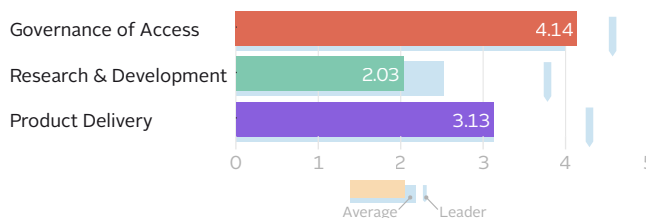
PERFORMANCE IN THE 2022 INDEX

12th place. Eisai has an average performance. The company has an average performance in access strategies for products on the market. Eisai engages in R&D for priority diseases, but the majority of late-stage pipeline projects do not have an access plan. It performs well by having processes in place to ensure the continuous supply of medicines in LMICs.

Governance of Access: 10th place. Eisai has an average performance in this area. It has a clear access-to-medicine strategy that is integrated into its overall corporate strategy, although the strategy does not fully extend across its pipeline and portfolio. It also has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, but it shares the outcomes of its access-to-medicine activities for only a subset of initiatives.

Research & Development: 14th place. Eisai has a below average performance in this area. It has an average-sized priority pipeline, but only applies access plans to a small number of

How score was achieved



late-stage candidates. It has an average performance in R&D capacity building.

Product Delivery: 13th place. Eisai has an average performance in this area. It has access strategies in place for most of its products in upper-middle and lower-middle income countries. The company engages in high-quality supply chain capacity building but has a comparatively poor performance in terms of health systems strengthening and manufacturing capacity building.

OPPORTUNITIES FOR EISAI

Ensure all late-stage R&D projects have comprehensive access plans. Eisai has a structured process in place for R&D access planning that encompasses some projects in the pipeline. The company has access plans in place for 14% of late-stage projects analysed. These plans are for projects developed in partnership with DNDi. Eisai can apply access plans to all projects in the pipeline from Phase II onwards, for example, lecanemab for Alzheimer's disease.

Expand registration of epilepsy medicines. Eisai has one of the largest portfolios of on-patent antiepileptic products among the companies in scope. Its antiepileptic perampanel (Fycompa®) is currently not registered in any of the ten countries in scope with the highest burden of epilepsy. The company can register this product in those countries, including Guyana and Haiti.

Expand access strategies to reach populations in low-income countries. For its breast cancer treatment eribulin (Halaven®), Eisai deploys equitable access strategies and patient assistance programmes in at least two lower-middle income countries. The company can expand such strategies to low-income countries and other countries with a high burden of breast cancer, such as Armenia, Papua New Guinea and Morocco.

Expand supply chain capacity building to more disease areas. Eisai has one existing supply chain capacity building initiative that meets all Good Practice Standards, focusing on neglected tropical diseases. The company can work with local partners to expand its capacity building efforts to more diseases the company focuses on, such as epilepsy, in countries that have a high burden of disease, including Uganda.

CHANGES SINCE THE 2021 INDEX

- Established a pharmaceutical sales subsidiary in Vietnam.
- Signed the Kigali Declaration, the successor to the London Declaration, in June 2022, positioning neglected tropical diseases as an important area of focus.
- Participated in the AMR Action Fund, which was established to support the clinical development of new antimicrobial agents and to achieve a sustainable antimicrobial market, in collaboration with more than 20 leading pharmaceutical companies.
- Supported a project led by CA Medlynks which aims to build a new structure for the efficient testing framework for COVID-19 in Kenya through the setup of PCR testing laboratories, along with procurement of equipment necessary for testing and training of screening technicians.
- Expanded the long-term donation programme of diethylcarbamazine tablets to combat lymphatic filariasis in Nepal.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Pharmaceutical business and other business.

Therapeutic areas: Oncology and neurology.

Product categories: Innovative medicines.

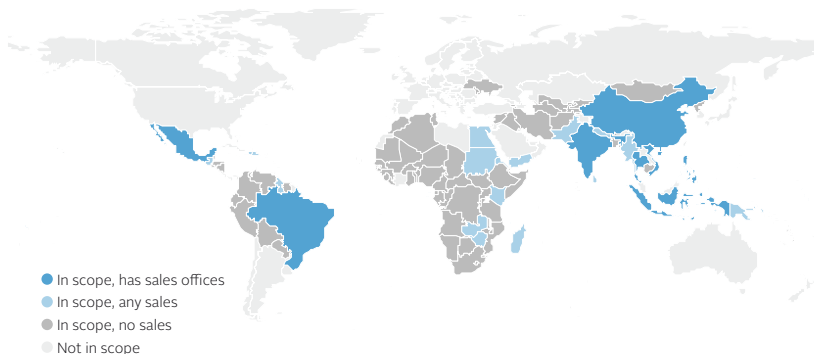
M&A news: Eisai acquired Arteryx Inc. in April 2022.

Eisai's products are sold in 33 out of 108 countries in scope of the Index. Eisai has sales offices in 8 countries, and sells via suppliers and/or pooled procurement in an additional 25 countries.

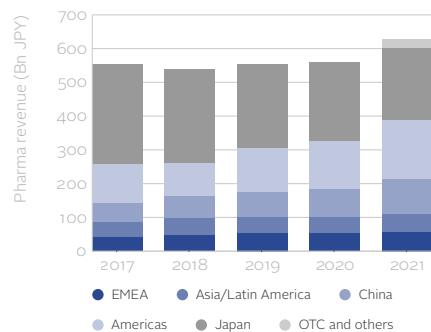
Revenue by segment (2021) – in JPY

Pharmaceutical business	626.28 bn
Other business	129.95 bn
Total	756.23 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

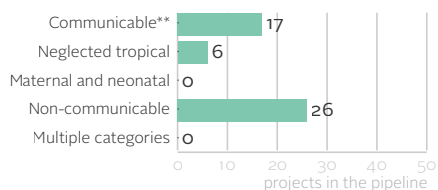
PIPELINE for diseases in scope

Eisai has a total of 49 R&D projects in scope with 23 of these projects targeting priority diseases. The other 26 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (13 projects). Of the projects targeting other diseases, the focus is on Alzheimer's disease (6) and oncology (18). Fourteen R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (11).^{*} Evidence of access planning was in place for 14% of these projects: one targeting a priority disease and one addressing a public health need in LMICs.

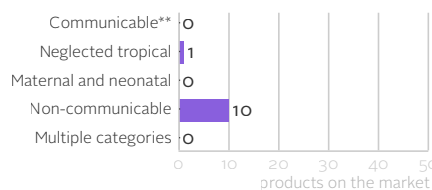
PORTFOLIO as selected for analysis by the Index

Eisai has 11 medicines in scope, six of which are on patent. 18% of the medicines (2) are on the WHO EML. The off-patent medicines (5) mainly target mental health (2). One product targets the neglected tropical disease lymphatic filariasis and one further product is for cardiovascular diseases. The on-patent medicines mainly target epilepsy (3) and oncology (2). In addition, one product is for Alzheimer's disease.

49 projects in the pipeline



11 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	10	9	1	1	2	0	0	23
Addresses needs of LMICs [*]			3	3	4	4	1	15
Other projects in scope			8	3	0	0	0	11

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	0	6			6
off patent	2	3			5
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. ^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Eisai Co, Ltd

GOVERNANCE OF ACCESS

RANK 10

SCORE 4.14

Has an access-to-medicine strategy with measurable objectives. Eisai has an above average performance. Its strategy is fully integrated within the overall corporate strategy and states a commitment to long-term sustainability solutions, including affordable pricing. It covers some of the therapeutic areas in which the company is involved, including Alzheimer's disease and cancer. The highest responsibility lies directly with the board.

Provides evidence of financial and non-financial access-related incentives at the executive level.

Eisai performs well. It incentivises its in-country managers, including country-level corporate officers or regional managers, to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives, linked, for example, to initiatives aiming at eliminating neglected tropical diseases (NTDs).

Publicly discloses outcomes of a subset of its access-to-medicine activities.

Eisai performs average in transparency of access activities. It discloses its commitments, measurable goals, objectives and targets for improving access to

medicine in countries in scope of the Index. It shares the outcomes of its access-to-medicine activities for a subset of initiatives, although it does so in a centralised manner in its Value Creation Report and directly on its website, including outcomes of activities supporting the elimination of NTDs such as lymphatic filariasis.

Performs above average in responsible promotional practices.

Eisai's sales agents are not solely incentivised on sales volume targets. Sales agent incentives are set at the individual, team and country levels. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by local regulations. The company has a country-specific policy limiting transfers of values to healthcare professionals.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

Eisai performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, a continuous

system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates), formal processes to ensure third-party compliance with company standards and country risk-based assessments. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health.

Eisai publicly shares support of the Doha Declaration on TRIPS and Public Health, highlighting that Article 31b (covering the use of compulsory licences) provides balance between the protection of both IP and public health under appropriate circumstances. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Eisai, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 14

SCORE 2.03

Access planning processes encompass some projects in the pipeline. Eisai has a structured process in place to develop access plans during R&D. The process is intended to be applied to a subset of R&D projects (both in-house and collaborative) for diseases in scope of the Index.

An average-sized priority R&D pipeline compared to peers, with 33% (1/3) of late-stage candidates supported by access plans.

Eisai has 23 projects including three late-stage candidates in its pipeline that target a priority product gap. The company's priority pipeline focuses mostly on malaria. Of Eisai's three late-stage candidates targeting a priority product gap, there is evidence of an access plan for one. This access plan for fosravuconazole as a treatment for patients with eumycetoma is in partnership with the Drugs for Neglected Diseases *initiative* (DNDi).

Many projects address a public health need in LMICs,* with 9% (1/11) of late-stage candidates covered by access plans.

In this analysis, Eisai has 11 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. The projects mainly focus on cancer and Alzheimer's disease. Eisai provides evidence of an access plan for one of the late-stage candidates. This plan concerns registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.

However,

Eisai does disclose fully disaggregated R&D investment data to Policy Cures Research.

One of the two R&D capacity building initiatives included meets all Good Practice Standards.

Eisai's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. Notably, Eisai partners with Seeding Labs to improve access to laboratory equipment for the scientific community in countries in scope of the Index. This initiative meets all GPS.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 13

SCORE 3.13

Public commitment not to enforce patents in countries in scope. Eisai publicly pledges to neither file for nor enforce patents in all Least Developed Countries and LICs. This commitment applies to infectious diseases, neglected tropical diseases and maternal and neonatal diseases.

Publicly discloses information on patent status. Like most of its peers, Eisai publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Eisai discloses patent information such as filing date, grant number, grant date and jurisdiction.

Is an average-performing company in terms of sharing intellectual property assets with third-party researchers. Eisai engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Eisai does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

No evidence of filing for registration its new product in any country in scope. Eisai did not disclose evidence of filing for registration its new product in any of the top ten high burden countries. Among old products, its most widely filed product, eribulin (Halaven®), indicated for breast cancer, has been filed for registration in 31 countries within scope of the Index, including three high burden disease countries, such as Morocco and Pakistan. Eisai filed two of its seven products assessed in one LIC.

Eisai is not eligible for assessment of supranationally procured products.

Has access strategies for the healthcare practitioner-administered product in scope of this analysis. Eisai performs above average in this area. The company provides examples of access strategies which consider affordability in both a UMIC and an LMIC for the only product assessed, including efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, Eisai obtained national reimbursement in China for eribulin (Halaven®), a breast cancer medicine as well as implemented

a patient assistance programme to reach additional patients. In India, Eisai company has a licensing agreement with Viartis to allow second brand manufacturing and increase access in the country. The company provides evidence of how patient reach has been increased through these approaches in India.

Has access strategies for its self-administered products for some countries in scope for this analysis. Eisai has an average performance in this area. The company provides examples of access strategies in UMICs and LMICs for all three products assessed, including efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, Eisai implemented the lenvatinib (Lenvima®) Easy Access Program (LEAP) in the Philippines, which offers two free boxes for every purchase of one box (of the same dose) to all patients regardless of their income since May 2017. The company provides evidence of how patient reach has been increased through these approaches.

Two manufacturing capacity building initiatives included for analysis. Neither manufacturing capacity building initiative included for analysis meets all Good Practice Standards (GPS). Eisai's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. In one of the included initiatives, since 2013 Eisai has built and improved pharmaceutical manufacturing capacity of an Indian local manufacturer, Saurav, to supply diethylcarbazine for lymphatic filariasis elimination.

The one supply chain capacity building initiative included for analysis meets all Good Practice Standards. Eisai's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. NTD Supply Chain Forum is a multi-partner initiative that aims to deliver the drugs of neglected tropical diseases for donations from the first to last mile and tracks progress and logistics improvement of operations in countries in scope of the Index.

Three health systems strengthening initiatives included for evaluation. None of the three health systems strengthening initiatives included for analysis meet all GPS. Eisai's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than

what is average for this indicator. One example of an initiative included for evaluation is the partnership with CA Medlynks Kenya and the government of Meru County to construct a screening framework for COVID-19 in Kenya.

Has engaged in piloting one inclusive business model but has not shown evidence of its involvement in scaling up any existing inclusive business models that meet all inclusion criteria. Eisai performs below average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The One-stop Online Service Platform: Yin Fa Tong in partnership with JD Health is a joint venture that aims to create a new solution that provides medical, health, and lifestyle services specifically for the elderly, especially those with dementia and their families.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Eisai is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Eisai has a policy for reporting SF medicines to national health authorities and the WHO within 24 hours to seven days. It provides evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed based on the Risk Evaluation Committee.

Donates in response to expressed need and monitors delivery. Eisai has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Since 2013, Eisai publicly commits itself to eliminating lymphatic filariasis by donating diethylcarbazine tablets in 25 countries in scope of the Index for an unlimited period of time.

RANK	SCORE
20	1.79
18 (2021)*	

Eli Lilly & Co

Stock exchange: NYSE • Ticker: LLY • HQ: Indianapolis, Indiana, United States • Employees: ~35,000

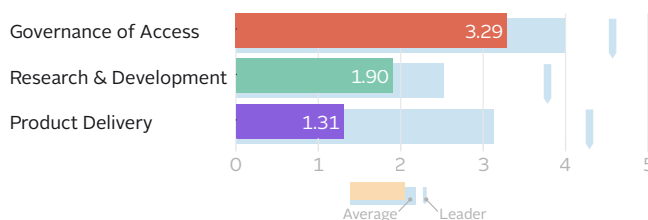
PERFORMANCE IN THE 2022 INDEX

20th place. Eli Lilly is in the lower ranks across all Technical Areas. The company has a small priority R&D pipeline and has no structured process for access planning during R&D. Its Governance of Access policies are comparatively poor, with no publicly-available evidence found of responsible promotional practices and top-level incentivisation to achieve access-related goals.

Governance of Access: 19th place. Eli Lilly performs poorly in this area. It has an access-to-medicine strategy centred around its Lilly 30x30 programme and publicly discloses outcomes of its access-to-medicine initiatives, but it discloses little information related to responsible promotional practices and lacks evidence of access-related incentives for its senior executives and in-country and regional managers as well as some compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 16th place. Eli Lilly performs below average in this area. Eli Lilly does not have an access planning

How score was achieved



framework in place for R&D projects. It has a small-sized priority pipeline compared its peers, with plans for registration for most late-stage pipeline candidates. Eli Lilly does not participate in R&D capacity building.

Product Delivery: 20th place. Eli Lilly performs poorly in this area. It does not disclose, neither publicly nor to the Index, access strategies for its products nor examples of manufacturing and supply chain capacity building initiatives. However, the Index identified several high-quality health systems strengthening initiatives in which the company participates. The company has a non-exclusive voluntary licensing agreement in place for one compound.

OPPORTUNITIES FOR ELI LILLY

Review sales incentive structure. Eli Lilly has an access-to-medicine strategy integrated within its overall corporate strategy and incentivises its CEO to achieve access-to-medicine goals. It can decouple sales incentives for its sales agents from sales volume in countries in scope of the Index.

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. Eli Lilly has access plans in place for 76% of late-stage R&D projects. The company can develop a structured access planning process in order to develop access plans for all late-stage R&D projects. For example, Eli Lilly can expand access plans for tirzepatide for type 2 diabetes, and new cancer treatments such as sintilimab, to include further access commitments beyond registration of the product in countries where it is conducting clinical trials.

Expand registration of medicines. Eli Lilly did not disclose any evidence of new data regarding registration filings. The company can expand registration of new products such as selpercatinib (Retevmo®/Retsevmo®), indicated for thyroid and lung cancer, and analogue insulins such as insulin lispro (Lyumjev™) and insulin glargine (Basaglar®).

Expand access strategies to patented cancer products. Eli Lilly can expand access to its patented cancer products, such as abemaciclib (Verzenio®) for breast cancer, by applying different access strategies, such as equitable pricing. Additionally, it can engage in non-exclusive voluntary licensing for this product to enable generic supply, as it did for baricitinib (Olumiant®) for the treatment of COVID-19, in India.

CHANGES SINCE THE 2021 INDEX

- Extended support in 2021 to the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act.
- Disclosed progress in patient reach through the Lilly 30x30 Programme, reaching 11.6 million people in 2021 out of the 30 million 2030 goal.
- Issued a royalty-free, non-exclusive voluntary license for baricitinib (a drug repurposed to treat COVID-19) to three Indian drug makers.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Expanded the initiative in partnership with Life for a Child to provide free immediate care as well as build sustainable diabetes care models for vulnerable populations. Starting in February 2021, the partners plan to expand access to care for youth with diabetes from approximately 23,000 in 2020 to approximately 150,000 in 65 countries over the next 10 years.
- Committed USD 14.4 million in a new partnership with UNICEF to help improve health outcomes for 10 million children and adolescents living with chronic, non-communicable diseases (NCDs) through 2025.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources. For

the 2022 Index, Eli Lilly declined to submit data to the Access to Medicine Index. The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where

the use of LMIC refers to lower-middle income countries as per the World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

*In the 2021 Index, dense ranking was used. In the 2022 Index, standard competitive ranking is used. Therefore, a direct comparison with Eli Lilly's previous rank is not possible.

SALES AND OPERATIONS

Business segments: Human pharmaceutical products.

Therapeutic areas: Diabetes, immunology, neuroscience, oncology and other therapies.

Product categories: Innovative medicines.

M&A news: Eli Lilly acquired Prevail

Therapeutics Inc. in January 2021 for USD 747.4 million. Eli Lilly also acquired Protomer Technologies in July 2021 for USD 1 billion.

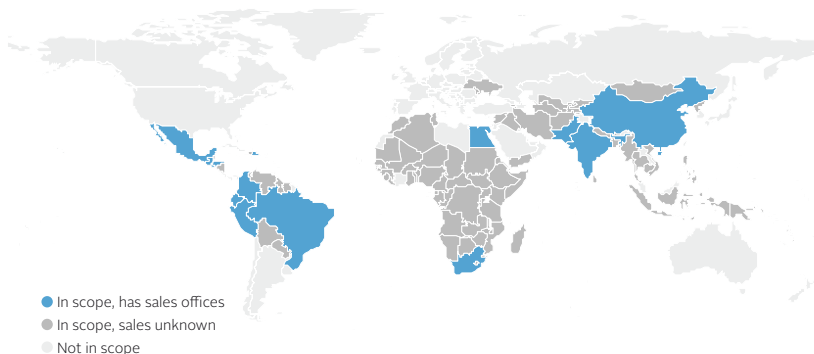
Eli Lilly's products are sold in 72* out of 108 countries in scope of the Index. Eli Lilly has sales offices in 14 countries and sells via suppliers and/or pooled procurement in 68* countries.

*In 2016, Eli Lilly reported sales in 72 countries.

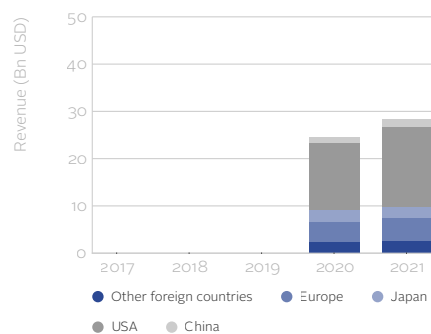
Revenue by segment (2021) – in USD

Human pharmaceutical products	28,32 bn
Total	28,32 bn

Sales in countries in scope



Sales by geographic region



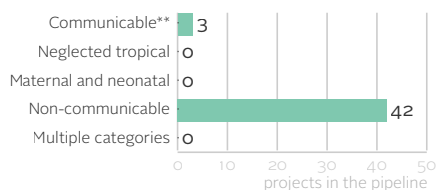
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Eli Lilly has a total of 45 R&D projects in scope with three of these projects targeting priority diseases. The other 42 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on COVID-19 (three projects). Of the projects targeting other diseases, the focus is on diabetes mellitus (13), oncology (12) and ischaemic heart disease (7).

Seventeen R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (14).^{*} Evidence of access planning was in place for 76% of these projects: three targeting a priority disease and ten addressing a public health need in LMICs.

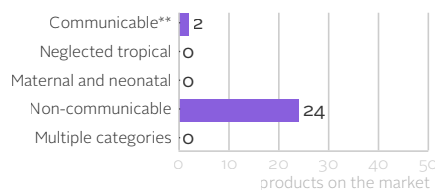
45 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Eli Lilly has 26 medicines in scope, 18 of which are on patent. 19% of these medicines are on the WHO EML (5). The off-patent medicines target non-communicable diseases (NCDs) such as diabetes (5), cancer (1) and unipolar depressive disorders (1). The on-patent medicines target NCDs such as diabetes (9), cancer (4) cardiovascular disease (1) and migraine (2).

26 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	0	0	0	3	0	3
Addresses needs of LMICs*			5	4	7	3	0	19
Other projects in scope			15	3	3	2	0	23

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	17			18
off patent	4	4			8
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

Eli Lilly & Co

GOVERNANCE OF ACCESS

RANK 19

SCORE 3.29

Has an access-to-medicine strategy with measurable objectives, integrated with its corporate strategy. Eli Lilly performs well. It has an access-to-medicine strategy, which covers some of the therapeutic areas in which the company is involved. The strategy is centred around the Lilly 30x30 programme, which focuses on diseases that disproportionately affect people in resource-limited settings. The highest responsibility lies indirectly with the board, with a senior executive responsible for access strategies and reporting to the Executive Committee, which is chaired by the CEO.

Provides evidence of financial access-related incentives at the executive level. Eli Lilly performs well. The CEO has access-related incentives linked to its ability to drive the 30x30 strategy and ensure progress. Eli Lilly does not disclose, however, whether senior executives and in-country managers are also incentivised toward access goals.

Publicly disclose outcomes of its access-to-medicine activities. Eli Lilly performs strongly in transparency of access activities.

It publicly discloses its commitments, objectives and targets related to improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its Lilly 30x30 Programme in a centralised manner within its ESG report.

Performs comparatively poorly in responsible promotional practices. Eli Lilly does not disclose whether sales agents are incentivised on measures other than sales volume. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by local regulations or trade associations.

Has compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Eli Lilly has an average performance, demonstrating evidence of some components looked for by the

Index: a continuous system to monitor activities, audits, formal processes to ensure third-party compliance with company standards and country risk-based assessments in every country or region where there is an Ethics & Compliance officer present. There is no evidence, publicly found or disclosed to the Index, of a fraud-specific risk assessment. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Eli Lilly does not publicly share any support of the Doha Declaration on TRIPS and Public Health, but disclosed to the Index that its position aligns with IFPMA. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Eli Lilly, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 16

SCORE 1.90

No structured process for access planning reported. Eli Lilly does not report a structured process to develop access plans during R&D. The company did not report a structured timeline for the development of access plans for its R&D projects.

A small-sized priority R&D pipeline compared to peers, with access plans in place for 100% (3/3) late-stage candidates. Eli Lilly has three late-stage candidates in its pipeline that target a priority product gap. These focus on COVID-19. The company did not disclose any access plans for these late-stage projects. However, evidence of access plans for all three COVID-19 projects was found in the public domain. For example, Eli Lilly has issued royalty-free, non-exclusive voluntary licenses to accelerate and expand the availability of baricitinib (Olumiant®) to treat COVID-19 in India. This plan also considers donations and registration in countries in scope. Eli Lilly considers supply, demand, and equitable

pricing for its bebtelovimab, a monoclonal antibody therapeutic for COVID-19. Through the Bill & Melinda Gates Foundation, Eli Lilly provided doses of bamlanivimab free of charge in Rwanda and Morocco.

Many projects address a public health need in LMICs,* with 71% (10/14) of late-stage candidates covered by access plans. In this analysis, Eli Lilly has 14 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. These projects focus on several diseases including Alzheimer's disease, diabetes mellitus (type 1 and 2), cancer and cardiovascular diseases. The company did not disclose any access plans for the late-stage projects. However, Eli Lilly has a

policy whereby once a product is approved, it commits to registering it in all countries where clinical trials have taken place. Therefore, plans for registration in countries where clinical trials are being carried out apply to 10 of the 14 late-stage projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Eli Lilly does not disclose disaggregated R&D investment data to global health organisations.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Eli Lilly's performance is below average in this area.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 20

SCORE 1.31

Public commitment not to enforce patents in countries in scope. Eli Lilly publicly pledges to neither file for nor enforce patents. This commitment, available online in the "2018 UNGC Communication on Progress" report, applies to all Least Developed Countries.

Publicly discloses information on patent status. Like most of its peers, Eli Lilly publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Eli Lilly includes information about patents, including filing date, grant number, grant date and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Eli Lilly engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets all inclusion criteria for evaluation. The company does not have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing agreements to enable generic supply. Eli Lilly has a non-exclusive voluntary licensing agreement in place for one compound, baricitinib (Olumiant®) in India. Details of this agreement are not publicly available.

No evidence of filing for registration new products in any country in scope on average. Eli Lilly did not disclose evidence of filing for registration any of its analysed products.

Eli Lilly is not eligible for assessment of supra-nationally procured products.

Has access strategies for one of its healthcare practitioner-administered products in scope of this analysis. Eli Lilly performs below average in this area. For one of five products assessed in this category, examples of access strategies in LMIC were found publicly. For example, the company has issued royalty-free, non-exclusive voluntary licences to three Indian drug makers, Cipla, Sun Pharmaceuticals and Lupin, to manufacture and distribute baricitinib (Olumiant®) to treat COVID-19. In addition, Eli Lilly has donated 400,000

baricitinib tablets to the Indian government for eligible hospitalised COVID-19 patients in India. On May 4 2021, Eli Lilly announced it would donate doses of baricitinib and bamlanivimab/etesevimab to Direct Relief. This donation would enable the humanitarian organisation to provide COVID-19 therapies at no cost to LMICs most heavily impacted by the pandemic. The number of doses donated was not disclosed.

No evidence of access strategies for any of its self-administered products in scope for this analysis. Eli Lilly has not disclosed, neither publicly nor to the Index, access strategies for any of the five products, assessed in this category. Four products in this category are indicated for diabetes mellitus treatment and one product is a cancer treatment.

No manufacturing capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Eli Lilly's performance is below average in this area.

No supply chain capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of supply chain capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Eli Lilly's performance is below average in this area.

Two of the four health systems strengthening initiatives included meet all Good Practice Standards. Eli Lilly's performance is average in this area. The number of initiatives meeting all inclusion criteria is average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, Eli Lilly is a partner in the Africa Health Worker Training Initiative with Living Goods and Last Mile Health which explores novel approaches to training and retaining community health workers. This initiative meets all GPS.

Has no inclusive business models that meet all inclusion criteria. There is no evidence that Eli Lilly has engaged in the piloting or scale-up of

any inclusive business models that aim to meet the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Eli Lilly performs below average in this area.

Shows average performance in terms of ensuring continuous supply of medicines in LMICs. Eli Lilly has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, manages a buffer stock of relevant products, and produces in-house active pharmaceutical ingredients to prevent shortages. However, there is no evidence that the company is involved in technology transfers to manufacturers in LMICs or supply chain capacity building initiatives that meet the inclusion criteria for evaluation.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index. Eli Lilly provides evidence of a policy for reporting SF medicines to relevant national health authorities. However, it does not disclose, publicly or to the Index, evidence that it requires reporting to occur within the timeframe of ten days looked for by the Index. Eli Lilly also does not provide evidence of shortened time frames for reporting cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Eli Lilly has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, the company is engaged in other structured donation programmes, such as the Life for a Child programme where it donates insulin lispro (Humalog®), an analogue insulin used to treat type 1 diabetes mellitus, in 23 countries since 2009.

RANK	SCORE
14	2.84
14 (2021)	

Gilead Sciences

Stock exchange: NASDAQ • Ticker: GILD • HQ: Forster City, California, United States • Employees: 14,000+

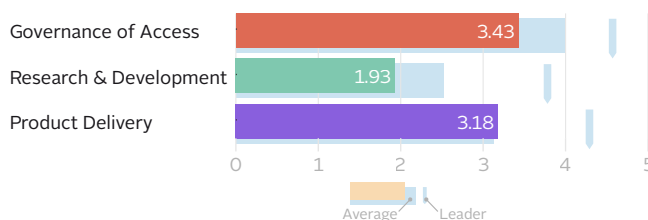
PERFORMANCE IN THE 2022 INDEX

14th place. Gilead has an average overall performance. The company performs well in access strategies for its products on the market, but for R&D it has few access plans in place. Gilead engages widely in non-exclusive voluntary licencing but has a comparatively poor performance in capacity building and aspects of governance of access.

Governance of Access: 15th place. Gilead performs below average in this area. It has an access-to-medicine strategy, although it is not fully integrated into the overall corporate strategy. There is evidence of access-related incentives for its senior executives and CEO, but it lacks evidence of some compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, namely a fraud-specific risk assessment and a continuous system to monitor activities.

Research & Development: 15th place. Gilead performs below average in this area. It has a structured access planning framework but does not apply this to all its late-stage candidates. It has an average performance in R&D capacity building.

How score was achieved



Product Delivery: 12th place. Gilead shows an average performance in this area. The company has access strategies in place for all products assessed in all country income classifications. Gilead leads for engagement in non-exclusive voluntary licencing, with the highest number of licencing agreements of all companies in scope but has comparatively poor performance in health systems strengthening and supply chain capacity building.

OPPORTUNITIES FOR GILEAD

Implement robust framework to mitigate non-compliance. Gilead has country risk-based assessments, third-party monitoring and auditing in place. It can strengthen these processes to mitigate the risk of non-compliant or corrupt activities occurring in countries in scope of the Index by incorporating additional control mechanisms into its operations, such as a continuous system to monitor activities and fraud-specific risk assessments.

Ensure all late-stage R&D projects have comprehensive access plans. Gilead developed access plans for 24% of late-stage projects. The company can develop access plans for all late-stage R&D projects, particularly projects targeting HIV/AIDS and hepatitis B. For example, it can improve the quality of access plans for lenacapavir (Sunlenca®), a long-acting inhibitor for treatment and prevention of HIV, by including additional components such as registration preparation, equitable pricing and/or non-exclusive voluntary licencing.

Expand registration filings of HIV products. Gilead has filed bictegravir/emtricitabine/tenofovir alafenamide (Biktaryv®) in one of the ten countries with the highest burden of HIV. It can take steps to file its HIV products for registration in more high-burden countries, such as Mozambique, Namibia and the Central African Republic.

Extend public commitments to donation programme for visceral leishmaniasis (VL). Gilead has a long-term donation programme that aims to eliminate VL in endemic countries since 2011 in partnership with WHO by donating liposomal amphotericin B (AmBisome®). Gilead has extended its public commitment until 2025. The company can publicly commit to extending the duration of its donation programme until VL is eliminated in endemic countries. The company can also expand the donation programme to more countries where VL is endemic such as Brazil and Somalia.

CHANGES SINCE THE 2021 INDEX

- Established a partnership with Boston University to train its Global Patient Solutions employees and cross-functional partners within Gilead on monitoring and evaluation best practices.
- Joined an initiative with the Partnership for Health Advancement in Vietnam (HAIVN) to address barriers that limit viral hepatitis diagnosis and care at primary healthcare facilities in Vietnam and the Philippines.
- Opened a Paediatric Drug Development Centre of Excellence, focused on developing new paediatric formulations for its portfolio of medicines.
- Announced USD 24 million in grants to help reduce health disparities, improve access to quality healthcare, advance medical education and support local communities most impacted by the HIV epidemic and COVID-19 pandemic. The Zeroing In: Ending the HIV/AIDS Epidemic programme, will support 116 organisations in 41 countries.
- Provided funds to support a global non-profit, FIND, in its project to help eliminate hepatitis C virus (HCV) among people incarcerated in India.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

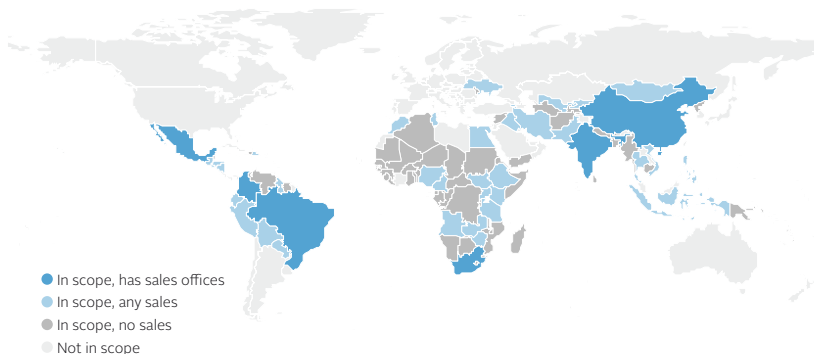
Business segments: Pharmaceutical
Therapeutic areas: Fibrotic diseases, inflammatory diseases, oncology and viral diseases.
Product categories: Innovative medicines.
M&A news: Gilead acquired MYR GmbH in March 2021 for USD 1.45 billion.

Gilead's products are sold in 41 out of 108 countries in scope of the Index.** Gilead has sales offices in 6 countries, and sells via suppliers and/or pooled procurement in an additional 35 countries.

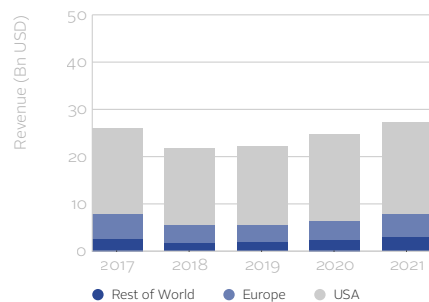
Revenue by segment (2021) – in USD

Pharmaceutical	27.31 bn
Total	27.31 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

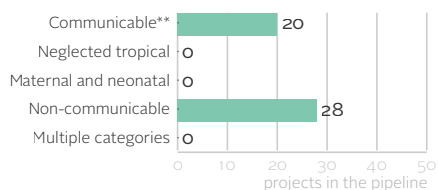
PIPELINE for diseases in scope

Gilead has a total of 48 R&D projects in scope with 17 of these projects targeting a priority disease. The other 31 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (11 projects). Of the projects targeting other diseases in scope, the focus is on oncology (27). Seventeen R&D projects are in late-stage development that target either a priority disease (12) or address a public health need in LMICs (5).* Evidence of access planning was reported for 24% of these projects: four targeting a priority disease and none addressing a public health need in LMICs.

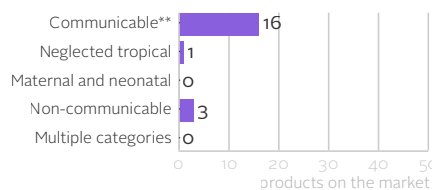
PORTFOLIO as selected for analysis by the Index

Gilead has 20 medicines in scope, 16 of which are on patent. 40% of these medicines (8) are on the WHO EML. The off-patent medicines target mainly communicable diseases, such as HIV/AIDS, hepatitis B as well as neglected tropical diseases such as leishmaniasis. One other product targets cardiovascular diseases. The on-patent medicines mainly target viral infections: HIV/AIDS (8), hepatitis B (1), hepatitis C (4) and coronaviral diseases (1). Two medicines target cancer.

48 projects in the pipeline



20 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	4	1	1	9	2	0	17
Addresses needs of LMICs*			1	3	2	0	0	6
Other projects in scope			9	6	8	2	0	25

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	5	11			16
off patent	3	1			4
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other†				0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
 ‡Other includes vector control products.

Gilead Sciences

GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

Has an access-to-medicine strategy with measurable objectives. Gilead has an average performance. Its strategy is not fully integrated within the overall corporate strategy, but it does have a business rationale. The access strategy is based on partnerships, and the company sees access as part of its corporate values. It covers some of the therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Nominating and Corporate Governance Committee overseeing pricing and access issues.

Provides evidence of financial access-related incentives at the executive level. Gilead performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine. The CEO also has incentives, linked to its performance in expanding access to HCV products.

Publicly discloses outcomes of a subset of its access-to-medicine activities. Gilead performs average in transparency of access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access in countries in scope of the Index. It shares information on the outcomes of only a subset of its

access initiatives, including for HCV and HIV/AIDS and its partnership with Boston University to evaluate its voluntary licensing program, although it does so in a centralised manner within its Year in Review 2021 Report.

Performs above average in responsible promotional practices. Gilead discloses to the Index, but not publicly, whether sales agents are incentivised solely on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for sales agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities) except as required by law, but does have a policy for limiting such transfers.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Gilead has an average performance, demonstrating evidence of some components looked for by the Index: audits (both internal and external, covering third parties and in all countries where it operates), country risk-based assessments and formal processes to ensure third-party compliance with

company standards. It does not, however, disclose to the Index whether it has a continuous system to monitor activities, or a fraud-specific risk assessment. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Gilead does not publicly share any support of the Doha Declaration on TRIPS and Public Health. It understands that TRIPS flexibilities, such as compulsory licensing, may play a role in responding to national public health emergencies in the absence of voluntary licensing, but it should only be used by governments as a last resort when all other options have been exhausted. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Gilead, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 15

SCORE 1.93

Access planning processes encompass all projects in the pipeline. Gilead has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Gilead begins developing access plans for R&D projects in Phase II/III of clinical development.

An average-sized priority R&D pipeline compared to peers, with access plans in place for (33%) 4/12 of the late-stage candidates. Gilead has 17 projects, including 12 late-stage candidates in its pipeline that target a priority product gap. These projects focus mainly on HIV/AIDS, hepatitis B and COVID-19. Of Gilead's 12 late-stage candidates targeting a priority product gap, four have evidence of an access plan in place. In these

plans, the availability and affordability of projects in development are considered.

Some projects address a public health need in LMICs.* In this analysis, Gilead has five late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules. Most target cancer. Gilead did not disclose evidence of access plans for any of the five late-stage projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Gilead does not disclose disaggregated R&D investment data

to global health organisations.

Two of the three R&D capacity building initiatives included meet all Good Practice Standards. Gilead's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all Good Practice Standards for this indicator. Notably, Gilead's Public Health Award: Viral Hepatitis Program, provides a grant to support early-stage research scientists in countries within the scope of the Index. This enables applicants to develop innovative strategies for the prevention, care and treatment of viral hepatitis.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 12

SCORE 3.18

No public commitment not to enforce patents in countries in scope. Gilead does not have a public commitment to not file nor enforce patents in low- to middle-income countries.

Publicly discloses information on patent status. Like most of its peers, Gilead discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Gilead discloses patent information such as filing date, grant number, grant date and jurisdiction.

Is an average-performing company in terms of sharing intellectual property (IP) assets with third-party researchers. Gilead engaged in one new IP-sharing agreement with third-party research institutions or drug discovery initiatives established during the current analysis period that meets all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current Index cycle and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. Gilead is the company with the highest number of licensing agreements. It has non-exclusive voluntary licensing agreements in place for 11 marketed compounds (for diseases in scope). Its broadest licences, for sofosbuvir (Sovaldi®), sofosbuvir/ledipasvir (Harvoni®), sofosbuvir/velpatasvir (Epclusa®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) encompass 92 countries within the scope of the Index, including 67 middle income countries. Gilead's recent license for remdesivir (Veklury®) includes nine sublicensees and covers 90 countries in scope, including 67 middle income countries.

Filed to register new products in six countries in scope on average. Gilead did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely filed is tenofovir alafenamide (Vemlidy®), indicated for viral hepatitis (B and C), filed in 35 countries in scope of the Index, including three of the top 10 high burden countries (Myanmar, Egypt and Cambodia). Emtricitabine/tenofovir alafenamide (Descovy®), for HIV/AIDS, has been filed for registration in seven of the top 10 high burden countries (Botswana, Central African Republic, Mozambique, Namibia, South Africa, Zambia and Zimbabwe).

Has access strategies for its supranationally procured product in scope for this analysis. Gilead has an average performance in securing access for the product procured supranationally. The company demonstrates strategies in countries eligible for supply from procurers and also in at least one non-eligible country. For example, Gilead's price for amphotericin b liposome (AmBisome®) is USD 16.25, and it is the same in all 116 countries covered by the company's volun-

tary licensing agreements for HIV/AIDS products. In addition, Gilead has a long-term donation partnership with WHO. In Mexico, a non-eligible country to benefit from the procurement agreement, Gilead does not apply the same price offered via such agreement, but it implements a tiered pricing policy. Evidence of additional access strategies is not provided but the company shares patient reach data.

Has access strategies for its healthcare practitioner-administered product for countries in the scope of the analysis. Gilead performs above average in this area. It provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) for the product assessed. For example, Gilead has a voluntary licensing programme for remdesivir (Veklury®), which includes a technology transfer to generic manufacturers developing this product and a waiver of royalties on COVID-19 therapies for use during the pandemic. The company reported that these efforts resulted in a four-fold increase in production during the peak of the COVID-19 surge in India, from 3 million vials to 13 million vials. In addition, Gilead donated vials to meet the patients' immediate needs in India. Evidence of patient reach in the three country examples is provided.

Has access strategies for all its self-administered products for countries in scope for this analysis. Gilead leads in this area. Examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) are provided for all its products assessed. The company makes efforts to reach additional patients through flat pricing strategies in LICs and non-exclusive voluntary licensing agreements. Evidence of tiered pricing policies considering public payers' ability to pay is available, such as in the Dominican Republic for sofosbuvir/velpatasvir (Epclusa®), where the company reached 3,078 patients.

One of the four manufacturing capacity building initiatives included meets all Good Practice Standards. Gilead's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In the initiative that meets all GPS, Gilead builds manufacturing capacity of its licensees in LMICs by initiating technology transfers for generic HIV/AIDS and hepatitis C treatments ahead of regulatory approval.

One supply chain capacity building initiative was included for analysis but does not meet all Good Practice Standards. Gilead's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. The Gilead GPS Dashboard training initiative teaches licensees

how to access several data sources to ensure continuous supply in multiple countries.

Two of the five health systems strengthening initiatives included meets all Good Practice Standards. Gilead's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all GPS than what is average for this indicator. For example, Gilead is partnering with the Vatican and others to reach people living with HIV/AIDS in the rural Shinyanga and Simiyu regions of Tanzania and quickly connect them to care. The programme aims to enable screening of 300,000 people and provide treatment for all those diagnosed. This initiative meets all GPS.

Has engaged in piloting one inclusive business model and has scaled up two existing inclusive business models during the current analysis period. Gilead performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Gilead continues to support the M-TIBA mobile wallets programme, which provides access to better healthcare by connecting people directly to healthcare payers and clinics through a health wallet on their mobile phones.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Gilead is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, and manages a buffer stock of relevant products. However, there is no evidence to show that the company is involved in supply chain capacity building initiatives.

Does not have a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index. Gilead does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to the relevant health authorities.

Donates in response to expressed need and monitors delivery. Gilead has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Since 2011, Gilead publicly committed itself to contribute to the elimination of visceral leishmaniasis by donating amphotericin B liposome (AmBisome™) in six countries in scope of the Index until 2025.

RANK	SCORE
1	4.06
1 (2021)	

GSK plc

Stock exchange: LSE • Ticker: GSK • HQ: Brentford, UK • Employees: 90,096

PERFORMANCE IN THE 2022 INDEX

1st place. GSK leads by ensuring its overarching access to medicine strategy is applied broadly to encompass both R&D and delivery of products on the market. GSK leads in the Research & Development Technical Area and performs strongly across all assessment criteria measured by the Index.

Governance of Access: 2nd place. GSK has a strong performance in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access-to-medicine and incentivises its senior executives, the CEO and in-country and regional managers to perform on access-to-medicine goals. It discloses outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 1st place. GSK leads in this area. The company has the largest priority pipeline of all companies in scope with access plans in place for the majority of late-stage pipeline candidates. It also performs strongly in R&D

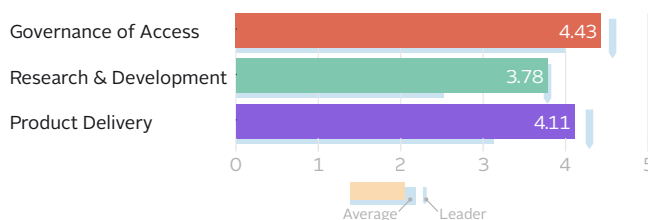
OPPORTUNITIES FOR GSK

Ensure all late-stage R&D projects have comprehensive access plans with a wide geographic scope. GSK has access plans in place for 89% of late-stage candidates analysed. It can expand these plans and apply them to all projects in the pipeline from Phase II onwards. Furthermore, it can broaden the geographic scope of existing plans to include more countries in scope of the Index.

Apply access strategies for its COPD product, umeclidinium bromide (Incruse®), in lower-income countries. GSK has access strategies in place across all country income classifications for two of its three products targeting chronic obstructive pulmonary disease (COPD), fluticasone propionate/salmeterol xinafoate (Seretide®) and salbutamol sulfate (Ventolin®). However, strategies for umeclidinium bromide are focused on upper-middle income countries and lower-middle income countries, such as Brazil and El Salvador. The company can expand these strategies to low-income countries and countries with the highest disease burden of COPD, such as Nepal and India.

Expand albendazole (Zentel®) donation and other efforts to control soil-transmitted helminthiasis. Since 2011, GSK's albendazole donation programme, carried out in partnership with WHO, has been targeted at controlling soil-transmitted helminthiasis in at-risk populations. During the 2022 Index cycle, the company extended the donation programme to include pre-school aged children as an additional at-risk group and expanded its public commitment to donating until 2025. GSK can further expand its public commitment by including other at-risk populations (e.g., women of child-bearing age).

How score was achieved



capacity building and has an access planning framework that covers all projects in the pipeline.

Product Delivery: 2nd place. GSK performs strongly in this area by applying tailored access strategies across different country income classifications in all product categories. The company also excels in high-quality capacity building initiatives, leading in manufacturing and supply chain capacity building. Through ViiV Healthcare, the company engages in non-exclusive voluntary licensing to enable generic supply, with three such licensing agreements in place for one compound.

CHANGES SINCE THE 2021 INDEX

- Established a new, dedicated Global Health Group, a non-commercial group aimed at enhancing pipeline progression of needed medicines and vaccines in low and lower-middle income countries.
- ViiV Healthcare, a global specialist HIV company majority owned by GSK, established a Global Health & Access forum which provides focus on and governance for access-related discussions across its portfolio.
- Signed two agreements with Gavi and UNICEF to supply the RTS,S/AS01 malaria vaccine (Mosquirix) for routine child immunisation in endemic countries following a recommendation by the WHO.
- Received regulatory approval for tafenoquine paediatric dose in March 2022, representing the first new relapse prevention treatment for *P. vivax* malaria in over 60 years.
- ViiV Healthcare signed a non-exclusive voluntary licensing agreement relating to dolutegravir in four countries within the scope of the Index, and (after the period of analysis) a new voluntary licensing agreement with the MPP to improve access to cabotegravir long-acting for HIV pre-exposure prophylaxis.
- GSK reaffirmed its long-term commitment to donate albendazole (Zentel®) until the elimination of lymphatic filariasis as a public health problem is achieved globally. In addition, 200 million tablets a year will be donated until 2025 to treat soil-transmitted helminthiasis.
- GSK expects to positively impact health of more than 2.5 billion people within the next ten years, with an ambition of 1.3 billion people in low- and lower-middle income countries.
- A generic formulation of Tivicay paediatric dose, a child-friendly dispersible tablet formulation, reached children in 29 Index countries less than a year after US FDA approval.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Consumer healthcare*, pharmaceuticals and vaccines.

Therapeutic areas: Respiratory, HIV, Immuno-inflammation, Oncology; Vaccines: Meningitis, Shingles and Influenza.

Product categories: Consumer health products*, innovative medicines and vaccines.

M&A news: GSK acquired Sierra Oncology in April 2022 for USD 1.9 billion.

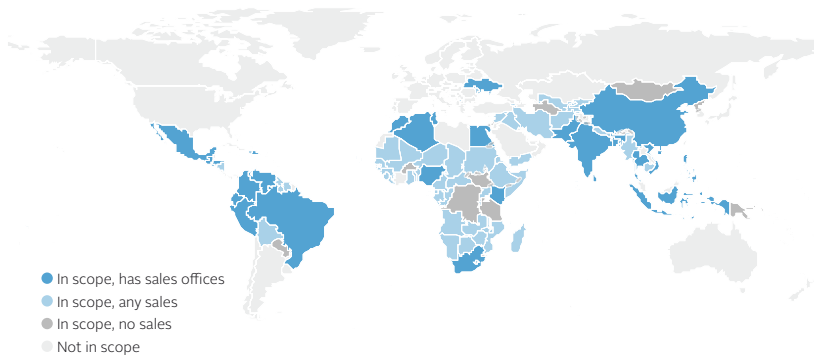
GSK's products are sold in 92 out of 108 countries in scope of the Index. GSK has sales offices in 27 countries, and sells via suppliers and/or pooled procurement in an additional 65 countries.

*As of July 2022, GSK no longer has a consumer health-care business.

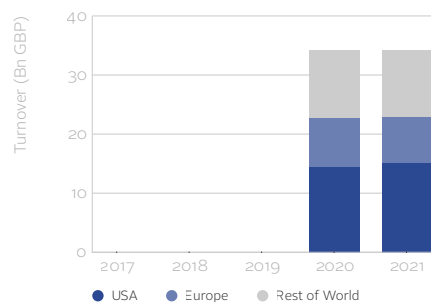
Turnover by segment (2021) – in GBP

Pharmaceuticals	17.73 bn
Vaccines	6.78 bn
Consumer healthcare*	9.61 bn
Total	34.11 bn

Sales in countries in scope



Sales by geographic region

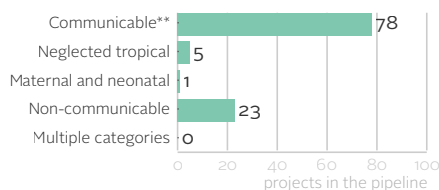


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

GSK has a total of 107 R&D projects in scope with 81 projects of these projects targeting priority diseases. The other 26 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (15 projects), COVID-19 (15), tuberculosis (14) and malaria (10). Of the projects targeting other diseases in scope, the focus is on oncology (14). Thirty-five R&D projects are in late-stage development that target either a priority disease (25) or address a public health need in LMICs (10).^{*} Evidence of access planning was in place for 89% of these projects: 23 targeting a priority disease and eight addressing a public health need in LMICs. Additionally, GSK provides evidence of access plans for two projects in Phase I of clinical development.

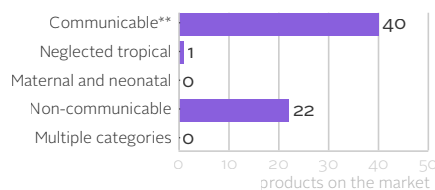
107 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

GSK has 42 medicines in scope, 23 of which are on patent, and 20 vaccines. 48% of the medicines (20) are on the WHO EML. In addition, the company markets one platform technology. The off-patent medicines target communicable diseases (CDs) (9) such as HIV/AIDS (4) and hepatitis B (2); non-communicable diseases (NCDs) (9) such as mental health (3) and cardiovascular diseases (4); and neglected tropical disease such as leishmaniasis (1). The on-patent medicines target CDs such as HIV/AIDS (10) and NCDs such as pulmonary diseases (6) and cancer (1). GSK's preventative vaccines (20) target CDs such as meningitis (6), rotavirus diarrhoea and malaria. The platform technology targets COVID-19.

63 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	25	13	15	12	5	8	3	81
Addresses needs of LMICs*			7	1	6	3	0	17
Other projects in scope			4	2	3	0	0	9

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	7	16			23
off patent	13	6			19
Vaccines	20	0			20
Contraceptives	0	0			0
Diagnostics			0		0
Other†				1	1

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
 ‡Other includes vector control products.

GSK plc

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. GSK performs strongly. It has a comprehensive access-to-medicines and vaccines strategy, along with ViiV Healthcare, dedicated to HIV/AIDS. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with its Corporate Responsibility Committee responsible for global health and access strategies.

Provides evidence of financial and non-financial access-related incentives at the executive level. GSK performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives included in its annual bonus plan.

Publicly discloses outcomes of its access-to-medicine activities. GSK performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving

access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Annual Report and ESG Performance Report.

Performs well in responsible promotional practices. GSK's sales agents are not solely incentivised on sales volume targets. In addition, it sets a capped variable pay component of incentives based on individual sales targets. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index, unless required by law or by local regulations, but it has a policy limiting such transfers, i.e. prohibiting payments for promotional activities in certain countries based on their scores in the Transparency International Corruption Perceptions Index.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. GSK performs strongly, demonstrating evidence of all components looked for by the Index:

fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. GSK publicly shares support of the Doha Declaration on TRIPS and Public Health and states that there are flexibilities which can allow countries to address their public health needs. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, GSK, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 1

SCORE 3.78

Access planning processes encompass all projects in the pipeline. GSK has a structured process to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, GSK begins developing access plans for R&D projects in Phase II of clinical development.

GSK has the largest priority R&D pipeline compared to its peers, with access plans in place for (92%) 23/25 of late-stage candidates. GSK has 81 projects including 25 late-stage candidates in the pipeline that target a priority gap. The priority pipeline focuses mostly on HIV/AIDS, COVID-19, tuberculosis and malaria. Of GSK's 25 late-stage candidates targeting a priority product gap, 23 have evidence of an access plan in place. Additionally, it has access plans in place for two Phase I projects. These plans contain a range of components that are conducive to access, including commitments to register in countries in scope of the Index, applying for WHO prequalification and plans to ensure sustainable supply. Notably,

ViiV Healthcare's cabotegravir extended-release injectable suspension (Apretude) became the first long-acting injectable for pre-exposure prophylaxis of HIV to receive stringent regulatory authority (SRA) approval, following its approval by the US FDA.

Many projects address a public health need in LMICs,* with 80% (8/10) of late-stage projects covered by access plans. In this analysis, GSK has ten late-stage candidates in its pipeline that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials conducted in countries in scope of the Index or are being developed for paediatric indications. The projects focus on several disease areas including cancer, asthma and kidney diseases. GSK provides evidence of access plans for eight of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, GSK does disclose fully disaggregated R&D investment data to Policy Cures Research.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. GSK leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, in collaboration with Novartis, the GRADIENT project researches genetic diversity across different regions in Africa and its potential impact on response to therapeutics. Local researchers are supported to explore responses to drugs used to treat several diseases, including malaria and tuberculosis.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 2

SCORE 4.11

Public commitment not to enforce patents in countries in scope. GSK publicly pledges to neither file for nor enforce patents in Least Developed Countries and LICs. For non-G20 LMICs, GSK may file for patents but can allow licenses to supply generic versions of its medicines.

Publicly discloses information on patent status. Like most of its peers, GSK discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. GSK discloses patent information, including filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property assets with third-party researchers. GSK engaged in new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. ViiV Healthcare has three non-exclusive voluntary licensing agreements in place for one compound (for diseases in scope). Its adult licence, its UMIC licence, and its paediatric licence for dolutegravir (Tivicay® and Tivicay PD), which encompasses 104 countries relevant to the Index, including 82 low-income and lower-middle income countries. For abacavir, ViiV Healthcare has a paediatric licence that covers 104 countries in scope. After the period of analysis, ViiV Healthcare has announced a voluntary licensing agreement for cabotegravir long-acting for HIV PrEP, that will allow selected generic manufacturers to develop, manufacture and supply generic versions of the product.

Filed to register new products in 11 countries in scope on average. GSK filed one of its new products in more than half of the top ten high burden countries. Dolutegravir (Tivicay PD), a new product indicated for paediatric HIV/AIDS, is filed in seven high burden disease countries and six of the 27 low-income countries in scope of the Index. Abacavir/dolutegravir/lamivudine (Triumeq®), indicated for HIV/AIDS, is widely filed in 27 countries relevant to the Index, including in three high burden disease countries.

Has access strategies for all supranationally procured products in scope of this analysis. GSK performs above average in securing access for products procured supranationally. For the five products assessed in this category, GSK demonstrates strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, GSK supplies its MMR vaccine (Priorix®) through tenders

in the private sector in Tunisia, a country not eligible to benefit from UNICEF supranational procurement. The price is defined using a tiered pricing policy model that considers patients' ability to pay. According to GSK, 49,000 vaccinations were procured.

Has access strategies for all its healthcare practitioner administered products in scope of this analysis. GSK performs above average in this area. The company provides examples of affordable access strategies in all assessed income levels (UMIC, LMIC, LIC) for its hepatitis B vaccine (Engerix® B), one of the three products assessed in this category. It makes efforts to reach additional patients through pricing strategies that consider relevant payers' ability to pay and patient assistance programmes (PAPs). For example, the company extended the PAP for mepolizumab (Nucala®) in India by offering further discounts for patients completing the first month of treatment. GSK provides evidence that the strategy has been able to increase patient reach and treatment adherence.

Has access strategies for its self-administered products for some countries in scope of this analysis. GSK has an above average performance in this area. For three of the five products assessed, GSK provides examples of access strategies that consider affordability in all assessed income levels (UMIC, LMIC, LIC). GSK also provides evidence of additional access strategies such as a non-exclusive voluntary licensing and health systems strengthening. For example, in Colombia, GSK implemented 'parity pricing'⁵ and competitor-based pricing for abacavir/dolutegravir/lamivudine (Triumeq®). GSK reports that, in the current analysis period, it supplied the treatment to 7,350 people in Colombia living with HIV/AIDS.

All five manufacturing capacity building initiatives included meet all Good Practice Standards. GSK is a leader in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. Since 2017, ViiV Healthcare in partnership with Clinton Health Access Initiative has established public-private partnerships that benefit generic manufacturers. These partnerships build capacity to manufacture dispersible tablets for paediatric dolutegravir and Triumeq®. This initiative meets all GPS.

All five supply chain capacity building initiatives included meet all Good Practice Standards. GSK is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, through the Strategic Training for Executives Programme (STEP 2.0), GSK invested GBP 1.4 million to train 78 immunisation supply chain managers in 15 Gavi countries.

Four of the five health systems strengthening initiatives included meet all Good Practice Standards. GSK's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, in the Frontline Health Worker Programme, GSK has invested over GBP 10 million in the Index period to support frontline health services in lower income countries providing education, skills and capacity building for local healthcare systems.

Has engaged in piloting one inclusive business model (IBM) and has scaled up two existing IBMs during the current analysis period. GSK performs above average in the use of IBMs aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. In one example, GSK's Project Respire is supporting patients with uncontrolled asthma in low-income counties in Lagos State, Nigeria through a multi-pronged approach including educating general practitioners and offering discounts on medication.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. GSK is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. GSK has a policy for reporting SF medicines to national health authorities and the WHO within five days. It provides evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed. In urgent situations where there is a significant risk of patient harm, the policy is designed to enable GSK to respond quickly.

Donates in response to expressed need and monitors delivery. GSK has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria. GSK has publicly committed itself since 1998 to contribute to the elimination of lymphatic filariasis by donating albendazole (Zentel®) in 38 countries in scope of the Index until goals are reached.

⁵The company sells all dolutegravir-containing regimens at the same price. Under this pricing approach, the private insurers, called Health Maintenance Organisations

(HMOs), pay the cost of dolutegravir as the core agent, while costs for other agents in the treatment are covered by GSK.

RANK	SCORE
2	4.03
3 (2021)	

Johnson & Johnson

Stock exchange: NYSE • Ticker: JNJ • HQ: New Brunswick, New Jersey, USA • Employees: 141,700

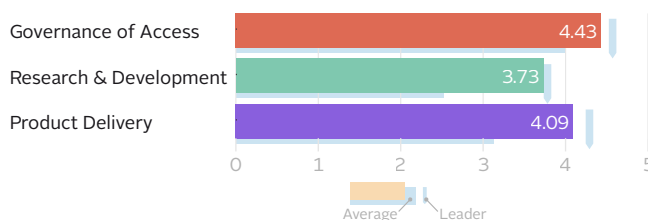
PERFORMANCE IN THE 2022 INDEX

2nd place. Johnson & Johnson is a leading company and demonstrates strong performance across all three Technical Areas. The company performs strongly across all assessment criteria including access strategies, R&D access planning and capacity building.

Governance of Access: 2nd place. Johnson & Johnson has a strong performance in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. It also incentivises its senior executives, the CEO and in-country and regional managers to perform on access-to-medicine goals and discloses the outcomes of its access-to-medicine activities.

Research & Development: 2nd place. Johnson & Johnson is a leading company in this area. The company has a large-sized priority pipeline compared its peers with access plans in place for all late-stage pipeline candidates. It also performs strongly

How score was achieved



in R&D capacity building and has an access planning framework that covers all projects in the pipeline.

Product Delivery: 3rd place. Johnson & Johnson performs strongly in this area. The company engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply chain and health systems strengthening). The company applies access strategies broadly, with several products having strategies across all country income classifications. It leads in its approach to access strategies for supranationally procured products.

OPPORTUNITIES FOR JOHNSON & JOHNSON

Improve the quality of access plans for R&D projects for non-communicable diseases. Johnson & Johnson has access plans in place for all its late-stage R&D projects in the pipeline. The company can plan beyond registration by including more access components such as equitable pricing plans for each project, including cetrelimab, a monoclonal antibody in development for bladder cancer, and apocitinan, an investigational treatment for hypertension.

Expand supply chain process reviews to more countries. Johnson & Johnson's Global Public Health unit conducted supply chain process reviews in sub-Saharan African countries including Kenya, Uganda and Nigeria. These reviews revealed a gap in leadership skills in the supply chain. In response, the company launched the Public Health Supply Chain CEO Forum. The company can conduct needs assessments in further countries in sub-Saharan Africa and expand the forum to additional countries where supply chain leadership gaps are seen.

File patented medicines for HIV for registration in more countries. Johnson & Johnson's antiretrovirals darunavir/cobicistat (Prezcobix®/Rezolsta®) and darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) have been filed in 12 and 5 countries in scope of the Index respectively. Both products can be filed for registration in countries with a high burden of disease, such as Mozambique, South Africa and Zimbabwe.

Expand access to patented products in countries with the highest burden of disease. Johnson & Johnson has access strategies in some LMICs for canagliflozin (Invokana®), indicated for type 2 diabetes mellitus, and for ibrutinib (Imbruvica®), indicated for leukaemia. The company can apply access strategies such as equitable pricing and/or non-exclusive voluntary licensing to expand patient reach, particularly in countries in scope of the Index where the burden of disease is the highest, such as Sri Lanka (for diabetes) and Afghanistan (for leukaemia).

CHANGES SINCE THE 2021 INDEX

- Expanded the scope of its Global Public Health organisation to include a focus on Global Surgery, including obstetric fistula.
- Launched new Health for Humanity 2025 Goals, including a goal on Global Access Plans.
- Shipped approximately 270 million doses of the Johnson & Johnson COVID-19 vaccine to Africa at a not-for-profit price.
- Entered into IP licensing agreements and conducted voluntary technology transfers for its COVID-19 vaccine across 10 manufacturing facilities, including in India and South Africa.
- Announced an agreement to provide its COVID-19 vaccine technology to South Africa-based Aspen SA Operations (Pty) Ltd to manufacture its own branded vaccine.
- Received WHO Prequalification for its Ebola vaccine (Ad26.ZEBOV-GP) (Zabdeno®) and Ebola vaccine (MVA-BN-Filo) (Mvabea®)
- Announced several initiatives to help find the 'Missing Millions' of undiagnosed people living with TB, including with the Global Fund.
- Launched a network of Global Health Discovery Centers to accelerate innovation and tackle pandemic threats.
- Completed Phase 1 clinical study evaluating dengue-specific antiviral for treatment and prophylactic use.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Commenced the first interventional clinical trial for schizophrenia in Africa.
- Marked over 2 billion doses of mebendazole (Vermox®) donated since 2006.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Consumer health, medical technologies and pharmaceutical.

Therapeutic areas: Cardiovascular, immunology, infectious diseases, metabolism, neuroscience, oncology, pulmonary hypertension and other diseases.

Product categories: Consumer health products, innovative medicines, medical technologies and vaccines.

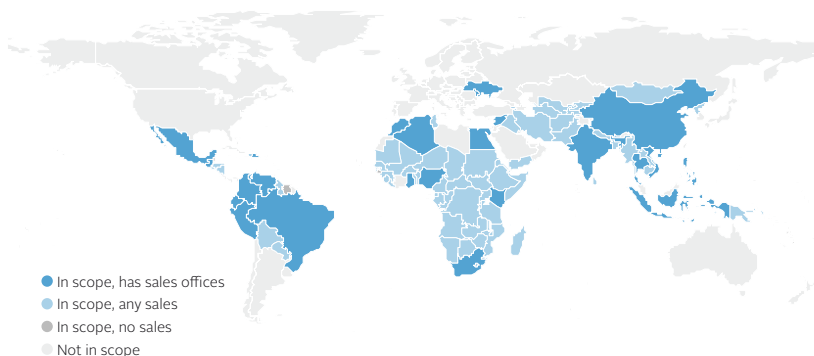
M&A news: Johnson & Johnson acquired Momenta Pharmaceuticals, Inc. in October 2020 for USD 6.5 billion.

Johnson & Johnson's products are sold in 95 out of 108 countries in scope of the Index. Johnson & Johnson has sales offices in 24 countries and sells via suppliers and/or pooled procurement in an additional 71 countries.

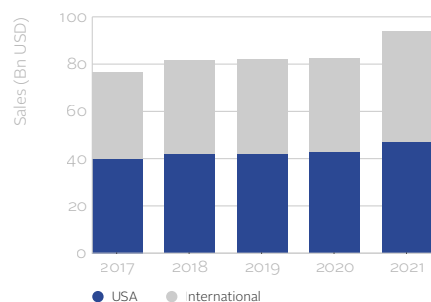
Sales by segment (2021) – in USD

Consumer health	14.64 bn
Pharmaceutical	52.08 bn
Medical technologies	27.06 bn
Total	93.78 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

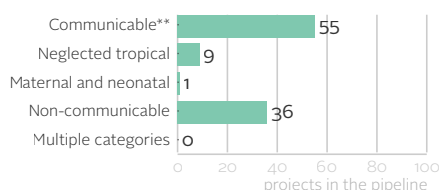
PIPELINE for diseases in scope

Johnson & Johnson has a total of 101 R&D projects in scope with 64 of these projects targeting priority diseases. The other 37 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on viral hepatitis (B and C) (12 projects), HIV/AIDS (11 projects), and tuberculosis (11 projects). Of the projects targeting other diseases in scope, the focus is on oncology (25). Forty R&D projects are in late-stage development. These target either a priority disease (19) or address a public health need in LMICs (21)*. Evidence of access planning was in place for 100% of these projects.

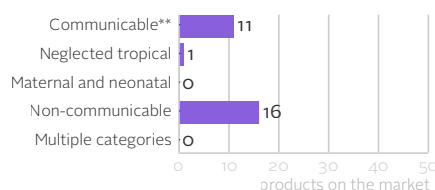
PORTFOLIO as selected for analysis by the Index

Johnson & Johnson has 26 medicines in scope, 19 of which are on patent, and two vaccines. 42% of the medicines (11) are on the WHO EML. The off-patent medicines target the neglected tropical diseases soil-transmitted helminthiasis and echinococcosis and the non-communicable diseases (NCDs) (6) relating to cancer (3), mental health conditions (2) and kidney diseases. The on-patent medicines target communicable diseases such as HIV/AIDS (8) and tuberculosis, and NCDs such as cancer (5), mental health conditions (2), diabetes (2) and Alzheimer's disease. The company also has two vaccines targeting Ebola and COVID-19.

101 projects in the pipeline



28 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	23	9	9	8	7	5	3	64
Addresses needs of LMICs*			4	7	13	1	0	25
Other projects in scope			9	2	1	0	0	12

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	6	13			19
off patent	5	2			7
Vaccines	0	2			2
Contraceptives	0	0			0
Diagnostics			0		0
Other†				0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
 ‡Other includes vector control products.

Johnson & Johnson

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Johnson & Johnsons performs strongly. Its access strategy, embedded in its Global Public Health unit and Janssen Access and Pricing Principles, covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Science & Technology Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level.

Johnson & Johnson performs strongly. It incentivises its senior executives, including its CEO and members of the Executive Committee, and regional managers to take action on access to medicine with financial and non-financial rewards. Senior management, including the CEO, have enterprise-level targets as well as access-related performance indicators, including KPIs to improve access to medicine, as part of their annual goals and objectives.

Publicly discloses outcomes of its access-to-medicine activities. Johnson & Johnson performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries

in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its annual Health for Humanity Goals Progress Scorecard.

Performs above average in responsible promotional practices. Johnson & Johnson's sales agents are not solely incentivised on sales volume targets. The company, however, sets sales incentives at the individual level for agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities) except as required by law or national/regional trade associations (e.g., EFPIA), though it has policies and procedures in place limiting transfers of values to healthcare professionals in countries in scope of the Index. In addition, the company reports not using sales and marketing representatives for some products related to diseases in scope, such as HIV/AIDS medicines.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Johnson & Johnson performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, coun-

try risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports international agreements, such as the Doha Declaration on the TRIPS agreement. Johnson & Johnson publicly recognises and supports international agreements including the TRIPS Agreement, and states that it advocates for strong intellectual property (IP) systems that promote innovation. The company expresses reservations on compulsory licensing, namely that it should be limited to certain circumstances when alternatives are exhausted. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Johnson & Johnson, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 2

SCORE 3.73

Access planning processes encompass all projects in the pipeline. Johnson & Johnson has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Johnson & Johnson begins developing access plans for R&D projects in Phase II of clinical development.

A large-sized priority R&D pipeline compared to peers, with access plans in place for 100% (19/19) of the late-stage candidates. Johnson & Johnson has a priority R&D pipeline of 64 projects, including 19 late-stage projects that target a priority gap. The company focuses on various priority areas, including viral hepatitis (B and C), HIV/AIDS and tuberculosis. Of Johnson & Johnson's 19 late-stage candidates targeting a priority product gap, all have evidence of an access plan in place. It provides evidence of access plans with a

range of components including equitable pricing strategies and plans for registration in countries in scope of the Index. Notably, the access plan for the two-shot regimen Ebola vaccine (Ad26.ZEBOV-GP) (Zabdeno®) and Ebola vaccine (MVA-BN-Filo) (Mvabea®) is multifaceted, comprising of WHO prequalification, health systems strengthening and capacity building initiatives through the Johnson & Johnson vaccination monitoring platform Vxnaid™, and product donations.

Many projects address a public health need in LMICs,* with 100% (21/21) of late-stage projects covered by access plans. In this analysis, Johnson & Johnson has 21 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope of the Index and/or are

first-in-class molecules. The projects mainly target cancer. Johnson & Johnson provides evidence of access plans for all 21 eligible projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, Johnson & Johnson does disclose fully disaggregated R&D investment data to Policy Cures Research.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. Johnson & Johnson leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, the Johnson & Johnson Global Public Health R&D Fellowship Program provides training in drug development to mid-career African doctors and scientists.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 3

SCORE 4.09

Public commitment not to enforce patents in countries in scope. Johnson & Johnson has had a specific policy since 2012 not to enforce the patents it owns and controls on the antiretroviral drug darunavir (Prezista®) in sub-Saharan Africa and Least Developed Countries. In 2015, it expanded the geographical scope of the policy for paediatric products used in LMICs.

Publicly discloses information on patent status. Like most of its peers, Johnson & Johnson discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Johnson & Johnson discloses patent information including filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Johnson & Johnson engaged in two new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current Index cycle and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. Johnson & Johnson has a non-exclusive voluntary licensing agreement for one compound (for diseases in scope). Its licence for rilpivirine (Edurant®) encompasses 83 countries in scope, including 57 middle income countries. It has also issued a non-assert declaration for one patented compound in scope, darunavir (Prezista®).

Filed to register new products in 15 countries in scope on average. Johnson & Johnson has filed six products in at least one country in scope of the Index with the highest burden of disease (for products that could be assessed with available global burden of disease data, which excludes COVID-19). Among new products, its most widely filed is the Johnson & Johnson COVID-19 vaccine, rapidly authorized in 41 countries within the scope of the Index, 13 of which are LICs. Examples include Somalia, Sudan and Uganda. Johnson & Johnson also received emergency use waivers or import permits in 31 countries in scope of the Index. Among old products, canagliflozin/metformin (Vokanamet®/Invokamet®) has been filed in 18 countries within the scope of the Index, including one high burden disease country.

Has access strategies for all supranationally procured products in scope for this analysis. Johnson & Johnson leads in securing access for products procured supranationally. For the four products assessed in this category, the company demonstrates strategies both in countries eligible for supply from such procurers, and also in at least one country not eligible for such supply. For example, the company supplied its Johnson & Johnson COVID-19 vaccine at a not-for-profit price via a supranational procurement agreement

with the African Vaccine Acquisition Trust (AVAT) as well as two advance purchase agreements with the South African government.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Johnson & Johnson performs above average in this area. For three of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). The company makes efforts to reach additional patients using strategies considering relevant payers' ability to pay. For example, Johnson & Johnson secured bendamustine hydrochloride (Ribomustin®) reimbursement in both public institutions and private health insurance in Brazil. The company provides evidence of how patient reach has been increased through the approaches used in some of the country examples provided.

Has access strategies for the majority of its self-administered products for countries in scope for this analysis. Johnson & Johnson performs above average in this area. For two of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). It makes efforts to reach additional patients through pricing strategies considering relevant payers' ability to pay and patient assistance programmes. For example, in an LIC for one cancer product, it provided evidence of pricing and non-pricing strategies to ensure continuous patient care while implementing health systems strengthening initiatives. Johnson & Johnson provides evidence of patient reach.

Four of the five manufacturing capacity building initiatives included meet all Good Practice Standards. Johnson & Johnson's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, the company collaborated with Aspen Pharmacare Limited, a manufacturer in South Africa to transfer technology to produce the Johnson & Johnson COVID-19 vaccine. This initiative meets all GPS.

All five supply chain capacity building initiatives included for analysis meet all Good Practice Standards. Johnson & Johnson is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, the company is involved in the Strategic Training Executives Programme (STEP 2.0) which is a targeted leadership and change management solution that trains public health supply chain managers and leaders in LMICs.

All five health systems strengthening initiatives included for analysis meet all Good Practice

Standards. Johnson & Johnson is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, Johnson & Johnson Global Public Health developed Vxnaid™, a vaccination monitoring platform which supports adherent vaccine administration in the framework of clinical studies or campaigns, including support of the Rwandan Ministry of Health's large-scale Ebola vaccination campaign. The company's ultimate goal is for the platform to be available on a more global scale.

Has engaged in scaling up two and piloting four inclusive business models. Johnson & Johnson performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Johnson & Johnson Impact Ventures, a fund within the Johnson & Johnson Foundation, helped to scale up South Lake Medical Center, a specialised low-cost primary care hospital in Naivasha, Kenya that runs a hub-and-spoke healthcare model.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Johnson & Johnson is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a procedure for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Johnson & Johnson has a procedure for reporting SF medicines to national health authorities within five days. The company reports aiming at reporting within two days if the case presents a direct and serious or life-threatening risk to patient or healthcare professional. It distinguishes quicker reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Johnson & Johnson has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Johnson & Johnson publicly commits to supporting the control of soil-transmitted helminthiasis as a public health problem through its donation of mebendazole (Vermox®) until the end of 2025 in 51 countries in scope of the Index.

RANK	SCORE
18	2.15
15 (2021)*	

Merck & Co, Inc

Stock exchange: NYSE • Ticker: MRK • HQ: Rahway, New Jersey, US • Employees: ~68,000

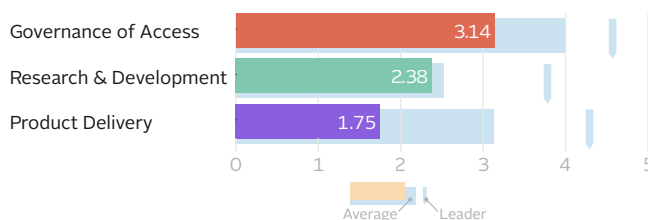
PERFORMANCE IN THE 2022 INDEX

18th place. MSD performs below average in two of the three Technical Areas. In Governance of Access, there was no publicly-available evidence found of policies governing responsible promotional practices. In the Product Delivery Technical Area, it performs below average in its approach to equitable access strategies. Research & Development however, the company has strengthened its access planning framework and has access plans in place for several late-stage candidates in the pipeline.

Governance of Access: 20th place. MSD performs poorly in this area. It has an access-to-medicine strategy with measurable objectives integrated within its overall corporate strategy, but there is no evidence that sales incentives are decoupled from sales volume targets, nor is there evidence that senior management and in-country/regional managers are incentivised to perform on access-related goals. It also lacks evidence of a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 11th place. MSD has an average performance in this area. The company now has a structured

How score was achieved



access planning framework in place, but evidence was not found that it applies this to all late-stage candidates. It has a small-sized priority pipeline but does participate in R&D capacity building.

Product Delivery: 19th place. MSD performs poorly in this area. One access strategy was identified for one product in an upper-middle income country. MSD has an average performance with regard to its participation in inclusive business models. The company engages in health systems strengthening and supply chain capacity building, but evidence of engagement in manufacturing capacity building was not found.

OPPORTUNITIES FOR MERCK & CO

Organise governance of access. MSD has an access-to-medicine strategy, guided by its Access to Health Statement of Guiding Principles. Financial and non-financial incentives for senior executives, the CEO and in-country managers can be linked to this strategy. Furthermore, the company can decouple sales incentives for its sales agents from sales volume in countries in scope of the Index.

Ensure all late-stage R&D projects have comprehensive access plans. MSD has an R&D access planning process in place and project-specific access plans for 43% of its late-stage R&D projects. The company can apply this process to all late-stage R&D projects, including tedizolid (Sivextro®) for *S. pneumoniae*, islatravir (MK-8591) for the treatment of HIV infection and its chikungunya virus vaccine (V184).

Expand access to patented medicines on the WHO Model List of Essential Medicines. MSD has a non-exclusive voluntary license in place for paediatric raltegravir (Isentress®), for HIV, with one generic company already manufacturing it under this licence. The company can expand access to raltegravir in countries with a high disease burden by expanding registration and applying equitable pricing. The company can also expand access to products such as pembrolizumab (Keytruda®), which has multiple cancer indications, through equitable pricing strategies and/or non-exclusive voluntary licensing.

CHANGES SINCE THE 2021 INDEX

- Entered into an agreement with UNICEF to supply up to 3 million courses of COVID-19 antiviral molnupiravir (Lagevrio®) to LMICs through the first half of 2022.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Licensed its COVID-19 antiviral molnupiravir (Lagevrio®) through the Medicines Patent Pool, covering 106 countries, 95 within the scope of the Index.
- Agreed with UNICEF to establish the world's first global Ebola vaccine stockpile of the Zaire ebolavirus vaccine (Ervebo®).
- Issued a USD 1 billion sustainability bond to support projects and partnerships that contribute to the advancement of the UN SDGs including access to healthcare and infectious disease research and development and to support initiatives that address access barriers and strengthen health systems.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources. For

the 2022 Index, MSD declined to submit data to the Access to Medicine Index. The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where

the use of LMIC refers to lower-middle income countries as per the World Bank income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

*In the 2021 Index, dense ranking was used. In the 2022 Index, standard competitive ranking is used. Therefore, a direct comparison with MSD's previous rank is not possible.

SALES AND OPERATIONS

Business segments: Animal health, pharmaceuticals and other segments.

Therapeutic areas: Cardiovascular, diabetes, hospital acute care, immunology, neuroscience, oncology and virology.

Product categories: Animal health, innovative medicines and vaccines.

M&A news: MSD acquired Acceleron Pharma Inc. in November 2021 for USD 11.5 billion.

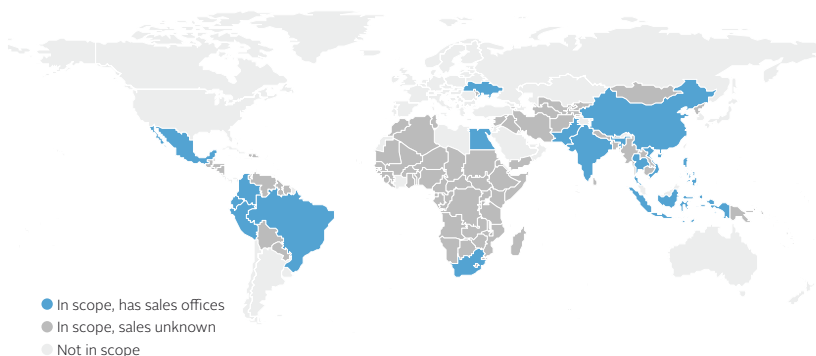
MSD's products are sold in 81* out of 108 countries in scope of the Index. MSD has sales offices in 15 countries and sells via suppliers and/ or pooled procurement in 66* countries.

*In 2016, MSD reported sales in 81 countries.

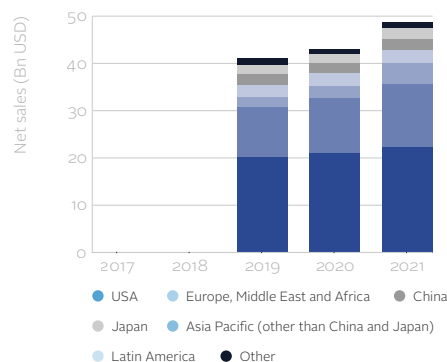
Net sales by segment (2020) – in USD

Animal health	4.70 bn
Pharmaceuticals	43.02 bn
Other segment sales	0.02 bn
Total	47.75 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

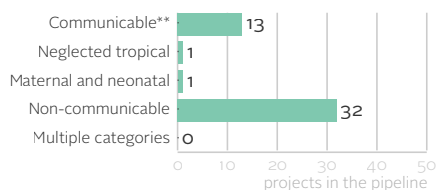
MSD has a total of 47 R&D projects in scope with 13 of these projects targeting priority diseases. The other 34 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (five projects). Of the projects targeting other diseases in scope, the focus is on oncology (29).

Twenty-eight R&D projects are in late-stage development that target either a priority disease (10) or address a public health need in LMICs (18)*. Evidence of access planning was reported in these sections for 43% of these projects: three targeting a priority disease and nine addressing a public health need in LMICs.

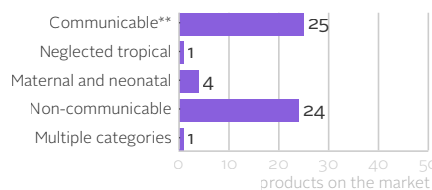
PORTFOLIO as selected for analysis by the Index

MSD has 37 medicines in scope, 23 of which are on patent, and 13 vaccines. 32% of the medicines (12) are on the WHO EML. In addition, the company markets one vector control product and four contraceptive methods and devices. The off-patent medicines target mainly non-communicable diseases (NCDs) (12) such as mental health (1) and cardiovascular diseases (4), cancer (2), asthma (2) and migraine (1); communicable diseases (CD) (3) such as HIV/AIDS, tuberculosis and hepatitis C. The on-patent medicines target CDs such as HIV/AIDS (5), hepatitis C (3), respiratory and other prioritised infections; and NCDs such as diabetes (6), cancer (3) and mental health (1). MSD's preventative vaccines (10) target CDs such as measles (2) and lower respiratory infections, and NCDs such as cancer (2). One vaccine is indicated for immunisation against HPV-related cervical cancer.

47 projects in the pipeline



55 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	3	3	5	2	0	13
Addresses needs of LMICs*			0	8	5	5	0	18
Other projects in scope			0	14	1	1	0	16

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	21			23
off patent	10	4			14
Vaccines	12	1			13
Contraceptives	2	2			4
Diagnostics			0		0
Other†				1	1

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. ‡Other includes vector control products.

Merck & Co, Inc

GOVERNANCE OF ACCESS

RANK 20

SCORE 3.14

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. MSD performs strongly. It has an access strategy, guided by its Access to Health Statement of Guiding Principles, which covers all therapeutic areas in which the company is involved. The highest responsibility for access lies indirectly with the board, namely with the Public Policy and Responsibility Council reporting to the Executive Committee.

Does not provide evidence of financial or non-financial access-related incentives at the managerial level. Merck's performance is below average. The company does not disclose access-related incentives for senior executives or in-country managers.

Publicly discloses outcomes of its access-to-medicine activities. MSD performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives, and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transpar-

ency by consistently sharing the outcomes of its MSD for Mothers initiatives in a centralised manner directly on its website.

Performs comparatively poorly in responsible promotional practices. MSD does not disclose whether its sales agents are not solely incentivised on sales volume targets. There is evidence that the company sets incentives based on sales targets at the individual level for agents. It has Guiding Principles for ethical business practices involving the medical and scientific community and discloses information related to transfers of values to healthcare professionals in countries in scope of the Index in accordance with law and local regulations and association guidance (e.g. payments for attending events or promotional activities).

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. MSD performs relatively poorly, demonstrating evidence of some components looked for by the Index: audits (both internal and external, covering

third parties and in all countries where it operates) and formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of fraud-specific risk assessment, country risk-based assessment, or a continuous system to monitor activities. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. MSD publicly shares support of the Doha Declaration on TRIPS and Public Health but expresses reservations on its provisions. That is, it challenges compulsory licensing, stating it should only be used in very limited circumstances. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, MSD, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 11

SCORE 2.38

Access planning processes encompass all projects in the pipeline. The company reported no information to the Index about its access planning processes. However, evidence of this was identified in the public domain. MSD has a structured process to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope of the Index. In general, MSD begins developing access plans for R&D projects in Phase II of clinical development.

A small-sized priority R&D pipeline compared to peers, with evidence of access plans for 30% (3/10) of the late-stage candidates. MSD has 13 projects, including ten late-stage candidates in its pipeline, that target a priority product gap. These projects focus mostly on HIV/AIDS. Of MSD's ten late-stage candidates targeting a priority product gap, three have evidence of an access plan in place. The company did not participate in the Access to Medicine Index data submission. However, evidence of access plans for three projects was found in the public domain.

For example, MSD agreed a non-exclusive voluntary licensing agreement with the Medicines Patient Pool for its COVID-19 antiviral molnupiravir (MK-4482 and EIDD-2801) before it received emergency regulatory authorisation.

Many projects address a public health need in LMICs*, with 50% (9/18) of late-stage projects supported by access plans. In this analysis, MSD has 18 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index or are first-in-class projects. Most target cancer. The company did not participate in the Access to Medicine Index data submission. However, MSD has a policy whereby once a product is approved, it commits to registering it in all countries where clinical trials for the product have taken place. Therefore, commitments to

register in countries in scope apply to nine of these projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, MSD does disclose fully disaggregated R&D investment data to Policy Cures Research.

One R&D capacity building initiative included for analysis meets all Good Practice Standards. MSD's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards than what is average for this indicator. The company did not participate in the Access to Medicine Index data submission. However, based on information in the public domain, one initiative could be included for analysis. In this initiative, MSD partners with Seeding Labs to improve access to laboratory equipment for the scientific community in LMICs.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 19

SCORE 1.75

Public commitment not to enforce patents in countries in scope. MSD publicly pledges to neither file for nor enforce patents. This commitment applies in LICs.

Publicly discloses information on patent status. Like most of its peers, MSD discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. MSD discloses patent information such as filing date, grant number, grant date and jurisdiction. Additionally, it discloses US patent numbers for its entire US portfolio of vaccines and biologics.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. MSD does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. MSD has a non-exclusive voluntary licensing agreement in place for two compounds (for diseases in scope). Its licence for its paediatric formulation of raltegravir (Isentress®), indicated for HIV/AIDS, encompasses 89 countries within the scope of the Index including 59 middle income countries. MSD also has a licence for its COVID-19 antiviral, molnupiravir (Lagevrio®), agreed with 27 sublicensees, covering 95 countries relevant to the Index including 68 middle income countries.

No evidence of filing for registration new products in any country in scope on average. MSD did not disclose evidence of filing for registration any of its analysed products.

Has access strategies for all its supranationally procured products in scope of this analysis. MSD performs below average in securing access for products procured supranationally. For all of the three products assessed in this category, examples of strategies both in countries eligible for supply from such procurers and in at least one non-eligible country were found publicly. For example, the company has a tiered pricing policy for vaccines, including the pneumococcal vaccine polyvalent (23-valent) (Pneumovax®23). Information regarding patient reach was not found in the public domain.

Has an access strategy for its healthcare practitioner-administered products in scope of this analysis. MSD performs below average in securing access for healthcare practitioner-administered products. Evidence of an access strategy that considers some affordability factors was found in China for pembrolizumab (Keytruda®), an oncology product. No evidence of access strategies for the remaining products were found in the public domain, nor was evidence regarding patient reach, either publicly or to the Index. The products are an oncology treatment, antibiotics and a product targeting ischaemic heart disease.

No evidence of access strategies for any of its self-administered products in scope of this analysis. MSD has not disclosed, either publicly or to the Index, access strategies for any of the five products assessed by the Index in this category. The products are diabetes treatments, a product targeting asthma and one targeting migraine.

No manufacturing capacity building initiatives included for analysis. There is no evidence — in the public domain or disclosed to the Index — of manufacturing capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. MSD's performance is below average in this area.

Both supply chain capacity building initiatives included for analysis meet all Good Practice Standards. MSD's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average but an average number of initiatives meet all Good Practice Standards (GPS) for this indicator. For example, MSD is a member of the Neglected Tropical Disease (NTD) Supply Chain Forum which provides a common platform for all partners to come together and explore options to manage the NTD drug supply chain.

One of the two health systems strengthening initiatives included meets all Good Practice Standards. MSD's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all GPS than what is average for this indicator. For example, MSD for Mothers is a USD 650 million global initiative, contributing the company's scientific and business expertise and financial resources to address preventable maternal deaths through supporting quality maternity care and access to modern contraception. This initiative meets all GPS.

Has engaged in scaling up two inclusive business models but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria. MSD performs average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. In Kenya, MSD is supporting the expansion of M-TIBA to include maternal health services through Mom Care, a new platform that links patients, providers and payers to improve the financing and delivery of maternity care.

Performs below average in terms of ensuring continuous supply of medicines in LMICs. MSD shows evidence of its involvement in supply chain capacity building initiatives and transfers technology with third-party manufacturers in LMICs. However, there is no evidence that the company works with relevant stakeholders to communicate issues that may affect the supply chain, maintains a network of several active pharmaceutical ingredient suppliers, nor manages a buffer stock of relevant products.

Does not disclose a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index. MSD does not disclose, publicly or to the Index, evidence of a policy in place to report SF medicines to relevant health authorities. However, it publicly discloses having a global Product Integrity Strategy on tackling counterfeit products, and reports that it responds in alignment with local regulatory requirements.

Donates in response to expressed need and monitors delivery. MSD has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria. In one programme, for over 15 years MSD has publicly committed to supporting the elimination of onchocerciasis and lymphatic filariasis by donating ivermectin (Mectizan®) in 27 countries in scope of the Index until goals are achieved.

RANK	SCORE
5	3.72
8 (2021)	

Merck KGaA

Stock exchange: XFRA • Ticker: MRK • HQ: Darmstadt, Germany • Employees: 60,334

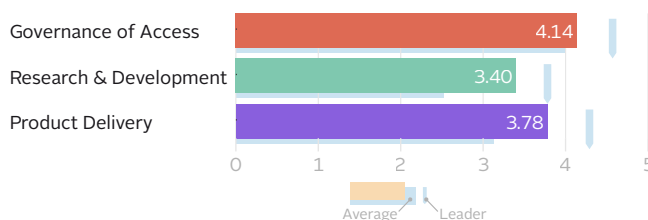
PERFORMANCE IN THE 2022 INDEX

5th place. Merck performs strongly and is now in the top five of the Index. Merck excels in R&D access planning and it performs well in its approach to patent transparency. It also engages in high-quality capacity building initiatives across all fields and has an average performance in Governance of Access.

Governance of Access: 10th place. Merck has an average performance in this area. It has a clear access-to-medicine strategy that is integrated into its overall corporate strategy, but it does not extend across its pipeline and portfolio. It discloses the outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index, but it provides limited evidence on access-related incentives for its CEO and no evidence of access-related incentives for in-country and regional managers.

Research & Development: 4th place. Merck performs strongly in this area. The company has a structured access planning

How score was achieved



framework in place and has access plans for all late-stage candidates. The company excels in R&D capacity building.

Product Delivery: 5th place. Merck performs well in this area. Merck performs strongly in sharing intellectual property assets with third-party researchers. It has improved in its approach to equitable access strategies, yet the focus is mostly on upper-middle and lower-middle income countries. Merck engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply and health systems strengthening).

OPPORTUNITIES FOR MERCK KGAA

Improve the quality of access plans for R&D projects for cancer. Merck has access plans in place for all late-stage R&D candidates. Most of these plans, focus solely on registration in countries in scope of the Index. Merck can expand its access plans beyond registration to consider more access components such as equitable pricing and licensing.

Expand manufacturing capacity building efforts beyond vaccines. Merck started the Merck Africa Biologics and Vaccine Initiative (MABVI), which aims to develop integrated solutions to deploy innovative manufacturing technologies that enable local biologics manufacturing across Africa. The initiative is currently active in eight countries in scope of the Index and focuses on vaccines. Merck can expand this initiative to focus on further products such as biological treatments. The company can also regularly monitor and share impact.

Expand access to cancer treatments. Merck implemented access strategies for avelumab (Bavencio®) in at least one upper-middle income country and one lower-middle income country. The company can increase patient reach through registration, equitable pricing and/or non-exclusive voluntary licensing, especially in countries where the burden of bladder cancer is the highest such as Egypt, Armenia and the Republic of Moldova.

CHANGES SINCE THE 2021 INDEX

- Added “country segmentation” to compliance risk management in all countries where Merck actively operates to classify countries in terms of their risk exposure.
- Donated research instruments and materials to the Eijkman Institute for Molecular Biology to support in its efforts in accelerating COVID-19 vaccine development research in Indonesia.
- The Merck Family Foundation donated EUR 100,000 to Business for Health Solutions (BHS), an initiative in which Merck employees dedicate time to build capacity in the local African healthcare sector. The initiative will be expanded to up to six healthcare companies in western Africa.
- Expanded its long-term donation programme to adult treatment for the elimination of schistosomiasis in Rwanda.
- Successfully completed the clinical development of the potential new medication (arpraziquantel) to treat schistosomiasis in children as of 6 years of age and below.
- Submitted the WHO prequalification dossier of an optimised praziquantel (Cesol® 600) formulation.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Electronics, healthcare and life sciences.

Therapeutic areas: Endocrinology, fertility, general medicine, immunology, immun-oncology and neurology.

Product categories: Diagnostics, innovative medicines and medical devices.

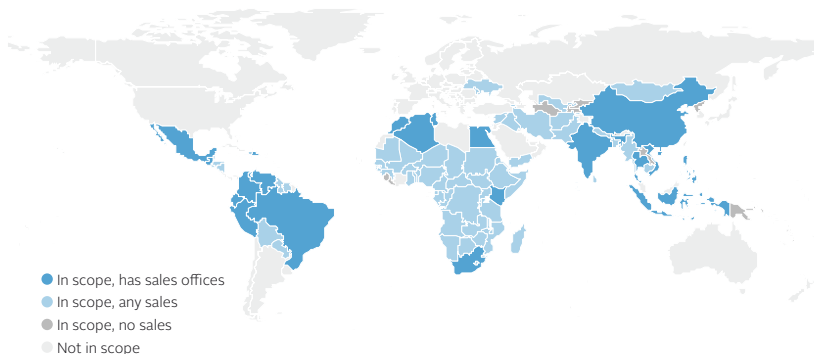
M&A news: Merck KGaA acquired Exelead in February 2022 for approximately USD 780 million.

Merck's products are sold in 89 out of 108 countries in scope of the Index. Merck has sales offices in 20 countries, and sells via suppliers and/or pooled procurement in an additional 69 countries.

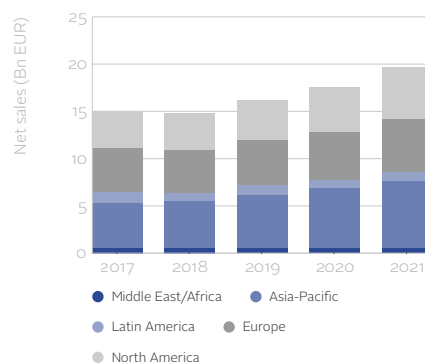
Net sales by segment (2021) – in EUR

Life sciences	8.99 bn
Healthcare	7.09 bn
Electronics	3.61 bn
Total	19.69 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

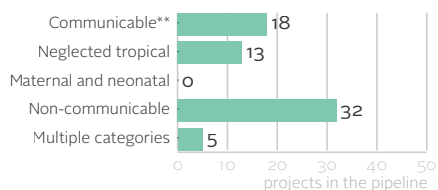
PIPELINE for diseases in scope

Merck has a total of 68 R&D projects in scope with 33 of these projects targeting priority diseases. The other 35 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on schistosomiasis (13 projects) and malaria (11). Of the projects targeting other diseases, the focus is on oncology (34). Thirteen R&D projects are in late-stage development that target either a priority disease (3) or address a public health need in LMICs (10).^{*} Evidence of access planning was in place for 100% of these projects.

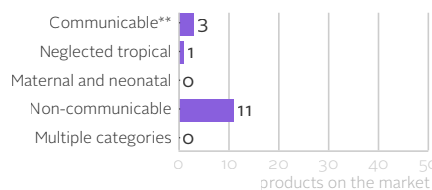
PORTFOLIO as selected for analysis by the Index

Merck has 13 medicines in scope, two of which are on patent. 38% of these medicines (5) are on the WHO EML. In addition, the company markets two diagnostics for HIV/AIDS. The off-patent medicines target non-communicable diseases (9) such as cardiovascular diseases (5), cancer (1) and diabetes (3). Furthermore, the company markets chloroquine for malaria and praziquantel for parasitic worm infections. The on-patent medicines target cancer (2).

68 projects in the pipeline



15 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	17	0	1	1	0	2	12	33
Addresses needs of LMICs*			13	7	1	2	0	23
Other projects in scope			4	4	0	0	4	12

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	0	2			2
off patent	5	6			11
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			2		2
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. ^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Merck KGaA

GOVERNANCE OF ACCESS

RANK 10

SCORE 4.14

Has an access-to-medicine strategy with measurable objectives, integrated within the overall corporate strategy. Merck performs well. It has a Global Health strategy focused on availability, affordability, awareness and accessibility. The strategy covers some of the therapeutic areas in which the company is involved, with a focus on the elimination of schistosomiasis, malaria, and the prevention and control of non-communicable diseases (NCDs) in LMICs. The highest responsibility for access lies directly with the CEO of Healthcare at Merck, who manages Global Health on behalf of the Executive Board.

Provides evidence of financial and non-financial access-related incentives at the executive level. Merck performs well. It incentivises the CEO and other senior executives with objectives related to sustainability. It publicly states that the CEO's Long-Term Incentive Plan (LTIP) is connected to a Sustainability Factor consisting of three sustainability indicators, and the goal of the first indicator is to achieve human progress for more than one billion people by 2030 through sustainable science and technology.

Publicly discloses outcomes of its access-to-medicine activities. Merck performs

strongly in transparency of access activities. It publicly discloses commitments, including on combating NCDs, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Sustainability Report.

Has an average performance in responsible promotional practices. Merck's sales agents are not solely incentivised on sales volume targets. However, additional details on how the company addresses sales incentives for sales agents are unavailable. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by law or by local regulations, though it has policies and procedures in place limiting transfers of values to healthcare professionals.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Merck performs strongly, demonstrating evi-

dence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Merck publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on the implementation of its provisions. That is, it highlights compulsory licensing as a risk of undermining innovation. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Merck, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 4

SCORE 3.40

Access planning processes encompass all projects in the pipeline. Merck has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Merck begins developing access plans for R&D projects in Phase II or earlier of clinical development.

An average-sized priority R&D pipeline compared to its peers, with evidence of access plans in place for 100% (3/3) of late-stage candidates. Merck has 33 projects, including three late-stage candidates that target a priority product gap. The priority pipeline focuses mainly on schistosomiasis and malaria. There is evidence of access plans for all three of Merck's late-stage candidates. Notably, the access plan for the potential new treatment option for schistosomiasis (arpraziquantel) includes plans for

WHO prequalification, priority registration in high burden African countries, engagement with access-oriented funding organisations and local manufacturing arrangements to ensure equitable and sustainable access and supply.

Many projects address a public health need in LMICs,* with 100% (10/10) of late-stage candidates covered by access plans. In this analysis, Merck has ten late-stage R&D projects that target a disease and/or product gap not yet designated as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules. All target cancer. Merck provides evidence of access plans for all ten of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Merck does not disclose disaggregated R&D investment data to global health organisations.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. Merck leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, Merck partners with Seeding Labs, to improve access to lab equipment for the scientific community in countries in scope of the Index. Additionally, Merck is the founding sponsor of the TeleScience platform, an online platform that provides teaching and training to scientists in LMICs.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 5

SCORE 3.78

Public commitment not to enforce patents in countries in scope. Merck publicly pledges to neither file for nor enforce patents. This commitment applies to all Least Developed Countries and LICs as well as in a subset of LMICs and UMICs, a total of 90 countries in scope of the Index.

Publicly discloses detailed information on patent status. Like most of its peers, Merck publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Additionally, Merck discloses the type of patents and their expiry dates on its website for a subset of products in scope of the Index.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Merck engaged in 17 new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Merck does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register new products in six countries in scope on average. Merck did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely registered is bisoprolol (Concor®/Concor® COR), indicated for cardiovascular diseases, filed in 63 countries relevant to the Index, including four high burden countries (Republic of Moldova, Syrian Arab Republic, Ukraine and Uzbekistan) and ten LICs.

Merck is not eligible for assessment of supra-nationally procured products.

Has access strategies for some healthcare practitioner-administered products in scope of this analysis. Merck has an average performance in this area. For one of the two products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC). The company makes efforts to reach additional patients using pricing mechanisms that consider payers' ability to pay and has implemented strategies to ensure patients' access to a product not available on the market yet. Merck provides evidence of how patient reach has been increased through the approaches used in the UMIC and LMIC country examples.

Has access strategies for its self-administered products for some countries in scope of this analysis. Merck performs below average in this area. The company provides examples of access strategies which consider affordability in UMIC and LMIC contexts for three of the five products assessed. Evidence of access strategies in LICs was not provided. Merck makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, in Egypt, the company participates in tenders to supply the diabetes medicine metformin/glibenclamide (Glucovance®) and it has initiatives to assist patients in disease management. The company provides evidence of the number of patients reached by this product in Egypt and Mexico.

Three of the five manufacturing capacity building initiatives included meet all Good Practice Standards. Merck's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, the Pediatric Praziquantel Consortium aims to reduce the global disease burden of schistosomiasis by addressing the medical need of infected children aged six and below. One of the goals of this program, led by Merck, is to establish a sustainable and affordable manufacturing and supply chain that involves sites in LMICs. This initiative meets all GPS.

Three of the five supply chain capacity building initiatives included meet all Good Practice Standards. Merck's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. Merck has been a member of CAMP-N Supply Chain Technical Working Group since its launch in 2017. This coalition of government agencies, private sector entities, non-governmental organisations, philanthropic foundations and academic institutions is dedicated to increasing access to medicines and health products for NCDs. This initiative meets all GPS.

Two of the five health systems strengthening initiatives included meet all Good Practice Standards. Merck's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all GPS than what is average for this indicator. For example, Merck and the NALA Foundation Partnership to Eliminate Schistosomiasis combines treatment, research and development and health education and WASH (water, sanitation and hygiene) to support the elimination of this neglected tropical disease in Ethiopia. This initiative meets all GPS.

The company has engaged in both scaling up and piloting one inclusive business model.

Merck performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. CURAFA™ points of care for integrated healthcare services, piloted in Kenya, aim to provide primary healthcare access to underserved populations in low-income communities in emerging economies.

Performs above average in terms of ensuring continuous supply of medicines in LMICs.

Merck is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Merck provides evidence of reporting confirmed SF medicines to the relevant national health authorities within ten days. When authorities request a visual assessment of an obvious counterfeit product (e.g., obvious artwork errors or a non-existing batch number), Merck commits to provide conclusions of the assessment to the relevant health authorities in less than ten days.

Donates in response to expressed need and monitors delivery. Merck has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Since 2007, Merck has publicly committed to supporting the elimination of schistosomiasis by donating praziquantel (Cesol®) in 43 countries in scope of the Index until goals are reached.

RANK	SCORE
4	3.87
2 (2021)	

Novartis AG

Stock exchange: SWX • Ticker: NOVN • HQ: Basel, Switzerland • Employees: ~108,000

PERFORMANCE IN THE 2022 INDEX

4th place. Novartis ranks among the top five companies in the Index. Novartis has comprehensive access plans in place for all late-stage candidates in the pipeline and performs strongly in high-quality capacity building initiatives across all fields. The company leads in its approach to access strategies for self-administered products.

Governance of Access: 15th place. Novartis performs below average in this area. It has integrated access-to-medicine into its corporate strategy under the Novartis Access Principles and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. However, the company was found to be the subject of a legal settlement during the period of analysis based on conduct by a former subsidiary.

Research & Development: 3rd place. Novartis performs strongly in this area. It has an access planning framework and applies this to all its late-stage pipeline candidates. Novartis performs strongly in R&D capacity building and leads by publicly disclosing R&D investments for priority neglected diseases.

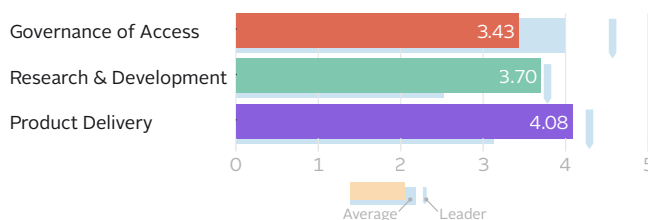
OPPORTUNITIES FOR NOVARTIS

Expand technology transfers to more countries. Novartis reports seven technology transfers to build manufacturing capacity. Capacity building is focused on countries like China, India and Brazil which have well-established pharmaceutical markets. The company can engage in further technology transfers in countries where its products address a high disease burden, aiming to expand access and regional availability. For example, Novartis can transfer technology for its products indicated for chronic obstructive pulmonary disease or products in its oncology portfolio.

Expand the geographic scope of the CancerPath to Care initiative. In 2022, Novartis announced the expansion of its donation and capacity building efforts for cancer products beyond chronic myeloid leukaemia (CML) through partnership with The Max Foundation called CancerPath to Care. Novartis will continue to support the Foundation with the delivery of the donation treatments for breast cancer, CML and rare cancers. Novartis can work with partners to expand donations and capacity building efforts through this initiative to more countries with a high disease burden.

Expand access to breast cancer and cardiovascular products. Novartis has access strategies in place for its breast cancer product, ribociclib (Kisqali®), in at least one upper-middle income country and lower-middle income country, and has committed to implementing an access strategy in at least three low-income countries (LICs) in the future. Novartis can provide evidence of implementing additional access strategies for ribociclib in LICs. In addition, it can expand patient reach via non-pricing access strategies such as non-exclusive voluntary licences (NEVLs). For example, Novartis has announced a NEVL for nilotinib (Tasigna®), indicated for leukaemia. Novartis could also pursue a NEVL for ribociclib.

How score was achieved



Product Delivery: 4th place. Novartis performs strongly in this area. The company has high quality access strategies in place across all country income classifications for a subset of its products. It has scaled up and piloted the highest number of inclusive business models of all companies. It also performs strongly in capacity building across all fields (i.e., manufacturing, supply chain and health systems strengthening). The company is engaging in non-exclusive voluntary licensing to enable generic supply of a non-communicable disease product in LMICs, the first agreement of its kind.

CHANGES SINCE THE 2021 INDEX

- Established an ESG Council which co-creates and oversees the development of the ESG strategy, formulates ESG targets and raises relevant topics to the Trust & Reputation Committee.
- Created an Access Solutions Center of Excellence within Novartis Corporate Affairs and Global Health to provide guidance on the Access Principles implementation across the full organisation (Pharma, Oncology, Global Health, R&D).
- New ESG framework will prioritise access as one of the two most important materiality topics.
- Publicly disclosed disaggregated R&D expenses on priority diseases (excluding COVID-19) and separately for malaria.
- Joined the Neglected Tropical Disease Supply Chain Forum in 2021 with its Leprosy Donation programme to the World Health Organisation.
- Entered a partnership with Save the Children to launch a pilot community health project tackling child mortality in Kenya's Kibera and Mathare slums.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.
- As part of ATOM Coalition, agreed to a non-exclusive voluntary license (NEVL) with the Medicines Patent Pool (MPP) for nilotinib, indicated for leukaemia, becoming the first company to have signed a NEVL for an oncology medicine.
- Issued a EUR 1.85 billion sustainability-linked bond (SLB), reinforcing its commitment to ESG principles and the 2025 Patient Access Targets. The first of its kind in the healthcare industry and the first SLB incorporating social targets.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Sandoz (generics and biosimilars) and Innovative Medicines.

Therapeutic areas: Oncology, cardiovascular, renal and metabolism, Respiratory and allergy, Immunology, hepatology and dermatology, Neuroscience, Infectious diseases, Ophthalmology.

Product categories: Innovative medicines, generic medicines, biosimilars.

M&A news: Novartis acquired Vedere Bio in October 2020, Cadent in December 2020,

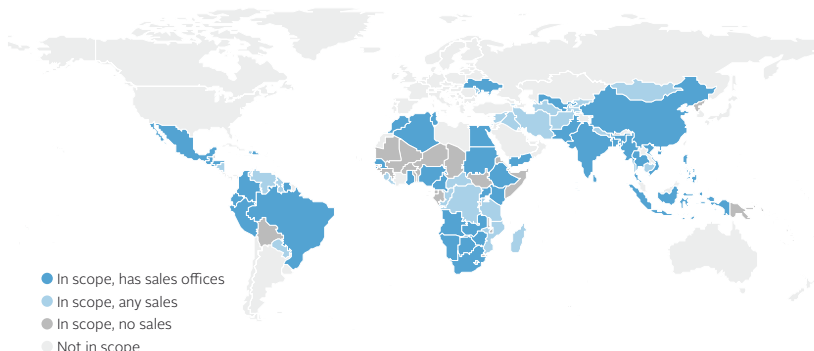
Arctos Medical in September 2021, GSK's cephalosporin antibiotics business in October 2021, Gyroscope Therapeutics in December 2021 and Kedalion Therapeutics in June 2022.

Novartis' products are sold in 72 out of 108 countries in scope of the Index. Novartis has sales offices in 43 countries, and sells via suppliers and/or pooled procurement in an additional 29 countries.

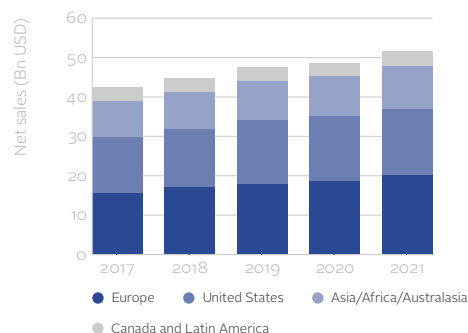
Net sales by segment (2021) – in USD

Innovative Medicines	42.00 bn
Sandoz	9.63 bn
Total	51.63 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

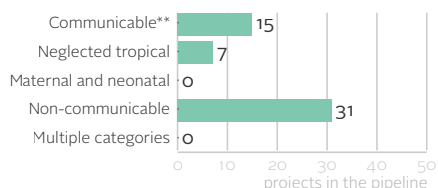
Novartis has a total of 53 R&D projects in scope with 22 of these projects targeting a priority disease. The other 31 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on malaria (11 projects) and Chagas disease (5). Of the projects targeting other diseases in scope, the focus is on oncology (22).

Seventeen R&D projects are in late-stage development that target either a priority disease (6) or address a specific need in LMICs (11).^{*} Evidence of access planning was in place for 100% of these projects.

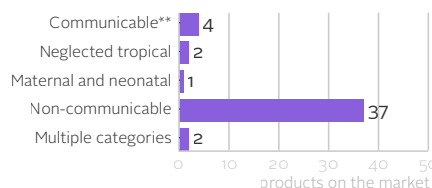
PORTFOLIO as selected for analysis by the Index

Novartis has 46 medicines in scope, 25 of which are on patent. 48% of these medicines (22) are on the WHO EML. The off-patent medicines target non-communicable diseases (NCDs) (14) such as cardiovascular diseases (6) mental health conditions (2) and cancer (3); neglected tropical diseases such as leprosy (2), communicable diseases such as tuberculosis (3); and one product for maternal haemorrhage. The on-patent medicines mainly target NCDs (25) such as cancer (10), respiratory diseases (6), cardiovascular diseases (3) and diabetes (2). In addition, one targets hepatitis B.

53 projects in the pipeline



46 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	10	2	4	4	1	0	1	22
Addresses needs of LMICs [*]			8	5	6	0	0	19
Other projects in scope			9	3	0	0	0	12

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	3	22			25
off patent	19	2			21
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. ^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Novartis AG

GOVERNANCE OF ACCESS

RANK 15

SCORE 3.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novartis performs strongly. Its strategy is embedded in its Novartis Access Principles and has a tailored approach for sub-Saharan Africa. The strategy covers all therapeutic areas in which Novartis is involved. The highest responsibility for access at Novartis lies directly with the board, namely with the Governance, Sustainability and Nomination Committee (GSNC).

Evidence of access-related incentives at the executive level. Novartis performs strongly. Novartis incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO and Executive Committee have access-related incentives included in their performance targets.

Publicly discloses outcomes of its access-to-medicine activities. Novartis performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving

access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Novartis in Society Integrated Report.

Performs above average in responsible promotional practices. Novartis' sales agents are not solely incentivised on sales volume targets. However, the company sets sales incentives at the individual level for agents. Novartis does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g., payments for attending events or promotional activities), unless required by law or by local regulations, but it does have policies and procedures in place limiting transfers of values to healthcare professionals.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novartis performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based

assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards.

Does not publicly take a position of support on the Doha Declaration on TRIPS and Public Health. Novartis does not publicly take a position of support of the Doha Declaration on TRIPS and Public Health as a whole, but it does publicly support, and/or adopts policies that it states exceed, several of the individual flexibilities embodied by the Doha Declaration. Novartis also supports the use of compulsory licensing in exceptional circumstances to address situations that require an extraordinary or urgent response to a pressing public need. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Novartis, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 3

SCORE 3.70

Access planning processes encompass all projects in the pipeline. Novartis has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Novartis begins developing access plans for R&D projects in Phase II of clinical development.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (6/6) of late-stage projects. Novartis has 22 projects, including six late-stage candidates in its pipeline, that target a priority product gap. These projects mainly focus on malaria. Novartis' six late-stage candidates targeting a priority product gap have access plans in place. The plans consider the availability and affordability of projects in development. For two projects targeting malaria, Novartis plans to expedite access by registering via the Marketing Authorization for Global Health Products (MAGHP) procedure in Switzerland. This aims to improve and accelerate

access to products in LMICs by involving national regulatory authorities in sub-Saharan Africa who will participate actively in the assessment in order to reduce approval timelines.

Many projects address a public health need in LMICs,* with 100% (11/11) of late-stage projects covered by access plans. In this analysis, Novartis has 11 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules or first-in-formulation projects. Projects target several diseases in scope of the Index including cancer, chronic obstructive pulmonary disease and sickle cell disease. Novartis provides evidence of access plans for all 11 late-stage projects which mainly focus on equitable pricing strategies and registration preparation in countries relevant to the Index.

Publicly discloses disaggregated R&D investment data for priority diseases, neglected tropical diseases and stages of development. In addition, Novartis also discloses fully disaggregated R&D investment data to Policy Cures Research.

Four of the five R&D capacity building initiatives included meet all Good Practice Standards. Novartis' performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, for the Ghana Sickle Cell Disease (SCD) Scientist Training Program, Novartis partners with the Sickle Cell Foundation of Ghana to train scientists that are working in the field of SCD. Training includes remote mentoring of scientists and a Postdoctoral Fellowship in natural product drug discovery at Novartis research labs.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 4

SCORE 4.08

Public commitment not to enforce patents in countries in scope. Novartis publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries, LICs and a subset of LMICs.

Publicly discloses information on patent status. Like most of its peers, Novartis discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Novartis discloses patent information, including filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Novartis engaged in three new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

Uses licensing agreements to enable generic supply. After the period of analysis, Novartis signed a non-exclusive licensing agreement with the Medicines Patent Pool (MPP) for its oncology medicine, nilotinib (Tasigna®), the first agreement of its kind for a non-communicable disease product.

Filed to register new products in 15 countries in scope on average. Novartis has filed one out of ten of its most recently registered products in half of the relevant top 10 high burden countries. Among new products, Erenumab (Aimovig®), indicated for migraine, has been filed for registration in five high burden countries in scope of the Index (Brazil, Egypt, Indonesia, Thailand and Vietnam). Among old products, its most widely registered is sacubitril/valsartan (Entresto™), indicated for ischaemic heart disease, filed for registration in 48 countries relevant to the Index, including five high burden disease countries (Armenia, Egypt, Republic of Moldova, Ukraine and Uzbekistan).

Has access strategies for all supranationally procured products in scope of this analysis. Novartis has an average performance in securing access for products procured supranationally. For two of the four products assessed in this category, it demonstrated strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, the company offers the same price in South Africa for the malaria medicine artemether/lumefantrine (Riamet®/Coartem®) as it does in the Global Fund eligible countries. Novartis provides evidence of patient reach, reporting that approximately 26,000 patients in South Africa have received the product through the public channel in the period from April 2020 to February 2022.

Has access strategies for its healthcare practitioner-administered products in scope of this

analysis. Novartis has an average performance in this area. For two of the four products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). Novartis makes efforts to reach additional patients using pricing strategies considering relevant payers' ability to pay. For example, the company launched an Emerging Market Brand of crizanlizumab (Adakveo®), a treatment for sickle cell disease in India. Known as Ryverna, the product is currently available at a lower price than the original brand in several Indian national accounts, in accordance with the Novartis Global Oncology Pricing Tiers Guidance, and the company is working for inclusion in further state tenders. In addition, Novartis implemented a patient support programme to supply the medicine at no cost to eligible patients. Novartis provides evidence of how patient reach has been increased through these approaches.

Has access strategies for the majority of self-administered products in scope of this analysis. Novartis leads in this area. For four of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients applying pricing strategies considering relevant payers' ability to pay. For example, in India, Novartis supplies nilotinib (Tasigna®) and ribociclib (Kisqali®) through national tenders. In addition, the company provides access to nilotinib to patients in out-of-pocket segments via the Novartis Oncology Access program, a contributions model where the company bears the majority of the cost. The programme also includes disease counselling activities to improve compliance and adherence to the treatment. Novartis provides evidence of how patient reach has been increased through the approaches used.

Four of the five manufacturing capacity building initiatives included meet all Good Practice Standards. Novartis' performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, since 2019 Novartis has worked on the Hibiscus transfer project, supporting contract manufacturers to improve the quality of their production and reduce their carbon footprint.

All five supply chain capacity building initiatives included for analysis meet all Good Practice Standards. Novartis is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. Through the Value Chain Academy, Novartis offers educational workshops for quality in supply, falsified medicines and supply chain management. These courses are offered to several supply chain stakeholders including governmental associations, distributors, hospital

pharmacies and non-governmental organisations.

All five health systems strengthening initiatives included for analysis meet all Good Practice Standards. Novartis is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, in the Strengthening the Translational Ecosystem for Lifesaving Local Access initiative, Novartis and academic partners have developed and are piloting a logistics management information system with the aim to reduce supply chain bottlenecks and improve access to medicines.

Has engaged in scaling up four and piloting three inclusive business models. Novartis leads in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Novartis Biome SSA is an innovation hub that was initiated in November 2021 and spearheads the development of innovative local sustainable business models and technology-driven solutions to improve access to healthcare in the sub-Saharan Africa region.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Novartis is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Novartis has a policy for reporting SF medicines to both national health authorities and the WHO within seven days. The policy classifies incidents following categories according to the impact or potential impact and degree of severity, which may enable faster action.

Donates in response to expressed need and monitors delivery. Novartis has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it shows evidence of monitoring the delivery of donations to recipient organisations.

Publicly commits to the achievement of elimination, eradication or control goals in two structured donation programmes for neglected tropical diseases or malaria. In one programme, Novartis publicly commits itself to contributing to the elimination of leprosy by donating the combination of clofazimine (Lamprene®), dapsone (Dapsone) and rifampicin (Rimactane®) from 2000 to 2025 in 83 countries in scope of the Index.

RANK	SCORE
11	2.97
10 (2021)	

Novo Nordisk A/S

Stock exchange: Nasdaq Copenhagen • Ticker: NOVO-B • HQ: Bagsværd, Denmark • Employees: 48,478

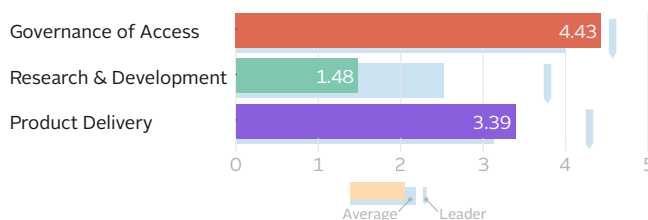
PERFORMANCE IN THE 2022 INDEX

11th place. Novo Nordisk has an average overall performance. It performs strongly in Governance of Access where it has an access-to-medicine strategy integrated into its overall corporate strategy. The company also engages in some high-quality capacity building initiatives. However, it performs comparatively poorly in Research & Development, where it has a small pipeline.

Governance of Access: 2nd place. Novo Nordisk has a strong performance in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. It incentivises its senior executives, including the CEO, and in-country and regional managers to perform on access-to-medicine goals and discloses the outcomes of its access-to-medicine activities.

Research & Development: 19th place. Novo Nordisk performs poorly in this area. The company has a general process

How score was achieved



for access planning during R&D and does not engage in R&D capacity building initiatives. It has a small-sized R&D pipeline compared to its peers.

Product Delivery: 10th place. Novo Nordisk has an average performance in this area. Novo Nordisk engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply chain and health systems strengthening). It has access strategies for most of its products in all country income classifications but does not share IP assets with third-party researchers.

OPPORTUNITIES FOR NOVO NORDISK

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. Novo Nordisk has access plans in place for 78% of late-stage projects analysed. It can develop a structured framework for access planning and ensure these plans cover all late-stage R&D projects. For example, the access plan for its once-weekly Insulin icodex, can be expanded to include access components such as equitable pricing.

Measure and share outcomes of iCARE. The iCARE initiative was launched in 2021 as a business-integrated model aimed towards improving access to diabetes treatment in 49 countries in sub-Saharan Africa. To scale up this initiative and support integration into local health systems, Novo Nordisk can track and share short and long-term patient outcomes as part of its impact evaluation of this programme, in addition to outcomes such as patient reach and volumes of insulin sold.

Expand access to innovative products. Novo Nordisk has an equitable pricing strategy, that applies to recombinant human insulins for all Least Developed Countries, all low-income countries (LICs), and some middle-income countries with large low-income populations. It can expand this equitable pricing strategy to long-acting analogue insulins, such as insulin degludec (Tresiba®), and to other innovative diabetes medicines, such as liraglutide (Victoza®).

Expand registration to insulins listed in the WHO Model List of Essential Medicines. Novo Nordisk has filed long-acting analogue insulin degludec (Tresiba®) for registration in 48 countries within the scope of the Index. The company has not filed this product for registration in any additional countries in scope since 2017. The company can expand registration for this product, especially in countries such as Bolivia and Cameroon, where human insulins have already been filed. In addition, Novo Nordisk can expand registration of human insulins in LICs, such as Sierra Leone, Somalia and South Sudan.

CHANGES SINCE THE 2021 INDEX

- Embedded social responsibility criteria (both access and environmental) into the R&D strategic processes across therapy areas, thereby ensuring such considerations and strategic decisions take place.
- Re-evaluated the thermal stability of short-acting and intermediate-acting human insulin products and will seek national approvals of more flexible storage conditions in relevant LMICs following the positive scientific opinion from the European Medicines Agency.
- Invested USD 50 million into the newly launched Antimicrobial Resistance (AMR) Action Fund through the Novo Nordisk Foundation and USD 25 million through the company itself.
- Extended the Changing Diabetes in Children initiative until 2030, launching the programme in ten new countries. Entered into a collaboration with Harvard University School of Public Health with the aim to improve data, research, innovation and capacity building in type 1 diabetes in LMICs.
- Launched the iCARE initiative based on learnings from the Base of the Pyramid Program. iCARE is a sustainable and fully integrated business model aimed at improving access to affordable diabetes treatment in the Novo Nordisk Middle Africa region.
- Expanded its humanitarian programme with the launch of the Senselet project in Ethiopia and DonateAble.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Biopharm, diabetes and obesity care.

Therapeutic areas: Biopharmaceuticals, diabetes care, obesity care and other serious chronic diseases.

Product categories: Innovative medicines.

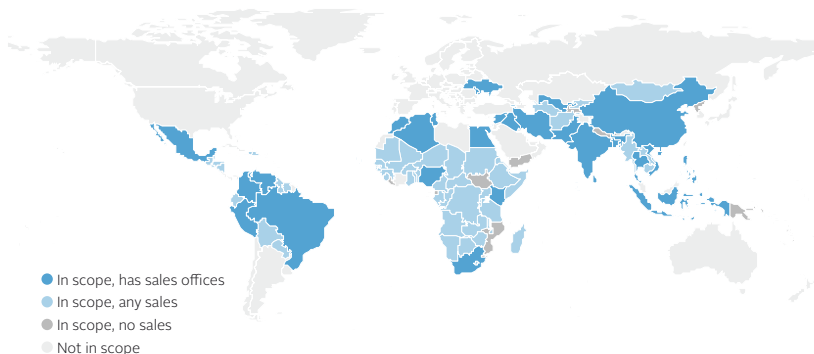
M&A news: Novo Nordisk acquired Dicerna Pharmaceuticals, Inc. in December 2021 for DKK 573 million.

Novo Nordisk's products are sold in 87 out of 108 countries in scope of the Index. Novo Nordisk has sales offices in 28 countries, and sells via suppliers and/or pooled procurement in an additional 59 countries.

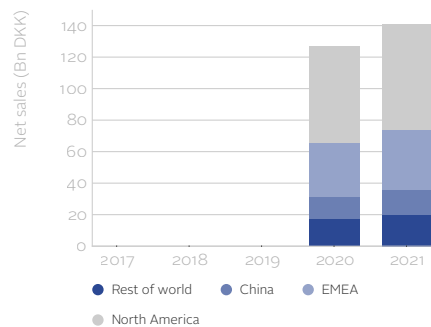
Net sales by segment (2021) – in DKK

Diabetes and obesity care	121.60 bn
Biopharm	19.20 bn
Total	140.80 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

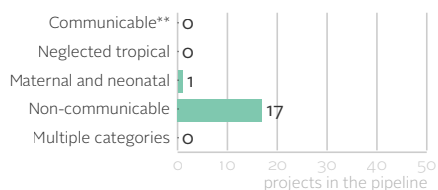
PIPELINE for diseases in scope

Novo Nordisk has a total of 18 R&D projects in scope with one project targeting a priority treatment gap. 17 projects target other diseases in scope. The focus of these projects is on diabetes (11 projects). Nine R&D projects are in late-stage development that target either a priority disease (1) or address a specific need in LMICs (8).^{*} Evidence of access planning was in place for 78% of these projects: one targeting a priority disease and six addressing a public health need in LMICs.

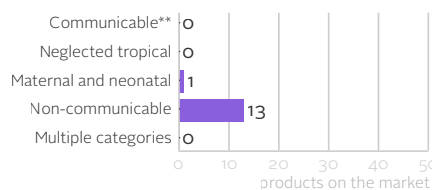
PORTFOLIO as selected for analysis by the Index

Novo Nordisk has 14 medicines in scope, eight of which are on patent. 36% of these medicines (5) are on the WHO EML. Most medicines are indicated for the treatment of diabetes.

18 projects in the pipeline



14 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	0	0	0	1	0	1
Addresses needs of LMICs*			0	2	5	1	0	8
Other projects in scope			5	4	0	0	0	9

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	6	0	0	8
off patent	3	3	0	0	6
Vaccines	0	0	0	0	0
Contraceptives	0	0	0	0	0
Diagnostics	0	0	0	0	0
Other [‡]	0	0	0	0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. ^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Novo Nordisk A/S

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novo Nordisk performs strongly. Its Defeat Diabetes strategy is structured around three focus areas: Prevention, Innovation and Access and Affordability, and includes an Access to Insulin Commitment focused on lowering the ceiling price for LMICs and humanitarian settings globally. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the CEO, under the supervision of the Board of Directors.

Provides evidence of financial and non-financial access-related incentives at the executive level. Novo Nordisk performs strongly. It incentivises its senior executives and in-country leaders to deliver on its access to care objectives. The CEO also has access-related incentives, linked to long-term social targets.

Publicly discloses outcomes of its access-to-medicine activities. Novo Nordisk performs strongly in transparency of access activities. It publicly discloses commitments, including Access to Insulin, measurable goals, objectives and targets for improving access in countries

in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities, including its Changing Diabetes in Children programme, in a centralised manner within its Year in Review report.

Performs above average in responsible promotional practices. Novo Nordisk's sales agents are not solely incentivised on sales volume targets. However, the company sets sales incentives at the individual level for agents. Novo Nordisk publicly discloses information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), where required by law and/or by local regulations, including consent related regulation, and it has policies and procedures in place governing transfers of values to healthcare professionals.

Has a robust set of compliance controls designed to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novo Nordisk performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a

continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Novo Nordisk does, however, publicly state that health emergencies requiring exceptions to intellectual property (IP) rights can and should be accommodated under the international legal framework, but only under extraordinary circumstances. It does not support the routine use of compulsory licensing (e.g. absence of local manufacturing should never be a ground for issuing compulsory licenses). There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Novo Nordisk, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 19

SCORE 1.48

A general process for access planning is disclosed. Novo Nordisk has a general process in place to include access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.

A small-sized priority R&D pipeline compared to its peers, Novo Nordisk has one late-stage project in its pipeline that targets a priority product gap. Eptacog alfa (NovoSeven®) was recommended for approval for the treatment of severe postpartum haemorrhage by the European Medicines Agency during the period of analysis. For this project, Novo Nordisk provides evidence that they are considering plans for registration in several countries in scope of the Index.

Some projects address a public health need in LMICs,* with 75% (6/8) of late-stage projects covered by access plans. In this analysis, Novo Nordisk has eight late-stage R&D projects that target a disease and/or product gap not yet designated as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects are first-in-class molecules and/or they significantly reduce the administrative burden or healthcare costs compared with existing products. Most target diabetes mellitus or ischaemic heart disease. Novo Nordisk provides evidence of access plans for six of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Novo Nordisk does not disclose disaggregated R&D investment data to global health organisations.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Novo Nordisk's performance is below average in this area.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 10

SCORE 3.39

Public commitment not to enforce patents in countries in scope. Novo Nordisk publicly pledges to neither file nor enforce patents. This commitment applies in Least Developed Countries and LICs.

Publicly discloses detailed information on patent status. Novo Nordisk publicly discloses the patent statuses for biologics on its website and for small molecules via the Pat-INFORMED database. Novo Nordisk's disclosure includes information about patents, patent number and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Novo Nordisk does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does not have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Novo Nordisk does not engage in voluntary licensing for products in scope of the Index.

Filed to register new products in 17 countries in scope on average. Novo Nordisk did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among new products, none have been filed in LICs. Among old products, its most widely registered is isophane human insulin (Insulatard®), for diabetes mellitus, filed in 83 countries within the scope of the Index, including four of the top ten high burden countries (Guyana, Mexico, Sri Lanka and Suriname).

Novo Nordisk is not eligible for assessment of supranationally procured products.

Novo Nordisk is not eligible for assessment of healthcare practitioner-administered products.

Has access strategies for its self-administered products for the majority of countries in scope of this analysis. Novo Nordisk performs above average in this area. For four of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels

(UMIC, LMIC, LIC). It makes efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay and donations. For example, the company's Access to Insulin Commitment involves the provision of biphasic human insulin (Mixtard®), insulin human (rdna) (Actrapid®) and isophane human insulin (Insulatard®) in 76 LMICs, including Ethiopia, Sudan and Congo, Dem. Rep. at ceiling prices set at USD 3 per vial. Novo Nordisk provides evidence of how patient reach has increased. For example, 76,740 patients in Ethiopia were reached in the current period of analysis, compared to 7,291 patients reached previously.

Both manufacturing capacity building initiatives included for analysis meet all Good Practice Standards. Novo Nordisk's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average but an average number of initiatives meet all Good Practice Standards (GPS) for this indicator. For example, Novo Nordisk is actively working with governments in countries in scope of the Index to ensure access to affordable diabetes treatment. The company conducts detailed technical assessments and due diligence of potential partners as a foundation of the capacity building projects.

Two of the three supply chain capacity building initiatives included meet all Good Practice Standards. Novo Nordisk's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all GPS for this indicator. The Sustainable Healthcare Supply Chain Programme in Ethiopia aims to 1) strengthen long-term supply of Ethiopian specialists in pharmaceutical supply chain handling 2) enhance institutional capacity to handle supply chains of non-communicable disease medicines and 3) strengthen responsiveness of the humanitarian medical supply chain. This initiative meets all GPS.

Four of the five health systems strengthening initiatives included meet all Good Practice Standards. Novo Nordisk's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, Cities Changing Diabetes (CCD) is a partnership programme to accelerate the prevention of diabetes and obesity by addressing the systemic change in urban environments: which are home to two-

thirds of people with diabetes. This initiative meets all GPS.

Has engaged in both scaling up and piloting one inclusive business model. Novo Nordisk performs above average in the use of inclusive business model aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. iCARE is a sustainable and fully integrated business model aimed at improving access to affordable diabetes treatment in the Novo Nordisk Middle Africa region through capacity building, safeguarding affordable insulin, strengthening supply chains and patient support and education.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Novo Nordisk is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, produces in-house active pharmaceutical ingredients, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Novo Nordisk has a policy for reporting SF medicines to relevant health authorities within seven days. It does not provide evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Novo Nordisk has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, the company is engaged in another structured donation programme: Changing Diabetes in Children where it has donated insulin human (rdna) (Actrapid®), isophane human insulin (Insulatard®) and biphasic human insulin (Mixtard®) to 21 countries in scope of the Index since 2009.

RANK	SCORE
6	3.62
4 (2021)	

Pfizer Inc

Stock exchange: NYSE • Ticker: PFE • HQ: New York, New York, United States • Employees: ~79,000

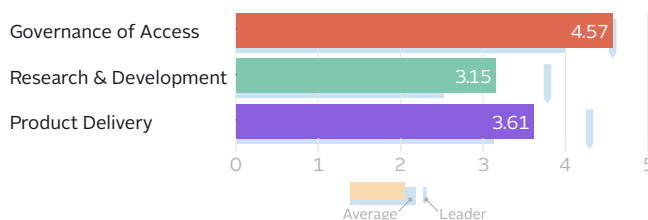
PERFORMANCE IN THE 2022 INDEX

6th place. Pfizer leads in Governance of Access, excelling in its approach to incentivising responsible promotional practices. It performs well in the other two Technical Areas, engaging in high-quality capacity building initiatives across all fields, and performing well in access planning and strategies.

Governance of Access: 1st place. Pfizer leads in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access to medicine and incentives for its senior executives, including the CEO, and in-country and regional managers. It discloses outcomes of its access-to-medicine activities, has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index and demonstrates best responsible promotional practices relative to other companies in scope of the Index.

Research & Development: 5th place. Pfizer performs well in this area. Pfizer has a structured access planning framework and has access plans for the majority of late-stage candidates

How score was achieved



in its pipeline. The company has an average-sized priority pipeline and performs well in R&D capacity building.

Product Delivery: 6th place. Pfizer performs well in this area. The company has comprehensive access strategies in place for its products, but for healthcare-practitioner administered products the strategies focus mostly on upper-middle and lower-middle income countries. It engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply chain and health systems strengthening).

OPPORTUNITIES FOR PFIZER

Improve access planning for R&D projects for non-communicable diseases. Pfizer has access plans in place for 64% of projects for non-communicable diseases. These plans primarily focus on registration preparation in countries in scope. Pfizer can establish access plans for all projects from Phase II onwards, including danuglipron for type 2 diabetes. Furthermore, it can enhance existing plans to incorporate more access components such as equitable pricing and sustainable supply.

Expand technology transfers to manufacturers in more LMICs. Pfizer has transferred technology for the on-patent pneumococcal vaccine (Pnevnar 13[®]) and the COVID-19 vaccine (Comirnaty[®]) to manufacturers in Brazil and South Africa. Pfizer can partner with more manufacturers in LMICs to build manufacturing capacity and improve local availability of additional products such as subcutaneous depo medroxyprogesterone acetate (Sayana Press[®]), a long-acting reversible contraception.

Measure and share outcomes of An Accord for a Healthier World. In 2022, Pfizer launched its An Accord for a Healthier World which aims to provide all its patented medicines and vaccines at not-for-profit prices to 45 lower-income countries. To scale up this initiative and support integration into local health systems, Pfizer can track and share both short- and long-term patient outcomes as part of its impact evaluation of this programme, in addition to outcomes such as patient reach and product volumes sold.

Expand access to on- and off-patent cancer treatments to low-income countries. Pfizer has access strategies for four of its cancer treatments, including on-patent product palbociclib (Ibrance[®]) for breast cancer and off-patent product vincristine (Vincristine) for leukaemia, in upper-middle income countries and lower-middle income countries. Pfizer can expand access to these products in low-income countries as part of its commitment to An Accord for a Healthier World.

CHANGES SINCE THE 2021 INDEX

- Launched 'An Accord for a Healthier World' in May 2022, which commits to provide all its current and future patent protected medicines and vaccines available in the United States or European Union on a not-for-profit basis to 45 LMICs.
- Received FDA Emergency Use Authorisation for the oral antiviral medicine nirmatrelvir/ritonavir (Paxlovid[®]) and signed a procurement agreement with UNICEF to supply up to 4 million treatment courses in LMICs.
- Adopted the ESG Scorecard, which will be used as a tool to assist in determining the funding for the annual short-term incentive plan.
- Received FDA regulatory approval for its COVID-19 vaccine, (Comirnaty[®]) and filed for registration in 37 countries in scope of the Index.
- Established new COVID-19 partnerships with UPS Foundation, Zipline, and Global Environment and Technology Foundation among others to address vaccine supply and delivery issues in LMICs.
- Supplied its COVID-19 vaccine (Comirnaty[®]) through the COVAX facility and pledged to provide 2 billion doses to LMICs in 2021 and 2022.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Signed a non-exclusive voluntary licensing agreement with the Medicines Patent Pool (MPP) for nirmatrelvir/ritonavir (Paxlovid[®]), used as an oral COVID-19 treatment. This agreement covers 95 countries.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Biopharmaceutical products and consumer health.

Therapeutic areas: Hospital care, immunology, inflammation, internal medicine, oncology, rare diseases and vaccines.

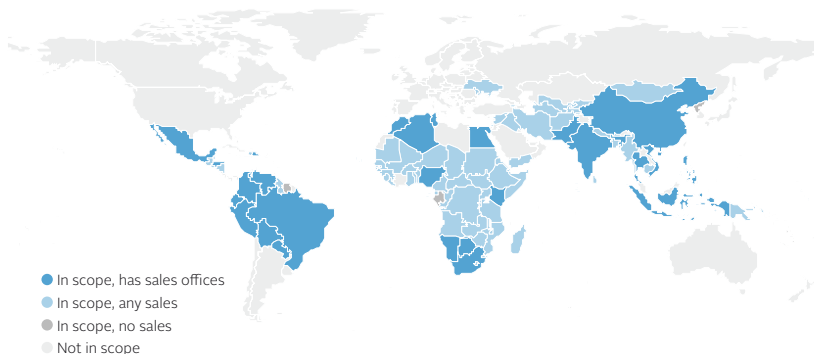
M&A news: Pfizer acquired Arena Pharmaceuticals in March 2022 for USD 6.7 billion.

Pfizer's products are sold in 98 out of 108 countries in scope of the Index. Pfizer has sales offices in 27 countries, and sells via suppliers and/or pooled procurement in an additional 71 countries.

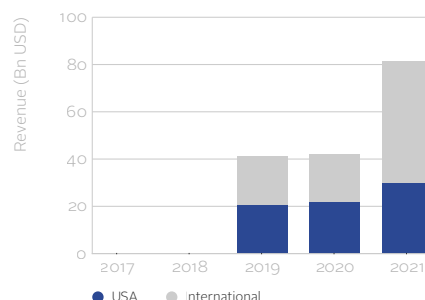
Revenue by segment (2020) – in USD

Biopharmaceutical products	41.91 bn
Total	41.91 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

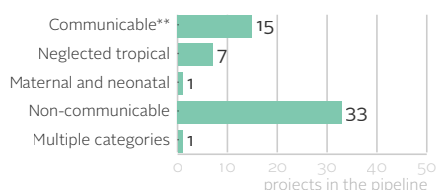
PIPELINE for diseases in scope

Pfizer has a total of 57 R&D projects in scope with 21 of these projects targeting priority diseases. The other 36 R&D projects target other diseases in scope. Of the projects targeting priority diseases the focus is on coronaviral diseases (six projects) and lower respiratory tract infections (5). Of the projects targeting other diseases in scope, the focus is on oncology (22). Twenty-six R&D projects are in late-stage development that target either a priority disease (13) or address a public health need in LMICs (13)* Evidence of access planning is in place for 85% of these projects: 13 targeting a priority disease and nine addressing a public health need in LMICs.

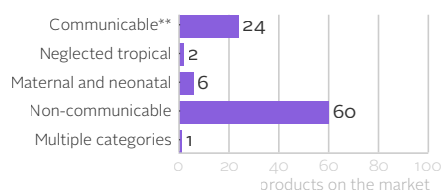
PORTFOLIO as selected for analysis by the Index

Pfizer has 84 medicines in scope, 18 of which are on patent, and five vaccines. 56% of the medicines (47) are on the WHO EML. In addition, the company markets four contraceptive methods and devices. The off-patent medicines target communicable diseases (CDs) (15) such as HIV/AIDS (4) malaria (3) and tuberculosis (5); non-communicable diseases (NCDs) (46) such as cancer (26), cardiovascular diseases (10) and mental health conditions (3). One off-patent medicine is indicated for the treatment of the neglected tropical disease soil-transmitted helminthiasis. The on-patent medicines target CDs such as respiratory infections (3), HIV/AIDS (1) and NCDs such as cancer (12), stroke (1) and unipolar depressive disorders (1). Pfizer's preventative vaccines (5) target CDs such as meningitis (3), lower respiratory infections and COVID-19.

57 projects in the pipeline



93 products as selected for analysis by the Index†



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	4	2	2	3	7	3	0	21
Addresses needs of LMICs*			12	9	3	1	0	25
Other projects in scope		4	4	2	1	0		11

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	16			18
off patent	45	21			66
Vaccines	4	1			5
Contraceptives	3	1			4
Diagnostics			0		0
Other†				0	0

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
 †Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
 ‡Other includes vector control products.

Pfizer Inc

GOVERNANCE OF ACCESS

RANK 1

SCORE 4.57

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Pfizer performs strongly. Its access strategy is integrated within its Purpose Blueprint, which outlines Pfizer's strategic direction, and covers all therapeutic areas in which the company is involved, including rare diseases. The highest responsibility for access lies directly with Pfizer's executive management team with board oversight, namely with the Corporate Governance & Sustainability Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Pfizer performs strongly. It incentivises its senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives linked to the Purpose Blueprint goals, including improving access through partnerships.

Publicly discloses outcomes of its access-to-medicine activities. Pfizer performs strongly in transparency of access activities. It publicly discloses its commitment to global

public health, including new commitments in response to the COVID-19 pandemic, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities, including its progress on SDG3-related targets, in a centralised manner within its ESG Report.

Performs well in responsible promotional practices. Pfizer's sales agents are not solely incentivised on sales volume targets. The company does not set incentives at the individual level. It has a global policy on interactions with healthcare professionals, but does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by law or by local regulations.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

Pfizer performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, audits (both internal and external, covering third parties and in all countries where it operates), formal processes to ensure third-party compliance with company standards and a continuous system to monitor activities. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Pfizer publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, namely on the use of compulsory licensing. There is evidence of industry association lobbying on intellectual property (IP) and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Pfizer, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 5

SCORE 3.15

Access planning processes encompass all projects in the pipeline. Pfizer has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (13/13) of the late-stage candidates. Pfizer has 21 projects including 13 late-stage candidates in its pipeline that target a priority product gap. These projects focus mostly on lower respiratory tract infections and coronaviral diseases. All of Pfizer's 13 late-stage candidates targeting a priority product gap have access plans in place. Notably, Pfizer signed a non-exclusive voluntary licensing agreement with the Medicines Patent Pool (MPP) for its COVID-19 antiviral nirmatrelvir (PF-07321332) when the compound

was still in development. The agreement allows sub-licensees to produce generic versions of the drug for supply in countries in scope of the Index.

Many projects address a public health need in LMICs,* with 69% (9/13) of the late-stage projects covered by access plans. In this analysis, Pfizer has 13 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects have clinical trials in countries in scope of the Index or are first-in-class molecules. Most target cancer. Pfizer provides evidence of access plans for nine of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment

data disaggregated by disease category, product type or phase of development. Pfizer does not disclose disaggregated R&D investment data to global health organisations.

Three of the five R&D capacity building initiatives included meet all Good Practice Standards. Pfizer's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, in collaboration with the Wellcome Trust, the SPIDAAR program (Surveillance Partnership to Improve Data for Action on Antimicrobial Resistance) builds antimicrobial resistance (AMR) surveillance capacity in Africa by tracking resistance patterns to better understand the burden of AMR on patients living in LMICs.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 6

SCORE 3.61

Public commitment not to enforce patents in countries in scope. Pfizer publicly pledges not to enforce patents in Least Developed Countries.

Publicly discloses information on patent status.

Like most of its peers, Pfizer publicly discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. It discloses the patent status of its entire small molecule portfolio. The information includes filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers.

Pfizer engaged in two new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current Index cycle and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. Pfizer has one non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence for nirmatrelvir/ritonavir (Paxlovid®), agreed with 38 sublicensees, encompasses 95 countries, with 93 countries relevant to the Index, including 66 middle income countries.

Filed to register new products in 14 countries in scope on average. Pfizer did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries (for products that could be assessed with available global burden of disease data, which excludes COVID-19). Among new products, its most widely registered is the COVID-19 vaccine (Comirnaty®), rapidly authorized in 37 countries in scope of the Index. Bevacizumab-bvzr (Zirabev), indicated for colorectal cancer among other cancer types, has been filed in four of the top ten high burden disease countries such as Democratic People's Republic of Korea, Thailand and Ukraine.

Has access strategies for all supranationally procured products in scope for this analysis. Pfizer performs above average in securing access for its products procured supranationally. For the five products assessed in this category, the company demonstrates strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, the company supplied COVID-19 vaccine (Comirnaty®) in Rwanda via multiple supply pathways, including via the COVAX Facility. This supply supported the local government in achieving their target vaccination rate aligned with local policy recommendations. The price offered is a not-for-profit price and consistent across all supply pathways. In 2021, around 7.4 million doses were supplied in support of the government's vaccination program.

Has access strategies for the majority of healthcare practitioner-administered prod-

ucts in scope of this analysis. Pfizer has average performance in this area. The company provides examples of access strategies which consider affordability in both UMICs and LMICs for the five products assessed, yet falls short at providing examples for LICs. It makes efforts to reach additional patients using pricing strategies considering relevant payers' ability to pay. For example, while Pfizer is negotiating with the national authority in Ghana for the inclusion of the ceftaroline fosamil (Zinforo®) in the National Insurance Scheme, the company has initiated a patient affordability programme in 2021, which offers the product at 50% of the total cost and patients are allowed to complete payment over 60 days. Pfizer provides evidence of how patient reach has been increased through this approach.

Has access strategies for most of its self-administered products in the scope of this analysis.

Pfizer performs above average in this area. For four of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients using pricing strategies considering relevant payers' ability to pay for the treatments. For example, Pfizer Mexico implemented a pricing strategy for lorlatinib (Lorbrena®) as second line of NSCLC treatment that considers public sector affordability. While in the private market, Pfizer Mexico offers tiered discounts for lorlatinib based on the remaining insurance policy coverage from insurance providers and the ability of patients to pay, receiving first line and subsequent lines of NSCLC treatment. The company provided evidence of patient reach increase for three products in UMIC and LMIC country examples.

All five manufacturing capacity building initiatives included for analysis meet all Good Practice Standards. Pfizer is a leader. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, the company is working with both The Biovac Institute in South Africa as well as Eurofarma in Brazil to transfer technology to manufacture the COVID-19 vaccine for distribution in the African Union and Latin America respectively.

Two of the five supply chain capacity building initiatives included meet all Good Practice Standards. Pfizer's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average but an average number of initiatives meet all GPS for this indicator. Pfizer has partnered with Zipline, to test and develop an end-to-end distribution solution for COVID-19 vaccines in Ghana in order to safely distribute these to the last mile and reduce waste to expiry. This initiative meets all GPS.

All five health systems strengthening initiatives included for analysis meet all Good Practice Standards. Pfizer is one of the leaders in this area.

The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, the Ghana Sickle Cell Disease Newborn Screening and Comprehensive Care Program seeks to advance the study and treatment of sickle cell disease (SCD) across Ghana and, ultimately, other countries in sub-Saharan Africa, by piloting and testing a newborn screening program for SCD including introducing treatment protocols and understanding the willingness and ability of families to enroll in follow-up care.

Has engaged in scaling up four inclusive business models but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria.

Pfizer performs average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Pfizer Foundation supported the development and implementation of a dengue reduction programme through Reach52. Reach52 aims to bring high-quality healthcare to remote and rural areas through data-driven programs that leverage a network of community health workers empowered by Reach52's digital health platform.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Pfizer is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, produces the majority of its active pharmaceutical ingredients in-house, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index. Pfizer has a policy for reporting SF medicines to the relevant national health authorities but does not specify time frames. Instead, Pfizer reports that it follows locally mandated time frames. It does not provide evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Pfizer has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Pfizer publicly commits to contributing to the elimination of trachoma by donating azithromycin (Zithromax®) from 1998 to 2030 in 29 countries in scope of the Index.

RANK	SCORE
10	3.23
9 (2021)	

Roche Holding AG

Stock exchange: SIX • Ticker: ROG.SW • HQ: Basel, Switzerland • Employees: 100,920

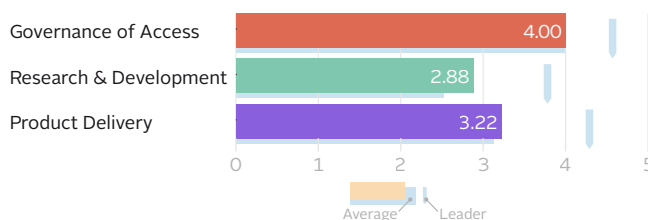
PERFORMANCE IN THE 2022 INDEX

10th place. Roche ranks among the top ten companies of the Index. The company performs well in Research & Development, strengthening its performance in R&D access planning. The company has an average performance in Governance of Access, but its strategies for equitable access are below average for some products.

Governance of Access: 12th place. Roche has an average performance in this area. It has an access-to-medicine strategy integrated into its corporate strategy and publicly discloses outcomes of its access-to-medicine activities. However, it lacks a fraud-specific risk assessment as part of its compliance framework to mitigate the risk of non-compliance in countries in scope of the Index and a formal policy to limit transfers of values to healthcare professionals in countries in scope of the Index.

Research & Development: 8th place. Roche performs above average in this area. Roche has a structured access planning framework, with access plans in place for the majority of late-

How score was achieved



stage pipeline candidates. The company has a small-sized priority pipeline and has an average performance in R&D capacity building.

Product Delivery: 11th place. Roche has an average performance in this area. The company provides evidence of comprehensive access strategies for a subset of products, yet the focus is mostly on upper-middle and lower-middle income countries. Roche engages in high-quality supply chain capacity building and health systems strengthening initiatives, but its involvement in manufacturing capacity building is comparatively poor.

OPPORTUNITIES FOR ROCHE

Ensure all late-stage R&D projects have comprehensive access plans. Roche has access plans in place for 90% of late-stage R&D projects. These predominantly focus on plans for registration filings. The company can expand existing plans beyond commitments to register in countries where it is conducting clinical trials to include more access components such as equitable pricing and licensing.

Expand access strategies for oncology products. Roche has seven on-patent medicines listed on the WHO Model List of Essential Medicines, including erlotinib (Tarceva®), a first-line treatment for lung cancer, and atezolizumab (Tecentriq®), indicated for multiple cancer types. Roche applies access strategies for erlotinib in upper-middle income countries, including an intra-country pricing strategy in Peru. It can apply similar equitable access strategies and non-exclusive voluntary licensing in lower-middle income countries and low-income countries with high burden of lung cancer such as Tunisia and Vietnam.

Expand manufacturing capacity building activities to additional countries. Roche is involved in technology transfer initiatives to regional manufacturers in Bangladesh, China and Algeria to improve availability of the company's oncology products. Through partnerships to build local manufacturing capacity, including technology transfers, Roche can improve availability of its products in more countries, such as Nigeria, Ghana and South Africa.

CHANGES SINCE THE 2021 INDEX

- Expanded the Global Access Program in 2021 to include molecular PCR diagnostic tests for COVID-19.
- Expanded the proportion of access plans in its pipeline.
- Roche initiated a clinical trials framework, activating the first pharma sponsored oncology trial in East Africa.
- Suspended patents on tocilizumab (Actemra®/RoActemra®) in LMICs after the World Health Organization (WHO) recommended it as a treatment for severe COVID-19.
- Entered a partnership with The Global Fund to support LMICs in strengthening critical diagnostics infrastructure.
- Received WHO prequalification for HIV and HCV tests, and WHO guidelines now include cobas® MTB and cobas® MTB-RIF/INH tests.
- Launched a human papillomavirus (HPV) self-sampling solution, expanding cervical cancer screening options for patients living in areas with limited healthcare resources.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Diagnostics and pharmaceuticals.

Therapeutic areas: Diabetes care, haemophilia A, immunology, infectious diseases, neuroscience, oncology and ophthalmology.

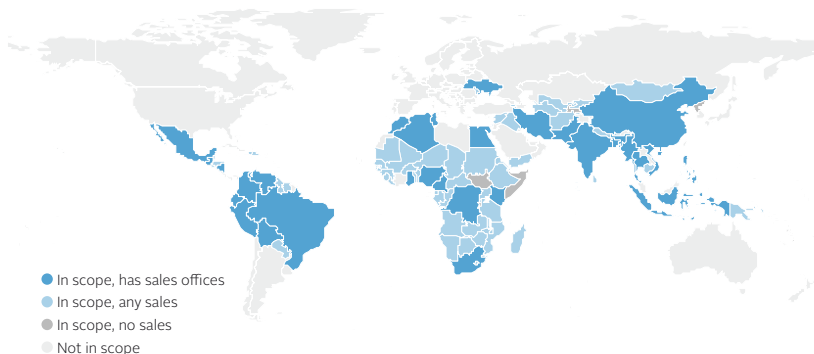
M&A news: Roche acquired GenMark Diagnostics in March 2021 for USD 1.8 billion.

Roche's products are sold in 93 out of 108 countries in scope of the Index. Roche has sales offices in 31 countries, and sells via suppliers and/or pooled procurement in an additional 62 countries.

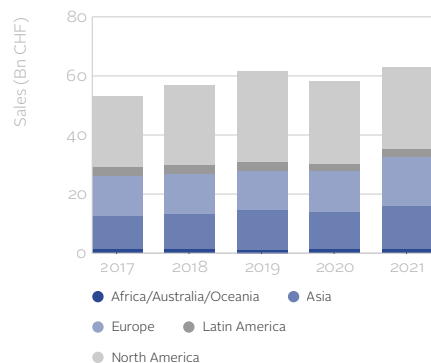
Sales by segment (2021) – in CHF

Pharmaceuticals	45.04 bn
Diagnostics	17.76 bn
Total	62.80 bn

Sales in countries in scope



Sales by geographic region



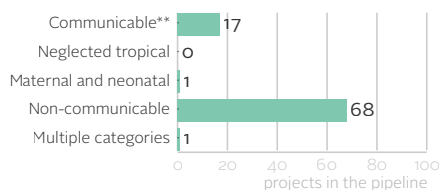
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Roche has a total of 87 R&D projects in scope, with 17 of these projects targeting priority diseases. The other 70 R&D projects target other diseases in scope. In total, 14 of the 87 projects are diagnostic R&D projects. Of the projects targeting priority diseases the focus is on hepatitis B (five projects). Of the projects targeting other diseases in scope, the focus is on oncology (53).

Twenty R&D projects are in late-stage development that target either a priority disease (5) or address a public health need in LMICs (15).^{*} Evidence of access planning was in place for 90% of these projects: five targeting a priority disease and 13 addressing a public health need in LMICs.

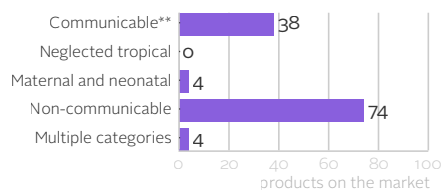
87 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Roche has 29 medicines in scope, 23 of which are on patent, and 81 diagnostics. 41% of the medicines (12) are on the WHO EML. In addition, the company markets 13 platform technologies. The off-patent medicines target communicable diseases (CDs) (3) such as hepatitis C, malaria and lower respiratory infections and non-communicable diseases (NCDs) (4) such as cancer (2) and cardiovascular diseases (2). The on-patent medicines target NCDs such as cancer (15) and kidney diseases (2), and CDs such as HIV/AIDS and coronaviral diseases. The platform technologies target respiratory infections, diabetes, cancer and other diseases in scope of the Index.

123 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	0	0	4	3	0	2	8	17
Addresses needs of LMICs [*]			1	5	9	1	1	17
Other projects in scope			23	11	14	1	4	53

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	7	16			23
off patent	5	1			6
Vaccines	0	0			0
Contraceptives	0	0			0
Diagnostics			81		81
Other [†]				13	13

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis. ^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index. ^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics). [†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. [‡]Other includes vector control products.

Roche Holding AG

GOVERNANCE OF ACCESS

RANK 12

SCORE 4.00

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Roche performs strongly. Its strategy is focused on understanding local barriers to access and covers all therapeutic areas the company is involved in. The highest responsibility for access lies directly with the board, namely with the Corporate Governance and Sustainability Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Roche performs well. It incentivises its CEO, senior executives and in-country managers to perform on access to medicine with financial and non-financial rewards.

Publicly discloses outcomes of its access-to-medicine activities. Roche performs strongly in transparency of access activities. It publicly discloses its commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its

access-to-medicine activities, including its Global Access Programme, in a centralised manner within its Annual Report.

Has an average performance in responsible promotional practices. Roche's sales agents are not solely incentivised on sales volume targets. However, the company sets sales incentives at the individual level for agents. Roche has an internal tracking mechanism but does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by law or by local regulations. The company does not place limits on transfers of value to healthcare professionals, but reports setting remuneration in line with fair market value.

Has some compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Roche has an average performance, demonstrating evidence of some components looked for by the Index: country risk-based assessment, a contin-

uous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. There is no evidence, publicly found or disclosed to the Index, of fraud-specific risk assessment. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Roche publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, namely on the effectiveness of compulsory licensing to lower drug prices. There is evidence of industry association lobbying on intellectual property (IP) and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Roche, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 8

SCORE 2.88

Access planning processes encompass all projects in the pipeline. Roche has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects for diseases in scope of the Index.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 100% (5/5) of the late-stage candidates. Roche has 17 projects including five late-stage candidates in its pipeline that target a priority product gap. These focus mostly on hepatitis B and coronaviral diseases. Roche has access plans in place for all five late-stage priority candidates. These plans mainly concern registration preparation in countries in scope of the Index. Notably, the access plan for tocilizumab (Actemra®/RoActemra®) for the treatment of COVID-19 uses a multifaceted approach that considers availability, affordability and supply. The plan includes registration preparation in countries in scope of

the Index, a new pricing policy, WHO prequalification, patent waivers in LMICs, product donations and scaling up production capacity to meet demands.

Many projects address a public health need in LMICs,* with 87% (13/15) of late-stage projects covered by access plans. In this analysis, Roche has 15 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index. Most target cancer or Alzheimer's disease. Roche provides evidence of access plans for 13 of these projects. These plans mostly relate to an intention to register in countries where Roche is carrying out clinical trials.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Roche does not disclose disaggregated R&D investment data to global health organisations.

Two of the three R&D capacity building initiatives included meet all Good Practice Standards. Roche's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all Good Practice Standards (GPS) for this indicator. For example, Roche builds R&D capacity by educating lab researchers through its Fondation Roche Recherche en Afrique scholarship programme. This initiative provides scholarships to students in Côte d'Ivoire to increase the number of skilled medical laboratory technicians and meets all GPS.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 11

SCORE 3.22

Public commitment not to enforce patents in countries in scope. Roche publicly pledges to neither file for nor enforce patents in all Least Developed Countries and LICs within the scope of the Index. Roche does not file nor enforce patents for its antiretroviral HIV medicines in sub-Saharan Africa.

Publicly discloses information on patent status. Like most of its peers, Roche discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Roche's disclosure includes information about patents, patent number and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Roche does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Roche does not engage in voluntary licensing agreements for products in scope of the Index.

Filed to register new products in 22 countries in scope on average. Roche has filed for registration one of its newest products in eight of the top ten high burden countries. This product, Elecsys® Chagas, used for diagnosis and screening of Chagas disease, has been filed for registration in 15 countries in scope of the Index. The majority of Roche's products considered for analysis have not been filed for registration in LICs.

Has access strategies for its supranationally procured products in scope of this analysis. Roche performs below average in securing access for products procured supranationally. The company supplies three products assessed via its Global Access Program (GAP), developed in consultation with international partners including CHAI, PEPFAR, USAID, UNITAID and the Global Fund. Roche did not provide examples of how access was secured for countries not eligible for the GAP. However, Roche has been expanding the GAP by including new diagnostics for HPV-related cervical cancer, tuberculosis and hepatitis in 2019 and molecular PCR diagnostic tests for COVID-19 in 2021. The company demonstrated expansion of patient reach: to date over 11 million children have been tested for HIV with Roche tests.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Roche shows average performance in this area. The company provides examples of access strategies in both UMICs and LMICs for four of the five products

assessed. Examples of access strategies in LICs were not provided. Roche makes efforts to reach additional patients using patient assistance programmes (PAPs). For example, Roche applies differential pricing for pertuzumab (Perjeta®) in Egypt based on the patients' ability to pay, and it implements both pricing and non-pricing support to out-of-pocket patients through a PAP while strengthening the health systems with capacity building initiatives. Roche provides evidence of how patient reach has been increased through the approaches used, reporting that patient reach has more than doubled in 2021.

Has access strategies for its self-administered products for few countries in scope of this analysis. Roche performs below average in this area. The company provides examples of access strategies which consider payers' affordability in UMICs and LMICs for one of the four products assessed: alectinib (Alecensa®), a cancer drug. This included efforts to reach additional patients using pricing strategies that consider relevant payers' ability to pay. For example, the company has implemented a four-tiered pricing strategy for alectinib in the Philippines, the ALIVE programme, based on the country's profile and patients' economic status. In addition, the company created a PAP to reduce the out-of-pocket costs for patients. Roche has further initiatives to support medicine access such as deferred payment schemes and capacity building initiatives to strengthen the healthcare system. Evidence of patient reach increase is provided.

None of the manufacturing capacity building initiatives included for analysis meet all Good Practice Standards. Roche's performance is below average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. In one of the included initiatives starting in 2018, Roche built manufacturing capacity by transferring technology for secondary packaging of bevacizumab (Avastin), trastuzumab (Herceptin®) and rituximab (MabThera®) in Algeria.

Three of the four supply chain capacity building initiatives included meet all Good Practice Standards. Roche's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, the Global Philanthropic Secondment Program provides the mechanism to share Roche employee expertise with NGOs that are helping to improve global health and education, including the topic of supply chain, logistics and project management.

All five health systems strengthening initiatives included for analysis meet all Good Practice Standards. Roche is one of the leaders in this

area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, Project ECHO® (Extension for Community Health Outcomes) aims to help broaden access to best practice cancer treatment in LMICs by training and mentoring healthcare personnel in underserved areas.

Has engaged in scaling up three inclusive business models but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria.

Roche performs average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Project TRACMA aims to solve access hurdles of breast cancer patients in Angola and provide therapies to the patients who can benefit from them.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Roche is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index. Roche has a policy for reporting SF medicines to relevant health authorities, but does not strictly specify the reporting timeframe. Roche, however, states that reporting typically occurs within 24 hours once a case is confirmed. Earlier reporting prior to the end of the investigation is possible when visual inspection is sufficient for confirmation.

Donates in response to expressed need and monitors delivery. Roche has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Has no long-term donation programmes for neglected tropical diseases (NTDs) or malaria that are eligible for analysis under this indicator. Roche is not engaged in any structured donation programmes for NTDs or malaria where elimination, eradication or control goals are possible and that are eligible for analysis under this indicator.

RANK	SCORE
8	3.47
5 (2021)	

Sanofi

Stock exchange: EPA • Ticker: SAN • HQ: Paris, France • Employees: 95,442

PERFORMANCE IN THE 2022 INDEX

8th place. Sanofi ranks among the top ten companies in the Index. The company has strong policies governing access to medicine and patent transparency. It leads in applying access strategies for supranationally procured products and engages in R&D for neglected tropical diseases.

Governance of Access: 2nd place. Sanofi has a strong performance in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access-to-medicine and incentives for its senior executives, including the CEO, and in-country and regional managers. It discloses outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 8th place. Sanofi performs above average in this area. It has a structured access planning framework and applies this to most of its late-stage pipeline candidates. The company has an average-sized priority pipeline and performs well in R&D capacity building.

OPPORTUNITIES FOR SANOFI

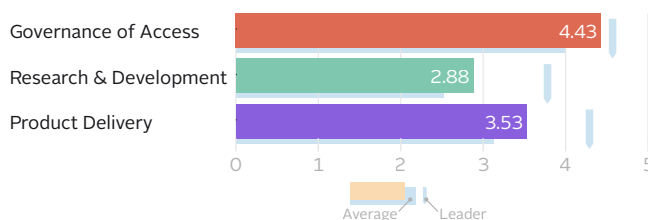
Ensure all late-stage R&D projects have comprehensive access plans. Sanofi has access plans in place for 81% of its late-stage projects. It can apply plans to all late-stage candidates from Phase II onwards, including the Pneumococcal Conjugate Vaccine (Skypac, SPO202).

Expand registration of analogue insulins. Sanofi has six analogue insulins in its portfolio. Insulin glargine (Toujeo®) has been filed in 30 countries within scope of the Index. Sanofi can expand the registration of this product as well as insulin lispro (Admelog®) and Insulin aspart Sanofi, especially in countries with a high burden of diabetes such as Sri Lanka, Guyana and Suriname.

Expand access to insulin and diabetes products. For insulin glargine (Lantus®), Sanofi implements access strategies considering payers' ability to pay in at least one upper-middle income country and one lower-middle income country. The company can apply access and pricing strategies in low-income countries (LICs) to improve the affordability of diabetes medicines such as glimepiride/metformin (Amaryl® M) and insulin glargine in LICs, following through on the commitments made through the company's Global Health Unit.

Measure and share outcomes of Sanofi Global Health Unit. In 2021, Sanofi launched its Global Health Unit, which will expand on the company's work with partners to increase access to 30 of its medicines for communicable and non-communicable diseases. To scale up this initiative and support integration into local health systems, Sanofi can track and share both short- and long-term patient outcomes as part of its impact evaluation of this programme, in addition to outcomes such as patient reach and product volumes sold.

How score was achieved



Product Delivery: 8th place. Sanofi performs well in this area. The company applies comprehensive access strategies for healthcare-practitioner administered products, with the majority covered by strategies across all country income classifications. However, the strategies for self-administered products tend to focus on upper-middle and lower-middle income countries. The company engages in high-quality health systems strengthening and manufacturing capacity building initiatives. It has strengthened its performance with respect to inclusive business models.

CHANGES SINCE THE 2021 INDEX

- Established Sanofi Global Health Unit, a non-profit unit aimed at providing access to essential medicines and care through affordable prices and supporting local capacity building with programmes for specific low and lower-middle income countries.
- Through the Global Health Unit, Sanofi has shared a commitment to expand access to analogue insulins, namely glargine and glulisine, with the target to reach 300,000 insulin-dependent patients by 2030.
- Launched a new brand of standard care medicines called Impact®. These medicines are produced by Sanofi for non-profit distribution by the Sanofi Global Health Unit to at-risk populations in 40 LMICs.
- Integrated a new CSR strategy which places more focus on Access via its Affordable Access and Vulnerable Communities strategic pillars.
- Announced the development of a global access plan for all new products, with aims to make them available within two years post first launch wherever this can make an impact for patients (including in countries within scope of the Index).
- Sought regulatory authorisation alongside GSK for its COVID-19 vaccine.
- Renewed partnership with the World Health Organization (WHO) to fight neglected tropical diseases and eliminate sleeping sickness before 2030 through its long-term donation programme of pentamidine eflornithine, melarsoprol and fexinidazole.
- Joined the Access to Oncology Medicines (ATOM) Coalition, a new global initiative that aims to improve access to essential cancer medicines in LMICs.
- Issued EUR 1.5 billion bond linked to access to medicine.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Pharmaceuticals, Vaccines and Consumer healthcare.

Therapeutic areas: Oncology, Immunology & Inflammation, Neurology, Rare Blood Disorders, Rare Diseases, Diabetes and Cardiovascular Diseases.

Product categories: Innovative medicines, Vaccines and Consumer health products.

M&A news: Sanofi acquired Kiadis Pharma N.V., Kymab Group Ltd. and Tidal Therapeutics in

April 2021. Additionally it acquired Translate Bio in September 2021, Kadmon Holdings, Inc. in

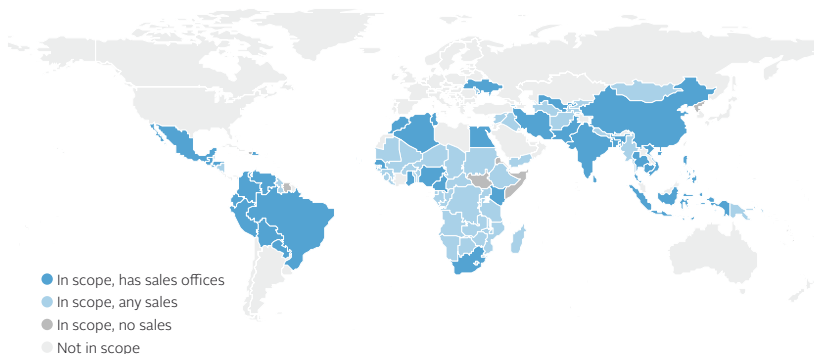
November 2021, Origimm Biotechnology GmbH in December 2021 and Amunix Pharmaceuticals, Inc. in February 2022.

Sanofi's products are sold in 92 out of 108 countries in scope of the Index. Sanofi has sales offices in 36 countries, and sells via distributors in an additional 56 countries.

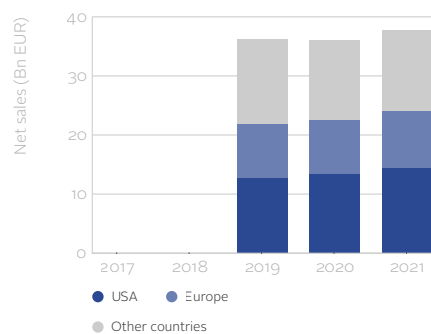
Net sales by segment (2021) – in EUR

Pharmaceuticals	26.97 bn
Vaccines	6.32 bn
Consumer healthcare	4.47 bn
Total	37.76 bn

Sales in countries in scope



Sales by geographic region

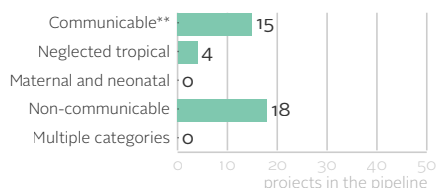


SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope

Sanofi has a total of 37 R&D projects in scope, with 16 projects targeting a priority disease. The other 21 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on lower respiratory tract infections (seven projects). Of the projects targeting other diseases in scope, the focus is on oncology (14). Twenty-one R&D projects are in late-stage development that target either a priority disease (8) or address a public health need in LMICs (13).^{*} Evidence of access planning was in place for 81% of these projects: six targeting a priority disease and 11 addressing a public health need in LMICs.

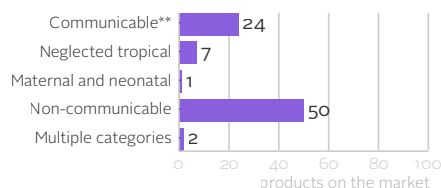
37 projects in the pipeline



PORTFOLIO as selected for analysis by the Index

Sanofi has 65 medicines in scope, 12 of which are on patent, and 15 vaccines. 54% of the medicines (35) are on the WHO EML. In addition, the company markets four platform technologies. The off-patent medicines target communicable diseases (11) such as tuberculosis (6), malaria (3) and HIV/AIDS (1); non-communicable diseases (NCDs) (36) such as diabetes (6), cardiovascular diseases (10), mental health conditions (10); and certain neglected tropical diseases. The on-patent medicines target mainly NCDs such as cancer (3), diabetes (3) and kidney diseases (2). Sanofi's preventive vaccines (15) target diseases such as tetanus, meningitis and yellow fever.

84 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	2	3	2	2	3	3	1	16
Addresses needs of LMICs*			0	3	5	5	0	13
Other projects in scope			5	3	0	0	0	8

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	10			12
off patent	33	20			53
Vaccines	14	1			15
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				4	4

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
 **Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
 ***Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

Sanofi

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Sanofi performs strongly. Its access to healthcare strategy, recently revamped in 2021, is integrated in the activities of its three core global business units: Sanofi Pasteur, Sanofi Genzyme and General Medicines and its standalone business unit, Consumer Healthcare. A fifth non-profit business unit was created, Sanofi Global Health. The strategy covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with board-level members seated on the Corporate Social Responsibility (CSR) committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Sanofi performs strongly. It incentivises its senior executives and in-country managers to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives beyond CSR goals.

Publicly discloses outcomes of its access-to-medicine activities. Sanofi performs strongly in transparency of access activities. It publicly dis-

closes commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Access to Healthcare Programmes Report and in its quarterly results press release.

Performs well in responsible promotional practices. Sanofi's Sales Incentive Plan is primarily driven by sales volume, but qualitative components are adjusted depending on the specific situation. The company sets sales incentives at the national level for agents in most of the countries that are in scope of the Index. It has a policy on service engagement with scientific experts, but it does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities), unless required by law or by local regulations.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

Sanofi performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on TRIPS and Public Health. Sanofi publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, stating that compulsory licensing should only be used in extraordinary and very limited circumstances. There is evidence of industry association lobbying on intellectual property and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Sanofi, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 8

SCORE 2.88

Access planning processes encompass all projects in the pipeline. Sanofi has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Sanofi begins developing access plans for R&D projects in Phase II of clinical development.

An average-sized priority R&D pipeline compared to its peers, with access plans in place for 75% (6/8) of the late-stage candidates. Sanofi has 16 projects, including eight late-stage candidates in its pipeline that target a priority product gap. The company focuses on various priority areas, including lower respiratory tract infections, coronaviral diseases and human African trypanosomiasis. Of Sanofi's eight late-stage candidates targeting a priority product gap, there is evidence of an access plan for six. These plans prioritise WHO prequalification and registration

in countries in scope of the Index. Notably, Sanofi partners with Drugs for Neglected Diseases *initiative* (DNDi) for two projects using fexinidazole to treat for two different types of human African trypanosomiasis. These access plans include WHO prequalification, a donation programme managed by WHO and plans for registration in countries with a high burden of disease.

Some projects address a public health need in LMICs,* with 85% (11/13) of late-stage projects covered by access plans. In this analysis, Sanofi has 13 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* Primarily, these projects concern clinical trials in countries in scope of the Index and/or are first-in-class molecules. Most target cancer. Sanofi provides evidence of access plans for 11 of these

projects. These plans mostly relate to planning registration in countries where it is conducting clinical trials.

Publicly discloses disaggregated R&D investment data for phase of development. In addition, Sanofi also discloses fully disaggregated R&D investment data to Policy Cures Research.

Three of the four R&D capacity building initiatives included meet all Good Practice Standards. Sanofi's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, through the Sanofi Global Site Partnership, Sanofi partners with over 80 institutes to build clinical trial capacity in countries in scope of the Index.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 8

SCORE 3.53

Publicly pledges not to enforce patents. Sanofi publicly pledges to neither file for nor enforce patents. This commitment applies in all Least Developed Countries and LICs and in a subset of LMICs and UMICs.

Publicly discloses information on patent status.

Sanofi publicly discloses on its website information relating to the status of its patents for products on the WHO Model List of Essential Medicines (EML).

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers.

Sanofi does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Sanofi does not engage in voluntary licensing agreements for products in scope of the Index.

Filed to register new products in 14 countries in scope on average. Sanofi did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among new products, its most widely filed is the booster vaccine (Tetraxim), indicated for tetanus and pertussis prevention, filed in 38 countries within the scope of the Index, including four high burden disease countries and eight LICs.

Has access strategies for all supranationally procured products in scope for this analysis.

Sanofi leads in securing access for products procured supranationally. For the five products assessed in this category, the company demonstrates strategies both in countries eligible for supply from such procurers and in at least one non-eligible country. For example, the company offers the same terms to Brazil and Mexico for the influenza trivalent vaccine (Vaxigrip® TIV) as it does for PAHO-eligible countries. Sanofi provides evidence of how patient reach has been increased through these approaches.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis.

Sanofi performs above average in this area. For three of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients through pricing strategies considering relevant payers' ability to pay

for treatments. For example, Sanofi supplies its meningitis vaccine (Menactra®) via tenders run by international and local public authorities in 23 countries in scope of the Index, of which six are LICs. The company offers a price that is adjusted to local tenders' specifications and considers countries' ability to pay. In parallel, it supports local healthcare systems by providing training to public managers. This training includes cold chain management and vaccination surveillance. Sanofi provides evidence of how patient reach has been increased through these approaches.

Has access strategies for its self-administered products for some countries in scope of this analysis.

Sanofi has an average performance in this area. For one of the five products assessed, the company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC), including efforts to reach additional patients through pricing strategies that consider local payers' ability to pay and disease management initiatives. For example, Sanofi ensured the inclusion of glimepiride/metformin (Amaryl® Min) in Colombia's mandatory national health plan which offers 100% coverage to eligible patients. The company has additional strategies to improve disease early diagnosis, treatment adherence and patient health outcomes. Sanofi provides evidence of patient reach, reporting that approximately 920 patients receive the treatment yearly.

Four of the five manufacturing capacity building initiatives included meet all Good Practice Standards.

Sanofi's performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, Sanofi has been working with the May & Baker manufacturing site since 2015. The company provides training on hygiene, on-site safety and good manufacturing practice. This initiative meets all GPS.

One of the five supply chain capacity building initiatives included meets all Good Practice Standards.

Sanofi's performance is average in this area. The number of initiatives meeting all inclusion criteria is higher than average but fewer initiatives meet all GPS than what is average for this indicator. Sanofi partnered with the Vietnam Vaccine Joint Stock Co. to build capacity in supply chain planning. This includes improving forecasting and warehouse planning to meet vaccine demand. This initiative meets all GPS.

Four of the five health systems strengthening initiatives included meet all Good Practice Standards.

Sanofi's performance is above average in this area. The number of initiatives meeting

all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, the My Child Matters programme was initiated by the Sanofi Espoir Foundation in 2006 in order to fight childhood cancer and reduce health inequalities worldwide. This initiative meets all GPS.

Has engaged in both scaling up and piloting one inclusive business model.

Sanofi performs above average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. The Sanofi Global Health Unit is a new non-profit unit that sells and/or donates 30 of Sanofi's products at affordable prices to approximately 40 low and lower-middle income countries.

Performs above average in terms of ensuring continuous supply of medicines in LMICs.

Sanofi is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient (API) suppliers/produces in-house APIs, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days.

Sanofi has a policy for reporting SF medicines to national health authorities or the WHO within seven days. It does not provide evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery.

Sanofi has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria.

Sanofi publicly commits to contributing to the elimination of human African trypanosomiasis by donating pentamidine (Pentacarinat®), eflornithine (Ornidyl®), melarsoprol (Arsobal®) and fexinidazole (Fexinidazole Winthrop®) in 21 countries in scope of the Index until goals are reached.

RANK	SCORE
7	3.51
6 (2021)	

Takeda Pharmaceutical Co, Ltd

Stock exchange: NYSE • Ticker: TAK • HQ: Tokyo, Japan • Employees: 47,347

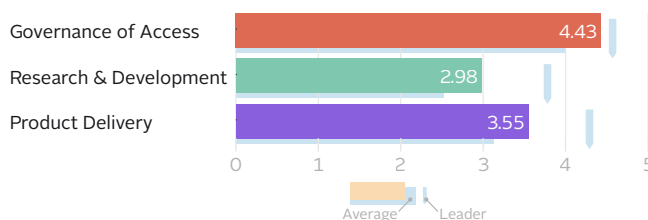
PERFORMANCE IN THE 2022 INDEX

7th place. Takeda ranks among the top ten countries in the Index. The company performs strongly in Governance of Access and engages in high-quality capacity building initiatives across all fields. Despite having a small pipeline, it also performs well in Research & Development, by applying comprehensive access plans to all late-stage pipeline candidates.

Governance of Access: 2nd place. Takeda performs strongly in this area. It has an integrated access-to-medicine strategy with direct board-level responsibility for access to medicine and incentives for its senior executives, including the CEO, and in-country and regional managers. It discloses outcomes of its access-to-medicine activities and has a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index.

Research & Development: 7th place. Takeda performs above average in this area. It has a structured access planning framework and applies this to all of its late-stage pipeline candi-

How score was achieved



dates. The company also performs strongly in R&D capacity building. However, it has a small-sized priority pipeline compared to its peers.

Product Delivery: 7th place. Takeda performs well in this area. It leads in applying access strategies for healthcare practitioner-administered products across all country income levels but it has a comparatively poor performance for sharing intellectual property assets, with no evidence of engaging in new agreements during the period of analysis. It has a strong performance in supply chain capacity building and health systems strengthening but shows average performance in building manufacturing capacity.

OPPORTUNITIES FOR TAKEDA

Expand the geographic coverage of project-specific access plans for non-communicable diseases. Takeda has comprehensive access plans in place for all late-stage R&D projects analysed. The company can increase the number of countries included in these plans. For example, the access plan for mobocertinib (Exkivity™) for lung cancer can be expanded to include more low- and lower-middle income countries.

Expand registration of cancer products. Takeda has four on-patent cancer medicines in its portfolio, including non-Hodgkin lymphoma treatment brentuximab vedotin (Adcetris®). This product has been filed in 21 countries in scope of the Index, including three countries with a high burden of non-Hodgkin lymphoma. The company can further expand the registration of this product, especially in countries where the burden of non-Hodgkin lymphoma is the highest, such as Myanmar, Afghanistan and Suriname.

Expand the use of tools to assess patients' ability to pay and determine differential prices to more products and countries. Takeda developed a sophisticated Patient Assistance Tool to assess individual patients' ability to pay. The company can apply this tool to more of its products, such as its lung cancer treatment brigatinib (Alunbrig®), in countries where the tool is already being applied for other products. The patient assistance tool and intra-country pricing strategies can be applied in more countries in scope with a high burden of lung cancer such as China and Thailand.

CHANGES SINCE THE 2021 INDEX

- The launch of Corporate Philosophy Dashboard, including the launch of the Growth and Emerging Market Transformation and Aspiration Dashboard which provides a framework of measuring progress against priorities included access metrics.
- Successful completion of an innovative digital authentication technology pilot in Kenya which will allow the authentication of Takeda products and now preparing for launch readiness in higher risk markets.
- Evaluating a novel field and rapid analytical technology based on time-domain nuclear magnetic resonance (TD-NMR) that has been adapted for testing biologics and vaccines counterfeit suspects to provide immediate results.
- Sought regulatory authorization for its dengue vaccine candidate (TAK-003). Takeda is participating in the EMA's first-ever parallel assessment of a medicinal product for use in the European Union (EU), and through the EU-M4all procedure for countries outside of the EU.
- Joined the Antimicrobial Resistance (AMR) action fund, which was established to support the clinical development of new antimicrobial agents and to achieve a sustainable antimicrobial market.
- Scaled up the Blueprint for Innovative Healthcare Access initiative concept to Nigeria in partnership with BIO Ventures for Global Health (BVGH) to build diagnostic and treatment capacity and in Uganda and Tanzania with the International Cancer Institute (ICI).
- Partnered with UNITAR and the local authorities of Rwanda and South Africa to launch the new Value-based Healthcare (VBHC) Hub, which facilitates locally led initiatives that will promote and advance the implementation of VBHC models in low-income and resource-limited settings.
- Takeda takes a co-leadership role in the Corona Accelerated R&D in Europe (CARE) programme.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Pharmaceuticals.
Therapeutic areas: Oncology, Rare Diseases, Neuroscience, Gastroenterology (GI) and Plasma Derived Therapies.
Product categories: Innovative medicines and vaccines.

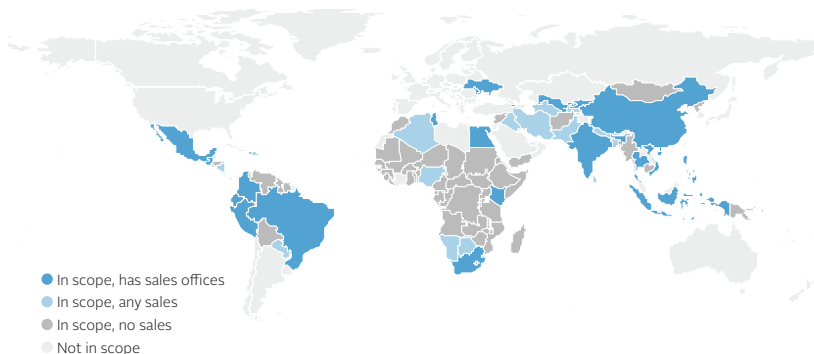
M&A news: In March 2021, Takeda announced it would acquire Maverick Therapeutics for USD 525 million. Takeda acquired GammaDelta Therapeutics in November 2021.

Takeda's products are sold in 37 out of 108 countries in scope of the Index. Takeda has sales offices in 21 countries, and sells via suppliers and/or pooled procurement in an additional 16 countries.

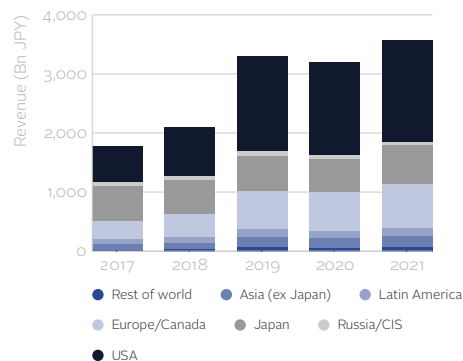
Revenue by segment (2021) – in JPY

Pharmaceuticals	3,569.01 bn
Total	3,569.01 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

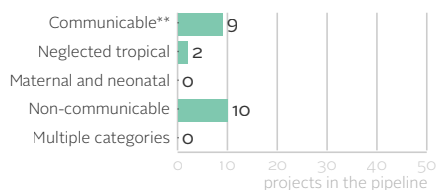
PIPELINE for diseases in scope

Takeda has a total of 21 R&D projects in scope with 11 of these projects targeting priority diseases. The other ten R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on coronavirus diseases (6). Of the projects targeting other diseases in scope, the focus is on oncology (7). Four R&D projects are in late-stage development that target either a priority disease (1) or address a public health need in LMICs (3).^{*} Evidence of access planning was in place for 100% of these projects.

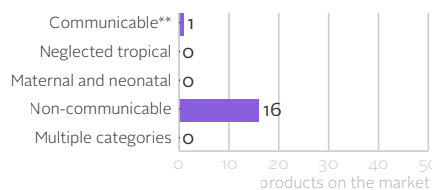
PORTFOLIO as selected for analysis by the Index

Takeda has 16 medicines in scope, 12 of which are on patent, and one vaccine. 42% of these medicines (5) are on the WHO EML. The off-patent medicines target non-communicable diseases (NCDs) such as cancer (1), cardiovascular diseases (2) and kidney diseases (1). The on-patent medicines target NCDs (12) such as diabetes (5), cancer (4), cardiovascular diseases (2) and kidney diseases (1). Takeda's preventative vaccine targets lower respiratory infections.

21 projects in the pipeline



17 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other ^{***}	Total
Targets established R&D priorities	1	8	1	0	0	1	0	11
Addresses needs of LMICs [*]			1	0	2	1	0	4
Other projects in scope			3	3	0	0	0	6

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	1	11			12
off patent	3	1			4
Vaccines	1	0			1
Contraceptives	0	0			0
Diagnostics			0		0
Other [†]				0	0

^{*}50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in

the clinical phase of development were included for this analysis.
^{**}Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
^{***}Other includes projects that have a technical lifecycle and projects that fol-

low a different development cycle (e.g. diagnostics).
[†]Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
[‡]Other includes vector control products.

Takeda Pharmaceutical Co, Ltd

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy.

Takeda performs strongly. Its strategy, called The Corporate Philosophy, aims to increase sustainable access of innovative medicines globally and covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely the CEO of the Takeda Executive Team.

Provides evidence of financial and non-financial access-related incentives at the executive level.

Takeda performs strongly. It incentivises its senior executives and in-country managers in Growth and Emerging Markets units to take action on access to medicine with financial and non-financial rewards. The CEO also has access-related incentives.

Publicly discloses outcomes of its

access-to-medicine activities. Takeda performs strongly in transparency of access activities.

It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transpar-

ency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its Access to Medicines Progress Report and its Annual Integrated Report.

Performs above average in responsible promotional practices.

Takeda's sales agents are not solely incentivised on sales volume targets. Employee KPIs are based on company or global KPIs which are then passed onto the business unit or function. It does not publicly disclose information related to transfers of values to healthcare professionals (HCPs) in the bulk of countries in scope of the Index (e.g., payments for attending events or promotional activities), unless required by law or by local regulations. However, Takeda reports that it has standard operating procedures to control HCP engagement in all countries in scope of the Index and has implemented automation/digitalisation initiatives to increase controls around HCP activities.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities.

Takeda performs strongly, demonstrating evidence of all components looked for by the Index:

fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards which has recently been updated and enhanced. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports the Doha Declaration on

TRIPS and Public Health. Takeda publicly shares support of the Doha Declaration on TRIPS and Public Health, but expresses reservations on its provisions, stating that it does not view compulsory licensing as a sustainable solution and should only be used in exceptional circumstances and as a last resort. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Takeda, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 7

SCORE 2.98

Access planning processes encompass all projects in the pipeline.

Takeda has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) in the company's pipeline. In general, Takeda begins developing access plans for R&D projects in Phase II or earlier of clinical development.

A small-sized priority R&D pipeline compared to its peers.

Takeda has 11 projects, including one late-stage candidate in its pipeline that target a priority product gap. These projects focus on communicable diseases including coronavirus diseases, Zika, malaria, dengue, chikungunya and tuberculosis. There is evidence of an access plan for Takeda's late-stage candidate targeting a priority product gap. This plan for the dengue vaccine candidate (TAK-003) is currently undergoing regulatory review in the European Union through the EU-Medicines for all (EU-M4all) procedure which intends to facilitate patient access to essential medicines or vaccines that prevent or treat diseases of major public health interest.

The plan considers innovative methods to ensure availability, affordability and supply.

Some projects address a public health need in LMICs,* with 100% (3/3) of late-stage projects covered by access plans.

In this analysis, Takeda has three late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs.* These projects have clinical trials in countries in scope of the Index or the project is a first-in-formulation treatment. They focus on cancer and epilepsy. Takeda provides evidence of access plans for all three late-stage projects. These access plans mainly focus on registration preparation and continuous supply.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development.

However, Takeda does disclose fully disaggregated R&D investment data to Policy Cures Research.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards.

Takeda leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. Takeda builds R&D capacity through the following initiatives:

- Strengthening clinical trial capacity in LMICs with BIO Ventures for Global Health.
- Clinical care and lab capacity building with Partners in Health, AMPATH, Foundation for Cancer Care Tanzania (FCCT) and Healthcare Partners for Access (HPA).
- Instrumental Access Program with Seeding Labs to strengthen local research and diagnostic capabilities.
- ReGRoW (Repurposing Grants for the Rest of the World) program with Cures Within Reach fosters repurposing research to address health inequities and improve access to medicines.

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to

patients in LMICs. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 7

SCORE 3.55

Public commitment not to enforce patents in countries in scope. Takeda publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and LICs.

Publicly discloses information on patent status. Like most of its peers, Takeda discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Takeda discloses patent information, including filing date, grant number, grant date and jurisdiction.

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Takeda does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Takeda does not engage in voluntary licensing for products in scope of the Index. It publicly states it would consider granting non-exclusive voluntary licences in certain circumstances.

Filed to register new products in seven countries in scope on average. Takeda did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among old products, its most widely filed is brentuximab vedotin (Adcetris®), for the treatment of non-Hodgkin lymphoma, is filed in 21 countries within the scope of the Index, including three high burden countries (Ecuador, Peru and Ukraine).

Takeda is not eligible for assessment of supra-nationally procured products.

Has access strategies for all its healthcare practitioner-administered products in scope of this analysis. Takeda is leading in this area. For the two products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). It makes efforts to reach additional patients using tiered inter-country pricing strategies and intra-country pricing strategies through patient assistance programmes. For example, Takeda evidenced an increase in patient reach of 41% through patient assistance programmes for Adcetris in Thailand and the Philippines and the company developed a pricing strategy that considers patients' ability to pay for its oncology medicine leuprolide acetate (Enantone®) in Thailand. The product is listed

on the National List of Essential Medicines and more than 75% of patients can access it. Takeda provides evidence of patient reach.

Has access strategies for its self-administered products for some countries in scope of this analysis. Takeda has an average performance in this area. The company provides examples of access strategies in countries of all assessed income levels (UMIC, LMIC, LIC) for two of the five products assessed. It makes efforts to reach additional patients through pricing strategies that consider payers' ability to pay and patient affordability programmes (PAPs). For example, in Indonesia, for brigatinib (Alunbrig®) Takeda applies an inter-country tiered pricing strategy. In addition, it launched two projects: the Market Access Scheme programme in which patients get fixed price reductions based on their healthcare practitioner's discretion, and a PAP which provides further cost reduction based on a patient affordability assessment. Forecasted patient reach for the programme is available. In addition, the company provides evidence of how patient reach has been increased through the approaches used.

The one manufacturing capacity building initiative included for analysis meets all Good Practice Standards. Takeda's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average and fewer initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. From 2017 until 2021, Takeda was involved in a partnership with Biological E. Limited in India where the company agreed to transfer technology to manufacture affordable combination vaccines for measles. This initiative meets all GPS.

All five supply chain capacity building initiatives included meet all Good Practice Standards. Takeda is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, Takeda's five-year partnership with the World Food Programme (WFP) aims to make health systems and public health supply chains more resilient and enhance targeted countries' ability to absorb and respond to health emergencies and pandemic preparedness. This initiative meets all GPS.

All five health systems strengthening initiatives included for analysis meet all Good Practice Standards. Takeda is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, Healthy Village aims to

achieve "healthy villages" by reducing preventable deaths among mothers and children by strengthening training for 1,400 community health workers and providing approximately 500,000 people in local communities with healthcare-related knowledge and services to prevent disease and protect lives.

Has engaged in scaling up one inclusive business model but has not shown evidence of its involvement in piloting any new inclusive business models that meet all inclusion criteria. Takeda performs average in the use of inclusive business models aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. Blueprint for Innovative Healthcare Access in Rwanda, Tanzania, Uganda and Nigeria aims to save and improve the lives of patients with cancer and other non-communicable diseases using a practical framework to sustainably strengthen healthcare systems at a local level and provide innovative affordability programmes.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Takeda is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives in LMICs.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Takeda has a policy expecting reporting of SF medicines to national health authorities and the WHO within seven days. It provides evidence of shortened reporting timeframes for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Takeda has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations until they reach the patient.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, the company is engaged in another structured donation programme: the Max Access Solutions whereby it donates ponatinib (Iclusig®) for chronic myeloid leukaemia in 17 countries since 2015.

Appendices for the 2022 Index

229	I Key parameters for evaluation
234	II Indicators and scoring guidelines
246	III Identifying best practices
247	IV The Good Practice Standards framework for capacity building
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APPENDIX I

Key parameters for evaluation

PIPELINE AND PORTFOLIO

R&D pipeline and product portfolio inclusion process

The Index team reviewed both marketed products and projects in companies' R&D pipelines, prior to including them for analysis. This review ensured the products and projects were within the scope of the 2022 Index and met relevant inclusion criteria.

Furthermore, before scoring and analysis began, companies' products and R&D projects were verified and updated against public sources of information to ensure that the most up-to-date and accurate pipelines and portfolios were represented. Public data could include pipeline and portfolio information found on company websites, in approvals from stringent regulatory authorities, the website clinicaltrials.gov and information on relevant product development partnership pipelines. Companies were given the opportunity to verify ongoing R&D projects and notified the Index team when a project had been divested or discontinued, while also confirming each product in their portfolios. These final pipelines and product portfolios were then entered into the final datasheets and sent to companies at the beginning of the data collection cycle.

Inclusion criteria for R&D projects

For R&D projects the following inclusion criteria were utilised:

1. Projects which target a disease, condition or pathogen within the disease scope of the Index and belong to a product type in scope (as detailed below) were included in the pipeline if they fell into one of the following categories:
 - Collaborative projects which the company continued to actively contribute resources and expertise to, during the period of analysis.
 - All projects which target a priority R&D product gap identified by Policy Cures Research and/or WHO, regardless of the stage of development.
 - Clinical-stage projects which do not target a priority R&D product gap identified by Policy Cures Research and/or WHO, but do target a disease, condition or pathogen within the scope of the Index.

The six lists that the Index uses to determine priority product gaps are:

- WHO Priority Pathogen List (2017)¹
- WHO Initiative for Vaccine Research (2010)²
- WHO R&D Blueprint (2022)³
- Policy Cures Research G-FINDER emerging infectious diseases (2020)⁴
- Policy Cures Research G-FINDER sexual & reproductive health (2020)⁵
- Policy Cures Research G-FINDER neglected diseases (2021)⁶

Cancer projects inclusion criteria

1. For cancer projects, R&D projects were included only if they contained a chemical or biological entity that had not previously been approved for a given cancer type before the period of analysis. For example, if a medicine had been approved as a monotherapy for one form of leukaemia before the period of analysis, further projects for the development

of this medicine as a monotherapy for another form of leukaemia or in combination with a medicine that had also previously been approved for leukaemia would be excluded.

2. If a medicine that had previously been approved for a specific cancer type is being developed for the same cancer type, but in combination with a medicine that has not received an approval for treating this cancer type, the project was included. Where multiple projects were ongoing for a single cancer type and the medicine(s) had not yet been approved for this cancer type, the latest stage of development was included. Projects were pre-populated and clustered by multiple group indications if these indications were being examined as a group within the same clinical trial(s) (e.g., a Phase II trial of a medicine for patients with breast, lung and colorectal cancer was counted as one project for all three cancer types; if a new chemical or biological entity was being tested in a Phase II trial for breast cancer only and in a Phase II trial for colorectal cancer only, these projects were listed separately).

Product types in scope

This scope is deliberately broad in order to capture the wide-ranging product types available to support the prevention, diagnosis and treatment of relevant conditions and diseases in the 108 countries covered by the Access to Medicine Index.

Medicines

All innovative and adaptive medicines, branded generics and generic medicines used to directly treat the target pathogen or disease process, regardless of formulation, are included. Medicines used only for symptomatic relief are not included.

Microbicides

These include topical microbicides specifically intended to prevent HIV.

Therapeutic vaccines

This covers vaccines intended to treat infections.

Preventive vaccines

This covers vaccines intended to prevent infections.

Diagnostics

This covers diagnostic tests designed for use in resource-limited settings (i.e., designed to be cheaper, faster, more reliable and easier to use in the field).

Vector control products

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides which are intended for global public health use and specifically aim to inhibit and kill vectors that transmit diseases in scope of the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors asso-

ciated with transmitting Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Contraceptive methods & devices

This covers instruments, apparatuses, appliances, implants and other similar or related articles intended to be used to control contraception (e.g., condoms or diaphragms). It also includes combination products that deliver medicines (e.g., hormone-delivery contraceptive rings).

Platform technologies

Only products that are specifically directed at meeting the needs of people living in the countries covered by the Index are included. These comprise, for example, general diagnostic platforms, adjuvants, immunomodulators and delivery technologies and devices. Implants and platform technologies for reproductive health are also included in this category. Platform technologies that have utility for accelerating the development of health products for 'Disease X', a term used by WHO to refer to currently unknown pathogens that could cause a serious international epidemic, are also included.

Process for registered product inclusion

Registered products also went through a verification process. Products targeting a disease, condition or pathogen listed in the disease scope (based on information from regulatory authorities such as U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Japanese Pharmaceuticals and Medical Devices Agency (PMDA)) were included in the portfolio under several conditions:

- Medicines which are:
 - Patented
 - Off-patent and listed on the 2021 WHO Model List of Essential Medicines (EML) AND where it was determined that companies had significant ability to shape the market, have a mean and/or median number of manufacturers <4.0 in a set of ten representative LMICs: Brazil, China, Egypt, India, Mexico, Morocco, Philippines, South Africa, Tunisia and Vietnam, per IQVIA MIDAS data; OR,
 - Off-patent and not listed on the 2021 WHO EML but listed as a first- or second-line treatment for a disease in scope by one of the five sets of guidelines (WHO, Centers for Disease Control (CDC), National Institute for Health and Care Excellence (NICE), National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO)) used by the Index team AND where it was determined that companies had significant ability to shape the market.
- To determine where companies had significant ability to shape the market, the Index team used IQVIA MIDAS data. Market dominance was defined for products:
 - Which have a mean and/or median number of manufacturers <4.0 in a set of ten representative low- and middle-income countries (LMICs: Brazil, China, Egypt, India, Mexico, Morocco, Philippines, South Africa, Tunisia and Vietnam), per IQVIA MIDAS data OR
 - Where a listed company has >70% of the market share in these countries by volume of sales, per IQVIA MIDAS data.
- Diagnostics which are listed on the 2020 WHO Model List of Essential In Vitro Diagnostics, with the addition of diagnostics for COVID-19.
- Vaccines, vector control products and platform technologies.

Determining patent status

Patent status for each product in scope of the Index was determined through a process of external research combined with verification from participating companies for the purpose of including or excluding products. This process was developed in consultation with experts from diverse constituencies. Patent status was first researched through the related regulatory authority websites (i.e., South-African CIPC Intellectual Property database,⁷ the US FDA Orange Book,⁸ Health Canada)⁹ and/or patent databases (MedsPaL and Pat-INFORMED)^{10,11} and later verified with companies. The Index clarifies that for the patent status in South Africa, if the information was not available, the Index looked at the status in the US and in some cases (e.g., for biologics) in Canada. However, it is not intended to be a presentation of patent rights worldwide, nor does it capture all patents that might apply to a product. It is therefore reasonable to assume that this Index may underreport where patents are in place. It should only be used as a proxy description and cannot be used as an indication of patent status outside of South Africa and/or the US and Canada. In some instances, the patent status of a particular product was identified as off-patent in South Africa, the US or Canada but on-patent in other jurisdictions.

Determining countries with high disease burdens

The Index considers in which of the countries in scope each of the companies have registered their ten most newly approved products. The Index used data from the Institute for Health Metrics and Evaluation's 2019 Global Burden of Disease (GBD)¹² to determine which countries in scope have the highest burden of disease. Countries in which companies have filed for registration were compared to the ten countries in scope with the highest burden of disease for the main indication of that product.

- When a product has multiple indications, the burden of disease for the main indication is used for analysis. If a product has two main indications, the five countries with the highest burden of disease for each indication are used, to complete the ten countries.
- Since only one country in scope of the Index, Kosovo, was not in the database, that country was not considered in the analysis for indicators related with GBD.
- By default, the data considered is for all ages. When there was a paediatric product, the settings were modified to search only for that specific age group.

SCORING

Neutral scoring protocol

Neutral scoring is used to avoid double negative marking of a company for the lack of a policy, strategy, programme or initiative whose score has already been impacted negatively once and for which the company cannot meet the additional expectations. For example, when a company has no R&D priority projects in their pipeline, it is assessed for scoring in the relevant R&D indicator (RD1a). However, for the indicator relating to access plans for R&D priority projects (RD3a) a neutral score is applied, as the company has already been evaluated for not having R&D priority projects in the pipeline. In that case, a proxy measure was identified for that indicator. The proxy measure includes the average score of the company across all indicators within the Technical Area. In 2022, neutral scoring was applied within the following areas: long-term donation programmes (PP2b), supra-nationally procured products: access strategies (PP3), healthcare practitioner-administered products: access strategies (PP4) and access-oriented licensing (PPL4/PPL5).

Scoring

Companies were assessed and scored by the Index in three Technical Areas: Governance of Access, Research & Development and Product Delivery, with each area composed of several indicators. Analysis was carried out based using a wide range of sources including data submitted by the companies themselves, independent reports and databases or documents from WHO, other multilateral organisations and non-governmental organisations. Public data sources, including information shared on company websites, in annual reports and through local health authorities, helped to triangulate data. The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process, beginning with scoring per company by the analyst during the first round of the data collection period, followed by re-scoring after companies have provided further clarification in areas identified by the analyst. This was followed by verification by the analyst, including an extensive quantitative and qualitative check of each indicator for each company. The research manager and research lead perform a quality assurance check on all scores to ensure consistency, with senior management performing a final spot check. Each analyst then cross-checked their Technical Area ranking, before the final ranking was cross-checked and verified by the data coordinator and research manager.

REVIEW PROCESS

Following clarification with companies, cross-check of company scores and consultation with experts, the Index team wrote the various sections of the Index report. The company report cards were fact checked by companies and confidential information was requested to be lifted for publication. Global health experts have provided reviews on each Technical Area analysed in the Index. Following internal review by the Foundation's management team, the entire Index was reviewed by the Chair of the Expert Review Committee (ERC), Professor Hans Hogerzeil.

METHODOLOGY LIMITATIONS

Limitations exist in every study of this design. Significant limitations specific to this study are discussed here. These and other methodological limitations will be considered in the methodology review for the 2024 Access to Medicine Index.

Disease, product scopes and country comparability

The outputs analysed in this study and the findings generated relate only to the geographical, disease, product and company scopes, as determined by the ERC during the methodology review process and as published in the Access to Medicine Index Methodology 2022.

- Although the Foundation recognises that all products, diseases, countries, access and product initiatives are not the same, in general in most Technical Areas in this study they are treated equally. For example, in R&D, nearly all compounds are treated equally if they meet the inclusion criteria, regardless of their mechanism of action or expected efficacy.
- In the registration indicator PR1, the Index used data from the Institute for Health Metrics and Evaluation's 2019 Global Burden of Disease (GBD)¹² results to prioritise the ten countries in scope with the highest disability-adjusted life year (DALY) rate. These disease-specific subset of countries with the highest burden of disease were given credit in this indicator. However, global burden of disease was not considered for the following indications:

- COVID-19, due to its pandemic nature
- Contraceptive methods, since these cannot be considered a disease
- Thalassaemia, since there is no GBD in IHME19
- In access strategies, for indicators PP3, PP4 and PP5 a maximum of five products was evaluated per company. These products were identified using criteria such as either on patent or off patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.
- For all four types of capacity building, PCB1, PCB2, PCB3 and RD6, companies could submit a maximum of five initiatives to be considered for analysis. This means that our analysis is not able to capture an overview of involvement in capacity building but instead an evaluation of the quality of selected examples.

Longitudinal comparability

Comparability between companies over successive indices is not always possible or appropriate, especially when the scoring criteria of an indicator had been refined. During the period of analysis, where trend analysis was useful, the Index team compared raw data from past Indexes with raw data from 2022.

Company comparability

The objective of the Index is to produce a standardised relative ranking of the 20 companies' access-to-medicine performances. However, not all companies are the same. Some have large portfolios and pipelines. Some have a comparatively narrow disease focus. Some have a comparatively narrow scope of country operations. Others have generic pharmaceutical subsidiaries. Companies differ in size, geographical reach and capability for recording and reporting information. The Index uses various methods to correct for these variations between companies. In order to minimise the variability of information sourced from companies, all companies were provided with training on the data submission process and the analytical parameters for each indicator were clearly outlined during the data collection process. In addition, a clarification round was carried out, giving companies an opportunity to provide additional data where there were gaps, inconsistencies or where clarifications were necessary.

In several indicators that measure quantitative elements, in general, the Index makes adjustments for company size. In the case of some R&D indicators in this Index, the company's pipeline size was used as an additional differentiator to group companies together, so that both large and small companies' performances were scored relative to peers of similar size.

DISEASES IN SCOPE FOR THE 2022 ACCESS TO MEDICINE INDEX

Diseases are included based on their burden of disability-adjusted life years (DALYs) in countries in scope,¹³ WHO classifications and the relevance of pharmaceutical interventions. With the new addition of thalassaemia, the disease scope for the 2022 Index has expanded from 82 to 83 diseases, conditions and pathogens.

TABLE 6 Diseases, conditions and pathogens in scope of the 2022 Access to Medicine Index

Non-communicable diseases (18)	Communicable diseases (23 + 1 disease category covering 12 priority pathogens)	Neglected tropical diseases (20)	Maternal and neonatal health conditions (10)	Priority pathogens*(12)
Alzheimer's disease	Arenaviral haemorrhagic fevers (Lassa fever)	Buruli ulcer	Birth asphyxia and birth trauma	<i>Acinetobacter baumannii</i> (carbapenem-resistant)
Anxiety disorders	Bunyaviral diseases	Chagas disease	Contraceptive methods	<i>Campylobacter spp.</i> (fluoroquinolone-resistant)
Asthma	Coronaviral diseases	Dengue and chikungunya	Hypertensive disorders of pregnancy	<i>Enterobacteriaceae</i> (carbapenem-resistant, 3rd generation cephalosporin-resistant)
Bipolar affective disorder	Disease X	Dracunculiasis	Maternal abortion and miscarriage	<i>Enterococcus faecium</i> (vancomycin-resistant)
Cancer**	Diphtheria	Echinococcosis	Maternal haemorrhage	<i>Haemophilus influenzae</i> (ampicillin-resistant)
Chronic obstructive pulmonary disease	Emergent non-polio enteroviruses	Foodborne trematodiasis	Maternal sepsis	<i>Helicobacter pylori</i> (clarithromycin-resistant)
Diabetes mellitus	Enteric disease	Human African Trypanosomiasis	Neonatal sepsis and infections	<i>Neisseria gonorrhoeae</i> (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)
Endometriosis	Filoviral diseases	Leishmaniasis	Obstructed labour	<i>Pseudomonas aeruginosa</i> (carbapenem-resistant)
Epilepsy	Henipaviral diseases	Leprosy	Other neonatal conditions	<i>Salmonella spp.</i> (fluoroquinolone-resistant)
Hypertensive heart disease	HIV/AIDS	Lymphatic filariasis	Preterm birth complications	<i>Shigella spp.</i> (fluoroquinolone-resistant)
Ischaemic heart disease	Leptospirosis	Mycetoma, chromoblastomycosis and other deep mycoses		<i>Staphylococcus aureus</i> (methicillin-resistant, vancomycin-intermediate and vancomycin-resistant)
Kidney diseases	Lower respiratory infections	Onchocerciasis		<i>Streptococcus pneumoniae</i> (penicillin-non-susceptible)
Migraine	Malaria	Rabies		
Schizophrenia	Measles	Scabies and other ectoparasites		
Sickle cell disease	Meningitis	Schistosomiasis		
Stroke	Other prioritised antibacterial-resistant infections*	Snakebite envenoming		
Thalassaemia	Pertussis	Soil-transmitted helminthiasis		
Unipolar depressive disorders	Rheumatic fever	Taeniasis/cysticercosis		
	Sexually transmitted infections (STIs)	Trachoma		
	Tetanus	Yaws		
	Tuberculosis			
	Viral hepatitis (B and C)			
	Yellow fever			
	Zika			

*This refers to 12 species of bacteria with critical, high, and medium antibiotic resistance defined by WHO, which are collectively referred to as 'other prioritised antibacterial-resistant infections' by the Index, and counted as one communicable disease.

** The 19 cancer types are collectively counted as one non-communicable disease.

CANCERS IN SCOPE FOR THE 2022 ACCESS TO MEDICINE INDEX

Cancer remains in scope for the 2022 Index, with 19 cancer types included. The 18 cancer types in scope for the 2021 Index have been retained and osteosarcoma is newly in scope. The inclusion of cancer types is based on high incidence both globally and in countries in the scope of the Index, using data from the Global Cancer Observatory (GLOBOCAN, 2020).¹⁴ Ovarian and uterine cancer remain in scope as they have comparably higher incidences compared to other sex-linked cancer types. As in the methodologies for previous Indexes, products for the management of pain and supportive treatments (for e.g., antiemetics) are not included.

TABLE 7 Cancer types in scope

Cancer types in scope (19)
Bladder
Brain, nervous system
Breast
Cervical
Colorectal
Gallbladder
Head and neck
Kaposi sarcoma
Leukaemia
Liver
Lung
Non-Hodgkin lymphoma
Oesophageal
Osteosarcoma
Ovarian
Prostate
Stomach
Thyroid
Uterine

APPENDIX II

Indicators and scoring guidelines

A GOVERNANCE OF ACCESS 15%

Indicator

GA1 Governance structures & incentives

The company has a governance system that includes both direct board-level responsibility and accountability for its access-to-medicine initiatives. To facilitate effective implementation of the strategy, senior management (i.e., CEO and/or senior executives) and in-country operational managers have access-to-medicine objectives and incentives to reward the effective delivery of initiatives that improve access to medicine in countries and for diseases within the Index scope.

- 5 The company has a board member or board-level committee directly responsible for its access-to-medicine approach. Its CEO and/or senior executives have (long-term) access-related objectives and incentives. Its regional and/or in-country managers also have objectives and incentives to improve access in countries in scope of the Index.
- 4 The company has a board member or board-level committee (directly or indirectly) responsible for its access-to-medicine approach. There is evidence of access-related incentives in place at an executive or managerial level (for senior management or regional/in-country managers in countries in scope of the Index.
- 3 The company has a board member or board-level committee responsible for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level.
- 2 The company has an executive manager or executive committee, that directly reports to a board member or to a board-level committee, responsible for its access-to-medicine approach. There is no evidence of access-related incentives in place at an executive or managerial level in countries in scope of the Index.
- 0 The company has no board or executive level responsibility for its access-to-medicine approach.

GA2 Access-to-medicine strategy

The company has an access-to-medicine strategy and demonstrates that it is integrated within its corporate strategy. The strategy extends across the company's portfolio and pipeline, within the Index scope.

- 5 The company has a clear access-to-medicine strategy with evidence of alignment with corporate/business strategy. It includes measurable objectives to improve access to medicine. The company demonstrates evidence that the strategy is integrated through the application of it across the company's portfolio and pipeline, within the Index scope.

- 4 The company has a clear access-to-medicine strategy with evidence of alignment with corporate/business strategy. It includes measurable objectives to improve access to medicine. The company demonstrates evidence that the strategy applies to a subset of the company's portfolio and pipeline, within the Index scope.
- 3 The company has an access-to-medicine strategy with a business rationale that covers all or some of their projects.
- 2 The company has no existing access-to-medicine strategy with a business rationale but is in the process of implementing one.
- 1 The company has made commitments to improve access to medicine but does not have an access-to-medicine strategy.
- 0 The company neither has access-to-medicine strategy, nor has commitments for improving access to medicine.

GA3 Public disclosure of access-to-medicine outcomes

The company has time-bound measurable objectives, goals and targets related to improving access to medicine in countries in scope of the Index. It publicly shares progress against such objectives, goals and targets, as well as outcomes.

- 5 The company publicly discloses its commitments to access to medicine, alongside targets, measurable goals, objectives, and outcomes (or plans to report outcomes when available) related to improving access to medicine in a consistent manner and facilitates accountability and transparency by reporting targets and outcomes directly on their website in a centralised manner with regular updates.
- 4 The company publicly discloses its commitments to access to medicine, alongside targets, measurable goals, objectives, and outcomes (or plans to report outcomes when available) related to improving access to medicine in a consistent manner and facilitates accountability and transparency by reporting targets and outcomes, but reporting is not centralised or not updated regularly.
- 3 The company publicly discloses its commitment to access to medicine, targets, and measurable goals, objectives, and outcomes (centrally or non-centrally) related to improving access to medicine, but not for all initiatives in which it is involved.
- 2 The company publicly discloses its commitment to access to medicine, targets, and measurable goals, objectives related to access to medicine.
- 1 The company publicly discloses commitments related to improving access to medicine.
- 0 The company does not publicly disclose any of the above information.

GA4 Responsible promotional practices

The company mitigates the risk of unethical sales practice (e.g., by decoupling bonuses for sales agents from sales volumes only). Further, it takes a voluntary approach to publicly disclose information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope (e.g., payments for attending and/or speaking at events, continuing medical education, promotional activities, or other non-monetary values directed at HCPs).

- 5 The company takes a voluntary approach to publicly disclose information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope. It has a policy to limit transfers of value to HCPs in countries in scope. Sales agent incentives not driven exclusively by sales volume targets, and targets are not set at the individual level.
- 3-4 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope only when required by law, regulation, or trade association. It has a policy to limit transfers of values to HCPs in countries in scope of the Index. Sales agent incentives are not driven exclusively by sales volume targets, but some targets are set at the individual level.
- 2 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope only when required by law, regulation, or trade association. There is a policy to limit transfers of values to HCPs in countries in scope of the Index. Sales agent incentives are driven exclusively by sales volume targets and targets are set at the individual level.
- 1 The company publicly discloses information regarding actual transfers or its approach to transfers of value to healthcare professionals in countries in the Index scope only when required by law, regulation, or trade association. It has no policy to limit transfers of values to HCPs in countries in scope of the Index and sales agent incentives are driven (almost) exclusively by sales volume targets.
- o The company makes no disclosure regarding its approach to transfers of values to HCPs nor does it disclose its approach to incentives for sales agents.

GA5 Compliance controls

The company demonstrates that it has robust controls in place to mitigate the risk of non-compliance in its operations in countries in scope of the Index (i.e. in the areas of ethical marketing, anti-corruption, and clinical trials), which include the following components:

- a) fraud-specific risk assessment;
- b) country risk-based assessment;
- c) a live/continuous monitoring system for compliance (other than auditing);
- d) auditing and review mechanisms, which involve the use of both internal and external resources, apply to all third parties and all countries where it has operations, based on risk assessment;
- e) formal processes in place to ensure compliance with these standards by third parties and the company demonstrates that it takes enforcement action for non-compliance in countries in scope of the Index.

- 5 The company has all of the above-mentioned elements in place.
- 4 The company has 4 of the above-mentioned elements in place.
- 3 The company has at least 3 of the above-mentioned elements in place.
- 2 The company has at least 2 of the above-mentioned elements in place.
- 1 The company has 1 of the above-mentioned elements in place.
- o The company does not have any of the above-mentioned elements in place or does not disclose information.

GA6 Incidence of breaches

The company has not been found to be the subject of negative legal rulings or settled cases for unethical marketing practices/corrupt practices/ anti-competitive practices / misconduct in clinical trials in countries within the scope of the Index during the past two years.

- 5 The company has not been the subject of any settlements for criminal, civil or regulatory infractions in countries within the scope of the Index during the past two years (pending cases, allegations and cases under appeal are not included).
- 3 The company has not been the subject of any criminal or civil infractions in countries within the scope of the Index, but it has been the subject of one breach of a code of practice in one of the countries within the scope of the Index.
- 2 The company has been the subject of more than one breach of a code of practice in countries within the scope of the Index.
- o The company has been the subject of at least one negative ruling or settlement in a country within the scope of the Index, over the period of analysis.

GA7 Trade policy: IP and access to medicine

The company publicly discloses its support of the policy flexibilities intended to protect public health confirmed by the Doha Declaration on TRIPS and Public Health. Further, the company employs an intellectual property (IP) strategy that is conducive to access to medicine, operating in accordance with the international consensus on IP standards as it pertains to public health, confirmed by the Doha Declaration. This is evidenced by an absence of IP-related anti-competitive practices in relation to access to medicine in countries in scope.

- 5 The company publicly discloses support for the Doha Declaration and the usage of TRIPS flexibilities. There is no evidence-based information that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.
- 4 The company publicly discloses general support for the Doha Declaration and the usage of TRIPS flexibilities, though reservations on its provisions can be expressed. There is no evidence-based information that the company is involved in IP-related anti-competitive practices* in relation to access to medicines.

- 3 The company publicly discloses general support for the Doha Declaration and the usage of TRIPS flexibilities, though reservations on its provisions can be expressed. However, it has been involved in one IP-related anti-competitive practice* via industry associations.
- 2 The company does not publicly support the Doha Declaration and the usage of TRIPS flexibilities and has been involved in one IP-related anti-competitive practice* via industry associations.
- 1 The company has been involved in more than one IP-related anti-competitive practice* via industry associations.
- o The company has been directly involved in anti-competitive IP-related practices*.

*Patenting in Least Developed Countries, lobbying against the usage of TRIPS flexibilities by country governments within the Index scope (including through trade associations), lobbying for strengthening of IP standards beyond TRIPS in countries within the scope of the Index, evergreening.

B RESEARCH & DEVELOPMENT 30%

Indicator

RD1A R&D pipeline: Prioritised diseases

The company engages in the development of products that target priority product gaps identified by global health research organisations.* This includes both innovative and adaptive R&D and both in-house and collaborative R&D.

- 5-1 The total size of each company's 'priority R&D' pipeline within the scope of the Index that targets an externally defined R&D gap from Policy Cures Research and/or WHO, scaled across all companies and scored.
- o The company has no projects within the scope of the Index in its research pipeline for which it targets specific needs in countries in scope as defined by Policy Cures Research and/or WHO.

*Currently, R&D priorities are categorised using lists from WHO and Policy Cures Research.

RD1B R&D Pipeline: Other diseases

The company engages in the development of products that address a clear need in LMICs beyond the R&D priorities identified by global health research organisations.* This includes innovative and adaptive R&D that, for example, addresses heat stability issues, targets populations for which further studies/specific formulations are needed (such as children and pregnant women, etc.) as determined by stakeholder consensus.

- 5-1 The total size of each company's pipeline that does not target externally defined R&D gaps from Policy Cures Research and/or WHO but meets stakeholder-informed criteria of possessing product characteristics or target populations that are highly relevant to patients living in countries in scope, scaled across all companies and scored.
- o The company has no projects within the scope of the Index in its research pipeline that meets stakeholder-informed criteria of possessing product characteristics or target populations that are highly relevant to patients living in countries in scope

*Currently, R&D priorities are categorised using lists from WHO and Policy Cures Research.

RD2 Planning for access: Structured framework

The company has a process through which equitable access is planned for products successfully developed both in-house and collaboratively.

- 5 The company has a structured process in place and commits to develop access plans during development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations. Access plans are initiated no later than Phase II of development.
- 4 The company has a structured process in place and commits to develop access plans during development for all its R&D projects (both in-house and collaborative) targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations.

- 2 The company has a structured process in place to develop access plans for a subset of its R&D projects targeting diseases and countries within the scope of the Index. The process includes consideration of different plans for different product types, disease targets and target populations.
- 1 The company has a general process in place to include access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.
- o The company has no processes in place in this area or applies access planning on an ad hoc basis.

RD3A Planning for access: Project-specific plans for prioritised diseases

The company provides evidence that its R&D projects for diseases prioritised by WHO and Policy Cures Research are supported by detailed commitments and strategies to improve access to products in countries within the scope of the Index.

- 5-1 The company's late-stage R&D projects that meet externally defined priorities identified by Policy Cures Research and/or WHO are assessed on the breadth and depth of access plans in place for these projects, scaled across all companies and scored.
- o The company provides no evidence of access plans for any late-stage R&D projects that meet externally defined priorities within the scope of the Index. Nor does it provide evidence of any partnerships with access-oriented organisations for these projects.

RD3B Planning for access: Project-specific plans for other diseases

The company provides evidence that its R&D projects for diseases not prioritised by WHO and Policy Cures Research (but are deemed by the Index to have a public health in LMICs) are supported by detailed plans to improve access to products in countries within the scope of the Index.

- 5-1 The company's late-stage R&D projects that do not meet externally defined R&D priorities but do meet stakeholder-informed criteria of a clear relevance to patients in countries in scope are assessed on the breadth and depth of access plans in place for these projects, scaled across all companies and scored.
- o The company provides no evidence of access plans for any late-stage R&D projects that do not meet externally defined priorities but do meet stakeholder-informed criteria of a clear relevance to patients in countries in scope. Nor does it provide evidence of any partnerships with access-oriented organisations for these projects.

RD4 Disclosure of resources dedicated to R&D

The company publicly discloses the resources dedicated to its R&D activities which are conducted in-house and/or in collaboration for diseases within the scope of the Index and suitable for countries relevant to the Index.

- 5 The company publicly discloses its R&D investments, disaggregated at least at the following levels: disease, project and phase of development.
- 3 The company publicly discloses its R&D investments disaggregated to some degree: disease category, product type, aggregated phase of development (e.g., clinical versus pre-clinical) etc. and the company voluntarily discloses disaggregated R&D investment data to organisations that present anonymised aggregate data for global health purposes, such as Policy Cures Research.
- 2 The company publicly discloses its R&D investments disaggregated to some degree: disease category, product type, aggregated phase of development (e.g., clinical versus pre-clinical) etc.
- 1 The company does not publicly disclose R&D investment data that has been disaggregated at any level. However, it voluntarily discloses disaggregated R&D investment data to organisations that present anonymised aggregate data for global health purposes, such as Policy Cures Research.
- o The company does not publicly disclose R&D investment data that has been disaggregated at any level and does not contribute data to Policy Cures Research.

RD6 Capacity building in R&D

The company increases local capacity for health research (including clinical trial capacity) and product development by undertaking R&D capacity building initiatives in partnership with local universities and public sector research organisations in countries within the scope of the Index. The Index assesses whether these initiatives meet all Good Practice Standards.*

- 5 The company provides evidence of five R&D capacity building initiatives that meet inclusion criteria, of which at least three meet all Good Practice Standards.
- 4 The company provides evidence of three R&D capacity building initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four R&D capacity building initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five R&D capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.
- 3 The company provides evidence of one to five R&D capacity building initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three R&D capacity building initiatives of which two meet all Good Practice Standards.
- 2 The company provides evidence of at least two R&D capacity building initiatives that meet inclusion criteria, of which none meet all Good Practice Standards.
- 1 The company provides evidence of one R&D capacity building initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.
- o The company does not provide any examples of R&D capacity building initiatives that meet all inclusion criteria.

*Has a good governance structure in place, has goals aligned with or support institutional goals, measures progress or outcomes, aims for sustainability and long-term impact.

C PRODUCT DELIVERY 55%**Indicator****PR1 Registration**

The company files to register its most recently launched products* targeting diseases within the scope of Index in countries within scope that have the highest disease burden.

- 5 The company filed all of its products in scope for registration in a majority of countries with the highest disease burden and in a majority of countries in scope of the Index.
- 4-1 Scaled compared to peers. Number of newer products** that are filed for registration in number of countries with the highest disease burden and in a number of countries in scope. Number of older products** that are filed for registration in number of countries with the highest disease burden and in a number of countries in scope of the Index.
- o The company provides no evidence of filing to register any of its products in scope that target diseases in the Index scope in any countries in scope.

*Most recently launched refers to the date the product was first approved to be marketed anywhere globally. The Index analyses information for up to 10 of the company's most recently launched products, depending on the size of the company's portfolio.

**Newer product refers to a product that was first approved to be marketed in the last 5 years anywhere globally, that targets diseases within scope.

***Older product refers to a product that was first approved to be marketed within the last 5 to 20 years anywhere globally, that targets diseases within scope.

PP2A Access strategies: Ad hoc donations

The company has policies and supply processes in place to ensure ad hoc donations* are carried out rapidly in response to expressed need.

- 5 The company meets all of the following criteria with respect to ad-hoc donations: a) it has policies/agreements/supply processes in place to ensure all of its ad hoc donations are carried out rapidly in response to expressed needs; b) Company or its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user, being the patient.
- 2.5 The company has policies/agreements/supply processes in place to ensure all of its ad hoc donations are carried out rapidly in response to expressed needs. However, neither the company nor its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user, being the patient.
- o The company meets none of the following criteria with respect to ad hoc donations: a) it has policies/agreements/supply processes in place to ensure all of its ad hoc donations are carried out rapidly in response to expressed needs; b) Company or its partners have policies/processes in place to ensure monitoring of the delivery of donations until receipt by the end-user, being the patient.

*A gift of products for which there is no clear, defined long term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

PP2B Access strategies: Long-term donation programmes

The company engages in long-term, sustainable product donation programmes for diseases where elimination, eradication or control goals are possible and publicly commits to the achievement of such goals.

- 5 The company publicly commits to remain engaged in at least one long term donation programme for the achievement of elimination, eradication, or control goals with no time limit.
- 3 The company publicly commits to engage in long term donation programmes to support elimination, eradication, or control goals for a time-limited period.
- 1 The company is engaged in donation programmes which support elimination, eradication or control, but makes no public commitment regarding this engagement.
- NS Companies without structured donation programmes receive a neutral score. Moreover, companies with structured donation programmes that have no elimination, eradication, or control goals also receive a neutral score.

PP3 Access strategies: Supranational products

The company applies access strategies to the products for which it has marketing rights and that are supranationally procured*, through engaging with international procurers, advanced market commitments etc. The company extends those strategies to countries graduating from development assistance or countries that do not qualify for such assistance.

- 5 For all its supranationally procured products in scope, the company meets all following criteria:
 - a) it applies equitable pricing strategies, takes affordability into account and demonstrates using demographic and economic factors to determine the price per programme;
 - b) it applies the same terms of the supranational agreement in countries that do not qualify for assistance from these mechanisms, or are/have graduated from these programmes;
 - c) it applies additional non-pricing initiatives to maximize the reach across different segments of the population;
 - d) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries covered.
- 4-1 For a subset of its supranationally products in scope, the company meets a number of the following criteria:
 - a) it applies equitable pricing strategies, takes affordability into account and demonstrates using demographic and economic factors to determine the price per programme;
 - b) it applies the same terms of the supranational agreement or equitable access strategies in countries that do not qualify for assistance from these mechanisms, or are/have graduated from these programmes;
 - c) it applies additional non-pricing initiatives to maximize the reach across different segments of the population;

- d) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries covered by these programmes.
- o For its supranationally procured products in scope, the company meets none of the above listed criteria.
- NS Companies without products that are supranationally procured receive a neutral score.

For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on-patent or off-patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

*Products for which international procurement, advanced market commitments or market-shaping facilities exist. These products include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria and other neglected tropical diseases. Companies which do not market these products will not have this indicator applied to them.

For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on-patent or off-patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

PP4 Access strategies: Healthcare practitioner-administered products

The company takes into consideration both the relevant payer(s) ability to pay and the demographic* factors of a country to determine its access strategy, with the aim to increase the reach of its healthcare practitioner-administered products** across the income pyramid.

This is evidenced by:

- a) an approach which demonstrates how pricing strategies incorporate factors which determine payer's ability to pay for different segments of the population (e.g., patients paying out of pocket) and non-pricing initiatives (i.e., patient assistance programmes, donations, voluntary licensing, technology transfer, health systems strengthening initiatives) complement those pricing strategies to maximize reach, and
 - b) evidence of how the approach has increased the patient number since the product was introduced, and
 - c) plans to increase patient numbers for the following X years, and
 - d) it applies initiatives to boost the health system's strength to improve the availability of the products.
- 5 For all its healthcare practitioner-administered products in scope, the company meets all the following criteria for the countries' examples selected:
- a) it applies pricing strategies that take into account the ability to pay, per payer types within different segments of the population. It provides evidence that demographic and economic factors are considered to set the prices in the public and/or private sectors;
 - b) it applies additional non-pricing initiatives to maximize the reach across different segments of the population;
 - c) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries' examples selected;
 - d) it applies initiatives to boost the health system's strength to improve the availability of the products.

- 4-1 For a subset of its healthcare practitioner-administered products in scope, the company meets X number of the following criteria in X number of selected countries:
 - a) it applies pricing strategies that take ability to pay per payer types into account, within different segments of the population. It provides evidence that demographic and economic factors are considered to set the prices in the public and/or private sectors;
 - b) it applies additional non-pricing initiatives to maximize the reach across different segments of the population;
 - c) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries' examples selected;
 - d) It applies initiatives to boost the health system's strength to improve the availability of the products.
- o For its healthcare practitioner-administered products in scope, the company meets none of the above listed criteria.
- NS Companies without healthcare practitioner-administered products receive a neutral score.

*The characteristics of a population such as age, sex, income level, education level, employment, etc.

**Healthcare practitioner-administered products are products that typically require either hospital administration of the product or the continued attention of a skilled healthcare professional for administration, such as an intravenously administered oncology medicine. Companies who do not market these products will not have this indicator applied. For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on patent or of patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

PP5 Access strategies: Self-administered products

The company takes into consideration both the ability-to-pay of the payer and the demographic* factors of a country to determine its access strategy, with the aim to increase the reach of its healthcare practitioner-administered products** across the income pyramid.

This is evidenced by:

- a) an approach which demonstrates how pricing strategies incorporate factors which determine payer's ability to pay for different segments of the population (e.g., patients paying out of pocket) and non-pricing initiatives (i.e., patient assistance programmes, donations, voluntary licensing, technology transfer, health systems strengthening initiatives) complement those pricing strategies to maximize reach, and
 - b) evidence of how the approach has increased the patient number since the product was introduced, and
 - c) plans to increase patient numbers for the following X years.
- 5 For all its self-administered products in scope, the company meets all the following criteria for the countries' examples selected:
- a) it applies pricing strategies that take ability to pay per payer types into account, within different segments of the population. It provides evidence that demographic and economic factors are considered to set the prices in the public and/or private sectors;

- b) it applies additional non-pricing initiatives to maximize the reach across different segments of the population;
 - c) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries' examples selected.
- 4-1 For a subset of its self-administered products in scope, the company meets X number of the following criteria in X number of selected countries:
- a) it applies pricing strategies that take ability to pay per payer types into account, within different segments of the population. It provides evidence that demographic and economic factors are considered to set the prices in the public and/or private sectors;
 - b) it applies additional non-pricing initiatives to maximize the reach across different segments of the population;
 - c) it provides evidence to demonstrate how this approach has increased or is planned to increase the number of patients reached in the countries' examples selected.
- o For its self-administered products in scope, the company meets none of the above listed criteria.

*The characteristics of a population such as age, sex, income level, education level, employment, etc.

**Healthcare practitioner-administered products are products that typically require either hospital administration of the product or the continued attention of a skilled healthcare professional for administration, such as an intravenously administered oncology medicine. Companies who do not market these products will not have this indicator applied. For this indicator, a maximum of five products was evaluated per company, and identified using criteria such as either on patent or of patent, on EML and high market share. Companies received an opportunity to verify and adjust as appropriate.

PPL1 Patent filing & enforcement

The company publicly commits to not filing for or enforcing patents related to diseases within the Index scope in Least Developed Countries (LDCs), low-income countries (LICs), and a subset of lower-middle income countries (LMICs) and upper-middle income countries (UMICs).

- 5 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products for diseases in scope of the Index in all LDCs, LICs, and a subset of LMICs and UMICs.
- 4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs, LICs, and a subset of LMICs. Or all LDCs, LICs and a subset of LMICs and UMICs for a subset of products.
- 3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs, a subset of LICs, and LMICs.
- 2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to all products in scope of the Index in all LDCs and/or LICs.

- 1 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in scope of the Index and/or in a specific region or regions (e.g., some LDCs and/or LICs).
- o The company makes no commitment in this area.

PPL2 Patent status disclosure

The company publicly discloses the patent status of its products for diseases relevant to the Index.

- 5 The company publicly discloses the patent status for all on-patent products within the Index scope. This information is updated periodically, and the standard of transparency achieved is analogous to or greater than that set out by the US FDA's Orange Book* (expiry date of the patent included).
- 4 The company publicly discloses the patent status for a subset of the on-patent products, within the Index scope. This information is updated periodically, and the standard of transparency achieved is analogous to or greater than that set out by the US FDA's Orange Book.
Also, companies that disclose patent status for all on-patent products even if the standard of transparency achieved falls short of that set out by the US FDA's Orange Book.
- 3 The company publicly discloses the patent status for a subset of the on-patent products, within the Index scope. This information is updated periodically, but the standard of transparency achieved is less than that set out by the US FDA's Orange Book.
- 2 The company publicly discloses patent status for a subset of the on-patent products within the Index scope. There is no evidence that this information is updated periodically, and the standard of transparency achieved is less than that set out by the US FDA's Orange Book. OR only off-patent products are disclosed.
- o The company makes no public disclosure in this area.

*The FDA Orange Book includes product patent data, patent number and expiry date.

PPL3 IP sharing

In addition to existing agreements, the company provides evidence of newly sharing its intellectual property (e.g., molecules library, patented compounds, unpublished data) through agreements with public research institutions and/or drug discovery initiatives (e.g., WIPO Re:Search, Medicines for Malaria Venture) to accelerate R&D for developing products targeting diseases relevant to the Index. These agreements include terms conducive to enabling access to medicine in countries in the scope of the Index.

- 5-2 The company has previously made available its intellectual property through agreements with research institutions or drug discovery initiatives as described above and these agreements remain valid. In addition, the new agreements that each company has made during the period of analysis are weighted, added together, ranked and scored accordingly.
- 1 The company has previously made available its intellectual property through agreements with research institutions or drug discovery initiatives as described above and these agreements remain valid.
- o The company does not provide evidence of sharing its intellectual property.

PPL4 Access-oriented quality licensing; and

PPL5 Licensing: Geographical scope

The company engages in voluntary licensing agreements to enable the generic supply of products in their portfolio. Licences are non-exclusive, transparent and include access-oriented clauses to facilitate the affordable supply of quality products in wide range of countries in scope of the Index.

- 5 The company has at least one NEVL (non-exclusive voluntary licensing) that includes most of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in all the countries of scope of the Index.
- 4-3 The company has at least one NEVL that includes x of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in x countries of scope of the Index.
- 2-1 The company has at least one voluntary licence (VL) that includes x of the designated access-oriented clauses* in the terms of the voluntary licences it has agreed for products relevant to the Index, in x countries of scope of the Index.
- o Companies without any VL for patented products within the Index scope, considering that their portfolio contains relevant products to pursue a VL.
- NS Companies without any VL for patented products within the Index scope, with no relevant products for pursuing a VL in the portfolio.

*1. Licence agreed prior to or shortly after approval of originator product, 2. ability to manufacture and source active pharmaceutical ingredients without restriction, 3. ability to supply countries where no granted patents are infringed (including where compulsory licences are issued), 4. optional provision for technology transfer, 5. absence of no challenge clauses, 6. provision to facilitate rapid registration of product, 7. inclusion of quality assurance measures in line with WHO requirements, 8. affordability in small markets (if applicable).

PQ1 Ensuring continuous supply

The company has a process in place to ensure continuous supply of all its products within the Index scope in low- and middle-income countries (LMICs) and works to improve local supply capacity in LMICs through technology transfers and strengthening supply chains. This process includes the following elements:

- a) Working with relevant stakeholders (e.g., government agencies, distributors, hospitals, warehouses, wholesalers or other relevant networks) to communicate issues that may affect the supply chain;
- b) Managing a safety stock of relevant finished products;
- c) Working with several active pharmaceutical ingredient (API) suppliers and/or producing in-house APIs to prevent shortages;
- d) Working to enhance local third-party supply capacities and strengthen supply chains in LMICs; and
- e) Transferring technology to third-party manufacturers in LMICs to build manufacturing capacity and improve regional availability.
- 5 The company has elements (a) through (e) in place and provides an example of implementing these activities to improve supply in at least one country in scope of the Index.
- 4-1 The elements that the company does implement are added, weighted and summed together and companies are scored relative to one another.
- o The company does not have elements (a) through (e) in place or does not disclose information about them.

PQ2 Reporting substandard and falsified medicines

The company has a policy/protocol for reporting substandard and falsified (SF) medicines in countries within the scope of the Index that specifies timeframes for reporting to relevant stakeholders (i.e., national regulatory authorities and WHO Rapid Alert).

- 5 The company provides evidence of a policy or approach to report confirmed cases of SF medicines as soon as possible and within ten working days to WHO Rapid Alert and local regulatory authorities, when visual inspection (e.g., confirmation of mislabelling, confirmation of fake packaging) is sufficient to establish that the product packaging is falsified. In cases where laboratory analysis is required for confirmation of substandard or falsified medicines, the policy should require reporting of cases of SF medicines as soon as possible and within ten working days once this confirmation has taken place to WHO Rapid Alert and/or local regulatory authorities.
- 4 The company provides evidence of a policy or approach to reporting confirmed SF cases to WHO Rapid Alert and/or local regulatory authorities within ten days of the confirmation in countries within the scope of the Index.
- 3 The company provides evidence of a policy or approach to reporting SF cases to WHO Rapid Alert and/or local regulatory authorities but does not specify a reporting timeframe.

- 2 The company provides evidence/examples to the Index of reporting cases of SF medicines on a case-by-case basis, in countries within the scope of the Index, to relevant authorities
- o The company does not provide evidence of such a policy or approach or provide examples of reporting SF medicines.

PCB1 Capacity building in manufacturing

The company engages in manufacturing capacity building initiatives in partnership with third-party manufacturers in countries in scope of the Index. The Index assesses whether these initiatives meet Good Practice Standards.*

- 5 The company provides evidence of five manufacturing capacity building initiatives that meet inclusion criteria, of which at least three meet all Good Practice Standards.
- 4 The company provides evidence of three manufacturing capacity building initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four manufacturing capacity building initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five manufacturing capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.
- 3 The company provides evidence of one to five manufacturing capacity building initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three manufacturing capacity building initiatives of which two meet all Good Practice Standards.
- 2 The company provides evidence of at least two manufacturing capacity building initiatives that meet inclusion criteria, of which none meet all Good Practice Standards.
- 1 The company provides evidence of one manufacturing capacity building initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.
- o The company does not provide any examples of manufacturing capacity building initiatives which meet all inclusion criteria.

*guided by clear, measurable goals and/or objectives; measures outcomes; has long term aims/aims for sustainability.

PCB2 Capacity building in supply chains

The company engages in supply chain capacity building initiatives, addressing local needs of supply chain stakeholders (e.g., ministries of health, procurement, logistics and distribution agencies) in countries within the scope of the Index. These initiatives build capacity beyond the company's own supply chain. The Index assesses whether these initiatives meet Good Practice Standards.*

- 5 The company provides evidence of five supply chain capacity building initiatives that meet inclusion criteria, of which at least three meet all Good Practice Standards.
- 4 The company provides evidence of three supply chain capacity building initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four supply chain capacity building initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five supply chain capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.
- 3 The company provides evidence of one to five supply chain capacity building initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three supply chain capacity building initiatives of which two meet all Good Practice Standards.
- 2 The company provides evidence of at least two supply chain capacity building initiatives that meet inclusion criteria, of which none meet all Good Practice Standards.
- 1 The company provides evidence of one supply chain capacity building initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.
- o The company does not provide any examples of supply chain capacity building initiatives which meet all inclusion criteria.

*Is guided by clear, measurable goals and/or objectives; measures outcomes; has long term aims/aims for sustainability

PCB3 Health systems strengthening

The company engages in health systems strengthening initiatives in partnership with local stakeholders in countries within scope of the Index, addressing local needs, with outcomes clearly measured. The initiative has processes in place to mitigate or prevent conflicts of interest. The Index measures whether these initiatives meet Good Practice Standards.*

- 5 The company provides evidence of five health systems strengthening initiatives that meet inclusion criteria, of which at least three meet all Good Practice Standards.
- 4 The company provides evidence of three health systems strengthening initiatives that meet all inclusion criteria and all Good Practice Standards OR the company provides evidence of four health systems strengthening initiatives that meet inclusion criteria, of which at least two meet all Good Practice Standards OR the company provides evidence of five health system strengthening capacity building initiatives that meet inclusion criteria, of which two meet all Good Practice Standards.
- 3 The company provides evidence of one to five health systems strengthening initiatives, of which one meets all Good Practice Standards OR the company provides evidence of two or three health systems strengthening initiatives of which two meet all Good Practice Standards.
- 2 The company provides evidence of at least two health systems strengthening initiatives that meet inclusion criteria, of which none meet all Good Practice Standards.
- 1 The company provides evidence of one health systems strengthening initiative that meets inclusion criteria, but it does not meet all Good Practice Standards.
- o The company does not provide any examples of health systems strengthening initiatives which meet all inclusion criteria.

*Has good governance structures in place; publicly discloses outcomes; has long term aims or achieves integration within the health system.

PBM1 Inclusive business models

The company has contributed to the development and implementation of scalable inclusive business models done in partnership that aim to meet the access needs of populations at the base of the income pyramid* in countries within scope of the Index. For all models, the company discloses resources invested into the model and there is evidence of, or projections for financial sustainability.

- 5 The company has contributed to the development of one or more inclusive business models during the analysis period as described above and has scaled up one or more existing inclusive business models.
- 4 The company has scaled up one or more existing inclusive business models as described above but has not contributed to the development of new inclusive business models during the analysis period.
- 3 The company has contributed to the development of one or more inclusive business models during the analysis period as described above but has not scaled up any existing inclusive business models during the analysis period.
- o No inclusive business models identified in this area that met inclusion criteria described above.

*This may include vulnerable populations (e.g. children, girls and women, men who have sex with men, people living with HIV) that face additional barriers to access.

The 2022 Access to Medicine Index indicator weights

TABLE 8 2022 Access to Medicine Index indicator weights

Technical area	Indicator	Description	%
Governance of Access 15%	GA1	Governance structures & incentives	2.14
	GA2	Access-to-medicine strategy	2.14
	GA3	Public disclosure of access-to-medicine outcomes	2.14
	GA4	Responsible promotional practices	2.14
	GA5	Compliance Controls	2.14
	GA6	Incidence of breaches	2.14
	GA7	Trade policy: IP and access to medicine	2.14
Research & Development 30%	RD1a	R&D pipeline: Prioritised diseases	6.75
	RD1b	R&D Pipeline: Other diseases	4.50
	RD2	Planning for access: Structured framework	2.25
	RD3a	Planning for access: Project-specific plans for prioritised diseases	5.25
	RD3b	Planning for access: Project-specific plans for other diseases	5.25
	RD4	Disclosure of resources dedicated to R&D	3.00
	RD6	Capacity building in R&D	3.00
Product Delivery 55%	PR1	Registration	5.00
	PP2a	Access strategies: Ad hoc donations	2.00
	PP2b	Access strategies: Long-term donation programmes	4.00
	PP3	Access Strategies: Supranational products	6.50
	PP4	Access Strategies: Healthcare practitioner-administered products	6.50
	PP5	Access Strategies: Self-administered products	6.50
	PPL1	Patent filing & enforcement	2.00
	PPL2	Patent status disclosure	1.50
	PPL3	IP sharing	1.50
	PPL4	Access-oriented quality licensing	Grouped with PPL5
	PPL5	Licensing: Geographic scope	2.50
	PQ1	Ensuring continuous supply	3.00
	PQ2	Reporting substandard and falsified medicines	3.00
	PCB1	Capacity building in manufacturing	3.00
	PCB2	Capacity building in supply chains	3.00
	PCB3	Health systems strengthening	3.00
PBM1	Inclusive business models	2.00	

APPENDIX III

Identifying best practices

The diffusion of best practices is one of the Access to Medicine Index's mechanisms for supporting the pharmaceutical industry in achieving greater access to medicine. Similarly, recognising those companies trialling or scaling up innovative unique-in-industry policies or initiatives is an important way of acknowledging those companies prepared to stand out from peers and to risk new approaches.

BEST PRACTICES

Best practices are ones that can be accepted as being the most effective way of achieving a desired end, relative to what the industry is currently doing in that area and what stakeholder expectations are. It can also be described as a benchmark. Best practices are not new practices – they have already been conceived of, applied and proven to meet at least some of the following criteria:

- Sustainability;
- Replicability;
- Alignment with external standards/stakeholder expectations; and
- Proven effectiveness.

In different areas of analysis (for example, in Research & Development vs. in Governance of Access) how a best practice is identified may be different. A best practice need not be unique amongst companies. A best practice might be an example of a 'gold standard' of practice; a best-in-class policy; or a strategy, programme, product initiative or group of behaviours closely aligned with stakeholder expectations. Best practices should be considered as the exemplar of positive practices in the corresponding research area in comparison to those of the other companies that submitted data within the current period of analysis. These best practices are identified based on evidence of progress submitted in the data collection period and verified with public information and through consultation with experts, where appropriate.

PROCESS

To determine which of the company's practices would be highlighted as best practice, the Foundation's research team evaluated all aspects of company practices, compiling those that met the criteria used for the purpose of scoring with additional standards for each Technical Area, where necessary. Practices that met these outlined criteria were reviewed and finalised by the Foundation's senior management with additional input from experts in the corresponding field, when required.

APPENDIX IV

The Good Practice Standards framework for capacity building

This framework has been developed to convey stakeholders' expectations for good practice in capacity building. The framework is tailored for four subthemes of capacity building included in the Index and is comprised of six standards. All company initiatives are measured against this framework.

Good Practice Standards for initiatives:

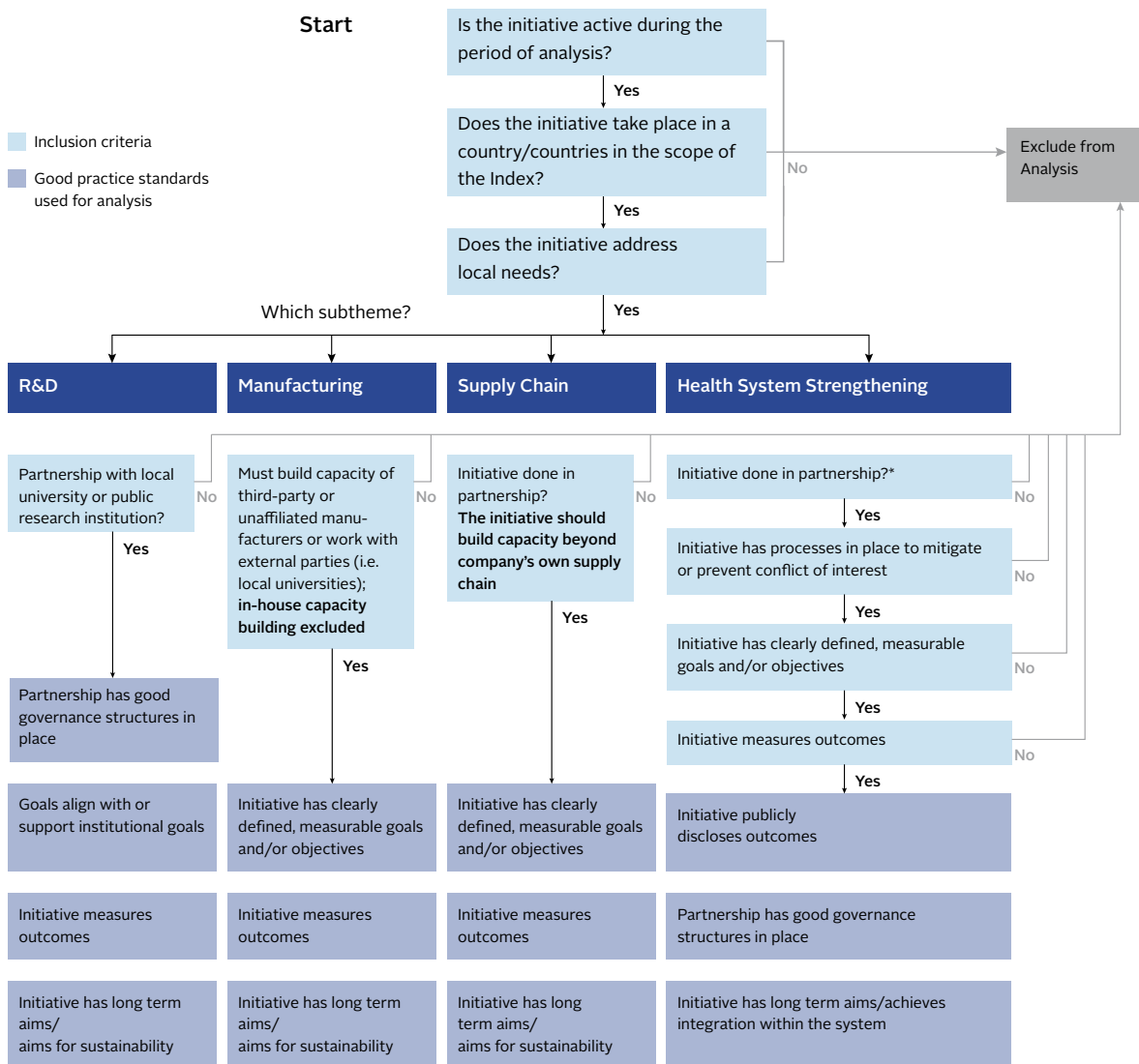
- Has good governance structures in place (including for mitigating or preventing conflicts of interest)
- Goals align with or support the partnered institutional goals
- Guided by clear, measurable goals or objectives
- Includes regular monitoring, evaluation of outcomes
- Publicly shares outcomes, including approaches, progress and learnings
- Has long term aims or achieves integration within the health system

There are three basic criteria that all initiatives must meet:

1) be active during the period of analysis, 2) take place in a country/countries in scope of the Index and 3) address a clearly defined local need. Initiatives in all sub-themes are expected to be done in partnership, save in manufacturing where there may be a direct engagement with contracted third-party manufacturers. Health systems strengthening initiatives must also have processes in place to prevent conflict of interest; have clearly defined, measurable goals and/or objectives; and measure outcomes in order to be eligible. Initiatives are excluded if they do not meet all inclusion criteria, with excluded initiatives not being considered for scoring or further analysis. Initiatives that meet all inclusion criteria are assessed against the remaining Good Practice Standards.

Capacity building initiative flowchart

The chart provides a guide to the criteria by which submitted company initiatives are included for analysis in the Index and the criteria by which they are analysed. The chart is broken down by subtheme/area of capacity building. The expectations from stakeholders vary slightly for each area based on the nature of the activities which typically fall within that area. This chart was developed as a tool for companies to guide them in selection of their five initiatives per area during the data collection process.



*Done with appropriate, relevant partners, including local partners

APPENDIX V

Guide to Report Cards

The Guide to Report Cards provides a description of each section of the Report Cards for the 2022 Access to Medicine Index.

Section	Description	Source
General information (heading)	Stock exchange ticker(s) Location of Headquarters Number of employees	Annual reports and/or the company's website
Change since the 2021 Index (text)	This section provides an update of the company's access-to-medicine performance since the 2021 Index. It covers: <ul style="list-style-type: none"> • New commitments • New, expanded, or unchanged strategies, activities and programmes • Areas in which the company continues to perform particularly strongly or poorly • Interesting developments, initiatives or activities that can influence access to medicine • Notable new developments that have influenced its performance in the Index. 	Index analysis
Performance in the 2022 index (text)	This section explains the company's position in the 2022 Index, while summarising its access-to-medicine performance. It covers: Drivers behind its ranking, including a breakdown of performance for the three technical areas assessed by the Index. Main areas where the company scores well or poorly compared to peers.	Index analysis
How score was achieved (graph)	This graph shows the company's scores in each of the Index's three Technical Areas, benchmarked against the industry average and the leader's score in each area. The company's overall score is calculated using a weighted combination of these scores.	Index analysis
Opportunities (text)	This section outlines tailored opportunities for the company to improve access to medicine, taking account of company-specific characteristics, business models, strategies, policies and practices, such as its access-to-medicine strategy, compliance system, R&D pipeline, product portfolio, equitable pricing strategies and approach to IP management, as captured in the 2022 Index. Opportunities are aligned to global health priority lists, such as those developed by organisations including the Medicines Patent Pool (MPP) and Access to Oncology Medicines Coalition, as well as to World Bank/UNDP global burden of disease data.	Index analysis
Sales in countries in scope (figure)	This figure shows the countries in scope in which the company has sales.	Raw data submission to the Index
Sales by geographical region (graph)	This figure shows a geographic breakdown of the company's gross or net sales/revenue/turnover over the last two to five years. Sales are broken down into the geographic distribution reported by the company is used.	Company financial statements
Pipeline for diseases and countries in scope (text)	The company's R&D pipeline is described using the following factors: total number of the pipeline projects, number of projects targeting R&D priorities (as defined by G-FINDER and other global health organisations) and the number of R&D projects and the number of other (non-priority projects). In addition, the pipeline section describes the total number of late-stage projects (i.e. from Phase II onwards) that target a priority disease or have value to LMICs (as per Access to Medicine Index methodology) and the percentage of these which have access plans in place. These numbers are derived from the verified pipelines submitted by companies. Please refer to the accompanying document for more specific guidance on how these figures were calculated.	Verified pipeline submitted by company and public sources such as clinicaltrials.gov
Portfolio as selected for analysis by the Index	The product portfolio section indicates the number of medicines on patent and number of medicines included in the 2021 WHO Model List of Essential Medicines. The number of vaccines, contraceptives, diagnostics and other (which includes vector control products and platform technologies), are also indicated. The disease category mainly covered by the off-patent and on-patent medicines is also mentioned, as well as examples of the main diseases covered by those products. (See Appendix I for inclusion criteria of products)	Data sources for the product portfolio are products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMA, PMDA, and the company's website
Pipeline projects per disease category (graph)	This figure shows the company's pipeline projects broken down by Index disease categories. The disease category 'Multiple categories' includes projects targeting more than one disease category.	Company pipeline data submission

Breakdown of pipeline projects (graph)	<p>This figure shows the breakdown of active pipeline projects per phase of development. Projects fall into three categories:</p> <ul style="list-style-type: none"> (1) Priority R&D; (2) Projects with value to LMICs; (3) Other: The remaining projects in the company pipeline that do not fall into categories (1) and (2). 	Index analysis of products submitted by the company for scoring and analysis in the Index
	<p>The 'approval' phase of development in this figure also includes projects with 'registration' as the phase of development.</p>	
Products per disease category (graph)	<p>This figure shows the total number of products in the company's portfolio within the disease scope of the Index, broken down by Index disease categories. The disease category 'Multiple categories' includes medicines that are indicated for multiple diseases within the Index scope and that cover multiple disease categories (e.g., broad spectrum antibiotics). Contraceptive methods and devices are included under maternal and neonatal health conditions.</p>	Products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMA, PMDA, and the company's website
Breakdown of products (graph)	<p>This figure shows the total number of the company's products within the scope of the Index, broken down by type of products: medicines (on- and off-patent), vaccines, diagnostics, contraceptives and other (which includes vector control products and platform technologies). In addition, the figure indicates number of products included in the WHO Model List of Essential Medicines (2021).</p>	Products submitted by the company for scoring and analysis in the Index, as well as any registered products identified from the FDA, EMA, PMDA, and the company's website
Performance by technical area (text)	<p>This section outlines a detailed breakdown of company performance for each indicator in the three Technical Areas; Governance of Access, Research & Development and Product Delivery.</p>	Index analysis

APPENDIX VI

Definitions

Access plans

Working definition, used for analysis

Plans to ensure that public health needs are taken into consideration during R&D. Access plans can be developed in-house or in collaboration and include commitments and strategies as well as more concrete access provisions: agreed-upon measures typically developed in partnership to enforce accountability. These plans facilitate availability, accessibility and affordability for patients in countries within the scope of the Index (e.g., registration commitments, equitable pricing strategies, sufficient supply commitments, non-exclusive in specified territories, waiving patent rights, royalty-free provisions and applying for WHO prequalification).

Access initiatives

Working definition, used for analysis

An access initiative - within the context of the Access to Medicine Index - is an initiative a company is involved in which seeks to address access to medicine constraints in low- and middle-income countries. This may or may not be in partnership with others and may or may not involve improving access to specific pharmaceutical products. Where access initiatives relate to products, it may be either an equitable pricing strategy, a non-exclusive voluntary licensing approach, technology transfer or structured donation programme. Examples of access initiatives which do not involve products include, e.g., awareness-raising activities in health system strengthening. Where products are involved in an access initiative, this will be clearly identified within the text of the Access to Medicine Index report.

Access-to-medicine strategy

Working definition, used for analysis

A strategy specifically intended to improve access to medicine, that includes all the typical elements of a strategy (a clear rationale, targets, objectives and expected outcomes). In low- and middle-income countries where the company operates, the strategy may apply to a defined set of diseases, products or therapeutic areas, or to the whole pipeline and portfolio.

Ad hoc donation programmes

Working definition, used for analysis

A gift of products for which there is no clear, defined long-term strategy to control, eliminate or eradicate a disease. This may include a company donating a range of medicines based on the explicit needs of a country. Donations made during emergency situations, such as conflicts and natural disasters, are also included here.

Adaptive product R&D

Working definition, used for analysis

The adaptation of existing/registered New Chemical Entities (NCEs), New Biological Entities (NBEs) or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products, microbicides or other health products that may address an unmet need in countries in scope, e.g., new demographic segments (e.g., infants/children, pregnant women), environmental conditions (e.g., heat-resistant formulations) or new formulations (e.g., oral formulations).

Affordability

Working definition, used for analysis

A measure of the payer's ability to pay for a product (whether or not they are the end user). The Index takes this into account when assessing pricing strategies for relevant products. Pharmaceutical companies use many different criteria to assess affordability.

Base of the income pyramid

The base of the income pyramid, also referred to sometimes as the working poor, designates the people living on less than USD 8 a day.

Compliance controls

Working definition, used for analysis

Compliance controls evaluated in the Index are processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour of the company's employees and, if applicable, the third parties the company formally engages with across its operations in low- and middle-income countries.

These processes include:

- Fraud-specific risk assessment to pro-actively identify vulnerabilities for fraud and actual cases;
- Auditing and review mechanisms conducted by external, independent specialists, applying to third parties in all countries the company is operating;
- A live/continuous monitoring system for compliance, other than financial auditing, to continuously monitor activities to detect discrepancies;
- Country risk-based assessments to identify vulnerabilities for noncompliant or corrupt activities in countries in scope where the company is operating; and
- Processes to ensure third party compliance (including e.g., contractual agreements, training on codes of conduct).

Budget impact*Working definition, used for analysis*

An estimated measure of the cost of treatment with a given therapy for a given number of patients in a specific population.

Conflict of interest

A conflict of interest is the conflict that arises when the commercial interests of a company are potentially at odds with the interests of the partnership, the partner (i.e., local stakeholders), or the health and well-being of the population the partnership intends to help.

Demographic factors*Working definition, used for analysis*

Characteristics of a population such as age, sex, income level, education level, employment, etc.

Equitable pricing strategy*Working definition, used for analysis*

A targeted pricing strategy which aims at improving access to medicine for those in need by taking the abilities to pay of individuals and healthcare systems into account in a manner that is locally appropriate.

Ethical marketing

Promotional activities that are aimed at the general public, patients, healthcare professionals/students and opinion leaders in such a way that transparency, integrity, accuracy, clarity and completeness of information can be ensured.

Fair market value assessment*Working definition, used for analysis*

Fair market value assessments define the appropriateness of payments made to healthcare professionals. These provide structure to ensure ethical interactions between the pharmaceutical industry and HCPs they engaged with.

Falsified medicine

Medical products that deliberately/ fraudulently misrepresent their identity, composition or source. [Definition from WHO, 2017]

Good governance structures*Working definition, used for analysis*

Good governance structures include three components: 1) the structures put in place which establish clear roles, responsibilities and decision-making structures; 2) the systems of communications whereby information is regularly conveyed to all concerned; and 3) the transparency and accountability for processes, decisions and outcomes of initiatives.

Good Practice Standards*Working definition, used for analysis*

A set of six standards that encompass good practice in capacity building initiatives. These standards form a framework used for the assessment of company capacity building initiatives. See appendix IV for more information on Good Practice Standards.

Healthcare practitioner-administered products*Working definition, used for analysis*

Products that typically require either hospital administration of the product or the continued attention of a skilled healthcare professional for administration, such as an intravenously administered oncology medicine.

Innovative product R&D*Working definition, used for analysis*

The development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventive vaccines, diagnostics, vector control products and microbicides which have not previously been approved for use.

National reimbursement authority*Working definition, used for analysis*

Governmental bodies with the authority to control, approve and determine pricing and reimbursement of medicinal products in a country.

Non-exclusive voluntary licences*Working definition, used for analysis*

Non-exclusive voluntary licences are defined as the licences which enable - on a non-exclusive basis, and according to the terms of the licence agreed - the manufacture and supply of generic versions of patented medicines by other manufacturers.

Non-pricing initiatives*Working definition, used for analysis*

Actions taken to increase the number of patients reached through access methods other than price. Non-pricing initiatives applied may include, but are not limited to, non-exclusive voluntary licensing, donations partnering with governments, patient assistance programmes, non-assert declarations, technology transfer and health systems strengthening initiatives.

Outcomes*Working definition, used for analysis*

Outcomes are the results achieved by a company's access-related activities. These can include short-term (e.g., an increased proportion of people with more knowledge on diseases, symptoms or treatments) and/or medium- to long-term outcomes (e.g., patients retained in care; number of patients diagnosed after community awareness and linkage to care programmes; availability of medicines at outlets). Outcomes can also reflect on the country health system (e.g., number of healthcare professionals trained).

Patient Assistance Programmes*Working definition, used for analysis*

Patient assistance programmes are defined as programmes initiated by pharmaceutical companies which provide financial assistance or free-of-charge medicines for a defined patient population with limited ability to pay.

Period of analysis

For the 2022 Index, the time period for which data will be analysed covers company activities which must be ongoing between 1 June 2020 and 31 May 2022, as this is the cycle of the Index. Projects that have ended before 1 June 2020 are not included.

Post-trial access

The continued provision of treatment to clinical trial participants who still require an intervention following the close of the clinical trials in which they participated.

Priority R&D*Working definition, used for analysis*

R&D that addresses product gaps that are needed by people living in low- and middle-income countries due to ineffective, maladaptive or non-existent products for certain diseases, conditions and pathogens in the scope of the Index. These product gaps are defined as being those listed in a series of six priority lists developed by WHO and Policy Cures Research, an independent research group.

Private sector*Working definition, used for analysis*

Private sector refers to payer types such as private insurance and patients paying out of pocket.

Self-administered products*Working definition, used for analysis*

Self-administered products are defined as those products which patients can typically take or administer to themselves without needing a skilled healthcare worker for regular usage. These products may or may not be prioritised by governments or by the global health community (e.g., treatments for non-communicable diseases such as diabetes, stroke and heart disease).

Substandard medical products

Also called 'out of specification', these are authorized medical products that fail to meet either their quality standards or specifications, or both. [Definition from WHO, 2017]

Supranationally procured products*Working definition, used for analysis*

Products for which international pooled procurement, advance market commitments, market-shaping facilities and significant public funding and donor support exist. These products include vaccines and products indicated for the treatment of HIV, tuberculosis, malaria, neglected tropical diseases and Maternal and Neonatal Health Conditions.

Structured donation programmes*Working definition, used for analysis*

A gift of products for which a defined strategy exists as to the type, volume and destination of donated products. Structured donation programmes are long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate or eradicate a disease.

Vulnerable populations*Working definition, used for analysis*

Vulnerable populations represent people at greater risk of facing stigma and additional barriers to access due to social, economic or health considerations. These populations are also disproportionately represented at the base of the income pyramid. These can include, but are not limited to, children, girls and women, members of the LGBTQIA+ community, people living with HIV, etc.

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1. World Health Organization. Prioritization of Pathogens to Guide Discovery, Research and Development of New Antibiotics for Drug-Resistant Bacterial Infections, Including Tuberculosis. World Health Organization; 2017. Accessed July 5, 2022. <https://apps.who.int/iris/handle/10665/311820>
2. World Health Organization. The Initiative for Vaccine Research strategic plan 2010-2020. World Health Organization. Published 2010. Accessed June 15, 2022. <https://apps.who.int/iris/handle/10665/70254>
3. World Health Organization. R&D Blueprint. Published 2022. Accessed July 5, 2022. <https://www.who.int/teams/blueprint/about>
4. Chapman N, Doubell A, Tuttle A, et al. G-FINDER | Landscape of Emerging Infectious Disease Research and Development: Preventing the Next Pandemic.; 2020. Accessed July 5, 2022. <https://www.policycuresresearch.org/analysis/>
5. Chapman N, Doubell A, Goldstein M, et al. G-FINDER | Sexual and Reproductive Health Research and Development: Understanding the Spectrum.; 2020. Accessed July 5, 2022. <https://www.policycuresresearch.org/analysis/>
6. Truong M, David S, Thakur S, et al. G-FINDER | Neglected Disease Research and Development: New Perspectives.; 2021. Accessed July 5, 2022. <https://www.policycuresresearch.org/analysis/>
7. Companies and Intellectual Property Commission. CIPC Intellectual Property Online. Accessed August 18, 2021. <https://iponline.cipc.co.za/Account/Login.aspx?pb=aVMvED-tYJoBv4STTqmvCTpb7MWDx-2eYoESHMO1dLY8+DkrV5AD-DUPw==>
8. U.S. FOOD & DRUG ADMINISTRATION. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Accessed August 18, 2021. <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>
9. Government of Canada. Patent register. Accessed August 18, 2021. <https://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp>
10. Medicines Patent Pool. MedsPaL. Accessed August 18, 2021. <https://www.medspal.org/?page=>
11. World Intellectual Property Organization. Pat-INFORMED. Accessed August 18, 2021. <https://www.wipo.int/patinformed/>
12. Institute for Health Metrics and Evaluation (IHME). Findings from the Global Burden of Disease Study 2019. Seattle, WA: IHME; 2020
13. Global Burden of Disease Collaborative Network. GBD Results Tool | GHDx. <http://ghdx.healthdata.org/gbd-results-tool>. Accessed July 23, 2021.
14. Global Cancer Observatory. Cancer Today. <https://gco.iarc.fr/today/online-analysis-table>. Accessed June 22, 2021.

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