

The Access to Medicine Index 2014





Access to Medicine Foundation

Scheepmakersdijk 5a
NL-2011 AS Haarlem
The Netherlands

On behalf of the Access to Medicine Foundation,
Please contact Jayasree K. Iyer, Head of Research
E jiyer@atmindex.org and info@atmindex.org
T +31 (0)23 53 39 187
W www.accesstomedicineindex.org

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Expert Review Committee

Hans Hogerzeil (Chair)
 Natacha Dimitrijevic
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 Prashant Yadav

Reviewers

Esteban Burrone
 Jennifer Dent
 Hans Hogerzeil
 Richard Laing
 Jillian Kohler
 Niranjana Konduri

Other contributors

Gbola Amusa
 Sara Brewer
 Theo K. Dijkstra
 Patrick Flochel
 Joost de Groot
 Esraa al Temimi

The Access to Medicine

Research team

Jayasree K. Iyer
 Delphi Coppens
 Danny Edwards
 Tara Prasad
 Laurien Rook
 Lisanne Urlings

Editorial team

Hans Hogerzeil
 Jayasree K. Iyer
 Anna Massey
 Ed Monchen
 Emma Ross
 Suzanne Wolf

Data collection and scoring

Sustainalytics
 Andrea van Dijk
 Teodora Blidaru
 Radoslav Georgiev
 Hazel Goedhart
 Vikram Puppala

Report Design

Explanation Design BV

IT

Efficiency Online BV

Printers

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Our clearest ever picture of the industry

In recent years, significant milestones for improving access to medicine have been achieved: including important new drugs for TB and hepatitis C, and a global drive to tackle neglected tropical diseases. For me, these developments show us how much we need the entrepreneurial power of pharmaceutical companies to address access to medicine. But while it is clear that companies have a role to play, there is still no sustainable model for ensuring the poorest patients have access to the medicine they need.

With this Index, we aim to provide companies with clear guidance, by reporting on what they and their peers are already doing well, and by showing where solutions are still needed. The methodology was refined with support from academics, NGOs, investors and governments, and the companies have been more transparent with their data and more open about their challenges than ever before. The result is our clearest ever picture of the industry's strengths, weaknesses, progress and struggles.

The industry continues to do more to address access to medicine. Leaders innovate constantly, while companies at the bottom of the Index continue to close the gap. It's clear that all companies address access issues in different ways – and that all companies can do more. There is still much to do. Yet, I see that companies are willing to learn from each other and to share their experiences. And that gives me confidence that we will continue to see progress in the years to come.

Sincerely,



Wim Leereveld

Founder and CEO
Access to Medicine Foundation



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At a glance

The Access to Medicine Index 2014

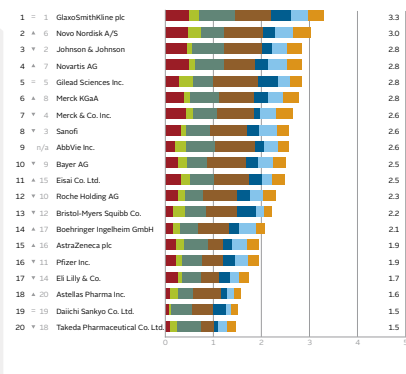


About this report

The fourth Access to Medicine Index report provides a finely detailed picture of how the world's 20 largest research-based pharmaceutical companies address access to medicine. The Index reports on these companies' access-related policies and practices based on an analysis of 95 indicators, in relation to 106 countries and 47 diseases. These two pages provide an overview of the report's main sections, findings and analysis highlights, as well as signposts to where you can read more.

2014 Index ranking

The 2014 Index is led by pack of six companies with a clear No.1 and a newcomer in the top three. Overall scores are very close in this leading group, but their access approaches differ. Across all positions in the Index, no company excels at everything and several stand out in certain specific areas. >> p. 26



Key Findings

Companies do more to improve access, but progress is uneven
The industry is progressing on several fronts. Yet in two important areas, the industry remains static.

Five companies are developing more than half of pipeline products for developing countries

The top 20 pharmaceutical companies are developing 327 relevant products, with more than half targeting the same five diseases.

More than half of companies are developing medicines for children
7% of the overall pipeline is devoted to "child-size" medicines, such as liquids, chewable tablets or new formulations.

Pricing strategies are increasingly tailored
More companies are using commercial pricing strategies that also take socioeconomic factors into account. >> p. 21

20 company report cards

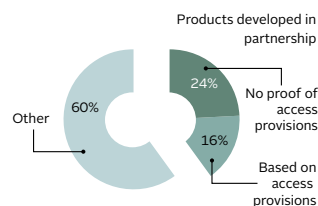
Each one summarises a company's performance in the 2014 Index, including strengths, weaknesses, best and innovative practices, and drivers behind ranking changes, as well as tailored opportunities for increasing access to medicine. >> p. 141



Innovation in all areas

In each of the seven areas of activity examined, the Index has found evidence of innovative practices, including new pilots and models, new platforms for R&D collaboration and new approaches to equitable pricing. >> p. 77

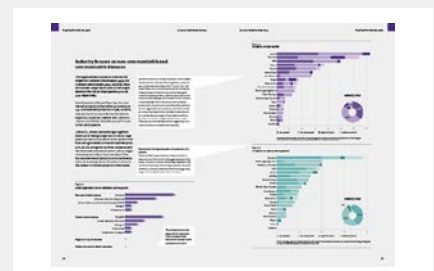
Almost half of all product development is collaborative



Pipeline and portfolio analysis

Companies are mainly developing and marketing products for a small group of diseases in scope. The same five diseases appear in both the top ten targeted by R&D pipelines and the top ten by marketed products. Several companies stand out but in different

ways, either for the size of their marketed portfolios or the size of their pipelines, while others have large ratios of clinical-stage products to products on the market. >> p. 32



Clickable Sections

The leaders

Companies have different access-related policies, practices and focuses, yet there are clear similarities in the approaches leaders take to improve access to medicine. The 2014 Index provides insights into what it takes to become and remain a leader in access to medicine. >> p. 29



Top insights per area

General Access to Medicine Management

Innovative business models

Six companies have innovative business models that aim to improve access to medicine for underserved populations. The Index has found 10 common factors that link them. >> p. 52



Public Policy & Market Influence

Behaviour vs. company size

The Index has mapped the relationship between company size (by revenue) and geographic reach, against the number of settlements or decisions relating to unethical behaviour. >> p. 62



Research & Development

R&D for high-burden diseases

There is evidence of sustained commitment to R&D for infectious diseases, with companies taking patients' needs into account. >> p. 72

Pricing, Manufacturing & Distribution

Analysing equitable pricing

For the first time, the 2014 Index has only captured pricing strategies that explicitly take societal needs and affordability into account, revealing greater diversity and greater involvement in equitable pricing. >> p. 87

Patents & Licensing

Licensing behaviour profiles

The Index has looked at companies with on-patent products, and addressed a series of questions aimed at revealing where they take a pro-access approach to IP management. >> p. 105

Capability Advancement

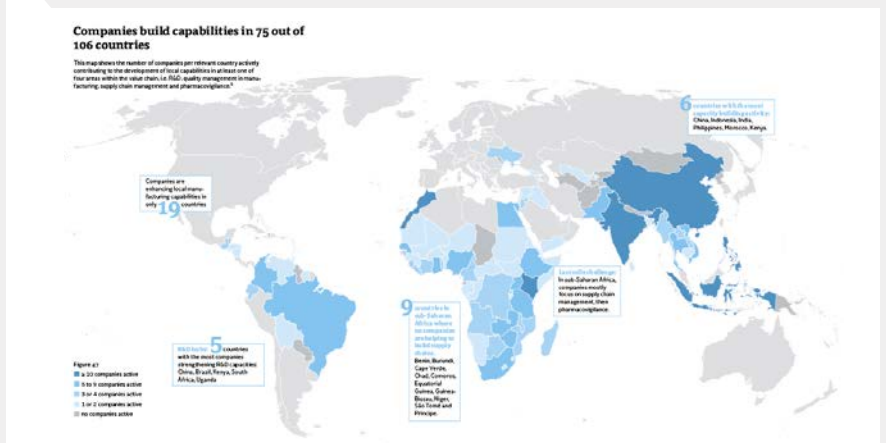
Building capabilities in 75 countries

More than two-thirds of companies are actively building local capabilities in at least one low income country. >> p. 116

Donations & Philanthropy

Timeline of donation programmes

15 companies are engaged in 28 donation programmes, several of which have been expanded or scaled-up during the past two years. >> p. 132



Executive Summary

Introduction

An estimated two billion people still do not have access to the health-related products they need. This access-to-medicine challenge is multifaceted and dependent on many stakeholders for solutions, including the largest pharmaceutical companies. As developers and manufacturers of life-saving products, they have a crucial role to play. They control unique products that can greatly alleviate the disease burden in developing countries; they have the expertise to meet the need for new and adapted innovative products; and they have the ability to strengthen supply chains and support healthcare infrastructures.

Every two years, the Access to Medicine Index analyses the top 20 research-based pharmaceutical companies and ranks them according to their efforts to improve access to medicine in developing countries. A total of 95 indicators make up a framework within which company performances relating to 47 high-burden diseases in 106 developing countries can be compared. The Index analysis brings out best practices and examples, highlights areas where progress has been made and areas where critical action is required. The Index also acts as a benchmark where companies can compare their own contributions to improving access to medicine with their peers. While companies are held to a single standard, they are different in the way they operate and in their portfolio of investigational and marketed products. The Index is a relative ranking: scores cannot be directly compared between Indices.

Refinements to the methodology have brought additional Latin American countries, including Brazil, into the Index's scope in 2014, as well as additional diseases, including mental health disorders and hepatitis C. The focus of the pricing analysis has shifted: it now only captures pricing strategies that explicitly take affordability into account. The 2014 Index also expanded its analysis of company breaches of codes of conduct or laws on ethical marketing, lobbying, corruption, bribery or anti-competitive behaviour to measure breaches worldwide.

This report outlines the key findings and overall ranking analysis of the 2014 Access to Medicine Index before presenting a detailed analysis of company performances and rankings in each of the seven areas of corporate activity the Index focuses on. The report concludes with detailed, tailored company report cards. These explain each company's rank in the Index by providing a contextualised analysis of company access-to-medicine performance, relevant product portfolio and pipeline, and by highlighting industry-leading practices and company-specific opportunities to improve access to medicine.

2014 Key Findings

- Companies are doing increasingly more to improve access to medicine in developing countries, with a raft of new initiatives, scale-ups and innovations over the last two years. Yet progress remains static in two important areas: Public Policy & Market Influence and Patents & Licensing.
- The top 20 pharmaceutical companies are developing 327 relevant products, with only five companies accounting for more than half the pipeline and more than half the products targeting only five diseases.
- More than half of the 20 Index companies are developing medicines tailored for children, with 7% of the overall research pipeline being devoted to "child-size" medicines.
- More companies are paying attention to socioeconomic factors such as people's ability to pay. Importantly, more are tailoring their prices to different segments of the population within countries.

The 2014 Index overall ranking

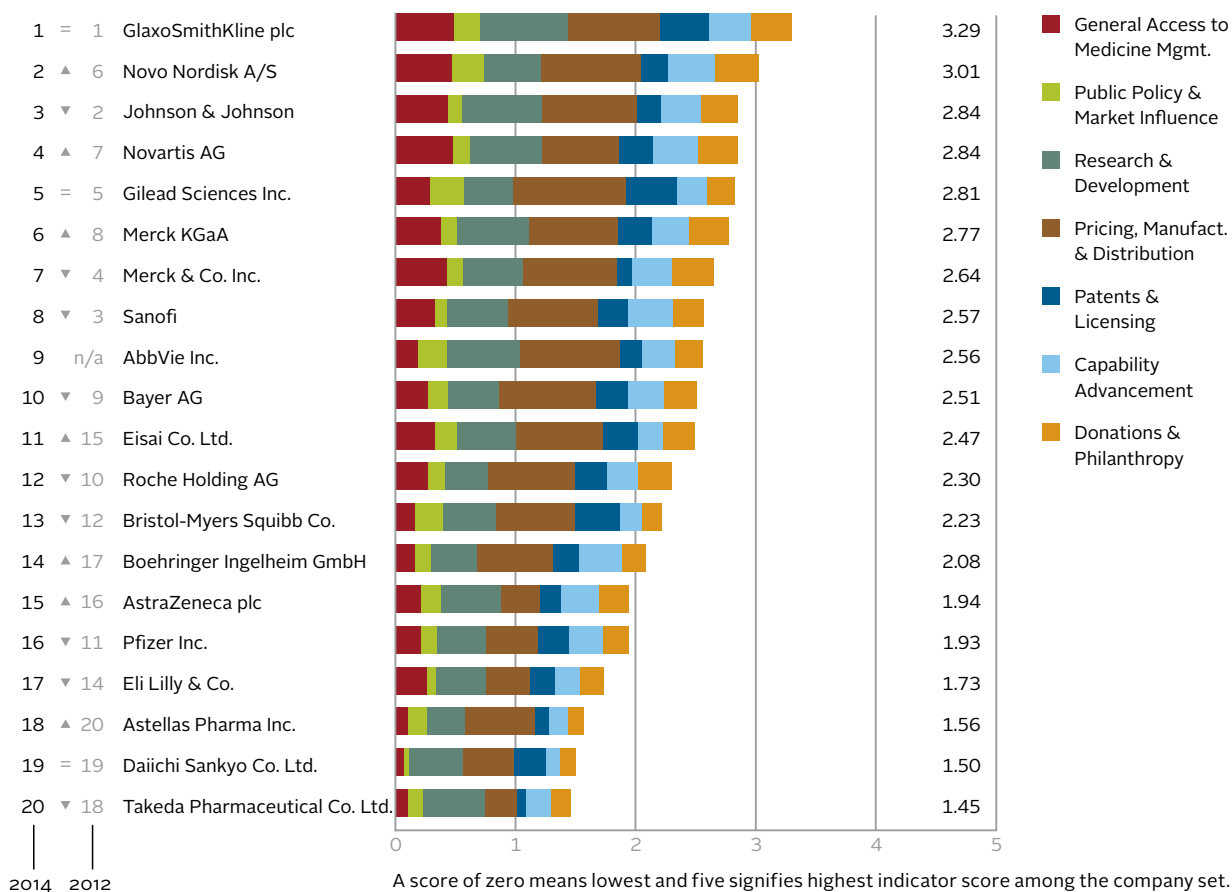
GSK leads the Index for the fourth time. It is followed closely by Novo Nordisk, which has made a remarkable leap from 6th place in the last Index. These are followed by a cluster of four companies – Johnson & Johnson, Novartis, Gilead and Merck KGaA – that have different access profiles but close overall scores. Other than Novo Nordisk, the biggest riser was Eisai. Sanofi and Pfizer fell down the rankings most significantly, while Astellas, Daiichi Sankyo and Takeda remain at the bottom of the league (albeit in a different order than in the 2012 Index).

Refinements to the Index methodology have made it possible to draw a much clearer picture of the industry’s strengths, weaknesses, progress and struggles. Evidence shows the industry is continuing to step up its efforts to improve access to medicine in developing countries. However, progress is not equal across all areas and companies, and there are some areas where the industry as a whole remains static. The leading companies continue to perform well across most of the seven Technical Areas covered by the Index. Most notably, companies at the bottom of the Index are narrowing the gap, with higher overall scores than in 2012.

No company excels at everything and several stand out in certain specific areas: for instance, Novartis has the largest pipeline of products for developing countries, Sanofi has the most products on the market and Johnson & Johnson dominates when it comes to developing child-friendly medicines.

Figure 1

The Access to Medicine Index 2014 – Overall Ranking



Marketed products & pipeline analysis

Companies are mainly developing and marketing products for a small group of diseases within the scope of the Index. More than 50% of the industry's relevant pipeline targets five diseases: lower respiratory infections, diabetes, cirrhosis of the liver (mostly for hepatitis), HIV/AIDS and malaria. The same five also appear in the top 10 diseases with the most products on the market. Just four companies (Sanofi, Novartis, GSK and Pfizer) account for 53% of all products on the market, while R&D pipelines differ hugely between companies, both in size and focus.

Non-communicable diseases and communicable diseases account for the largest shares of both marketed product portfolios and the clinical-stage pipeline. While there are many pipeline products for non-communicable diseases, companies are making limited efforts to ensure they are suitable for use by people living in developing countries. Least attention is being paid to maternal and neonatal health conditions, and most products for neglected tropical diseases are still in early stages of discovery.

During the period of analysis, 30 relevant products were approved by the EMA or US FDA. They target just 11 of the 47 conditions in scope, mostly diabetes and HIV/AIDS, and are almost evenly split between being new products and adapted versions of existing products.

Top findings per Technical Area

The Index measures company performance in seven main areas of corporate activity.

■ General Access to Medicine Management

- Access to medicine is more embedded in governance structures, with all companies now having established board-level representation for their access activities. This compares with 17 companies in 2010 and 19 in 2012.
- Companies use local stakeholder engagement to tailor access approaches to local needs and conditions.
- The number of business models addressing the needs of the poor is growing.

■ Public Policy & Market Influence

- Commitment to ethical behaviour does not correlate with performance. All have codes of conduct governing bribery and corruption, but 18 were the subject of settlements or fines for corrupt behaviour, unethical marketing or breaches of competition law.
- There is no simple correlation between a company's incidence of breaches and its size, which indicates that companies of all sizes can take measures to actively minimise the risk of breaches occurring.
- Four companies waive rights to data exclusivity, taking steps towards facilitating the entry of generic versions of their products.

■ Research & Development

- There is evidence of sustained commitment to R&D for relevant diseases, with most companies having an R&D strategy in place that explicitly takes patients in developing countries into account.
- R&D is mainly focused on five diseases, with 54% of products under development targeting lower respiratory infections, diabetes, hepatitis, HIV/AIDS and malaria.
- Consideration of access to compounds for non-communicable diseases is limited, with most companies struggling to demonstrate how new compounds targeting non-communicable diseases will be accessible to patients in countries covered by the Index. No company makes commitments to register such products in relevant countries.

- More companies provided strong evidence of having enforcement measures in place to ensure ethical clinical trial conduct for in-house and outsourced trails. This has increased from four in 2012 to 10.

■ Pricing, Manufacturing & Distribution

- Companies consider affordability in their pricing strategies for one-third of all relevant marketed products.
- More companies commit to or newly engage in equitable pricing, tailoring their prices to different population segments. Two companies have introduced equitable pricing between countries, but improvement in tailoring prices within countries is greater, with four companies newly implementing such schemes and three more committing to do so.
- On average, products are registered in only a few relevant countries, representing 17% of the Index's geographic scope and just 8% of low-income countries covered by the Index.

■ Patents & Licensing

- Companies remain conservative in their disclosure of where patents are active and when they will expire – information that is very useful to medicine procurers and generic medicine manufacturers. No company independently and publicly disclosed patent statuses for products relevant to the Index.
- Pro-access licensing agreements increase in number, with two more companies entering licensing agreements for products targeting relevant diseases, bringing the total to eight.
- The overwhelming majority of licenses are still for HIV/AIDS products, but there are early signs that some companies are taking steps to expand voluntary licensing to other diseases.
- Company support for pro-access intellectual property law is limited, but even the cautious company public stance is undermined by private lobbying against flexibilities in the TRIPS agreement.

■ Capability Advancement

- Most companies are building a range of local capacities, but their activities are often part of short-term collaborations.
- Smaller companies gain on larger peers in building local manufacturing capabilities. Since 2012, nine companies have increased efforts to build such capabilities locally. Of these, eight have annual revenues below USD25 billion.
- More companies are supporting local pharmacovigilance systems, with the number of companies involved more than doubling from eight in 2012 to 17.

■ Product Donations & Philanthropic Activity

- Neglected tropical diseases are the main focus of donations activities, with more than half of companies addressing one or more of these diseases via structured donation programmes.
- Philanthropic activities are becoming more needs-based.

Conclusion

The pharmaceutical industry is continuing to step up its efforts to improve access to medicine in developing countries. The number of relevant products in the pipeline has grown, companies are increasingly tailoring prices between countries and within countries, and more companies are experimenting with innovative access-oriented business models. Yet progress is uneven: companies remain conservative in their approach to patents, and all but two have been the subject of settlements or decisions relating to ethical marketing, bribery or corruption standards or competition laws in the last two years. Leaders innovate constantly and in multiple areas to maintain their top positions. Companies at the bottom continue to narrow the gap.

The access to medicine landscape

Access to medicine for people living in developing countries depends on a variety of complex factors, with many stakeholders playing different roles in the issue. While progress has been made in improving access to medicine, vaccines, diagnostic tests and other health technologies, an estimated two billion people who mostly live in developing countries, still do not have access to the health-related products they need.¹

Pharmaceutical industry plays a significant role

While the access to medicine challenge is multi-faceted and dependent on many stakeholders to address it jointly, the largest pharmaceutical companies have a crucial role to play. They have the expertise to develop and adapt innovative products, and to scale up their production. They also have several unique products on the market that can greatly help alleviate the burden of disease in developing countries, the ability to improve supply-and-demand challenges, and the collective power to make a difference with their assets.

Companies bear a significant responsibility in treading the fine balance between ensuring their products reach (and treat) as many people as possible, and ensuring profits to shareholders. Last century, this balance was more clearly cut: the multinationals served high income countries, where the profits were to be made. However, a geographical shift in emphasis on pharmaceutical spending is taking place: spending on drugs in North America, Europe and Japan will grow by no more than 1-4% annually until 2017. Spending in emerging markets, however, is due to jump by 10-13% a year over the same period.² Companies that know this are expanding their businesses and operations in emerging markets, and organising business units to suit the changing climate. In adapting to the newer role of serving emerging low-income and middle-income markets, companies come face-to-face with the challenge of adapting their businesses to suit these new environments. This inevitably means taking a more considered approach to affordability and to scale, and thus to developing more considered pricing strategies and more effective use of the capacity of generic medicine manufacturers though licensing.

Figure 2

Access to medicine depends on a number of factors:

Availability Ensuring that new products are developed or existing products are adapted for local use	Accessibility Ensuring that people can receive the product and understand how to use it
Affordability Ensuring that the patients, health-care providers and governments can afford the product	Quality/Acceptability Ensuring that the product works as intended, is efficacious and safe

Industry consolidation continues

The industry still shows signs of more consolidation, with some diversifying, specialising and strengthening their competitive advantage in key areas. Recent examples are as follows: AbbVie became an independent company in January 2013 after it was spun off from Abbott.³ It now holds Abbott's former research-based pharmaceutical business. In Feb 2014, Bristol-Myers Squibb completed the divestment of its share in the global diabetes business that was part of its collaboration with AstraZeneca.⁴ In April 2014, Daiichi Sankyo sold its majority stake in Ranbaxy to Sun Pharmaceuticals.⁵ Novartis and GSK announced in April 2014 that they will swap assets, with Novartis acquiring GSK's oncology business and selling its vaccine division (excluding influenza vaccines).⁶ GSK and Novartis will also in this arrangement combine their consumer

health divisions. In May 2014, Merck & Co. sold its consumer care business to Bayer.⁷ Pfizer made an unsuccessful bid to acquire AstraZeneca in May 2014,⁸ and in July 2014 announced the acquisition of Baxter's portfolio of marketed vaccines.⁹

Since the last Index, the landscape of access to medicine and international health priorities is evolving. There has been some significant response to calls and collaborative action seen since 2012. For the past decade, increased financing of collaborative product development has catalysed the testing of needed products for neglected tropical diseases (NTDs), and allowed for important partnerships to develop, where pharmaceutical companies, NGOs and other global health stakeholders work together to address gaps in product development. A recent initiative, the Global Health Innovative Technology Fund (GHIT),¹⁰ has embarked on a series of partnerships aimed at developing products for NTDs. In the same disease area, several companies responded to a 2012 call for action called the London Declaration on Neglected Tropical Diseases,¹¹ promising donations of critical medicines for the control, elimination and eradication of several NTDs. Progress made under this declaration is tracked in this Index.

Lessons still being learned from HIV/AIDS efforts

The international community rallied to ensure that access to HIV/AIDS medicines was drastically improved after the 1990s. Lessons from that effort can be applied to several other disease areas. In the rally against HIV/AIDS, organisations such as PEPFAR, the Global Fund to fight AIDS, Tuberculosis and Malaria, WHO and USAID ensure that investments in the global HIV/AIDS response continue to accelerate progress. Twenty-five countries have seen a 50% drop in new HIV infections since 2001.¹² With significant investments from many, there have been new partnerships, increased knowledge and innovations in the last 10 years.

Today, other diseases are threatening the access landscape. Non-communicable diseases (NCDs), mainly cardiovascular diseases, cancers, chronic respiratory disease and diabetes, cause about 36 million deaths annually (63% of all deaths), and 17 million premature deaths (below age of 70). About 86% of these deaths occur in low income and

middle income countries, with forecasted cumulative economic losses of USD7 trillion over the next 15 years and millions of people trapped in poverty. Better public policies and lifestyle management, better clinical management and better access to medicine could prevent many of these diseases. The burden of NCDs is expected to rise dramatically over the next 20 years in low income and middle income countries, and there are growing calls for greater action against NCDs. The World Health Assembly endorsed the recent Global Action Plan for the Prevention and Control of NCDs for 2013-2020,¹³ which aims to achieve nine global NCD targets by 2025. The plan identifies a need for more affordable medicines and for new medicines, vaccines, diagnostics and technologies.

The rising burden of hepatitis poses another challenge. Hepatitis C, a chronic infection that causes liver failure in many of the approximately 170 million people infected, can be cured with new treatments. Chronic hepatitis deaths will soon exceed HIV/AIDS-related deaths.¹⁴ There are currently many products in the pipeline for hepatitis C, and these will be entering the market in the next few years. However, just as the cost of antiretrovirals (ARVs) hampered access in the mid-1990s, the prohibitive cost of treatment in this disease is a looming challenge. New mechanisms to ensure affordable medicines, incentives for innovation and new mechanisms for ensuring competition (such as those developed by the Medicines Patent Pool for HIV/AIDS) need to start.

Over the past 15 years, the Millennium Development Goals (MDGs) have provided a framework for multilateral co-operation to address these and other challenges. Next year, the time allowed for achieving the MDGs will have elapsed, and they will be replaced by the Sustainable Development Goals (SDGs). Both frameworks emphasise the central importance of providing access to affordable drugs in developing countries. Importantly, current proposals for the new SDGs spell out the need for R&D to develop vaccines and medicines for both communicable and non-communicable diseases that affect developing countries. Clearly, the role of the pharmaceutical industry will continue to be a key component of the international framework for cooperation.

Ebola outbreak emphasises importance of access

An event that has underlined how important access to needed medicine is, and which continues to be a daily tragedy in West Africa, and a significant threat further afield, is the current outbreak of Ebola virus disease. This outbreak which started in March 2014,¹⁵ has made it clear that in order to innovate, rapidly scale up and treat scores of people effectively, regulators, global health experts and pharmaceutical companies must come together, and to do it quickly, and efficiently. The Index does not cover industry activity around this disease because Ebola does not fall within the scope of diseases included in the Index. It is one of several emerging infectious diseases that occur so sporadically, and in a limited number of hotspots, that there is no clear ownership of control efforts and little incentive to produce products for it, especially given the focus on pushing harder to meet the needs for diseases on WHO's list of neglected tropical diseases.

Intellectual property reform battles continue

2013 and 2014 have been significant years in the debate around intellectual property and access to medicine. Emerging markets, including Brazil and South Africa have made moves to reform intellectual property (IP) legislation in favour of greater competition. Least Developed Countries were granted exemption until at least 2021 from adhering to the minimum standards for intellectual property legislative frameworks, as set out in the Trade Related Aspects of Intellectual Property (TRIPS) agreement.¹⁶ In addition, the United States requested stronger IP protection during negotiations between countries in the Asia-Pacific region (Trans-Pacific Partnership).

More than a decade ago, the South African government fought multinational drug companies over access to HIV/AIDS medicines in what was dubbed "Big Pharma vs Nelson Mandela".¹⁷ This was a low point for the reputation of the pharmaceutical industry, and also marked a turning point in more constructive engagement in the treatment of intellectual property. The Innovative Pharmaceutical Association South Africa (IPASA) case earlier this year was a reminder that these battles continue. Leaked documents from a public

affairs consultancy indicated that a strategy had been commissioned by IPASA, with the advice of Pharmaceutical Research and Manufacturers of America (PhRMA), in response to the government of South Africa proposing reforms to its intellectual property laws to make it harder to get patents and easier for generic medicine manufacturers to enter the market.¹⁸ Since the publication of these allegations, Novo Nordisk and Roche have resigned from IPASA and Novartis has distanced itself through a news release.¹⁹

Bribery and corruption allegations highlight need for ethics enforcement

The recent allegations (and convictions) of bribery and corruption in China,²⁰ affecting several pharmaceutical companies, highlight the importance of good business ethics, and company-wide enforcement while delivering quality medicine. Perhaps the most-high-profile example concerned allegations of systemic corruption made against GSK by Chinese regulators, involving inappropriate payments made to healthcare professionals. After the period of analysis, GSK was found guilty by the Chinese courts, and fined USD500 million.²¹ In addition, private investigators contracted by GSK were convicted. These cases highlight the pharmaceutical industry's responsibility to maintain the highest standards in all countries it operates in.

The Access to Medicine Index evaluates company performance in the context of this evolving landscape, addressing issues highlighted in the above discussion.

The role the Index plays

Every two years, the Access to Medicine Index analyses the top 20 research-based pharmaceutical companies that are most active in producing products for the highest-burden diseases in developing countries and ranks them according to their efforts to improve access to medicine in these countries. It uses an elaborate methodology where almost 100 indicators make up a framework within which company performances can be compared. The Index analysis brings out best practices and examples, and highlights areas where progress has been made and areas where critical action is required. It also acts as a benchmark where companies can see the access-to-medicine profile of their peers and reflect on their

own contribution to improving access to medicine. While companies are held to a single standard, they are all different in the way they operate, and in their portfolio of investigational and marketed products. They each have an individual footprint on access to medicine and all have a unique opportunity to improve access to medicine. When taking this into account, an Index is a significant challenge, and thus we present here findings based on the standardised methodology while appreciating the individuality of companies.

Refinements to the 2014 Index methodology

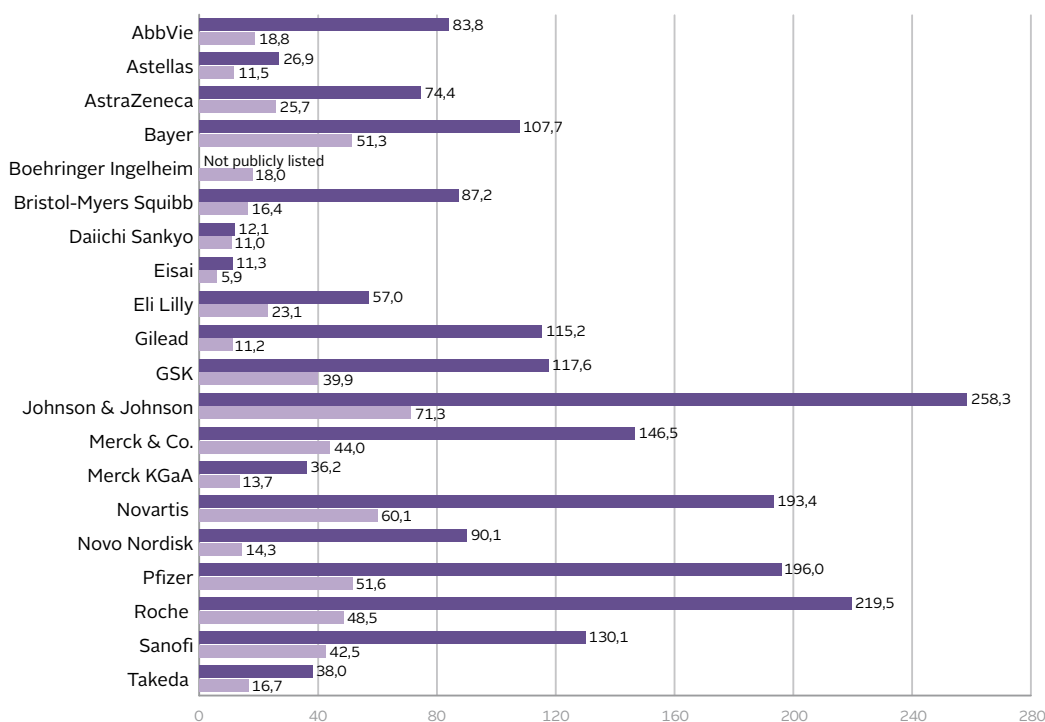
The methodology for the 2014 index was refined in several ways to make it more relevant, remove redundancies and to allow for a deeper analysis of certain areas. Notable were refinements to the way the Index measures the extent to which companies truly addressed access-to-medicine needs. For example, strict inclusion criteria were placed on products to ensure that products truly addressed needs, and long-term, sustainable

ideas were rewarded differently from ad-hoc initiatives. The way the Index measures how companies address affordability was overhauled. Previous indices measured tiered pricing and price differentials as indicators of affordability. However, after consultation with experts and reviewing the methodology, a shift was made to measure equitable pricing and ways that companies target the lowest paying tier of markets, with volume and price point disclosure as evidence of targeted strategies. Engagement in voluntary licensing was previously measured, but in this Index, the quality of licenses was also measured, by evaluating provisions in more than 200 licenses the companies have issued.

How we work

The Access to Medicine Index, published by the Access to Medicine Foundation, is a product of a two-year process. During year one, the Foundation focuses on reviewing and revising the Index methodology based on expert stakeholder feed-

Figure 3
2014 Index company scope



The companies covered by the Index account for more than 50% of the global pharmaceutical market.

■ Market cap as at 31 Dec 2013, Japanese companies as at 31 Mar 2014 (From Thomson Reuters 2014).
■ Total 2013 revenue

back. Year two is spent collecting and analysing pharmaceutical company data according to the latest Index methodology, with the help of an independent research partner. The results are then published in a new Access to Medicine Index, and the cycle begins again. In 2013, the Foundation conducted a thorough review and extensive consultations to ensure that the 2014 Index reflects evolving access-to-medicine priorities while maintaining consistency with previous Index iterations for the purposes of comparison and trend analysis. Internal analyses include both qualitative and statistical analyses of past indices and data. In addition to the internal analysis, external feedback was collected from experts, stakeholders and the public through various channels, including a public online survey, calls with companies ranked in the 2012 Index and various stakeholder meetings (See Appendix 1 for more detail). This external feedback was incorporated into both the qualitative and quantitative aspects of the review process as well as subsequent consultations with the Technical Subcommittees (TSCs) and the Expert Review Committee (ERC). Data collection and scoring in 2014 was performed by the research firm Sustainalytics, while the Index

research team undertook the final comparative analysis and writing of the Index. Experts (from the TSCs and ERC) were consulted as reviewers, and important discussions on corruption, innovation, licensing and pricing were among the topics discussed with the experts. All Technical Area chapters were reviewed by at least two independent reviewers and all sections were subjected to a further round of external review.

How we measure

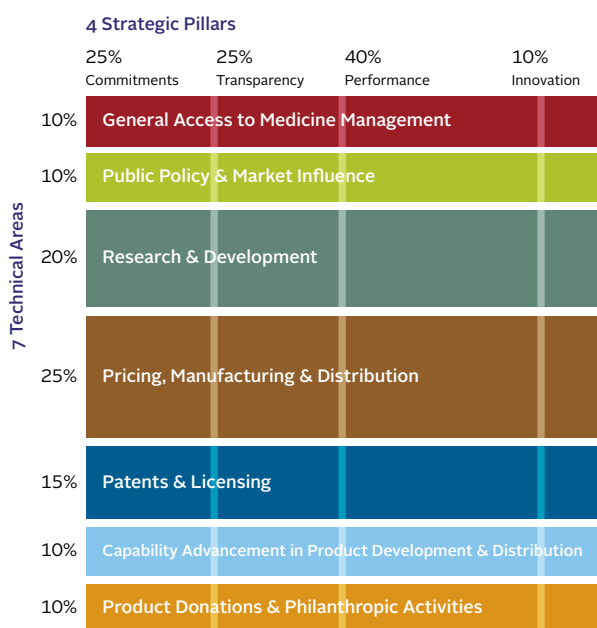
The Index uses a framework that evaluates company activities in seven areas of activity, or Technical Areas, considered to be key to enhancing access to medicine in developing countries, and across four important aspects of action, or Strategic Pillars. The Technical Areas and Strategic Pillars are weighted according to their relative importance for improving access to medicine. We analysed 95 indicators across the Technical Areas, and within each, indicators are distributed among the Strategic Pillars, which measure the level of commitment the company demonstrates, how transparent it is about what it is doing, what specific activities it is engaged in and how innovative its approach is.

What we measure

The Index focuses on the top 20 research-based pharmaceutical companies which comprise about 50% of the global pharmaceutical market. The Index measures what these companies are doing to bring not only medicine, but also vaccines, diagnostic tests, vector control products and health technologies to people in what the World Bank considers to be low income and lower-middle income countries. In addition, widespread inequality of human development within countries often inhibits access to medicine for the poorest populations segments; the Index has this year added four high-human-development countries that do not fall under the World Bank LIC or LMIC classification. This brings the total number of countries covered by the Index to 106. The 47 diseases covered in the Index include the top 10 communicable diseases based on disease burden (disability-adjusted life years); the top 12 non-communicable diseases; 17 of the ‘neglected tropical diseases’ and 8 maternal conditions and neonatal infections. The Index also captures activity on contraceptives.

Figure 4

Methodology Framework



Limitations of methodology

As does any study, the Access to Medicine Index has limitations, some of which are outlined below. A more detailed overview of limitations is in the Appendix. Further improvements are actively invited and will be made across all Technical Areas for the 2016 Index, to add more stringency and improvements to the measures used.

Measuring Outcomes and Impact

The study as currently designed is not intended to measure the direct impact of companies' access initiatives on patients and other groups. For example, within Capability Advancement, the impact of a company's training activities is not measured. Alternative measures are used as proxies for patient access or considerations of impact.

Disease Scope:

Some companies may not have received credit for access-oriented activities targeting diseases that were not covered by the Index. The disease scope will again be reviewed for the 2016 Index, and

new information will be balanced with the need to maintain comparability between Indices.

Capturing breaches of codes of conduct

In the 2014 Index, breaches in relevant countries and across the globe were counted quantitatively. As some of these countries may have weaker regulatory and enforcement resources, or out-of-court settlements may be more common, these breaches are sometimes difficult to capture, as is the level of transparency around them.

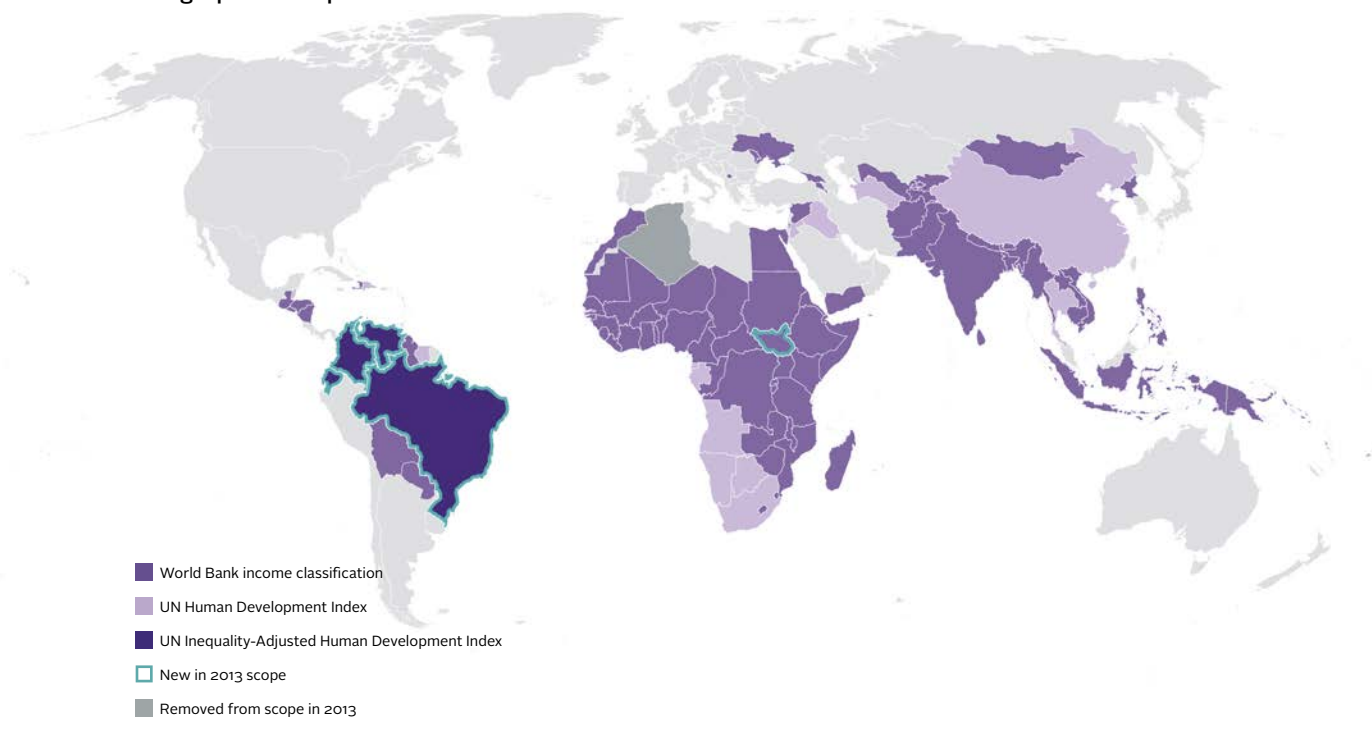
Data availability

Another limitation was the presence of sensitive data, which were provided to the Index under confidentiality agreements. All data were analysed, but due to legal constraints not all data were published. This has been a significant obstacle in finding and reporting trends in certain areas.

More details on the process of preparation and quality control of the 2014 Access to Medicine Index can be found on the website.

For numbered references, see the Appendix.

Figure 5
Geographical Scope



Key Findings

The world's leading pharmaceutical companies are doing increasingly more to improve access to medicine in developing countries. More companies are experimenting with innovative access-oriented business models, companies are granting more licenses for making and distributing generic versions of their products, and companies continue to improve their oversight of access policies and activities. Yet progress is uneven. The industry struggles to perform well in two important areas: companies remain conservative in their approach to patents, and all but two have been the subject of settlements or decisions relating to ethical marketing, bribery or corruption standards or competition laws in the last two years.

Regarding R&D, efforts are remarkably concentrated. More than half of all products relevant to the Index target the same five diseases. Furthermore, more than half of the overall pipeline is being developed by the same five companies. Half of Index companies are developing or adapting medicines for use by children – totalling 7% of the overall pipeline – with Johnson & Johnson developing the largest share.

Compared to 2012, pricing strategies are increasingly tailored, as more companies take account of socioeconomic factors, such as ability to pay. Importantly, more companies are setting different prices for different segments of national populations.

Companies do more to improve access, but progress is uneven

Companies are doing increasingly more to improve access to medicine in developing countries, with a raft of new initiatives, scale-ups and innovations over the last two years. Yet in two important areas, progress remains static.

Refinements to the Index have enabled a clearer picture of industry progress and struggles to emerge. The leaders tended to perform well across the majority of areas the Index tracks, and companies at the bottom of the Index have narrowed the gap with their peers. However, while overall scores are converging, companies differ in the areas where they perform better. The industry is progressing on several fronts, partly in response to calls for action shaping the global health agenda.

Progress

More companies are experimenting with innovative access-oriented business models. Three have introduced new models and three have expanded pilots. Examples include Merck & Co. offering patients in 11 cities in India zero-interest loans for the purchase of one of its hepatitis medicines; and Novo Nordisk making insulin products more accessible in India, Nigeria, Ghana and Kenya by identifying ways to integrate diagnosis, treatment and control in local communities. However, the impact of such models remains to be seen.

Companies are granting more licences to developing country companies to make and distribute generic versions of their medicines. Of the 16 companies that have patents on their products, eight engage in voluntary licensing. This compares with six companies in 2012. Some licences include groundbreaking new arrangements, such as tiered royalties.

Policies and activities to improve access to medicine continue to get better organised. All 20 companies now have established some form of board-level representation for access-to-medicine issues (up from 19 in 2012 and 17 in 2010). In 2014, seven companies link performance incentives for senior managers to enhancing access to medicine, compared with three in 2012.

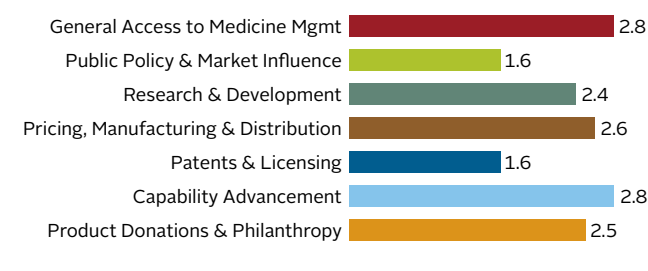
Struggles

However, companies struggle to perform well around some aspects of access to medicine, such as ethics breaches and disclosure of patent status.

All 20 companies commit to follow at least a minimum code of practice for ethical marketing. All have codes of conduct governing bribery and corruption and three-quarters report auditing their codes. However, 18 companies have been the subject of settlements or decisions relating to breaches in ethical marketing, bribery or corruption standards or competition laws. Breaches can range from paying or otherwise inappropriately incentivizing doctors to prescribe their products, to collusions delaying market entry of generic medicines and misrepresenting the efficacy and safety of their products or those of their competitors. This evidence raises questions over the commitment and effectiveness of company governance of this area.

Companies remain conservative in their disclosure of where patents are active and when they will expire – information that is very useful to medicine procurers and generic medicine manufacturers. Within the reporting period, no company independently and publicly disclosed its patent's statuses for any product relevant to the Index.

Figure 6
2014 Index average scores per Technical Area



Five companies are developing more than half of the products in the pipeline for developing countries

The top 20 pharmaceutical companies are developing 327 relevant products, with only five companies accounting for more than half the pipeline and more than half the products targeting only five diseases.

The 2014 Index offers a unique picture of the pipeline relevant to developing countries. In several cases, more than 35% of pipelines targets the conditions covered by the Index. However, research is concentrated, with Novartis, Johnson & Johnson, GSK, AbbVie and Sanofi developing 54% of the products in the relevant pipeline.

Disease focus

In addition, more than half of these products target diabetes, lower respiratory infections, hepatitis, HIV/AIDS and malaria. Hepatitis and diabetes have the most products in the clinical stage of development. Together with diarrhoeal diseases, tuberculosis, chronic obstructive pulmonary disorder, meningitis and Chagas disease, these diseases account for 71% of the total pipeline covered by the Index.

All disease classes are being targeted to varying extents. For instance, 47% of the products target communicable diseases. However, almost all of those address just six conditions: HIV/AIDS, malaria, lower respiratory infections, diarrhoeal diseases, tuberculosis and meningitis.

Another 36% of the pipeline targets non-communicable diseases, with 83% of such products in clinical development. About half are innovative products, while the other half are adaptations for developing country markets such as heat stable insulin, a sublingual tablet for bipolar disorder, fixed dose combinations for cerebrovascular disease and diabetes, long-acting formulations for mental disorders, and several paediatric formulations. However, plans to make these products available are limited; pricing strategies for them are also limited, and lag behind those for many communicable diseases.

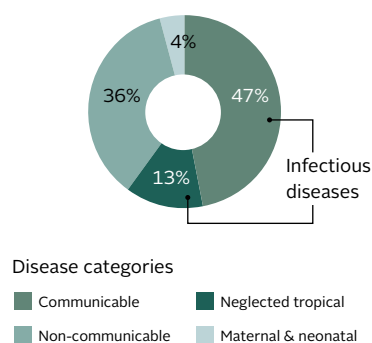
Least attention

Areas with least attention from companies, both in R&D and marketed products, are the neglected tropical diseases and maternal and neonatal health. About 13% of the relevant pipeline is devoted to neglected tropical diseases, with most of those products being in early stages of development. Investigational products in the clinical development stage are for Chagas disease, rabies, trypanosomiasis, and dengue. Meanwhile, maternal and neonatal health conditions, where the need for product development is small but well defined, are being targeted by 4% of the pipeline.

Moved through the pipeline

Since the 2012 Index, at least 30 relevant products from the pipeline, covering 11 diseases, have gained regulatory approval.

Figure 7
Most products are being developed for infectious diseases



The majority of all R&D products are being developed for infectious diseases (communicable diseases and neglected tropical diseases combined), followed by non-communicable diseases.

More than half of companies are developing medicines for children

More than half of the 20 Index companies are developing medicines tailored for children, with 7% of the overall research pipeline being devoted to “child-size” medicines.

Access to essential medicines for children is an important element in improving child health, saving children’s lives and meeting the Millennium Development Goals. The needs were for the first time recognised in 2006 when the World Health Organization identified serious gaps in research and several barriers to access, and indicated how to overcome them. The following year, the UN health agency launched the “Make Medicines Child Size” campaign, issuing, for the first time, a WHO model list of essential medicines for children.¹ The Index finds that the industry is responding to this need, although opportunities to do more remain.

Trends

The 2014 Index provides a unique analysis of the level of industry activity on child-tailored medicine since the WHO call for action. It finds that 11 companies are engaged in the effort. Out of the 327 products in the research pipeline for diseases in developing countries, only 23 products are being developed for children, as liquids, chewable tablets, child-appropriate doses, or new formulations. Only one paediatric fixed-dose combination is under development for HIV/AIDS but no such combinations for tuberculosis although the WHO had identified this as a priority need. Fixed-dose combinations can reduce the number of tablets patients need to take and therefore improve treatment compliance. Three of these products have gained regulatory approval since 2012.

Disease focus

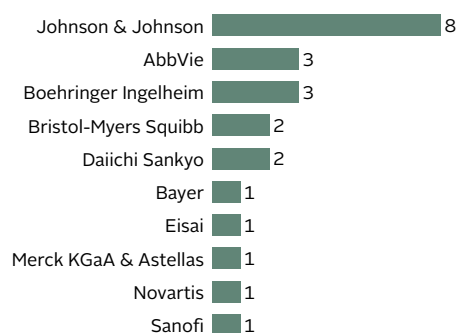
Sixteen (69%) of the “child-size” medicines under development target HIV/AIDS, diabetes, malaria, hepatitis and respiratory syncytial virus infections. Others target a wide range of conditions including cerebrovascular disease, Chagas disease, epilepsy, schistosomiasis, schizophrenia, soil-transmitted helminthiasis and drug-resistant tuberculosis.

Leaders

Johnson & Johnson is the leader in the development of “child-size” medicines, with eight products in its pipeline. AbbVie and Boehringer Ingelheim are developing three each, and Bristol-Myers Squibb and Daiichi Sankyo two each. Bayer, Eisai, Novartis, Sanofi, Merck KGaA and Astellas (the latter two working together) are developing one paediatric product each.

Figure 8

Johnson & Johnson is developing most medicines for children



11 companies are developing 23 medicines suited for children.

Pricing strategies are increasingly tailored

More companies are paying attention to socioeconomic factors such as people’s ability to pay. Importantly, more are tailoring their prices to different segments of the population within countries.

Pricing that focuses on the buyer’s ability to pay is a cornerstone of making medicines affordable in developing countries. It is also a tool for companies to expand into new markets. When addressing disparities in the ability to pay, it is important to differentiate pricing both *between* and *within* countries.

Progress

The number of companies using commercial pricing strategies that also take into account socioeconomic factors has increased from 16 in the 2012 Index to 18 in 2014. Half of these companies are applying such schemes to a greater proportion of their portfolio than they did two years ago.

Increasingly more companies are applying pricing schemes *within* countries, targeting different segments of the population with different prices. The number of companies engaged in such segmentation has grown substantially over successive Indices, from five companies in 2010,

to 12 in 2012, to 16 in 2014. However, the proportion of schemes that specifically target the poorest segment remains limited.

Products covered

Together, the industry has applied pricing strategies to one-third of the 700 relevant products on the market. Use of these strategies is uneven, with some companies using them in all countries they are active in and others restricting them to a few countries. Similarly, some companies apply them to a wide range of their products and others to one or two. The proportion of products under pricing schemes that cover the poorest segments of the population in the lowest price tier is 32%.

Diseases covered

The schemes cover products for 32 diseases, with HIV/AIDS having the most tailored pricing strategies applied to it. However, it is not possible to evaluate whether products have become more affordable for specific patients.

Figure 9
Companies consider affordability for one-third of products

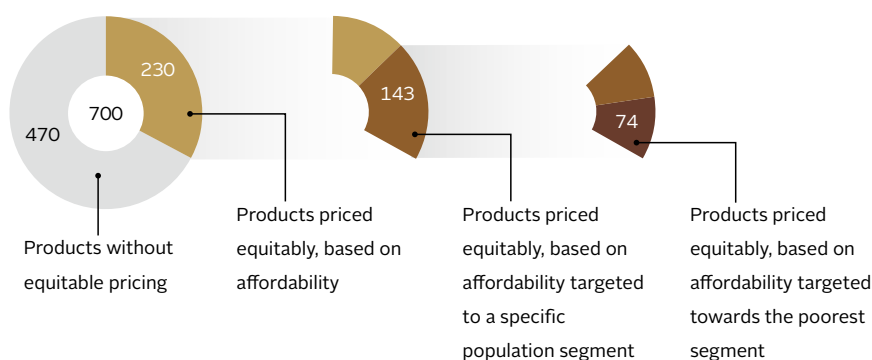
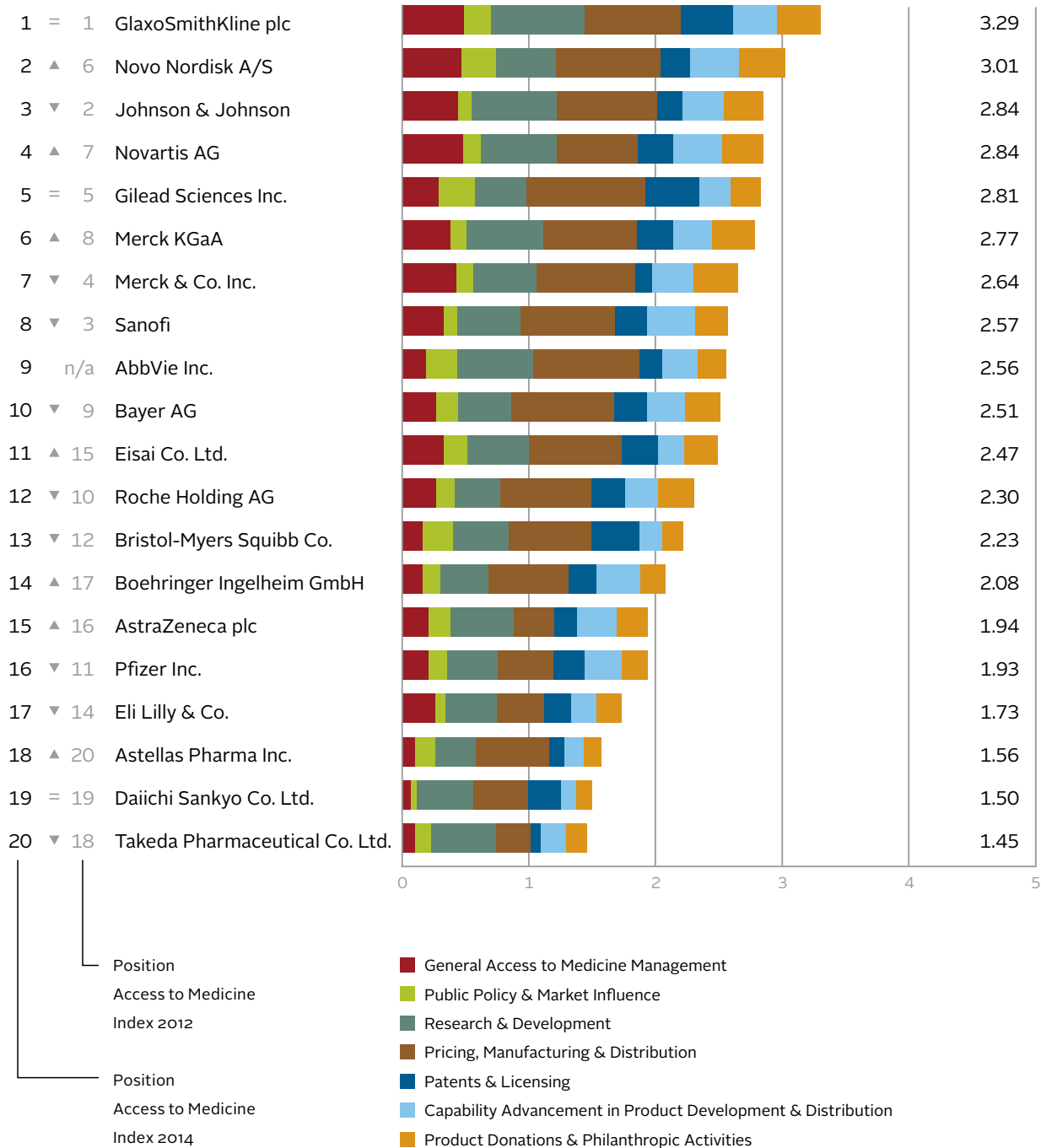


Figure 10

The Access to Medicine Index 2014 – Overall Ranking



A score of zero means lowest and five signifies highest indicator score among the company set.

Leaders innovate constantly

GSK tops the Index for the fourth time, ahead of Novo Nordisk and followed by four tightly packed companies. Overall scores are very close in this leading group of six. However, all companies approach access to medicine differently. Some focus on a few specific diseases, targeting them with deep, comprehensive programmes and initiatives. Others adopt wide-ranging, well-integrated approaches.

The top eight positions are taken by the same eight companies as in 2012, but in a different order, with Novo Nordisk making a remarkable leap into 2nd position. Sanofi and Pfizer fell down the rankings most significantly. Astellas, Daiichi Sankyo and Takeda remain at the bottom of the league, but in a different order, with Astellas rising from lowest place. Notably, despite stricter scoring criteria, these lowest-ranking companies continue to narrow the gap, with higher scores than in 2012.

In 2014, more companies are experimenting with innovative access-oriented business models and more companies take account of socioeconomic factors when setting pricing strategies. Plus, access-to-medicine activities continue to get more organised. Yet companies remain conservative in their approach to patents, and continue to breach ethical standards for corporate behaviour.

No company excels at everything and several stand out in certain specific areas: for instance, Novartis has the largest pipeline of products for developing countries, Sanofi has the most relevant products on the market and Johnson & Johnson dominates when it comes to developing child-friendly medicine. Top performers innovate constantly, usually in several areas at once, and continuously deepen and expand access programmes and initiatives.

How the industry performs

The pharmaceutical industry is continuing to step up its efforts to improve access to medicine in developing countries. However, progress is not equal across all areas or among companies, and there are some areas where the industry as a whole remains static.

The leading companies continue to perform well across most of the seven Technical Areas covered by the Index. Most notably, companies at the bottom are catching up, with higher overall scores than in 2012.

Access-to-medicine activities continue to get more organised, creating a more systematic enabling environment. For example, all 20 companies now have some form of board-level representation for access-to-medicine issues. This compares with 19 in 2012 and 17 in 2010. More companies are experimenting with innovative access-oriented business models. Six have either introduced new models or have expanded pilots; at least three of these have built upon previous pilots. More companies are taking socioeconomic factors, such as ability-to-pay, into account when setting pricing strategies, and are increasingly tailoring prices to different segments of national populations.

In addition, more companies now show evidence of having procedures in place to enforce compliance with standards for conduct of outsourced clinical trials; this has progressed from four companies in 2012 to 10 companies in the current Index.

Together, the companies are now developing 327 products that qualify for analysis, with in some cases more than 35% of company research pipelines targeting conditions relevant to the Index. This includes 137 new product development projects since 2012, the largest proportion of which target communicable diseases. Half of the companies are developing medicines tailored for children, with 7% of the overall industry pipeline being devoted to the development of relevant child-appropriate medicine. Since the 2012 Index, at least 30 relevant new products have gained

regulatory approval. Certain global initiatives have catalysed a proportion of these activities. Recent initiatives such as the Global Health Innovative Technology Fund, the World Health Organization's roadmap on NTDs, and the 2012 London Declaration on NTDs that the roadmap inspired, have led to more intense industry activity.

However, companies have struggled to perform well in other areas. In the area of Public Policy & Market Influence, the 2014 Index's broader investigation of breaches worldwide reveals evidence that almost all companies (18) were the subject of settlements or decisions relating to breaches for competition, bribery, unethical marketing or corruption. It also reveals limited evidence of companies fighting against bad behaviour. Information on breaches in countries beyond those covered by the Index has considerably increased the evidence base in this Technical Area.

In the field of Patents & Licensing, company behaviour has remained static across most areas of measurement. Companies maintain their conservative attitudes to disclosure of patent status and terms of engagement. Encouragingly, pro-access company management of intellectual property has improved, albeit mostly in one particular area: HIV/AIDS licences agreed through a third party, the Medicines Patent Pool.

Leaders

The 2014 Access to Medicine Index has a clear leader and a close second, followed by a cluster of four companies that occupy the 3rd, 4th, 5th and 6th positions. These four have different access profiles but total scores that are very close to each other, demonstrating how tight the competition is for the top slots.

GSK remains in the top position for the fourth consecutive Index. This is driven by robust performance across most areas, with several innovative practices. It has strong governance of access to medicine, an innovative business model focused on Africa and high transparency around its access-to-medicine strategy. The company also leads the Index in the area of Research & Development, with a large relevant portfolio, a large share of its pipeline dedicated to relevant diseases, and numerous access-oriented intellectual property sharing partnerships. However, it fell from its leading position in Pricing, Manufacturing & Distribution, and in Capability Advancement. It also fell in Public Policy & Market Influence, due to convictions or settlements for breaches of ethical marketing standards. Allegations concerning evidence of corrupt practice in China were settled outside the period of analysis for the 2014 Index. Novo Nordisk, despite being a company focused only on a single disease within the scope of the Index, has made a remarkable jump to 2nd place, after rising steadily over successive Indices, moving up from 6th place in 2012 and 8th place in 2010. This is partly due to its integrated approach to access to medicine, high level of transparency and robust codes of conduct, for which evidence of auditing was provided. It renewed its access strategy in 2013, has applied equitable pricing strategies for diabetes products in the majority of relevant countries, and is one of two leaders in rapid registration and filing for marketing approval.

Johnson & Johnson, Novartis, Gilead and Merck KGaA occupy the 3rd, 4th, 5th and 6th places respectively. It is striking that these companies are clustered so closely together, but there is substantial variation between them in their strengths and weaknesses across the areas the Index focuses on.

Johnson & Johnson maintains a strong performance in the Index, dropping one place to rank 3rd. The company is particularly strong in R&D, with a large and diverse pipeline of relevant products, many of which have progressed through the stages of development since 2012. The company ranks highly in its oversight of its access-to-medicine approaches. It also performs well in pricing, taking affordability into account for many products when setting its pricing strategies and applies these in many countries.

Leaders innovate constantly

Leaders usually perform well in several areas of analysis. They have typically strong research pipelines, with access-friendly terms and conditions in partnerships, pricing strategies that target the poor, and IP management policies that stimulate competition. Top performers innovate constantly, and in a competitive Index, usually innovate in several Technical Areas to maintain their role as a leader. Remaining a leader over time is only possible by showing improvements in access policies and practices – standing still means falling back in the Index, as other companies progress. Being a leader requires continuous deepening and expanding of access programmes, and measuring the impact of these programmes on health and socioeconomic outcomes; and publishing the results. It also implies remaining open-minded to developments in the global access-to-medicine agenda, and continuously adapting to any changing expectations, as reflected in refinements made to each new Index methodology.

Novartis climbs three places to 4th position, having made significant improvements in the management of its access-to-medicine activities. The company dropped in rank in Pricing, Manufacturing & Distribution, but a new access-to-healthcare strategy, approved in 2012, shows a clear link between its corporate strategy and its access approach. It has the largest relevant research pipeline of all companies. Novartis is the only company to voluntarily share pharmacovigilance data with national authorities beyond legal requirements.

Gilead has kept its 5th place. It remains a leader in intellectual property management, issuing a wide range of access-friendly licences for its HIV/AIDS products. It also has pricing strategies that take socioeconomic factors into account. The company waives data exclusivity within its licences and was one of only two companies that were not the subject of any settlements or convictions for breaches.

Merck KGaA has also risen up the ranks over successive Indices, from 17th place in the 2010 Index, to 8th in the 2012, to 6th position in the current Index. This is in part due to the development of a strategic focus on access to medicine through its revised Access to Healthcare (A2H) strategy. The company makes a strong commitment to taking a pro-access approach to IP management and licensing in a broad range of countries, has launched new initiatives and is overall highly transparent about its activities.

Laggards

Astellas, Daiichi Sankyo and Takeda once again occupy the last three positions in the Index, although in a different order. As a group they continue to close the gap with the rest of the pack, with improvement in their overall scores.

Astellas rises two places to 18th place, partly because it was linked to fewer breaches than others. It provided more evidence than previously regarding lobbying activities and adapts brochures and packaging to ensure rational use in all disease areas where it is active, and it is active in building local manufacturing capabilities. However, it still has no clear access-to-medicine strategy and does not clearly commit to equitable pricing. It did not disclose its relevant research pipeline, which resulted in a low score in Research & Development.

Daiichi Sankyo remains in 19th place, despite improved performance in some areas. It engages in more product development partnerships based on access provisions, but it has no clear access-to-medicine strategy, manages access issues to a

limited extent and restricts its access activities to philanthropy. Daiichi Sankyo notably has adopted a more access-oriented approach to IP management in this Index.

Takeda has dropped two places to 20th, despite improvements in several areas. It performs well in R&D, but in several areas its performance is significantly weaker than that of its peers. While it demonstrates a stronger focus on access to medicine than in 2012, Takeda does not have a clear access strategy yet and has no pro-access approach to intellectual property. It has a new commitment to intra-country equitable pricing but this has not been translated into strategies for products relevant to the Index.

Risers

Overall individual company movement between the 2012 Index and the 2014 Index is limited. The same companies occupy the top eight positions in the 2014 Index as in the 2012 Index, although Novo Nordisk is a newcomer in the top three. Likewise, the bottom three companies remain the same as in 2012.

The biggest risers in 2014 are Novo Nordisk and Eisai. Novo Nordisk, rising four places from 6th to 2nd, has made the most progress, improving in five of the seven areas the Index analysis focuses on (all except Research & Development and Patents & Licensing). It is now the leader in building local capabilities (Capability Advancement) and in Product Donations & Sustainable Philanthropy. Eisai has risen steadily with each Index. It ranks 11th, up four places from 15th in the 2012 Index, and up five places from 16th in 2010. It performs well in several areas, and rises in four. Eisai's centralised access department shows the company's

more organised approach to access to medicine. Compared with peers, Eisai makes the most progress in pricing, with a new global pricing strategy that will cover all new products.

Other risers include Novartis, Boehringer Ingelheim, Merck KGaA, Astellas and AstraZeneca.

Fallers

The biggest fallers in 2014 are Sanofi and Pfizer. Neither has provided evidence of significant improvement in access to medicine since 2012, and have been overtaken by other companies that demonstrate progress.

Sanofi has dropped five places from 3rd to 8th. It fell in ranking in all areas except for Patents & Licensing and Capability Advancement, where it retains its strong position. It has also lost ground in transparency. It is a leader in product development, and shows commitment to engaging in partnerships on access-oriented terms in certain disease areas, but not in all the disease areas in which it is involved. It is also less transparent than leading companies about terms and conditions of the partnerships it does engage in. It has the most relevant products in the market and applies equitable pricing strategies to many of them. But for a bulk of its products, there is limited evidence of equitable pricing.

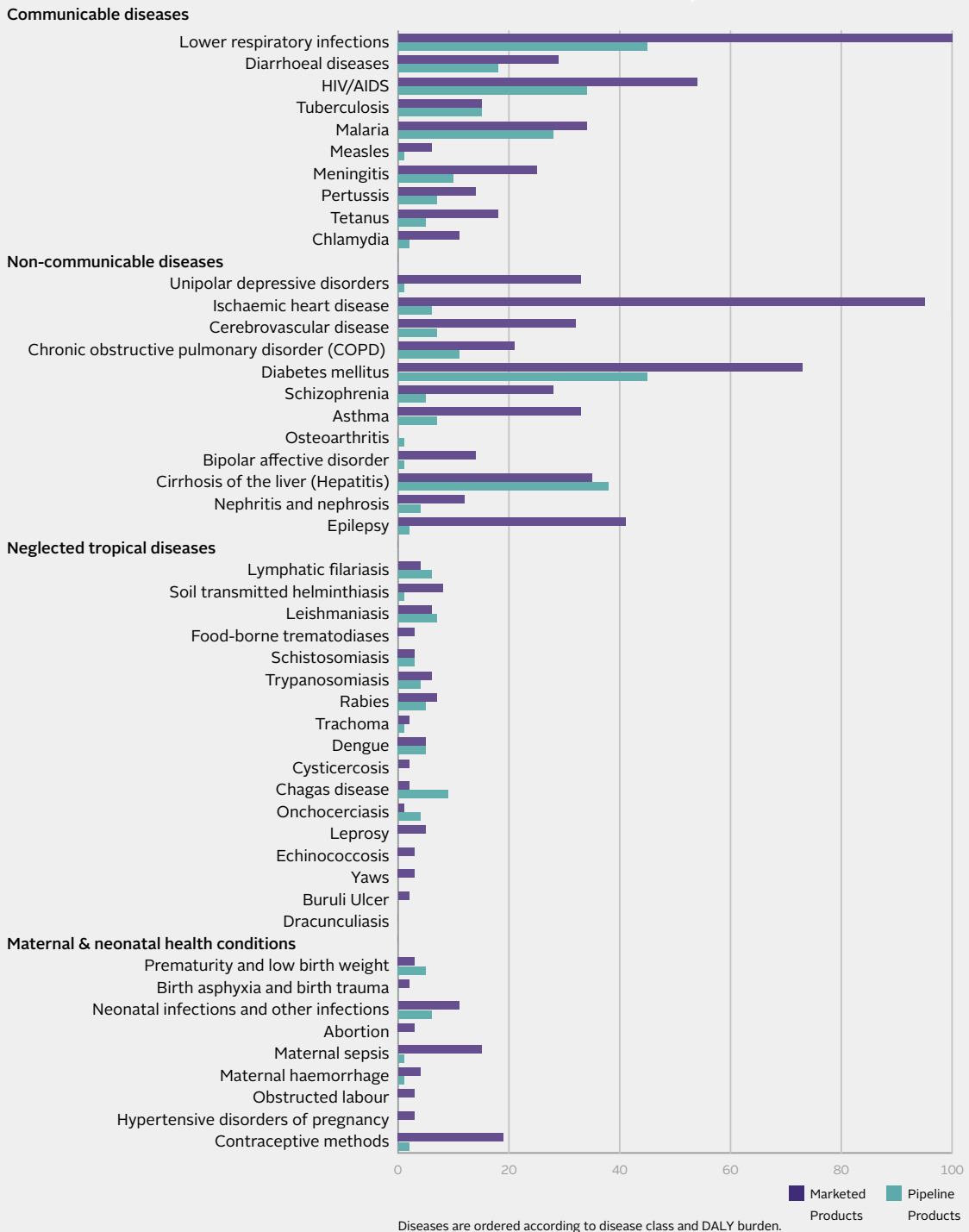
Pfizer has fallen five places from 11th to 16th. It retained its 2012 position in General Access to Medicine Management and Capability Advancement, but has been overtaken by companies performing better in other areas. The Index has identified limited evidence that Pfizer's equitable pricing strategies target the poorest segments of populations. The share of its pipeline relevant to the Index is relatively small, and has shrunk further since the 2012 Index.

Other companies that have fallen in rank include Merck & Co., Eli Lilly and Roche. Roche has fallen over successive indices, from 6th in 2010, to 10th in 2012, to 12th in this Index.

Figure 11

Products in the pipeline and on the market

Pharmaceutical companies focus mainly on 5 diseases: lower respiratory infections, diabetes, cirrhosis of the liver (hepatitis), HIV/AIDS and malaria.



Pipeline and portfolio analysis – where is the industry focusing?

Five diseases appear in both the top ten targeted by R&D pipelines and the top ten targeted by marketed products. Within the scope of the Index, companies are mainly developing and marketing products for a small group of diseases. More than 50% of the industry's

relevant pipeline targets just five diseases: lower respiratory infections, diabetes, cirrhosis of the liver (mostly for hepatitis), HIV/AIDS and malaria. The same five also appear in the top ten diseases with the most products on the market.

The ten diseases with the most marketed products cover 62% of all relevant products on the market: in order, lower respiratory infections, ischaemic heart disease, diabetes, HIV/AIDS, epilepsy, cirrhosis of the liver (mostly for hepatitis), malaria, asthma, unipolar depressive disorders and cerebrovascular disease.

The top ten diseases targeted by R&D pipelines account for 72% of all pipeline products captured by the Index: in order, lower respiratory infections, diabetes, cirrhosis of the liver (mostly for hepatitis), HIV/AIDS, malaria, diarrhoeal diseases, tuberculosis, chronic obstructive pulmonary disease (COPD), meningitis and Chagas disease.

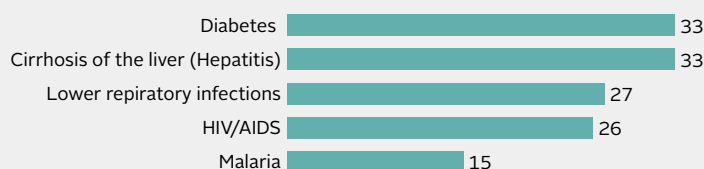
The least attention is being paid to maternal and neonatal health conditions and to neglected tropical diseases. Regarding maternal and neonatal health conditions, this is at least partly explained by the fact that there is less need for product development, and it is specific to local needs and conditions. For neglected tropical diseases, most pipeline products are in early-stage development, which means it will take years before new products reach

markets. Of all 17 neglected tropical diseases in scope, only Chagas disease, rabies, African trypanosomiasis and dengue have products in clinical-stages of development from relevant companies.

For non-communicable diseases, there is a need for products that are suitable for use in developing countries (as well as for other solutions that are beyond the remit of pharmaceutical companies, such as improved lifestyle management and health-system strengthening)¹. The Index observes that while there are many pipeline products for non-communicable diseases, companies are making limited efforts to ensure they are suitable for use by people living in developing countries. There are limited plans to make new products available there, should they gain approval. There are limited equitable pricing strategies relating to non-communicable diseases, particularly compared to the range of strategies for many communicable diseases. Access-oriented licensing strategies remain mostly limited to HIV/AIDS, but there are signs that other disease areas are beginning to be addressed.

Figure 12

Top five diseases in clinical stage pipeline



Clinical stages also focus on same five diseases

Cirrhosis of the liver (mostly for hepatitis) and diabetes receive the most attention: for both diseases, companies have 33 products in clinical stages. This reflects both the market opportunity and the medical need for such products. Other non-communicable diseases

receive comparatively less attention from these companies. Considering the number of products in clinical development, it is important to ensure that plans are put in place to bring these products to people living in developing countries.

For numbered references, see the Appendix.

Industry focuses on non-communicable and communicable diseases

The largest shares of products in the market target non-communicable diseases (49%) and communicable diseases (36%). Similarly, these two disease categories account for the largest shares of the clinical-stage pipeline (47% and 44% respectively).

Sanofi, Novartis, GSK and Pfizer have the most relevant products on the market (accounting for 53% of all marketed products in scope). Novartis, GSK and Sanofi are also in the top five with the largest R&D pipelines, together with Johnson & Johnson and AbbVie: these five account for 54% of the overall pipeline.

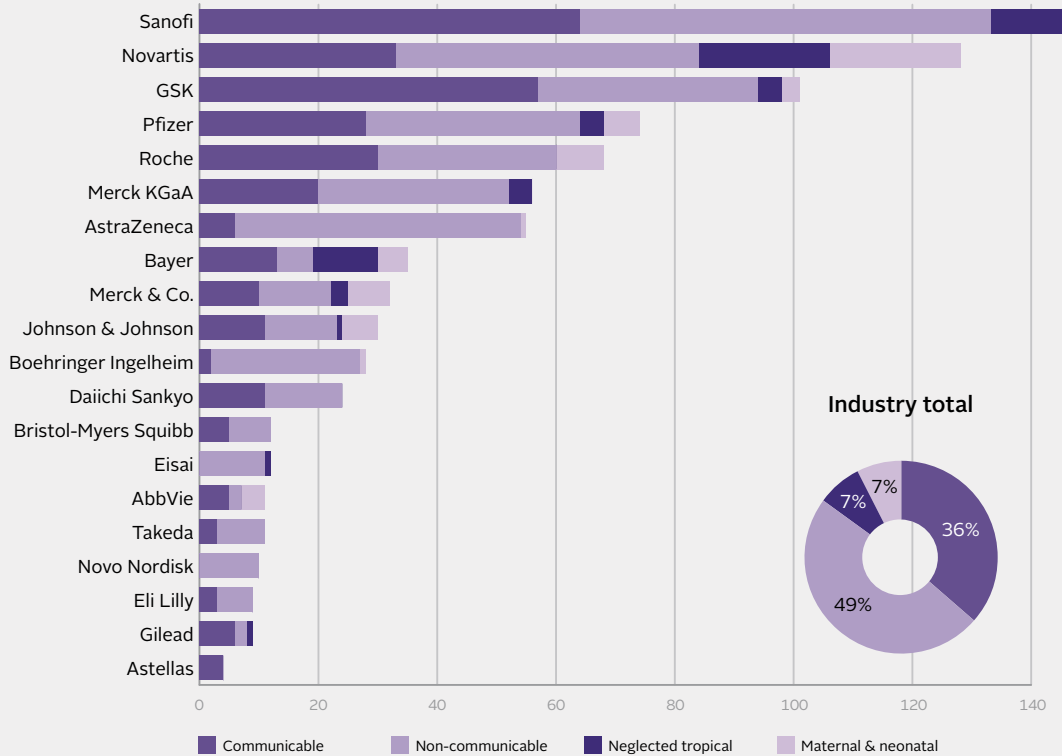
Johnson & Johnson and Boehringer Ingelheim stand out for having a large ratio of clinical-stage pipeline products to products on the market: both have average numbers of relevant marketed products, yet are among the top three companies with the most medicines and vaccines in clinical-stages of development. Others have low ratios: Pfizer has very few relevant products in clinical development, yet is among the top five when it comes to the number of relevant products on the market.

Sanofi has the most relevant products on the market
Sanofi, Novartis, GSK and Pfizer together account for 53% of all products on the market.^a Sanofi is the only one of these four to not have products for all disease classes in scope. It does, however, have the largest overall marketed portfolio, and the most products for communicable diseases and the most for non-communicable diseases. Novartis has the most marketed products for maternal and neonatal health conditions and for neglected tropical diseases. Almost all of the 20 companies measured by the Index have products for multiple disease classes. Only Astellas and Novo Nordisk are active in a single disease class in scope. The majority of marketed products target either non-communicable or communicable diseases.

Novartis has the highest number of products in the pipeline
Pipelines differ hugely between companies, both in size and focus. Novartis has the largest pipeline within scope. Johnson & Johnson, Boehringer Ingelheim, GSK and Sanofi have large clinical-stage pipelines. Novartis, Johnson & Johnson, AbbVie and Eisai have large early-stage relevant pipelines (not shown in chart).

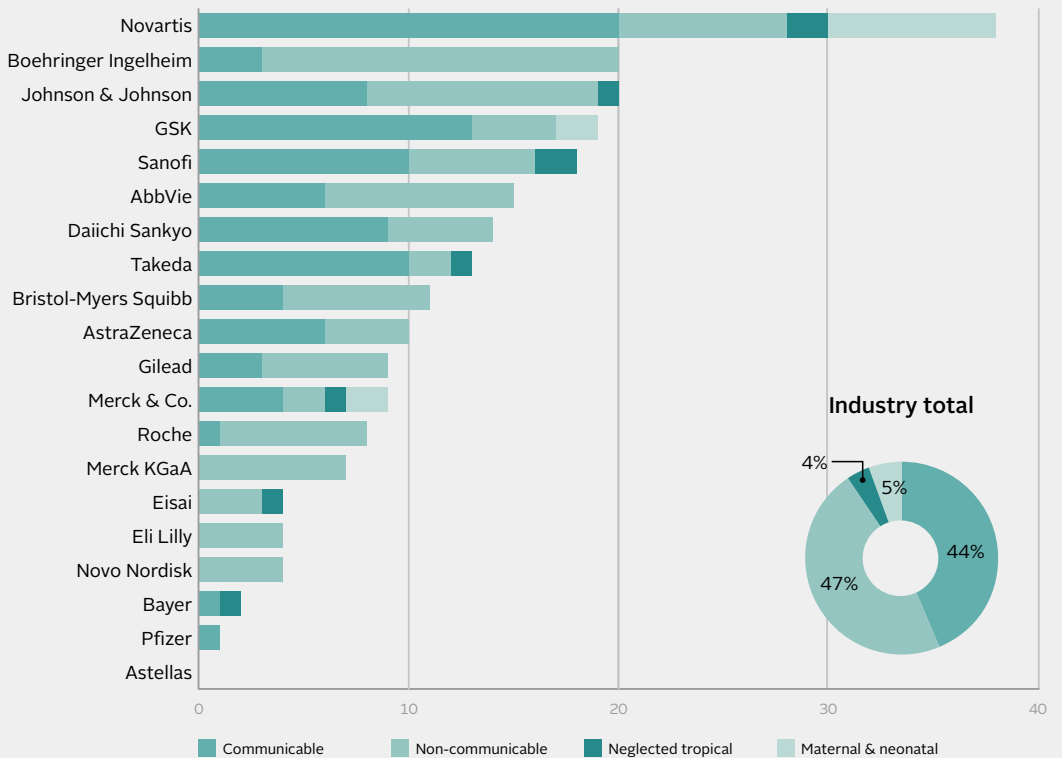
^a This count includes products with multiple indications across disease classes. The number may be higher than the total number of individual products.

Figure 13
Products on the market



Marketed products include medicines, vaccines, diagnostics, vector control products and platform technologies. Products that are indicated for use in multiple diseases are included more than once.

Figure 14
Products in clinical development



The clinical stage pipeline includes medicines (including microbicides) and vaccines only. Products that are being investigated for use in multiple diseases are included more than once.

Regulatory approvals in the last 2 years

During the period of analysis, 11 companies gained regulatory approval by the EMA or the US FDA for at least 30 relevant products targeting 11 diseases in scope: COPD, diabetes, epilepsy, hepatitis, HIV/AIDS, lower respiratory infections, meningitis, tetanus, pertussis, schizophrenia and tuberculosis. Most of these approvals are for products that target diabetes and HIV/AIDS,

including both adapted and innovative products. For HIV/AIDS, this includes a new child-dose tablet from Johnson & Johnson, a new paediatric indication for an existing drug from Bristol-Myers Squibb, and a once-a-day treatment from Gilead. The latter is supported by licences allowing the distribution of generic versions in 100 developing countries.

Figure 15
Johnson & Johnson leads in the number of regulatory approvals

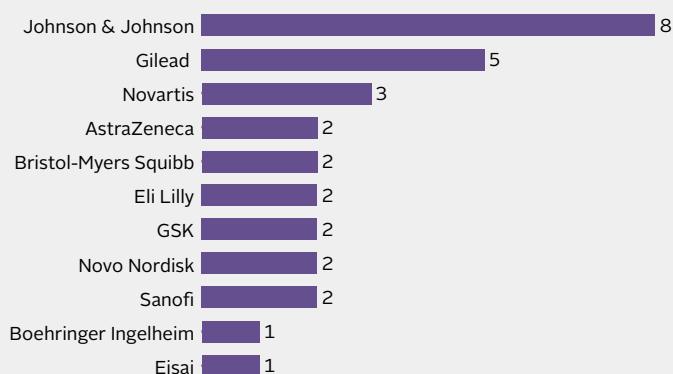
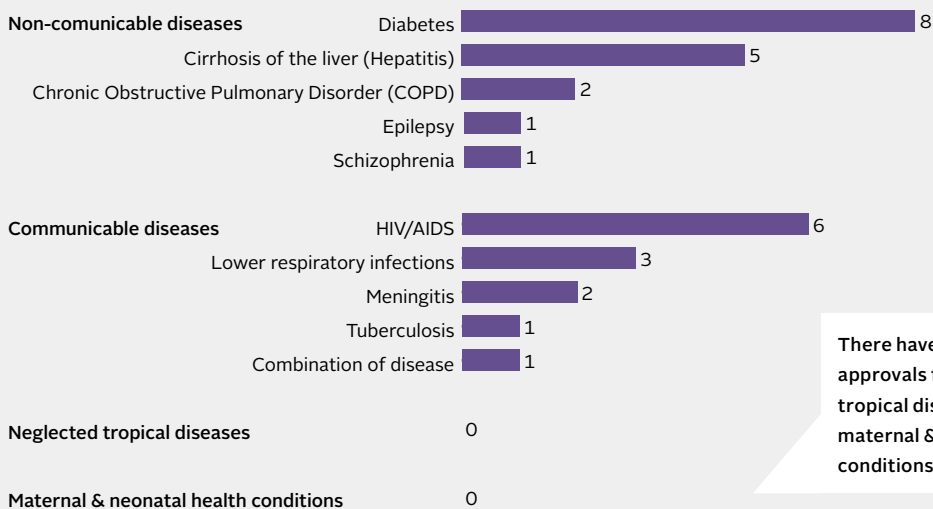


Figure 16
Most approvals are for diabetes and HIV/AIDS



There have been no new approvals for neglected tropical diseases and maternal & neonatal health conditions since 2012.

Table 1

30 products have been approved since 2012

Almost half of the products approved since 2012 are adaptations of existing products.

Company	Brand name (INN) [adaptation]	Index Disease	Product type
Johnson & Johnson	Intelence® (etravirine) - [new dosage strength: 25 mg – paediatric indication]	HIV/AIDS	Medicine
	Prezista® (darunavir) - [new dosage strength: 800 mg]	HIV/AIDS	Medicine
	Sirturo® (bedaquiline)	Tuberculosis	Medicine
	Invega® (paliperidone) - [paediatric indication]	Schizophrenia	Medicine
	Invokana® (canagliflozin)	Diabetes mellitus	Medicine
	Vokanamet® (metformin/canagliflozin) - [Fixed-dose combination]	Diabetes mellitus	Medicine
	Incivo® (telaprevir) - [new dosage strength: 1125 mg]	Cirrhosis of the liver (Hepatitis C)	Medicine
Olysio® (simeprevir)	Cirrhosis of the liver (Hepatitis C)	Medicine	
Gilead	Sovaldi® (sofosbuvir)	Cirrhosis of the liver (Hepatitis C)	Medicine
	Harvoni® (sofosbuvir/Ledipasvir) – [Fixed-dose combination]	Cirrhosis of the liver (Hepatitis C)	Medicine
	Stribild® (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate) – [Fixed-dose combination]	HIV/AIDS	Medicine
	Vitekta® (elvitegravir)	HIV/AIDS	Medicine
	Tybost® (cobicistat)	HIV/AIDS	Medicine
Novartis	Bexsero® (meningococcal group B)	Meningitis	Vaccine
	Ultibro® Breezhaler (indacaterol, glycopyrronium) – [Fixed-dose combination]	COPD	Medicine
	Seebri® Breezhaler (glycopyrronium bromide) – [new inhaler]	COPD	Medicine
Astra-Zeneca	Fluenz Tetra® (live attenuated influenza)	Lower respiratory infections	Vaccine
Zeneca	Zinforo® (ceftaroline)	Lower respiratory infections	Medicine
Bristol-Myers Squibb	Reyataz® (atazanavir) - [paediatric indication]	HIV/AIDS	Medicine
	Daklinza® (daclatasvir)	Cirrhosis of the liver (Hepatitis C)	Medicine
Eli Lilly	Abasria® (insulin glargine)	Diabetes mellitus	Medicine
	Trulicity® (dulaglutide)	Diabetes mellitus	Medicine
GSK	Fluarix® Quadrivalent (influenza)	Lower respiratory infections	Vaccine
	Nimenrix® (meningococcal group ACWY conjugate)	Meningitis	Vaccine
Novo Nordisk	Xultophy® (insulin degludec/liraglutide) – [Fixed-dose combination]	Diabetes mellitus	Medicine
	Ryzodeg® (insulin degludec/insulin aspart) – [Fixed-dose combination]	Diabetes mellitus	Medicine
Sanofi	Hexaxima® (hexavalent vaccine) – [fully liquid vaccine]	Meningitis, cirrhosis of the liver (Hepatitis B), tetanus and pertussis [outside Index Disease scope: diphtheria and polio]	Vaccine
	Lyxumia® (lixisenatide)	Diabetes mellitus	Medicine
Boehringer Ingelheim	Jardiance® (empagliflozin)	Diabetes mellitus	Medicine
Eisai	Fycompa® (perampanel)	Epilepsy	Medicine

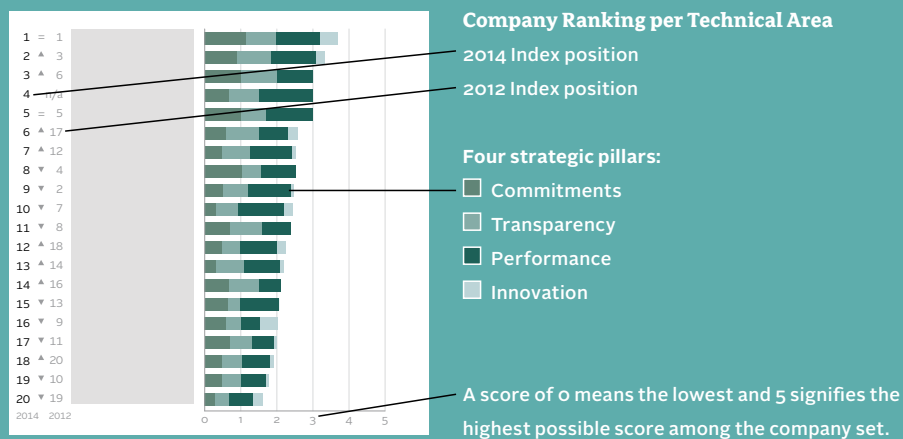
There are at least seven other products that are either in the process of registration or for which registration files are publicly unavailable.

Technical Areas

Analysis Chapters

The Index evaluates the world’s largest pharmaceutical companies using a framework of seven areas of activity. Called Technical Areas, these areas are considered key to enhancing access to medicine in developing countries. Within the framework, the Index analyses company behaviour in four further dimensions, called Strategic Pillars: commitments, transparency, performance and innovation. The following section of this report comprises seven analysis chapters, one for each Technical Area.

Each chapter follows a similar structure and is based on the same set of building blocks. The first block frames the chapter’s context of analysis. The second includes a separate company ranking supported by an analysis of how the individual companies performed. This is followed by an analysis of how the industry as a whole addresses the area in question, and then a series of more focused analyses of company policies and practices. For example, the chapter on R&D also includes focused analyses of company pipelines, of how companies engage in partnerships and of how they approach clinical trial conduct and data transparency.



A General Access to Medicine Management

As pharmaceutical companies search for new opportunities in developing countries, they have a responsibility to also increase access to their products for people on lower incomes. Achieving this balance requires companies to view access to medicine as a strategic issue, and to manage it as such.

To give scope and direction, companies need clear access-to-medicine strategies supported by strong rationales and commitment from top management. Companies are more likely to achieve long-term access goals if they formulate medium-term objectives supported by measurable, time-bound targets that are monitored on a regular basis.

Local stakeholder engagement can help companies tailor their strategies to local needs, increasing the chances of success. Engagement with stakeholders both globally and locally provides additional guidance, and helps companies to identify and respond to risks, opportunities and concerns.

In this chapter, the Index reports on how companies integrate access to medicine into their business strategies, governance structures, management systems and incentive structures. It examines how companies engage with stakeholders to share knowledge, identify risks and address access-related challenges and opportunities. In addition, it looks for innovative business models that improve access to medicine in a financially sustainable way.

Four areas of analysis

Managing for access-to-medicine outcomes

Reporting on how companies establish responsibility and accountability for access to medicine, and how they measure, manage and incentivise associated performance.

Access-to-medicine strategy

Reporting on the transparency of companies' access strategies and rationales, and on their alignment with corporate strategies.

Stakeholder engagement

Reporting on the extent and quality of stakeholder engagement, including senior management involvement and whether local stakeholder perspectives are incorporated into access-to-medicine approaches.

Innovation in business models

Reporting on whether companies are developing new business models that also address the needs of the poorest patients.

Top findings in General Access to Medicine Management

Access to medicine becomes more embedded in governance structures

For the first time, all companies have established some form of board-level representation for their access approach, compared to 17 in 2010 and 19 in 2012. Companies are starting to establish dedicated cross-functional senior-level committees that are responsible for defining, overseeing and reviewing access strategies and initiatives. Four companies have established such committees.

More dedicated units responsible for managing access approaches

Since 2012, three companies have newly established divisions or units responsible for developing, managing and implementing their access to medicine strategies and initiatives. These units or divisions are engaged in a range of activities that have an influence on access to medicine, from R&D to stakeholder engagement to pricing. In total, six companies now have such divisions.

Companies use local stakeholder engagement to tailor access approaches

Newly measured this year, the Index finds that pharmaceutical companies are engaging with local stakeholders to tailor their approaches to local needs and conditions. Eight companies engage with local stakeholders in a structured, targeted way that informs their access approaches. Several companies have best practices in this area.

More business models addressing the needs of the poor

The number of business models addressing the needs of the poor is growing. Companies are expanding models to include more countries, products and patients and new models are being developed. Newly measured in this Index, six companies provided evidence of piloting or expanding innovative models.

How the companies perform

As reported in 2012, companies score relatively well in this area, with a large leading group. Increasingly, companies view access to medicine as a strategic issue, and embed access more firmly in their governance and organisational structures and business strategies, and there is progress in the way they manage for access-to-medicine outcomes. Encouragingly, companies are expanding innovative pilots and models to include more countries, patients and products.

The leaders score in innovation

In this area, four groups of roughly the same size can be identified, with the highest variation in scores occurring in the leading group of six companies. As in 2012, GSK tops the ranking of this area. Novo Nordisk and Johnson & Johnson also remain among the leaders. Novartis and Merck & Co. complete the top five, replacing Sanofi and Bayer. Merck KGaA rose to 6th place, closely behind Merck & Co. The leading six companies score highly in all areas, and moreover are the only ones to receive credit for their innovative business models.

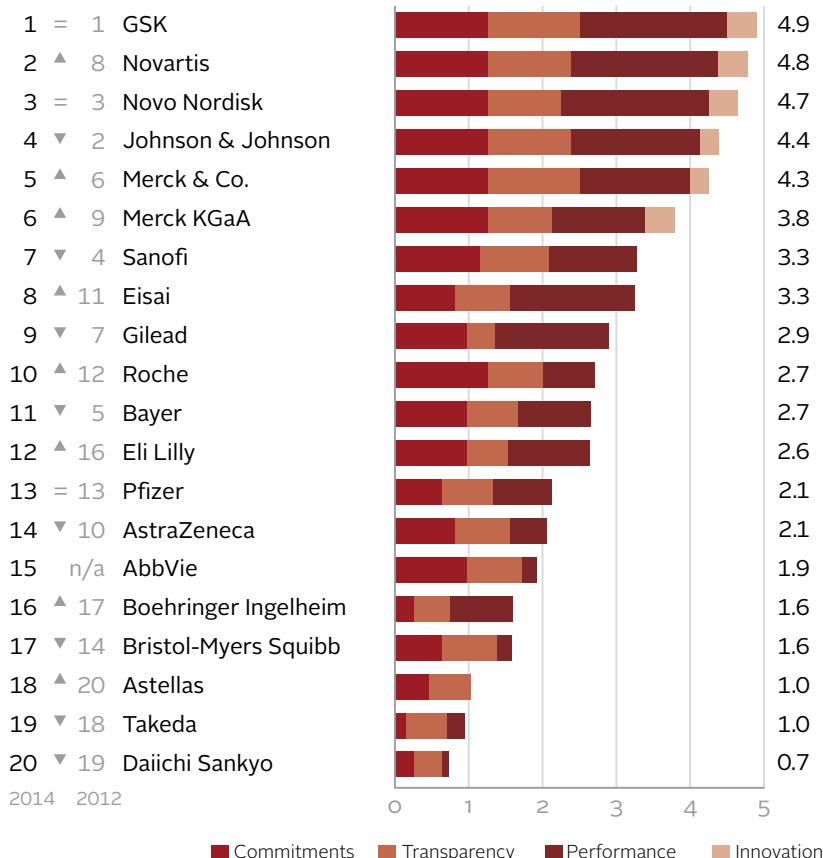
Large middle group

The next group consists of six companies with mixed scores across the board: Sanofi, Eisai, Gilead, Roche, Bayer and Eli Lilly. They all have clear board-level responsibility and accountability for their access-to-medicine approaches, and all show some evidence of having performance management systems in place to monitor access-related behaviour. However, they are generally less transparent than the leaders about their access-to-medicine strategies, rationales, targets and outcomes.

There are five companies in the lower-middle group; Pfizer, AstraZeneca,

Figure 17

Company Ranking General Access to Medicine Management



AbbVie, Boehringer Ingelheim and Bristol-Myers Squibb. Although their transparency levels are comparable to the upper-middle group, they exhibit lower levels of commitment and performance, particularly in the areas of performance management and local stakeholder engagement.

Laggards: no senior access ownership

As in 2012, the bottom rankings are occupied by Astellas, Takeda and Daiichi Sankyo. These three companies have no executive committee or executive individual that is clearly responsible for their company's approach to access to medicine. In this group, access mainly remains a question of philan-

thropy, rather than of business. This is reflected in the way in which access is organised here. In these companies, there is also a lack of strong management systems overseeing access to medicine (such as mechanisms for measuring performance and tracking progress).

Biggest risers: Novartis and Eli Lilly

Novartis is the most notable riser in this area, climbing six places to rank 2nd. In 2012, the Novartis Board of Directors approved a new access-to-healthcare strategy. Since then, the company has implemented a centralised performance management system that includes detailed, measurable targets,

as well as both mid-term and short-term goals. Progress against these targets is measured on a regular basis. Novartis publicly discloses its access-to-healthcare targets and any associated progress on its website and in its annual report. The company engages with a wide range of stakeholders at the global and local level and uses the outcomes to guide its access approach.

Eli Lilly has also risen markedly, by four places to 12th. Since the last Index, the company has implemented a new performance management system that includes access-related targets. For relevant senior managers, performance-related pay is linked to whether they meet these targets.

Steady risers since 2010

Merck KGaA and Eisai continue to rise. In 2012, Merck KGaA climbed from 16th position to 9th, and has now risen to 6th. Eisai jumped from 19th position to 11th in 2012, and is now ranked 8th. Since the 2010 Index, these companies have significantly improved the organisation of their access approaches, further integrating their access strategies and establishing divisions responsible for managing their access approaches.

Furthest fallers: Bayer and AstraZeneca

Bayer has fallen the furthest in rank, from 5th to 11th, partly as a result of stricter Index measurement criteria and new aspects of measurement. In addition, other companies have moved

past Bayer due to their disclosure of new approaches in the area of strategies, performance management and incentives.

AstraZeneca also fell relatively far, dropping four places, from 10th to 14th, due to a lack of progress and stricter Index measurement criteria in the area of stakeholder engagement. Although the company engages with some stakeholders, higher scoring companies show a more targeted and proactive approach. In addition, the company showed limited evidence of managing and incentivising access-related performance.

INDUSTRY

More companies view access to medicine as a business issue

There is evidence that companies continue to increasingly view access to medicine as a business issue and align their access strategies with their overall business objectives and priorities. Access is becoming more embedded in governance and organisational structures. Board-level representation is now standard and companies are starting to establish committees for defining, overseeing and reviewing access strategies and initiatives.

The industry is also showing some progress with regard to target setting and incentivising access-oriented performance compared to 2012. All companies set qualitative targets and the majority sets some time-bound, measurable quantitative targets for at least some of their initiatives. However,

most companies have yet to make real progress when it comes to systematically setting quantitative targets and integrating them into their formal performance management systems.

With regard to stakeholder engagement, more companies are engaging with stakeholders as a strategic tool to help shape access approaches and initiatives. Companies employ a variety of methods and processes for engaging with stakeholders, such as partnerships and collaborations; dialogues with individual organisations or groups of stakeholders; and conferences, panels and other platforms. There is still significant potential for the industry to continually engage with local stakeholders when developing and implementing access strategies in resource-limited settings.

It is encouraging to see that companies are experimenting and expanding innovative access-oriented models to include more countries, more patients and more products. Although the number of truly innovative models in the sector remains rather limited, companies are exploring opportunities in a variety of ways. This indicates that there is no 'one-size-fits-all' model: tailored approaches are required, based on specific, local conditions as well as on the company's product portfolio, strategic focus and capabilities.

Managing for access-to-medicine outcomes

Board-level representation now standard

Why this matters

The success of an access-to-medicine strategy largely depends on whether performance is measured, managed, motivated and rewarded: companies need to underpin their access strategies with performance management systems supported by meaningful targets and performance measures,

as well as appropriate governance structures to drive and oversee implementation.

Here, the Index analyses whether companies have established board-level responsibility and accountability for access to medicine. It also looks

at whether companies disclose their targets, performance measures and progress; at whether targets are supported by performance management systems; and at whether relevant performance is incentivised.

How the companies perform

All 20 companies have now established some form of board-level representation for access-to-medicine issues, indicating that access is increasingly discussed in boardrooms. This compares with 17 companies in 2010 and 19 in 2012. Looking over successive Indices, there are indications that establishing support and accountability for access-to-medicine issues at board- and executive levels can act as a starting point for more active and strategic approaches to access to medicine. In addition, a number of companies are establishing committees for defining, overseeing and reviewing access strategies and initiatives that are comprised of senior managers from different business units.

Companies are now more transparent about their targets and performance measures and the progress of access initiatives. In this regard, all companies set qualitative targets and the majority sets some time-bound, measurable quantitative targets for at least some of their initiatives. However, only a limited number provide evidence that they set them for the majority of their initiatives.

In terms of performance management and incentives regarding access, there is a lot of room for improvement. Only one-third of companies have

robust centralised systems in place for measuring and appraising relevant performance. In addition, one-third of companies provide evidence that incentives for senior managers are tied to access-related goals and targets.

The next step for many companies would be to set access-related targets more systematically, integrate them into formal, centralised performance management systems, and reward their achievement accordingly.

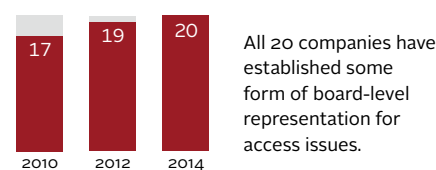
Leaders approach access as business issue

The leader in this area is GSK, followed very closely by Novartis and Novo Nordisk, Eisai, and then Merck & Co. and Johnson & Johnson. These companies all approach access as a business issue and manage it as such. They set detailed qualitative targets and measurable quantitative targets, and use performance measures or Key Performance Indicators (KPIs) to track progress. Furthermore, they use centralised performance management systems and incentives to manage and reward performance.

In addition, these companies have strong governance structures in place that ensure the integration of access to medicine in their decisions and operations, with all except for Eisai having

Figure 18

Access to medicine increasingly discussed in boardrooms



committees that serve as governance bodies for their access approaches. This clearly signals the strategic importance of access to medicine within these companies.

Companies set targets, but not systematically

When it comes to target setting, GSK and Merck & Co. are in the lead. For the vast majority of their access initiatives, they set detailed qualitative targets and time-bound quantitative targets; use pre-selected performance measures (KPIs) to evaluate performance; and regularly track progress towards targets. These companies have a clear idea of what they want to achieve with their initiatives and manage performance proactively.

All companies set qualitative targets related to their access initiatives.

Currently, however, it is less common for them to systematically set time-bound, quantitative targets and performance measures, or to monitor progress. Most companies either set quantitative targets for only some of their initiatives, or not at all.

Range of mechanisms for performance management

One-third of the companies track access-related performance using centralised performance management systems. These companies systematically monitor and report on progress and performance against targets and KPIs. Companies use a variety of mechanisms, including regular update meetings (internal or with external partners), online performance-management and monitoring tools, reports from partners (including distributors) and product specific metrics. At Merck & Co., Novartis and Novo Nordisk access objectives are included on the companies' corporate (balanced) scorecards, and are thus owned at executive level. There is still a lot of room for improvement in the industry: almost one-third of companies provide no evidence of how they manage and measure performance with regard to their access strategy.

Incentivising performance improves since 2012

The next important element of managing for access outcomes is incentivising access-related performance. In an improvement since 2012, for senior management, one-third of the companies now have clear financial and non-financial incentives tied to this area, compared to only three in 2012. Boehringer Ingelheim is the most notable riser in this area: for relevant senior managers, part of their performance-based pay is now dependent on the achievement of access-related goals. Employees involved in access-related activities in relevant countries also have access goals related to their performance-based remuneration.

Merck KGaA and Eisai have also improved, implementing incentive

systems that reward specific executives and directors based on the achievement of access objectives. Eli Lilly has implemented a new performance management system throughout the company that includes performance metrics related to access for relevant senior managers. Compensation for several vice presidents (VPs), senior directors and dedicated teams at Eli Lilly is also now dependent on achieving access-related objectives.

One-quarter of companies demonstrate no evidence of providing incentives for relevant performance. Companies can improve by starting to set personal objectives around promoting access for employees who are directly involved in the execution of access initiatives.

OBSERVATION

Companies starting to establish senior-level access committees

Merck & Co., Novartis, Novo Nordisk and Johnson & Johnson have established dedicated senior-level committees that act as separate governance bodies for defining, overseeing and reviewing their access strategies and initiatives. Committee members come from various business units, ensuring involvement from different parts of the business.

4 companies

Merck & Co., Novartis, Novo Nordisk, Johnson & Johnson

Merck & Co. established its Emerging Markets Access Committee in 2013. It is responsible for driving the company's access strategy and for implementing its Access to Health Guiding Principles. It brings together senior executives from Global Responsibility, Global Pricing, Global Policy, Manufacturing, Supply Chain Management and Regional Presidents of the Emerging Markets.

Novartis established its Access to Medicine Committee in 2014. It will be responsible for assessing opportunities for expanding access, setting and monitoring access-related targets and sharing best practices across the company. It is chaired by the Chief Executive Officer and includes other senior-level representatives from its businesses.

Novo Nordisk's Health Policy Committee oversees the renewed Novo Nordisk Strategy for Access to Diabetes Care. It is chaired by the President and Chief Operating Officer, and includes two Executive Vice Presidents and senior management representatives from China, Africa, Asia, the Gulf and Latin America.

Johnson & Johnson's Global Pharmaceutical Access Committee (GPAC) supervises the operational aspects of market access and pricing decisions, including access to medicine related performance metrics. It is chaired by the VP of Global Market Access, Commercial Strategy Operations & Global Public Health, and includes members of the Group Operating Committee (the most senior governance body in the pharmaceutical division).

There is only one company, AbbVie, with a dedicated Executive Council for a specific group of diseases: neglected diseases. The Council coordinates efforts on neglected diseases across the company and submits progress reports and recommendations to the Executive Board. AbbVie is considering the establishment of an Executive Council on Access that would be responsible for developing and aligning its access approach and would oversee the operational aspect of its access strategy and decisions.

OBSERVATION

More dedicated access divisions

Six companies now have a dedicated division or unit responsible for managing and implementing their access-to-medicine approaches. It is interesting to note that all these companies are in the top 10 for general access-to-medicine management.

6 companies

Eisai, Gilead, GSK, Johnson & Johnson, Merck KGaA, Sanofi

Eisai created its Global Access Strategies division in 2010 with the objective of developing and implementing new policies, initiatives and business models that will improve access to healthcare and products in developing countries.

Gilead's Access Operations and Emerging Market Division is responsible for the day-to-day execution of activities intended to increase access to the company's medicines in low- and middle income countries. This includes the management of manufacturing, product registration, distribution, pharmacovigilance, medical education, stakeholder engagement and partnerships with the Medicines Patent Pool and Indian and African generics licensees.

GSK is building on the success of its Developing Countries and Market Access unit by establishing a new Africa and Developing Countries Unit in March 2014, which covers more countries and aims to expand the company's business in sub-Saharan Africa. The unit brings together the company's commercial and access-related efforts in low- and middle income countries in sub-Saharan Africa, and aims to invest for growth in high-potential markets and to support development in less-developed markets.

Johnson & Johnson launched Janssen Global Public Health (GPH) in January 2014. This new group is responsible for the research, development and delivery of pharmaceuticals, diagnostics and services for diseases that affect resource-limited countries and emerging markets. In addition, it is responsible for developing, creating and implementing new access strategies.

Merck KGaA established its Access to Health (A2H) unit at Merck Group level in 2013. The unit is in charge of driving the A2H strategy across all regions and divisions, to ensure that it is integrated within the company's business units, offices and actions.

Sanofi's Access to Medicine Department is charged with developing innovative models that provide sustainable access to healthcare and medicines at differentiated prices. Its programmes focus on diseases for which Sanofi has expertise, including malaria, tuberculosis, neglected tropical diseases, mental disorders and epilepsy.

BEST PRACTICE

GSK – Strong senior sponsorship for access activities

For access-to-medicine strategies, success depends on receiving attention throughout the company, and on senior managers being made responsible for its execution.

GSK demonstrates a best practice in this area, with strong senior sponsorship for its access activities throughout the company. For example, in its 2012 Corporate Responsibility report, the company published ten 'Health for All' commitments. Each of these commit-

ments has a Corporate Executive Team sponsor and lead business owner that works with the business to ensure the delivery of the commitment. This will help ensure that plans are implemented and that progress is monitored and reported.

BEST PRACTICE

Novo Nordisk – Integrated performance management and incentives for access

Performance management systems, together with relevant incentive schemes for managers and employees, can be key drivers for the successful implementation of access-to-medicine strategies.

Novo Nordisk manages performance related to its new Access to Diabetes Care strategy at the business-unit level through the balanced scorecard; and at the employee level through its People, Performance, Process system (known as 3P), including the 3P of two Executives (Corporate VP for Corporate Stakeholder Engagement and the Executive VP for Corporate Relations). Its corporate balanced scorecard for

the executive management includes two access-related KPIs that are linked directly to the company's Long-Term Incentive programme that is offered to the top-720 managers (corporate VPs, VPs and Directors).

Access-to-medicine strategy

More integration: access strategies join business strategies

Why this matters

By disclosing their access strategies, targets, activities, and related progress, companies enable their stakeholders to reflect on the company's performance and gain insight into the future of its

access-to-medicine approach. The Index reports on the transparency of companies' access strategies, underlying rationales, and related objectives, targets and progress. Furthermore, the

Index reports on whether companies' access-to-medicine strategies are aligned with business objectives and priorities, as this tends to increase their chances of sustainability.

How the companies perform

Almost all companies publicly disclose information about their access-to-medicine approaches and strategies. However, when it comes to goals, objectives and targets, the majority only disclose long-term objectives. The industry can significantly improve here by publicly disclosing shorter-term targets that are more measurable, as well as related progress.

Almost one-third of companies are developing access-to-medicine strategies that are more integrated and aligned with their business objectives and priorities. This is reflected in the way companies report on these strategies and related progress metrics.

Leaders' high disclosure reveals relevance of access

Compared with other companies, companies performing well in this area publicly disclose more detailed information regarding their access-to-medicine strategies, for example in annual reports, corporate social responsibility reports and on their websites. They clearly demonstrate the relevance of access to their core businesses, and that their access strategies are integrated with wider business strategies. In addition, they publicly disclose relevant short-term measurable targets, against which they systematically measure and report progress, just as they do for their overall corporate strategies.

The leaders in this area are GSK, Merck & Co., Johnson & Johnson, Novartis and Sanofi, followed closely by Novo Nordisk. These companies show a clear link between their access-to-medicine strategies and business strategies. In addition, they all publicly disclose detailed information on their access strategies and activities, including associated objectives and quantitative targets. In its annual report, for example, Novartis discloses past and future targets and results relating to its Access to Healthcare approach, providing more detail on its website. For the first time, Sanofi published access-related objectives in its 2013 sustainability report, which will help stakeholders to monitor progress.

Laggards disclose less about objectives and targets

Companies performing less well in this area disclose far less about their access strategies and provide limited evidence that their access approaches are part of wider strategies. For example, although AstraZeneca reports on its access-to-healthcare strategy and long-term objectives, it does not publicly disclose clear, measurable, time-bound targets related to this strategy. Furthermore, although Boehringer Ingelheim has significantly increased its disclosure to the Index in this regard, its disclosure to the public remains very limited compared to that of its industry peers. Lower performers in this area can improve by being more

transparent about their access strategies, including the disclosure of general objectives and more specific, measurable and time-bound targets.

OBSERVATION

Regularly assessing access strategies

Since the 2012 Index, three companies have reassessed and revised their access-to-medicine strategies and approaches: Merck KGaA, Novartis and Novo Nordisk.

3 companies

Merck KGaA, Novartis, Novo Nordisk

Merck KGaA has significantly restructured its Access to Healthcare (A2H) strategy, moving from a mainly philanthropy-driven approach to one that is more strategic. Its A2H strategy is now aligned with business objectives and priorities across divisions. Its strategy focuses on the availability, accessibility, affordability of health solutions and creating awareness.

Novartis reassessed its access-to-healthcare strategy in 2012. This strategy is part of its overall corporate strategy and is based on three objectives: 1) pioneering new business and delivery models to reach underserved patients; 2) controlling and eliminating disease, with a focus on leprosy and

malaria; and 3) finding new treatments and adaptive solutions for diseases of the developing world. This strategy will be reviewed periodically to ensure progress against these objectives.

Novo Nordisk outlined its renewed strategy for Global Access to Diabetes

Care in 2013. The company has published on its website a detailed document in which it outlines the strategy's rationale, purpose, and ambitions, as well as how it is integrated with Novo Nordisk's overall business strategy. It has set the target of reaching 40 million people

with diabetes with its diabetes care products by 2020 and will scale up its efforts to: 1) reach the base of the pyramid; 2) contribute to the global education of healthcare professionals; and 3) promote health for the next generation.

FOCUS AREA 3

Stakeholder Engagement

Local engagement becomes a strategic tool

Why this matters

Systematically and proactively engaging with a wide range of global and local stakeholders enables companies to better understand different needs, perspectives and concerns relating to key access-to-medicine issues. This can help ensure the sustainability, relevance and effectiveness of companies' access approaches and strategies. In addition, engagement

with stakeholders can serve as a means to identify common agendas, and help stimulate the co-development of solutions that maximise value for all parties involved. As local stakeholders are closest to the patients, engagement with these stakeholders allows companies to better understand their needs and local factors inhibiting access.

How the companies perform

All companies engage with stakeholders to some extent, and most engage with a variety of stakeholders both on a global and a local level. However, the extent and quality of this stakeholder engagement varies widely. Companies increasingly seem to recognise the importance of engaging with stakeholders on the ground when developing and implementing their access strategies. Still, there is significant room for improvement, as only eight companies provide evidence of engaging with local stakeholders in a structured, targeted way that informs their access approaches.

Companies employ a variety of methods and processes for engaging with stakeholders, such as partnerships and collaborations; dialogues with individual organisations or groups of stakeholders; and conferences, panels and other platforms. These are

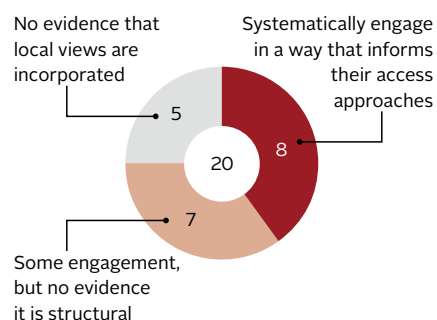
- commonly organised around:
- Specific disease areas, such as diabetes or neglected tropical diseases;
 - Specific access issues, such as health-care system strengthening;
 - Certain products or product types, such as vaccines or HIV treatments;
 - Access initiatives.

Leaders have clear strategies and platforms for engagement

GSK, Johnson & Johnson, Novartis and Novo Nordisk are the leaders in this area, followed very closely by Merck KGaA, Sanofi, Merck & Co. and Roche. They have a clear strategy and strong processes and platforms for stakeholder outreach, which indicates that, for these eight companies, engaging with stakeholders is a strategic tool they use to understand strategic opportunities and risks.

Figure 19

Do companies engage locally when developing and implementing access strategies?



They engage proactively with a broad range of stakeholders, from local communities to multilateral organisations, and for the vast majority of their access initiatives. The outcomes of this engagement are used to shape their global and local access approaches. They recognise that the factors inhibiting access differ widely from location to location, and, as a consequence, that effective access strategies require at least some degree of localisation. Therefore, they use local stakeholder engagement to tailor their approaches to local needs and conditions. In addition, these companies actively share information and stimulate dialogue with stakeholders around access issues, including via their senior managers.

GSK, Johnson & Johnson, Novartis, Novo Nordisk and Sanofi also lead at actively facilitating dialogue and knowledge sharing. Compared with other companies, they are more proactive when it comes to organising, supporting or hosting various conferences, symposia, workshops and other platforms, with participation by senior management. Plus, their approaches tend to be institutionalised.

Middle group engage less systematically

In this area, there is a large middle group of companies with mixed performance across indicators. Although there is evidence that they engage with stakeholders, their approaches tend to be less systematic and more limited in breadth and scope, which signals that they see engaging with stakeholders as less of a strategic tool.

Low engagement from laggards

Takeda, Daiichi Sankyo and Astellas occupy the lowest rankings. These companies have demonstrated limited evidence of stakeholder engagement related to countries or diseases that fall within the scope of the Index. This may be partly explained by the fact that their presence in these countries and focus on these diseases are more limited compared to many of their industry peers. They can improve by reaching out to a broader range of stakeholders in a more constructive way.

OBSERVATION

Companies establish platforms for wide dialogue

Access to medicine is a complex issue that involves a wide range of stakeholders. Companies can take an active role in solution-finding by bringing together the many stakeholders involved.

Merck KGaA has taken a more active approach to dialogue and knowledge sharing since 2012 through the launch of its Merck Access Dialogue Series. This is a platform for sharing information and best practices as well as for discussing ways of removing barriers to access. So far, the company has hosted dialogues on pricing, intellectual property and supply chains and is planning further dialogues on access metrics, universal health coverage and health literacy.

Novartis has organised a substantial number of relevant meetings and events, including in Africa, mainly through the Novartis Foundation for Sustainable Development. Topics discussed include health in Africa, malaria, leprosy and child health, and involve a wide range of stakeholders, such as multilateral organisations, patient organisations, academic institutions, governments and NGOs.

BEST PRACTICE

Novo Nordisk – Integrated approach to stakeholder engagement

Involving and stimulating ongoing dialogue with stakeholders can help companies to better understand the needs and concerns of stakeholder groups.

Novo Nordisk focuses its business model on diabetes, and has developed a holistic approach to stakeholder engagement for this disease. Internally, it uses the findings from its outreach activities to shape its access strategy. Externally, it uses them to advocate for better diabetes care. It is the only company that reports having a dedicated corporate VP for Global Stakeholder Engagement, which reflects the strategic importance of stakeholder engagement for the company.

The company advocates for better diabetes care through its “Changing Diabetes Leadership Forums & Policy Roundtables”, which it organises at the international, regional and national levels. At these events, the company aims to encourage payers, policy-makers and other parties to drive change in diabetes care. It convenes policy-makers, patient organisations, healthcare professionals, and NGOs, among others, in order to discuss solutions for alleviating the burden of diabetes and diabetes care. Since 2005, the company has organised 85 Diabetes Leadership Forums and Roundtables in more than 30 countries.

BEST PRACTICE

Merck & Co. – Structured approach to engagement with key stakeholders

Regular engagement with important stakeholders can help to develop mutually beneficial solutions.

In 2013, Merck & Co. launched its 'Strategic Relationship Leaders (SRLs)' approach, with the objective of enhancing engagement with key external stakeholders, including international funding organisations, NGOs and government aid agencies. The role of an SRL is to develop and implement a strategic plan for engaging with an international organisation. This

provides a structured way of regularly engaging with key stakeholders in order to better understand their objectives and needs, and to help develop mutually beneficial solutions. Primary therapeutic areas for engagement include HIV/AIDS, hepatitis, vaccines, family planning and maternal and child health.

BEST PRACTICE

Merck & Co. and Johnson & Johnson – Local engagement to overcome local barriers

Local stakeholders, from governments to NGOs and patient groups, have the best understanding of the local needs and hurdles to better healthcare.

Merck & Co.: on-the-ground engagement in sub-Saharan Africa
Merck & Co. has established an Institutional Business Africa unit. Through this unit, the company engages with key stakeholders to evaluate and address local public health needs. It works on the ground in sub-Saharan Africa with national governments, international donors and NGOs to help ensure the successful delivery of healthcare services, vaccines and contraceptives. The unit creates strategic partnerships and provides policy and technical guidance to countries in the areas of family planning, maternal health, HIV/AIDS, hepatitis and vaccines. Activities include stimulating scientific dialogue; providing medical education to healthcare workers regarding HIV/AIDS, vaccine-preventable diseases and family planning; and providing oversight and certification to capacity-building initiatives.

Johnson & Johnson: Systematic engagement in South America
In Johnson & Johnson, local and regional teams engage with a range of stakeholders to obtain a better understanding of conditions and needs on the ground. For example, in 2013 the company undertook a strategic initiative to understand how to better serve and expand access to medicine in Colombia. The initiative took five months and involved more than 30 members of staff from different functional areas. These employees performed in-depth interviews with multiple stakeholders, ranging from customers, physicians and government officials, to representatives of scientific societies, healthcare provider facilities, payers and patient advocacy groups. In another example, Johnson & Johnson carried out more than 500 interviews with women in Brazil to gather their views on contraception. The company used this engagement to help define its strategy for improving women's health.

INNOVATION

New models are expanding: more countries, patients, products

With mature markets stagnating, pharmaceutical companies are expanding their focus to developing markets and lower-income population segments. Conditions and circumstances in these markets are vastly different, due, for example, to a lack of healthcare infrastructure and trained health workers. In order to be successful here, it is argued that companies have to move away from the traditional business model.

There is a need for new, more inclusive business models that have the potential to increase access to medicine while also being financially sustainable. In a new area of investigation, the 2014 Index has found six companies with evidence of piloting or expanding innovative models. Our analysis shows that most of these models were first piloted in India.

The six companies are exploring opportunities in a variety of ways, indicating there is no ‘one-size-fits-all’ model. Tailored approaches are required, based on specific, local conditions as well as on the company’s product portfolio, strategic focus and capabilities.

Although more companies are experimenting with innovative, access-oriented models, the number of truly innovative models remains limited. Nevertheless, it is encouraging to see that pilots are expanding to include more countries, more patients and more products. In some cases, companies are continuing with ongoing roll-outs, while other companies have started to expand their pilots since 2012.

GSK, Novartis, Novo Nordisk and Merck KGaA provide evidence of adopting or expanding innovative business models that improve access to medicine for underserved populations in countries relevant to the Index. They are followed by Johnson & Johnson and Merck

Table 2

10 factors linking innovative access models

For the 2014 Index, companies submitted numerous business models for analysis. On examination, the Index identified six models that are innovative, have an explicit goal of improving health and access to medicine for underserved populations, and can be shown to be capable of generating financial returns for the company. Despite their significant differences, the Index has found 10 factors that occur repeatedly across these models.

Organisational factors

- 1 A connection between the model and the overall business strategy
- 2 A long-term investment horizon
- 3 A clear vision of what the model aims to achieve, supported by objectives, targets and regular progress monitoring
- 4 Senior-level support

Localisation mechanisms

- 5 A thorough understanding of regional and local factors that inhibit access to healthcare in general and medicine in particular, as well as underlying causes
- 6 An overarching potentially replicable model that allows for localisation
- 7 A tailored product offering based on local needs and disease prevalence
- 8 Substantial investments to build local capacities, healthcare infrastructure development and awareness

Stakeholder engagement

- 9 The involvement of local communities beyond the patient level
- 10 Cooperation with local partners throughout the lifecycle of the programme

6 companies with new or expanding models

GSK	Africa and Developing Countries Unit
Novartis	Healthy Family programme
Novo Nordisk	Base of the Pyramid innovation project
Merck KGaA	Su Swastha
Merck & Co.	Programme Sambhav
Johnson & Johnson	Impact bonds

& Co., whose innovative models are potentially successful, but it is unclear at this stage whether they are financially sustainable.

The expansion of several of these business models gives a clear signal that it is possible to develop new models that both increase access and are potentially financially sustainable. However, the

Index acknowledges this is challenging and requires significant commitment, investment and time. In addition, despite the potential of these models, it remains unclear whether and to what extent they improve health outcomes or health impact. The Index encourages companies to explore how health outcomes and impacts of these programmes can be measured effectively.

GSK – Africa and Developing Countries Unit

- Covers all countries in sub-Saharan Africa
- Builds on DCMA unit
- Active approach throughout value chain
- Includes wide range of products

In 2014, GSK announced the establishment of its new Africa and Developing Countries Unit. This builds on the success of its Developing Countries and Market Access (DCMA) unit, which was the company's fastest growing business unit between 2010 and 2013. The unit covers all African Less Developed Countries that were previously covered by the DCMA unit, as well as all sub-Saharan countries, including Ghana, Kenya and South Africa. The five core strategies of the unit are: 1) Create an Africa portfolio to target Africa-specific health needs; 2) Expand local manufacturing, optimise supply, design innovative distribution models; 3) Develop a long-term Africa talent portfolio; 4) Support the development of local healthcare infrastructure; 5) Create an Africa-specific operating model.

The model has the potential to significantly improve access to medicine throughout sub-Saharan Africa. In addition, because it aims to include a wide range of medicines, vaccines and consumer products, it has the potential to address a wide range of needs.

Novartis – Healthy Family Programme

- Programmes in India, Kenya, Vietnam and Indonesia
- Focus on prevention, awareness and treatment
- Programmes tailored to local health priorities and customs
- Includes wide range of essential medicines

Through its Social Business Group, Novartis has considerably expanded its "Healthy Family" programme, which focuses on expanding access to medicine, medical professionals and healthcare education for people living at the bottom of the income pyramid. It covers a wide range of products and focuses on prevention and awareness, as well as treatment. It was launched in India in 2007 (Arogya Parivar) and was expanded in 2012 to include Kenya (Familia Nawiri) and Vietnam (Cung Song Khoe). More recently, three pilots have been initiated in Indonesia (Keluarga Sehat). Each local version of the programme is unique: they are adjusted to fit local health priorities and customs. For example, in each country, the product portfolio and health education on offer is tailored to local disease burdens.

The collective reach of the programme is wide: according to the company, it has brought health education to more than 4.5 million people in rural areas in 2013, up from 2.5 million in 2012. More than 230,000 people have received diagnosis or treatment through its health camps. Furthermore, the products involved include a wide range of essential medicines, and the project has proven to be financially sustainable: it broke even within 30 months and sales have increased 25-fold since then.

Novo Nordisk – Base of the Pyramid (BOP) innovation project

- Programmes in India, Nigeria, Ghana and Kenya
- Improving diabetes care for working poor
- Replicable model, tailored to local conditions
- Formulates clear targets for the future

In 2011, Novo Nordisk established its Base of the Pyramid (BOP) innovation project. It aims to identify solutions for an integrated approach to diagnosis, treatment and diabetes control for the working poor in developing countries. Since then, the project has expanded: it is running in India, Nigeria, Ghana and Kenya, and working to, for example, establish an effective supply chain, reduce the need to travel for treatment and build capacity for treating diabetes:

- In India, travel costs and the loss of wages due to travel are the biggest reasons patients do not have access to diabetes care or treatment. As a result, the company is working with a social business model for making insulin available at the doorstep through flexible services.
- In Nigeria and Ghana, patients often have to visit multiple locations to receive diabetes care. The company has developed 'One-Stop Diabetes Support Centres', where patients can access all aspects of diabetes care. This concept was successfully piloted in 2013 in Nigeria. It is now being scaled up there and replicated in Ghana.

Through this model, Novo Nordisk has increased access to diabetes care and treatment. Its approach is replicable while leaving significant room for tailoring to local conditions and needs. In addition, the company has formulated clear targets for the future and is monitoring progress. By 2015, the company aims to roll out this project to additional African countries.

INNOVATION

Merck KGaA – Su-Swastha

- Pilot running in two states in India
- Increasing access to healthcare in rural areas
- Focus on awareness

In 2013, Merck KGaA launched its Su-Swastha ('Good Health') pilot in two provinces of India (Bihar and Uttar Pradesh). The project aims to increase access to quality healthcare products at an affordable price in rural India and addresses the lack of health-care infrastructure in rural areas. It offers community-level meetings and educational health programmes run by healthcare professionals, as well as products based on needs in its target areas and with adapted price bands. In addition, it aims to improve access to primary healthcare by distributing referral cards that enable patients to reach doctors. As part of this programme, the company is working with international NGOs on diarrhoea management and safe drinking-water programmes. When scaling up, the company is planning to expand the range of products to target additional diseases.

Although it is still a relatively small pilot, the programme has the potential to increase access to treatment in rural areas in India. To increase its potential impact, the Index encourages the company to increase its scope to include more products and extend its geographic reach.

Merck & Co. – Programme Sambhav

- Programme in 11 cities in India
- Financing model offering zero-interest, no-collateral loans
- Focus on hepatitis C

In 2012, Merck & Co. launched its pilot Hepatitis Financing Mechanism, or 'Programme Sambhav', in the state of Punjab in India. In-depth market research revealed that a lack of cash flow meant many patients could not manage the cost of treatment for hepatitis C. In response, for patients with limited or no insurance coverage, the company developed an innovative financing model for its hepatitis C medicine, peginterferon alfa-2b (PegIntron®). The programme offers zero-interest, no-collateral loans for eligible patients and a disease management option. Enrolment increased from just 21 patients at the end of 2012 to 450 by 2013. This represents about 30% of all patients under treatment in the State of Punjab. Due to its success, the company has expanded the programme to 11 cities across four states in India.

In addition, the company is planning to expand it to more states in India, Vietnam and the Philippines, and to include more products. An initial analysis phase for launching a similar programme for vaccines is underway.

Through this model, there is significant potential for more patients to gain access to treatment. However, micro-finance has received significant criticism and opinions about its effectiveness differ widely. The Index encourages Merck & Co. to measure the impact of this programme to ensure that it is financially sustainable for the patients enrolled.

Johnson & Johnson – Impact bonds

- In early phases of development
- Exploring new financing models based on DIBs and SIBs
- Focus on health outcomes

Part of Johnson & Johnson, Janssen Global Public Health is currently launching a number of pilot schemes designed to expand its efforts to measure the economic impact, effectiveness and sustainability of new access and funding models. The company is exploring how Developing Impact Bonds and Social Impact Bonds (DIBs and SIBs) can be used to finance R&D in the healthcare sector. DIBs and SIBs¹ are outcome-based contracts in which the public sector or international donors provide funding on the proviso that projects lead to significant improvements in social outcomes (e.g., health outcomes).

In 2012–2013, Janssen's Social Impact Bonds Team completed the first phases of a multi-phased, multi-year strategy to develop DIBs and SIBs in a healthcare context. Together with the Centre for Global Development, the company is exploring how this financing mechanism can be applied to support healthcare delivery in resource-limited settings, with special attention to improving access to medicines.

This project is still in a very early phase and its effectiveness still has to be proven, in particular in countries relevant to the Index. Nevertheless, the model represents a potentially new way to make investments in healthcare more efficient and more impactful.

¹For numbered references, see the Appendix.

✓ **GSK - Africa and Developing Countries Unit**

The unit covers all sub-Saharan countries, including these offices in Lagos, Nigeria.



✓ **Novartis - Healthy Family Programme**

Children in Vietnam's Nghệ An province receive a general health check.



^ **Merck KGaA – Su-Swastha**

The programme includes community-level meetings such as this one in Shiv poojan lala, a village in rural India, which is being run with government health and social workers.



^ **Novo Nordisk - Base of the Pyramid project**

Novo Nordisk works with faith-based organisations in Kenya to limit price mark-ups.

B Public Policy & Market Influence

Pharmaceutical companies operate in an environment where low R&D success rates^a, the pressure to maintain profits and a fiercely competitive landscape can increase the temptation to engage in inappropriate, unethical behaviour. Since 2012, multiple serious cases of bribery, lobbying, anti-competitive practices and improper marketing have occurred. Such activities risk harm and a negative impact on access to medicine: for example, by misrepresenting drug efficacy and safety; by offering inappropriate incentives to doctors; or by delaying the market entry of generic competition.

All companies measured by the Index operate in countries with increasingly stringent controls on behaviour: in the US, companies are now required to publicly disclose financial relationships with healthcare professionals.¹ Wherever companies operate, the Index expects them to meet the same standards as in more highly regulated countries, taking the initiative to expand existing policies and enforcement mechanisms to countries with weaker regulation.

The Index examines how companies self-regulate their behaviour, and reports on whether companies have been found in breach of relevant laws and standards in all countries in which they operate. The Index views breaches wherever they occur as an indication of whether company-wide policies and codes are functioning.

Five areas of analysis

Lobbying

Reporting on lobbying activity, particularly in relation to the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement.²

Competitive behaviour

Reporting on how companies support competition, for example by waiving rights to data exclusivity.

Ethical marketing

Reporting on improper marketing practice, and whether companies have training, auditing and enforcement mechanisms in place.

Anti-corruption and anti-bribery

Reporting on incidences of bribery and corruption and company measures for addressing and preventing such behaviour.

Innovation in Public Policy & Market Influence

Reporting evidence of innovation to ensure ethical behaviour across the breadth of company operations.

Top findings in Public Policy & Market Influence

Commitment to ethical behaviour does not correlate with good performance

All 20 companies commit to following at least a minimum code of practice for ethical marketing and all have codes of conduct governing bribery and corruption. Three-quarters report auditing their codes. However, 18 out of 20 companies were the subject of settlements or fines for corrupt behaviour, unethical marketing or breaches of competition law. Collectively, companies were found to have been accountable for almost 100 separate breaches.

No simple correlation between a company's incidence of breaches and its size

Due to their size and geographic reach, larger companies may be exposed to greater risk of breaches of regulations or laws governing ethical corporate behaviour. However the Index finds that companies' incidences of breaches do not directly increase with size and geographic reach, indicating that companies of all sizes can take measures to actively minimise the risk of breaches occurring.

No company discloses payments to health-care professionals in countries in scope

There has been a significant shift toward greater transparency in the US, as companies are now legally required to disclose their financial relationships with healthcare professionals. However, no company discloses the equivalent information in countries relevant to the Index. There is some indication of movement towards improving internal monitoring of these practices in Index countries, but greater public scrutiny would be valuable, especially in the wake of continuing evidence of unethical behaviour.

Four companies waive rights to data exclusivity

Four companies have waived rights to data exclusivity for some products under certain conditions. One other has shown readiness to do so, describing the situations where it would waive such rights. This is a constructive, albeit limited, approach towards facilitating the entry of generic competition.

How the companies perform

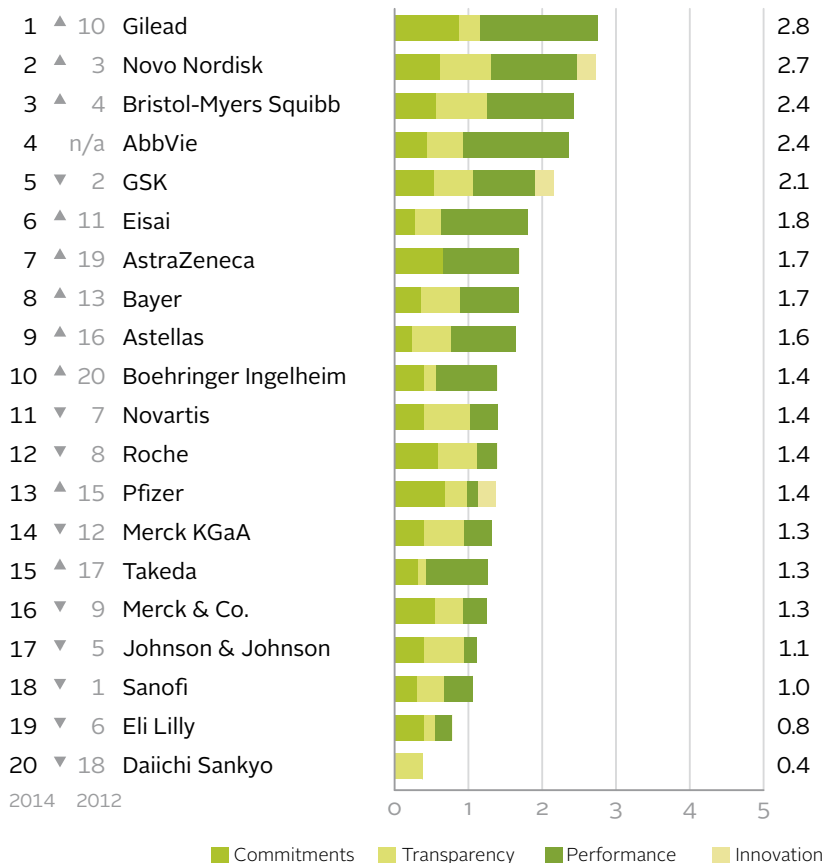
Scores are generally low in this chapter, particularly for transparency and innovation. Furthermore, there is a clear gap between companies' stated commitment to ethical behaviour and what actually happens in practice. Almost all companies have been the subject of settlements or decisions relating to corruption, ethical marketing or competition, despite almost all having codes of conduct to govern employee behaviour.

Only two companies not in breach
In general, the highest-scoring companies in this chapter incurred very few fines and settlements relating to improper marketing, bribery, corruption or anti-competitive behaviour. For only two companies, Gilead and AbbVie^b (a relatively young company), were no fines or settlements identified during the period of analysis. The higher scoring companies also share information about breaches where they occur, and are able to demonstrate how they take swift action against employees who commit offences.

Leaders share information, support competition, enforce policies
Gilead is the overall leader in this chapter, performing well across most focus areas. As well as having incurred no fines or settlements, it audits its codes of practice and shows evidence of having enforcement procedures in place, should a breach occur. In tandem with this, Gilead shows evidence of supporting greater competition through its approach to licensing and by waiving rights to data exclusivity for its HIV/AIDS portfolio.

Following Gilead in the ranking are AbbVie, Bristol-Myers Squibb and Novo Nordisk. These companies all exhibit good practice in different areas.

Figure 20
Company Ranking Public Policy & Market Influence



In 2nd place, Novo Nordisk demonstrates a comparatively high level of transparency about its various memberships and policy positions.

In 3rd place, Bristol-Myers Squibb also clearly articulates its support for competition, and discloses more than most companies about the financial contributions it makes to organisations based in countries within the scope of the Index.

In 4th place, AbbVie publicly shares detailed information about its board-level membership of different organisations. It also appears to be unique in conducting external audits of its

compliance with relevant codes of practice.

These companies also incurred fewer fines or settlements during the period of analysis than others (AbbVie incurred none). Where breaches did occur, those that were reported by companies or identified by the Index took place outside of countries relevant to the Index.

Large, low-scoring middle group
There is a large middle group with variable performances across the four areas of investigation relating to Public Policy & Market Influence. For example, GSK is in 5th place and is comparatively

transparent about some of its policy positions. There is also evidence that it supports competition, and is working towards greater disclosure of its global marketing activities. However, the company has been the subject of multiple breaches.

Eisai, in 6th place, shares comparatively detailed information about the mechanisms it employs to enforce its codes of conduct and about the action it has taken following incidences of misconduct. However, it is also one of the few companies that has not yet joined the United Nations Global Compact (UNGC). AstraZeneca, in 7th place, has a lack of lobbying transparency, but does demonstrate commitment to reforming its sales incentives, and takes a more open approach to data exclusivity in certain circumstances.

Further down the ranking, in 16th and 17th place respectively, Merck & Co. and Johnson & Johnson have been involved in multiple breaches, and, in the case of Johnson & Johnson, with at least one in a country within the scope of the Index. Merck & Co. remains, however, the only company in the Index that has joined the Partnership against Corruption Initiative (PACI.)

Laggards breach multiple standards

The companies at the lower end of the ranking are Sanofi, Eli Lilly and Daiichi Sankyo. These companies were the

subject of settlements and decisions. For all except Sanofi, at least one of these took place in a country within the scope of the Index.

Daiichi Sankyo occupies the last position. It has provided the Index with limited evidence of how its internal codes of conduct address the issue of ethical marketing. It refers to compliance with the IFPMA code of conduct,³ but leaves unclear how it monitors third-party contractors and enforces their compliance with these standards.

Biggest risers: AstraZeneca, Boehringer Ingelheim, Gilead

The biggest risers are AstraZeneca, Boehringer Ingelheim and Gilead, which climb 12, 10 and nine places respectively. In 2014, AstraZeneca disclosed a more constructive stance towards data exclusivity than in 2012, and also demonstrated how it enforces its codes of conduct and applies marketing regulations to third parties. Boehringer Ingelheim has markedly improved in transparency since 2012, sharing, for example, more comprehensive information about its code of conduct for marketing, as well as how it is enforced and applied to third parties. Like AstraZeneca, Gilead has also shown evidence of commitment to waiving its rights to data exclusivity, and was not found to have breached relevant codes or laws.

Biggest fallers: Sanofi, Eli Lilly, Johnson & Johnson

Sanofi is the biggest faller, dropping from 1st to 18th place. It is followed by Eli Lilly and Johnson & Johnson, which drop 13 and 12 places respectively. Each company was the subject of multiple settlements or decisions during the period of analysis. For Sanofi and Johnson & Johnson, these included incidences of both corruption and anti-competitive practice. For Eli Lilly and Johnson & Johnson, at least one took place in a country within the Index scope.

In 2014, Sanofi also failed to disclose information about its attitude towards data exclusivity, and shares limited information about its marketing programmes in countries within scope. Eli Lilly shares limited information about its lobbying activities, including payments made and memberships held. Johnson & Johnson does not demonstrate how (or whether) it has taken action against members of staff who have breached its codes of conduct.

Notably, GSK has fallen out of the top three. It was placed 1st in 2010, and 2nd in 2012. It is now in 5th place. The 2012–2014 drop is attributable to evidence of breaches relating to unethical marketing gathered during the reporting period.^c

INDUSTRY

Clear gap between commitments and practice

In general, companies conform to a baseline of performance. Regarding corruption and bribery, for example, all companies provide evidence of a code of practice, 75% provide evidence that they audit and enforce such codes, and all have whistleblower protection facilities in place.

However, there is a clear gap between what the majority of companies commit to doing, and what occurs in practice: almost every company (18)

was found to have been in breach of relevant laws or regulations at least once during the period of analysis. Company performance across the area of Public Policy & Market Influence is poor, especially when seen in the light of progress made in other areas of focus. The industry needs to considerably improve to ensure full compliance with the law, and there is ample room to demonstrate greater proactivity to address failings.

Increasing transparency

There are signs of a more progressive attitude towards the disclosure of specific actions, transactions, memberships and stances among some companies. Bristol-Myers Squibb publicly discloses some payments made to various organisations, including in some countries in scope. Roche discloses financial support provided to patient groups, including some in Index countries. However, most companies provide only limited or aggregate data.

Publicly available transaction-level information is scarce, and usually only disclosed where required by law. With respect to lobbying, companies tend to publicly disclose only high-level global policy positions, rather than specific lobbying activities. Johnson & Johnson is a notable exception, disclosing some information (albeit limited, and only to the Index) about political lobbying in some Index countries. Greater public disclosure by companies about their lobbying activities and memberships

of trade associations, think tanks, and interest groups could have a self-regulatory effect by ensuring greater external scrutiny of company behaviour.

Companies generally do not publicly endorse competition: most (16) limit themselves to committing to obeying the law and to not engaging in anti-competitive practices. Regarding commitments, Roche and Pfizer stand out, providing more detail than others about their positions on competition.

A small group of companies (Astra-Zeneca, Bristol-Myers Squibb, Gilead, ViiV Healthcare (GSK and Pfizer)) actively support competition, all waiving, or committing to waive, their rights to data exclusivity in limited circumstances. Eisai's commitment on data exclusivity has weakened. Previously it had committed not to pursue data exclusivity in least developed countries, but in 2014 it no longer gives this assurance.

EXTRA ANALYSIS

Analysis of breaches: Majority of companies subject of settlements or decisions

Breaches of legal or regulatory requirements are the differentiating factor in this chapter. Higher scoring companies generally have the lowest incidence of confirmed breaches.

Where breaches have occurred, higher scoring companies have voluntarily disclosed them and demonstrated that they have taken action to mitigate against the risk of similar breaches occurring in the future.

Research indicates that, in the public sector at least, there is a relationship between lower levels of corruption and having a code of conduct in place – so long as it is accompanied by processes for communicating its contents, is embedded in a supportive environment, and supported by adequate enforcement and auditing processes aimed at ensuring compliance.^{4,5,6,7} The Index views breaches of legal requirements and associated standards as an indication that a company's approach to communicating and enforcing its codes of conduct and related policies is not functioning optimally, and that it is not able to foster an environment that shows zero tolerance to corruption.

The Index captures information about fines and settlements, as well as about allegations and on-going cases. It looks at breaches of laws relating to

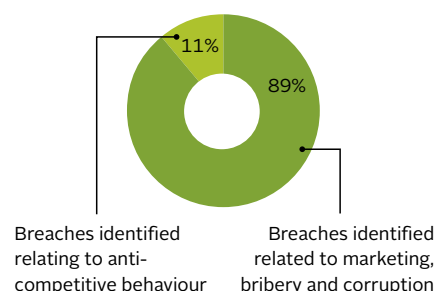
marketing, corruption, bribery and lobbying; as well as at breaches of industry codes of conduct for good marketing practice.

When assessing company performance, the Index only takes into account fines levied and decisions taken against the company in question within the period of analysis.^d This is referred to as the company's incidence of breaches. Sometimes the settlements reached and decisions taken against the company relate to reports of misconduct prior to the period of analysis, and thus corrective action taken by companies may not be fully captured within the 2014 analysis.

In countries relevant to the Index, evidence of breaches of codes of conduct and legislation is scarce and often limited to high-profile cases. It should be noted that the breaches captured by the Index are also a function of the nature and rigour of the various regional and national legal and regulatory frameworks. As such, fewer breaches are likely to be identified in countries with weaker or absent reporting systems and judicial controls.

This is the case in many of the countries that fall within the geographic scope of the Index. To give a better sense of how effectively companies

Figure 21
Most breaches relate to marketing behaviour



manage and apply standards and auditing and enforcement mechanisms, the 2014 Index also scores, for the first time, breaches that occur in countries outside of the scope of the index.

Only two companies with no breaches
Apart from Gilead and AbbVie, all companies measured by the 2014 Index were the subject of settlements or decisions regarding breaches of at least one standard or requirement somewhere in the world during the period of analysis. In total, almost 100 separate breaches were captured or self-reported. The majority of these (89%) concerned improper marketing, bribery and corruption. The remaining breaches relate to anti-competitive

behaviour. This balance is not surprising considering the breadth of marketing activity in this sector, the overlap of breaches concerning unethical marketing practice and bribery, and because specific regulatory structures in some jurisdictions (e.g., the US, the UK) mean that breaches of marketing codes and laws are more likely to be reported, and settlements publicly disclosed.

There is no simple correlation between a company's incidence of breaches

and its annual revenue, or with its geographic spread. Some smaller companies were implicated in breaches more often than larger peers. Similarly, some companies with wider geographic reach, such as Roche, were implicated in comparatively fewer breaches than peers with more limited operational spheres.

Risk can be mitigated

This indicates that, although some companies may be exposed to greater risk of breaches, breaches cannot and

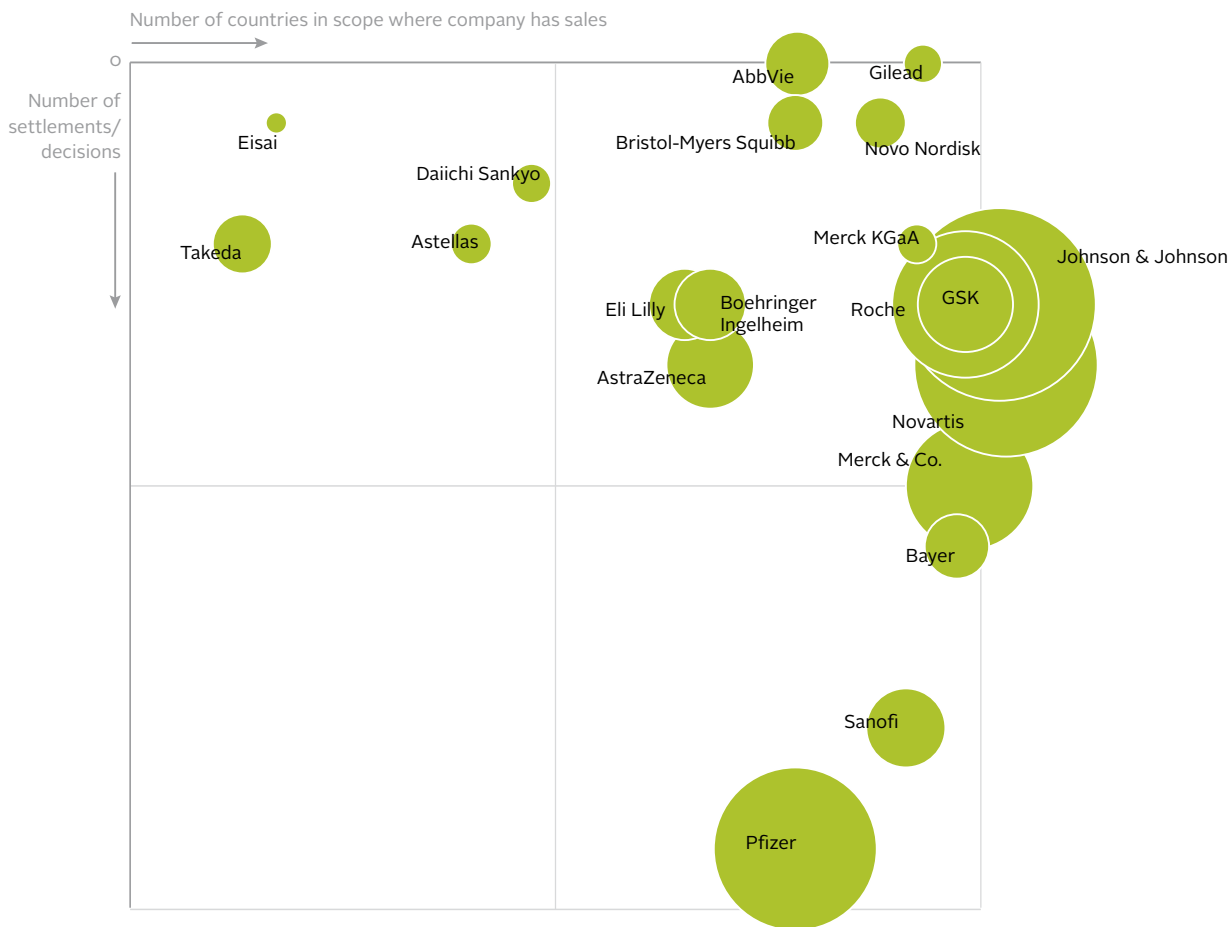
should not be straightforwardly characterised as a cost of doing business that increases with company size and geographic reach.

There are specific actions that every company can take to mitigate the risk of a breach: assign clear responsibility and accountability at the highest levels; encourage clear standards of behaviour at all levels; conduct external audits; conduct relevant training; and impose penalties for non-compliance.

Figure 22

No clear relationship between company behaviour and size

Of the 20 companies analysed, only Gilead and AbbVie were not found to have been the subject of settlements or decisions somewhere in the world during the period of analysis. AbbVie is a relatively young company. All incidences included in this figure are treated equally. In total, almost 100 separate breaches were identified or self-reported.



In its analysis of breaches, the 2014 Access to Medicine Index finds no simple correlation between the size of a company, its geographic reach and the number of settlements or decisions concerning corruption, bribery, improper marketing and anti-competitive behaviour. This indicates that breaches cannot simply be characterised as a cost of doing business that increases with a company's size and reach. Further, as both large and small companies are found to have lower incidences, it appears that companies of all size and scale can take mitigating action.

Circle size represents company revenue

Anti-bribery and anti-corruption

Standards and policies in place, but more needs to be done

Why this matters

Corruption and bribery can compromise patient safety, increase costs to the public purse, damage reputations and financial returns, and cost companies significantly in fines and settlements.^e Where the will exists, companies can take a range of actions to mitigate the risk of corruption and bribery occurring, including imple-

menting and enforcing robust self-regulatory policies (such as auditing) to complement external regulatory requirements; assigning board-level responsibility for compliance issues, and creating an atmosphere of trust in which whistleblowers can come forward. The Index looks for strong, transparent anti-bribery and

anti-corruption policies and codes of conduct that include monitoring and enforcement mechanisms. As an indication of the effectiveness of these measures, the Index examines how and where anti-corruption and anti-bribery laws and regulations are breached, and whether disciplinary action is taken.

How the companies perform

As noted in 2012, it is standard practice for all companies to have in place codes of conduct prohibiting corruption and bribery. The majority of companies (15) continue to participate in at least one global initiative that combats corruption. Change in company behaviour regarding bribery and corruption is limited to one area: in 2014, seven additional companies reported that they audit adherence to their codes of conduct for bribery and corruption – 15 in total, up from nine in 2012. Five companies (Roche, Sanofi, Takeda, Daiichi Sankyo and Astellas) did not provide evidence of auditing their code. In almost all (14) of these cases, evidence indicates that audits are conducted internally. AbbVie also reports the existence of external audits, the results of which tend to have more credibility.

Leaders do not breach standards

The leaders in this area are Gilead and AbbVie. They are the only two companies not found to have breached laws and regulations related to bribery and corruption. In addition, they both have clearly defined policies and procedures for taking action were a breach to occur.

Whistleblower policies now standard

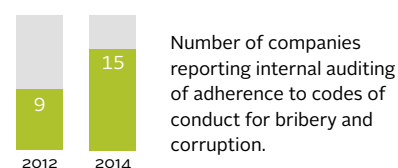
Encouragingly, companies recognise the importance of ensuring employees

feel able to report corruption or bribery: all companies have a whistleblower protection facility in place. The majority (17) explicitly report having a policy of non-retaliation against complainants. Board-level ownership of compliance issues is a strong indication that allegations are taken seriously and are dealt with in a timely and transparent manner. However, no company shares definitive information about how responsibility for breaches is taken at the board level. The most common arrangement is for a senior compliance staff member to report on compliance issues to the board. Ten companies (Sanofi, AbbVie, Bayer, Eli Lilly, Merck KGaA, Novartis, Novo Nordisk, Bristol-Myers Squibb, Astra-Zeneca, Eisai and Gilead) disclose their approaches for ensuring employees comply with their codes of conduct for corruption, bribery and ethical marketing. They also provide evidence of whether or not they took disciplinary action in the event of misconduct.

By joining international agreements against bribery and corruption, companies publicly commit to combating unethical conduct. In total, 15 companies are now members of the United Nations Global Compact (UNGC).^f Five companies have not yet signed up to it: AbbVie, Boehringer Ingelheim, Eisai,

Figure 23

More companies audit compliance



Gilead and Roche. Johnson & Johnson is the only new member of the UNGC since 2012. Merck & Co. remain the only pharmaceutical company to also be a member of the World Economic Forum's Partnership against Corruption (PACI).

Allegations in China

During the period of analysis, the Index also identified multiple allegations of breaches, including several high-profile allegations in 2013 of bribery by companies operating in China. Some of these allegations concern healthcare professionals being given direct incentives to influence sales (GSK was fined USD500 million by China in 2014).^{8,9,10} There appears to be a disconnect between having anti-corruption measures on paper and successfully enforcing them in different countries and contexts.

Ethical marketing

More transparency from leaders and promise of third-party monitoring

Why this matters

Improper marketing tactics can increase the risk of irrational prescribing and misinformed purchasing decisions, reduce drug efficacy and lead to adverse drug reactions. The Index looks at companies' codes of conduct and mechanisms for enforcing ethical marketing behaviour. In the absence of independent international guidelines, the Index examines whether companies' codes and mechanisms at least align with the Code of Pharmaceutical Marketing Practices set out by the International Federation of Pharmaceutical Manu-

facturers (IFPMA) and whether they meet national regulations or standards, where they exist.

The Index examines whether companies have training, auditing and enforcement mechanisms in place. As a proxy for company compliance across the breadth of operations, the Index captures reported breaches of ethical marketing guidelines and evidence of litigation wherever they occur.

With the signing of the Sunshine Act in the US and similar recommenda-

tions made by the European Federation of Pharmaceutical Industries and Associations (EFPIA)¹¹, companies are now required to publicly disclose their financial relationships with healthcare professionals in these regions. The Index looks at whether companies also take the initiative by disclosing equivalent information in countries relevant to the Index. In addition to helping regulate behaviour, this would enable stakeholders to explore how such activity affects local access to medicine.

How the companies perform

All companies commit to meeting the legal requirements of countries in which they operate, and to applying either their own marketing code, or at least to following the most recent code of the IFPMA. However, the volume and nature of unethical marketing practices captured during the period of analysis indicate that company commitments are in conflict with evidence that shows a continuing non-compliance with standards.

All companies except Gilead and AbbVie were found to have been the subject of settlements or decisions relating to ethical marketing laws and regulations somewhere in the world during the period of analysis.

Marketing breaches captured by the 2014 Index include breaches of industry-regulated codes of conduct in countries such as the UK¹², Australia¹³, South Africa¹⁴ and the Netherlands¹⁵. They also include more high-profile legal settlements brought in the US under the False Claims Act by the US

Department of Justice. Among these were USD3 billion and USD2.2 billion settlements against GSK and Johnson & Johnson respectively for promoting drugs for unapproved uses in the early part of the last decade.

Leaders extend policies to third parties

Gilead and AbbVie are the leaders in this area: they were found to have either no or very few breaches of ethical marketing requirements in countries within the scope of the Index or beyond. In addition, they have clearly defined and audited policies and procedures in place for taking disciplinary action, which they extend not only internally but also to third-party suppliers. These companies also demonstrate transparency, for example by sharing information about payments made to healthcare professionals.

13 companies were able to provide evidence of having policies, procedures and monitoring systems that also related to the behaviour of third-party

sales agents. These companies are AbbVie, AstraZeneca, Boehringer Ingelheim, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck KGaA, Merck & Co., Novartis, Novo Nordisk, Roche and Sanofi. Sixteen companies provided evidence of auditing their marketing codes of practice (those that did not were Astellas, Bayer, Daiichi Sankyo and Takeda).

The remaining companies, despite having relevant codes, did not provide similar evidence of this level of internal monitoring, control and review. At the bottom of the ranking, Daiichi Sankyo is the only company to provide no evidence of having an internal code or policy that specifically addresses ethical marketing. However, it does state that it complies with IFPMA guidance and national regulations in this area.

No disclosure of payments to doctors in countries in scope

The Physician Payment Sunshine Act (2010) is a US law requiring pharmaceutical companies to declare payments

and gifts made to physicians and teaching hospitals in the US in a public database. The database, which became operational in September 2014, allows the public to scrutinise the financial relationships between the industry and the medical profession in the US. Its intent is to limit undue “influence of industry on research, education and clinical decision making” and to “stop conflicts of interest which harm patients and their care”. In a related development, the EFPIA Disclosure Code (approved June 2013) states that member companies should publicly disclose “transfers of value” to healthcare professionals.

As a result of these changes, many companies are implementing more rigorous systems for tracking and reporting payments made to healthcare professionals. The Index looked at whether any company went further, and disclosed equivalent information in countries within the scope of the Index. No company provided evidence of this level of transparency. However, Novo Nordisk is working towards rolling out a comparable system in some countries relevant to the Index. Bristol-Myers Squibb is also evaluating an initiative that would also make disclosure of these kinds of payments possible. In the same vein, GSK is working towards

publishing aggregate global figures of such payments.

In order to make these leading practices, companies need to capture transaction-level information in countries within scope, and publish the resulting reports – whether or not local legislation requires it. Currently, no company provides detailed information about transaction-level payments made to healthcare professionals in countries relevant to the Index, preventing external evaluation of their appropriateness.

FOCUS AREA 3

Lobbying

Companies reluctant to share lobbying activities

Why this matters

The Index defines lobbying as any activity carried out to influence the policies and decisions of a government or institution in favour of a specific cause or outcome. Even when allowed by law, lobbying can give companies inappropriate influence that can distort markets and affect access to medicine. For example, companies lobby governments to strengthen intellectual property protection beyond what is internationally agreed to be reasonable. This can have a direct impact on access to medicine by delaying the entry of generic competition to the market.

Much lobbying activity occurs during private lunches, informal meetings and

similar interactions, making it difficult to record and review. Country-level lobbying to influence national legislation can be easier to track where countries have requirements in place for registering or disclosing lobbying activity. In the multilateral policy-making arena, for example in UN institutions, this type of influence can be more difficult to monitor.

Transparency about lobbying sheds light on relationships and positions that could have an impact on access to medicine. Furthermore, it enables stakeholders to hold companies and the recipients of their financial support publicly accountable. The Index reports on whether companies publicly

disclose their lobbying positions, policies regarding political contributions, and trade-association and board memberships. It also investigates specific reported incidences of inappropriate lobbying that occurred during the period of analysis, including via trade organisations.

Because companies can also exert their influence for the benefit of patients and access to medicine, the Index also examines whether companies engage in multi-stakeholder advocacy activities in support of access to medicine. Collaborating with a range of actors helps ensure that these activities are needs-based, and not solely geared towards a company's interests.

How the companies perform

Little has changed in this area since 2012: companies generally do not share information about lobbying positions or political contributions that may affect countries relevant to the Index. Nine volunteered no information at all in this

regard, either publicly or to the Index: namely AbbVie, Astellas, AstraZeneca, Boehringer Ingelheim, Eisai, Eli Lilly, Gilead, Merck KGaA and Takeda. Other companies simply referred to general policy statements, or statements about

the positions of relevant trade associations. None disclose political contributions in countries within scope.

The leader in this area, Johnson & Johnson, shows that greater degrees

of transparency about lobbying in countries within the scope of the Index are possible, although disclosure in this case was only to the Index, rather than public.

During the period of analysis, most companies were implicated in a single, high-profile allegation. This involved the Innovative Pharmaceutical Association of South Africa (IPASA) and Pharmaceutical Research & Manufacturers of America (PhRMA). Evidence emerged in early 2014 of a strategy aimed at delaying the South African Government's planned reform of its intellectual property legislation.¹⁶

The South African reform proposals include strengthening of patentability criteria, and implementing both pre- and post-grant opposition of patents and several TRIPS flexibilities, including enabling compulsory licensing where there is a lack of indigenous manufacturing capacity.

Companies continue to provide evidence of engaging in multi-stakeholder advocacy activities in support of access to medicine. For example, several companies continue to participate in the Uniting to Combat Neglected Tropical Diseases (NTDs) Initiative, a result of the 2012 London Declaration on NTDs. This initiative draws attention to the need for greater focus on the elimination or control of neglected tropical diseases.

Company behaviour can improve in all aspects of lobbying captured by the Index. In particular, there is a need for greater transparency, beyond legal requirements, and about transaction-level payments to interest groups and trade associations, especially where these payments occur in lower income countries.

Disclosure: low, but improving

Although no companies publish their lobbying positions and activities fully and frankly, the better performers in this area demonstrate a more confident approach towards public disclo-

sure. They publicly share details of their membership of interest groups; of board seats they hold; policies around political payments; and about certain lobbying positions held in countries relevant to the Index.

The leading companies in this area are Johnson & Johnson, GSK, Merck & Co., Novartis and Sanofi. These companies publicly share general global public policy positions that could have an impact on access to medicine – for example, their orientation towards compulsory licensing. Johnson & Johnson also shares with the Index more detailed information about the lobbying activities it has undertaken in countries relevant to the Index.

While some companies disclose specific political contributions that they have made in the US and the EU, this disclosure does not extend beyond what is either legally required or mandated by the industry body. Roche and Novartis go slightly further, also disclosing aggregate amounts of political contributions made in Switzerland, where such disclosure is not legally required.¹⁷ No companies disclose political contributions made in Index countries. Bristol-Myers Squibb publicly discloses its company policy not to make such payments outside of the US, and GSK has publicly committed to making no political contributions in any country.

Boehringer Ingelheim, Novo Nordisk and Roche show a more confident approach to sharing information about their memberships of, and specific payments made to, a variety of interest groups, trade associations and think tanks. However, they stop short of providing equivalent information related to countries within the scope of the Index.

Bristol-Myers Squibb goes further, disclosing information to the Index about its memberships of and contributions to interest groups based in countries relevant to the Index. AbbVie, Astellas, Bayer, Eisai, GSK, and Merck

KGaA all provide public information about their board-level memberships of industry associations and advisory bodies related to access issues for countries and diseases within the scope of the Index.

Other companies remain conservative about sharing details of the board seats they hold, the lobbying activities they undertake, the memberships of and contributions made to interest groups. The poorest performers in this area (AstraZeneca, Pfizer and Takeda) share limited information about board memberships and payments made to interest groups, and were unclear about their lobbying activities. Where disclosed, information was limited to countries outside the scope of the Index.

Broad evidence of harmful lobbying

All companies included in the 2014 Index are members of trade associations (most commonly EFPIA, IFPMA, IPASA and PhrMA). Via this membership, they have all been connected to the lobbying of national or regional governments for stronger intellectual property protection. The IPASA case mentioned above is the most high-profile and involves the most companies. Since the publication of these allegations, Novo Nordisk and Roche have resigned from IPASA and Novartis has distanced itself through a news release.^{18, 19}

Anti-competitive behaviour

Small group actively supports competition

Why this matters

It is generally accepted that competition supports lower prices. Companies can stifle competition through various means: by paying generic manufacturers to delay the market entry of competing products; colluding with peers on pricing; or insisting on their rights to data exclusivity.

Data exclusivity refers to a company's right to prevent generic competitors from using the company's clinical trial data when registering generic equivalents. It can delay the entry of the generic equivalent to the market, as

generic competitors are then required to repeat clinical trials unnecessarily, should they want to continue development. Under the declaration of Helsinki, such unnecessary repetition is considered unethical.²⁰

In this area, the Index looks for clear statements of support for competition with both generic medicine manufacturers and research-based peers. Company policy should include a commitment to refrain from undertaking activities that would undermine competition, but should also go beyond

a commitment to obey the law.

The Index looks at whether the company has been found to have breached competition law; and whether and under which circumstances companies waive rights to data exclusivity to facilitate greater access in countries covered by the Index. How companies facilitate competition through other mechanisms, such as licensing, is addressed in the chapter on Patents & Licensing.

How companies perform

As in 2012, the majority of companies give limited public support to the value of competition. For the 2014 Index, a small group of two leaders provided clear and precise company-wide policies that endorse competition with both their research-based peers and with the generic medicine industry. However, remaining companies restricted themselves either to broad statements in support of competition (three companies) or limited their commitment to adherence to the law (15 companies). Breaches related to anti-competitive behaviour were identified in slightly under half (nine) of the companies.

Concerning data exclusivity, it is encouraging to see a small group of companies prepared to relax their insistence on the maximum periods of data exclusivity available for some diseases in countries in scope. However, lobbying for stronger standards of data exclusivity appears to be industry-wide: most companies were connected to evidence of this kind of lobbying in at least one relevant country.

All companies can do more across the board. A more proactive approach to competition is possible, for example, through licensing, or by taking a more nuanced approach to data exclusivity, by waiving its application across a broader range of products and in a broader range of countries.

Willingness to share data

The leaders in 2014 go beyond committing to adhere to competition law, and have clear and precise policies that describe the benefits of competition for patients. They show evidence of waiving opportunities to extend market monopolies, for example by formalising exemptions to data exclusivity in certain cases in certain countries. Company performance is critical – to lead there needs to be no evidence of negative judgements concerning competition law over the reporting period.

Pfizer and Roche go further than most companies, publishing commitments that endorse the value of competition. They explicitly endorse the

4 companies waive rights to data exclusivity, albeit in limited circumstances:

Bristol-Myers Squibb
 Gilead
 GSK (ViiV Healthcare)
 Pfizer (ViiV Healthcare)

value of both generic and research-based competition, and commit to avoiding anti-competitive practice, demonstrating evidence of how this is enforced. Many (15) others have policies in place, but do not go beyond a commitment to adhere to the law.

Bristol-Myers Squibb also clearly articulates its support for competition within its company policies. In addition, it is one of a group of five companies to provide evidence of supporting competition in practice, albeit in limited cases: it has used the President's Emergency Plan for Aids Relief's (PEPFAR) tentative approval process to facilitate access to its clinical trial data for generic medicine manufacturers, expediting the development of generic

versions of its HIV medicines.²¹ GSK and Pfizer (through ViiV Healthcare), together with Gilead, are the other three companies that show leading behaviour. These companies report having waived their rights to data exclusivity in certain cases in certain countries relevant to the Index. In the case of Gilead, these commitments were made directly to Indian generic medicine manufacturers the company had partnered with, and through the terms of separate agreements with the Medicines Patent Pool. In the case of GSK and Pfizer, commitments relate to the terms of licences agreed between ViiV Healthcare and the Medicines Patent Pool. In addition, AstraZeneca has committed to waiving its rights to data exclusivity for products for specific conditions, including malaria, tuberculosis, lymphatic filariasis and leishmaniasis.

Other companies either disclosed no specific position in this area, or emphasised the general need for data exclusivity to protect clinical trial data. They did not acknowledge the possibility that a more flexible approach to data exclusivity would facilitate market

entry of generic competitors in areas of need. When compared with 2012, most companies have not significantly changed their commitments to waiving data exclusivity rights in support of generic competition.

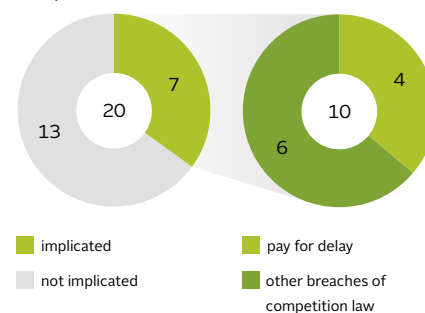
Seven companies in breach

Company behaviour is more important than commitment. During the period of analysis, the Index identified negative rulings involving seven companies over the period of analysis (Daiichi Sankyo, Johnson & Johnson, Merck KGaA, Novartis, Pfizer, Roche and Sanofi). This includes breaches that occurred in two countries within the scope of the Index (China and India) and involve Johnson & Johnson and Daiichi Sankyo. In the case of Daiichi Sankyo this was related to its generic pharmaceuticals subsidiary, Ranbaxy. These instances were both related to steps companies took to affect pricing. The Index captured multiple (four) instances of pay-for-delay, where companies either made or received payments to delay the entry of generic competitors onto the market. Companies associated with any sort of breach of competition law should ask what additional actions they

Figure 24

Pay-for-delay to stall competitors

Companies implicated in breach of competition law 10 breaches identified in breach of competition law



Seven companies were implicated in 10 breaches of competition law: Daiichi Sankyo, Johnson & Johnson, Merck KGaA, Novartis, Pfizer, Roche and Sanofi. Out of these, four relate to pay for delay, where companies either made or received payments to delay entry of generic medicine competitors to the market.

can take to ensure their stated policies are better specified and disseminated across the company, and how they can be better audited and enforced across the breadth of their operations.

INNOVATION

Innovation follows allegations

Over successive Indices, there has been very limited evidence of innovation in the area of Public Policy & Market Influence. Companies involved in breaches need to address their failings, and to do so proactively, rather than reactively. However, sometimes novel practices arise in reaction to reports or allegations of negative practice. They nevertheless represent innovation and are valued as such.

AstraZeneca and GSK are reforming the way they incentivise their sales agents. Incentive schemes that are based entirely on sales targets intensify an organisation's focus on sales figures while potentially undermining the appropriate, rational and more cost-effective use of medicine.

GSK has – uniquely – announced that, by the start of 2016, it will stop making direct payments to healthcare profes-

sionals that it has invited to speak at or attend medical conferences.

Movements towards greater transparency of activities in countries within scope are welcomed. Novo Nordisk has disclosed to the Index plans for achieving greater internal oversight and closer monitoring of payments in selected lower income countries. Public disclosure of this information would be unique.

For numbered references, see the Appendix.

a Recent estimates suggest 10.4% of drug candidates entering clinical development in phase 1 will achieve FDA approval in the US. Clinical development success rates for investigational drugs, Nature 2013.

b Two settlements were made against AbbVie during the period of analysis. However, they both related to transgressions that occurred before the company was divested and became a separate legal entity.

c The period of analysis is from 1 June 2012 to 30 May 2014

d The 2014 GSK conviction related to China, for example, will be addressed in the 2016 Index.

e Recent settlements under the Foreign Corrupt Practices Act in the US include USD45 mn and USD29 mn involving Pfizer and Eli Lilly, respectively (www.sec.gov/spotlight/fcpa/fcpa-cases.shtml)

f The United Nations Global Compact is a UN administered agreement that encourages businesses to align with 10 principles of responsible behaviour, including fighting corruption. However, it is not a performance-assessment tool, and is not enforceable.

C Research & Development

In the pharmaceutical industry, the current R&D model is facing considerable challenges.¹ Since the 1990s, new product approvals have been relatively rare while costs have continued to rise.² With mature markets stagnating, companies are looking elsewhere for growth. There is huge demand for R&D that targets the needs of people living in developing countries: needs for new products for certain diseases, and for adapted versions of existing products for specific populations and conditions. However, the pharmaceutical markets in many of these countries are fragile. As companies look to develop products with viable markets, it seems likely that certain diseases, conditions and patient groups will continue to be overlooked.

In this chapter, the Index reports on how companies are meeting the demand for new and adapted products in these countries through research and development. It also looks at how companies are engaging in new partnership models that aim to pool the risks associated with R&D.³

The Index examines how company pipelines target 47 high-burden diseases, grouped into four categories: communicable diseases; non-communicable diseases; neglected tropical diseases, and maternal & neonatal health conditions. Compared with 2012, the 2014 Index raises the bar, incorporating new areas of investigation, demanding higher standards of evidence and using more stringent scoring guidelines.

Four areas of analysis

Product development

Reporting on companies' approaches to product development for diseases covered by the Index.

Collaborations and IP sharing

Reporting on whether and how companies engage in R&D partnerships, and whether the underlying agreements are based on access-oriented terms and conditions.

Clinical trial conduct and data transparency

Reporting on clinical trial codes of conduct, evidence of oversight and enforcement mechanisms for these codes and on breaches of clinical trial conduct in countries within scope. It also examines transparency around clinical trials and whether companies share clinical trial data.

Innovation in R&D

Reporting any innovative, sustainable or open business model that addresses current gaps in product development for diseases within scope.

Top findings in Research & Development

Evidence of sustained commitment to R&D for relevant diseases

Most companies have an R&D strategy in place that explicitly takes patients in developing countries into account. The Index captured 327 R&D products that target high-burden diseases for countries within scope, a large proportion of which are new to the 2014 Index. Most companies have also successfully moved products along their pipelines:

11 companies have been granted regulatory approvals for 30 new products, collectively covering 11 of the 47 conditions within scope.

R&D is mainly focused on five diseases

More than half of all products in development (54%) target five diseases: diabetes, lower respiratory infections, hepatitis, HIV/AIDS and malaria. These same diseases also have the most products in clinical development. The most notable gaps are for maternal and neonatal health conditions: there is a lack of products being adapted for safe and effective use by pregnant women and neonates. The majority of products for neglected tropical diseases are early drug-discovery projects or pre-clinical studies. It will be some time before any of these products are on the market.

Companies devote large pipeline shares to relevant diseases

Almost half of companies are devoting significant shares of their pipelines to diseases within scope for patients living in countries within scope. For three companies this reaches over 35%. Another six companies devote more than 20% of their pipeline to relevant R&D projects. In total, the industry is developing more than 300 products for relevant diseases.

Substantial proportion of R&D takes place in access-oriented partnerships

Approximately 40% of all product development occurs in collaboration, with either publicly funded, privately funded or a mix of partners. More than a third (39%) of these product development partnerships are based on research contracts that include access provisions. Since the 2012 Index, the total number of R&D partnerships has increased by 35%, mainly due to an increase in drug-discovery and early-stage partnerships targeting neglected tropical diseases, malaria and tuberculosis.

Limited consideration of access to compounds for non-communicable diseases

Most companies struggle to demonstrate how innovative compounds targeting non-communicable diseases will be accessible to patients living in countries within scope. While there are several such compounds in clinical development, there is no implementation strategy that addresses these patients. No company makes commitments to registering such products in relevant countries. The terms and conditions of partnerships for non-communicable product development are not disclosed to the Index or to the public.

Movement towards stronger ethical clinical trial standards and enforcement

More companies provided strong evidence of having enforcement measures in place to ensure ethical clinical trial conduct for in-house and outsourced trials that are in line with guidelines on good clinical practice (ICH-GCP). This has increased from four companies in 2012 to ten. Seven companies incorporate aspects specific to the Declaration of Helsinki in their clinical trial codes of conduct.

How the companies perform

Companies receive a wide spread of scores in this area, driven largely by their performances in product development. Companies with the strongest relevant pipelines also have strong R&D strategies that are based on meeting the needs of patients in countries within scope. Once again, the industry is developing a substantial number of products for high-burden diseases, most of which are in clinical development.

In R&D, the companies are divided into three distinct groups. There are two companies in the lead, separated by a small margin – GSK and Johnson & Johnson. A pack of three companies follow close behind – Merck KGaA, AbbVie and Novartis. The following ten companies comprise the second group. Although the scores in this group decrease gradually, there is a major difference between the highest- and lowest-ranked company. Another five companies lag behind.

Leaders score highly across the board

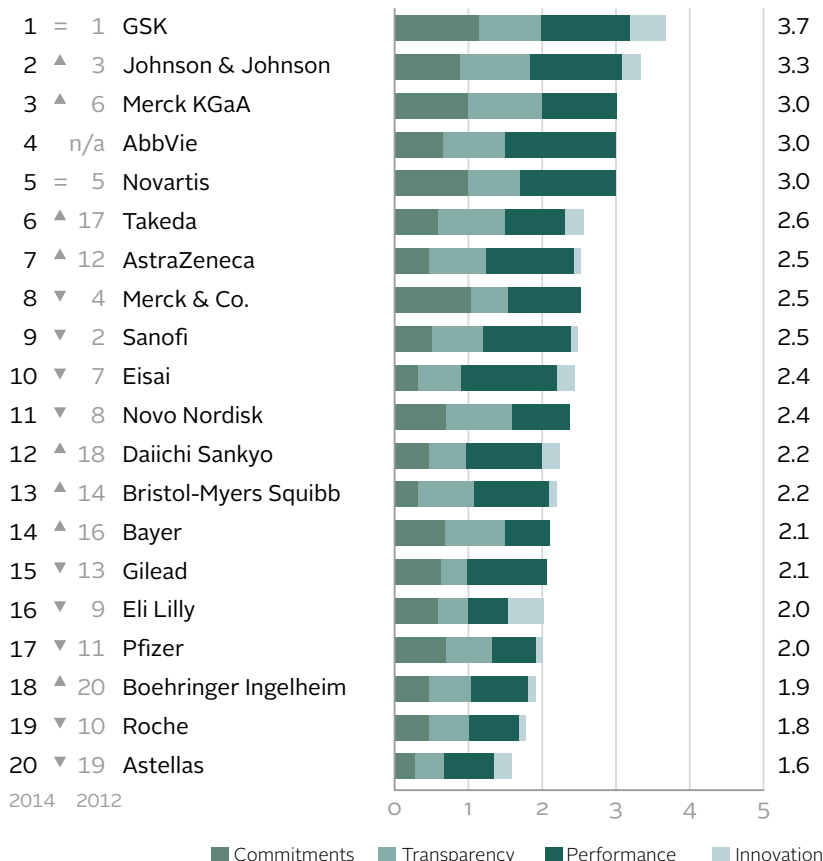
All the top five companies in R&D score highly for product development, measured across several parameters, including R&D strategies, R&D investments and how much of their overall pipeline is devoted to developing products relevant to the Index.

In 1st place, GSK remains the overall leader for R&D. As well as scoring highly for product development, it scores the highest for collaborations, IP sharing and innovation. It has a far-reaching R&D strategy, which specifically addresses unmet needs relating to neglected diseases, anti-microbial resistance and non-communicable diseases in Africa.

In 2nd place, Johnson & Johnson leads in product development, with an exten-

Figure 25

Company Ranking Research & Development



sive relevant pipeline that includes numerous adapted formulations, including fixed-dose combinations and paediatric formulations. Compared to its peers, it has moved the most products through its pipeline phases. Tied in 3rd place, Merck KGaA, AbbVie and Novartis have strong scores across the board. Merck KGaA focuses on developing medicines for non-communicable diseases. Its R&D strategy includes operationalisation strategies for relevant countries that cover multiple diseases, including diabetes and asthma. AbbVie also has a strong position in product development relating to the Index disease scope, including products inherited

from Abbott. Novartis has the largest relevant pipeline of all companies, with a strong focus on malaria, vaccines and maternal and neonatal health conditions.

The leaders are developing many of their products on access-oriented terms, as shown in the terms of their product development partnerships. This illustrates a strong level of commitment to tackling diseases with the highest burdens in countries with the poorest patients.

The leaders also go beyond compliance with the International Conference on Harmonisation guideline for Good

Clinical Practice (ICH-GCP)⁴ in their codes of conduct for clinical trials, and are moving towards compliance with the Declaration of Helsinki.⁵ Their codes of conduct include ethical study-design considerations, post-trial access to drug candidates and provisions for offering compensation following serious adverse events.

Partnerships push newcomers into middle group

There is a large middle group of ten companies with varying performances across all parameters. AstraZeneca and Takeda have risen to the top of this group since 2012, and both engage in a substantial number of R&D partnerships. Merck & Co. follows, with little movement along its relevant pipeline since 2012. Sanofi has a large number of relevant investigational products. However, when engaging in product development partnerships, it falls behind when it comes to taking access into account.

Eisai, Bristol-Myers Squibb and Gilead also have large relative pipelines, but do not meet the same standards as the leaders for clinical trial conduct and transparency. Novo Nordisk has strong ethical codes of conduct and procedures in place for its clinical trials, yet a small relevant pipeline. Daiichi Sankyo and Bayer both provide evidence of

having access-oriented R&D partnerships, yet also have small relevant pipelines.

Laggards have smaller pipelines

Eli Lilly, Pfizer, Boehringer Ingelheim, Roche and Astellas occupy the bottom of the ranking. For these companies, only a small share of their pipelines target diseases and countries within the scope of the Index, and they provide little evidence of taking access into account during R&D. Boehringer Ingelheim stands out from the other laggards for rising two places since 2012.

Biggest risers: Takeda, Daiichi Sankyo, AstraZeneca

Takeda and AstraZeneca climb 11 and five places respectively. Both engage in numerous IP-sharing partnerships and incorporate access provisions into a large proportion of their R&D partnerships. Takeda is involved in a product development partnership with the Medicines for Malaria Venture that has reached the clinical stage of development. During the period of analysis, AstraZeneca shared IP with numerous partners through the WIPO Re:Search initiative.³ AstraZeneca and Takeda comply with the WHO's standards for registering trials and publishing results, and consider sharing patient-level data on a case-by-case basis.

Daiichi Sankyo has also risen considerably, from 18th to 11th place. This is partly because, for the first time, it disclosed to the Index the relevant investigational products it obtained via the acquisition of Ranbaxy. Daiichi Sankyo also shares proprietary compounds for testing via the Global Health Innovative Technology Fund (GHIT).

Furthest fallers: Roche, Eli Lilly, Sanofi

Roche and Eli Lilly both fall from the middle of the ranking to the bottom (falling nine and seven places, respectively) due to low scores across the board. In addition, relatively small proportions of their pipelines qualify for analysis.

Sanofi also dropped seven places, despite its large pipeline. It is less transparent than the leaders about the terms and conditions of its product-development partnerships, and it does not explicitly commit to including access-oriented terms. Additionally, it did not disclose its criteria for selecting third parties when outsourcing clinical trials. Sanofi was also pushed out of the top five and into the middle group by strong performances from Merck KGaA, AbbVie, AstraZeneca and Takeda.

INDUSTRY

Evidence of sustained commitment to R&D for relevant diseases

Large shares of companies' R&D pipelines target conditions covered by the Index – over 35% in several cases. In total, companies are developing 327 products that target diseases relevant to the Index. Most products in development target infectious diseases. Communicable diseases account for 47% of the pipeline, followed by non-communicable diseases (36%), neglected tropical diseases (13%), and maternal and neonatal health conditions (4%). It is promising that approximately 64% of all investigational products included in the Index 2014

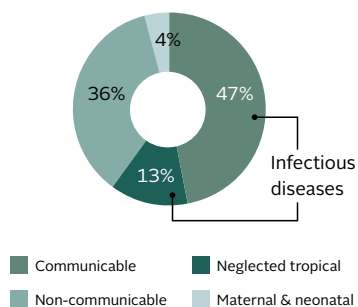
pipeline are medicines and vaccines being tested in clinical trials.

Since 2012, there has been a lot of movement in the industry pipeline, illustrating the industry's ongoing commitment to the development of innovative and adaptive products. Looking only at the scope of the 2012 Index, 42% of pipeline projects captured in 2014 are new. Most target communicable diseases, followed by non-communicable diseases. 33% of pipeline products captured by the 2014 Index were also captured in 2012.

Other projects have been discontinued since 2012, possibly due to compound failure or divestment. The proportion of the pipeline that is due to the expansion of the Index disease scope and pipeline inclusion criteria accounts for 25% of the industry pipeline.

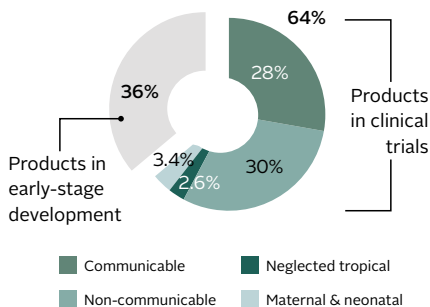
Most companies have also successfully moved products along the pipeline. Eleven companies have been granted regulatory approvals for 30 products, collectively covering 11 of the 47 conditions in scope.

Figure 26
Most products are being developed for infectious diseases



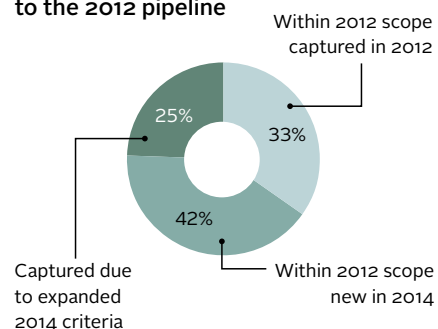
The majority of all R&D products are being developed for infectious diseases (communicable diseases and neglected tropical diseases combined), followed by non-communicable diseases.

Figure 27
Products in development, by disease category and phase



The majority of R&D products are in clinical trials, indicating that the risk of failure is relatively low.

Figure 28
Comparing the 2014 pipeline to the 2012 pipeline



The 2014 pipeline shows substantial movement compared to the 2012 pipeline. Many new projects have been newly added, while others qualify for inclusion this Index.

Companies generally take patients in relevant countries into account when developing products for communicable diseases and neglected tropical diseases. However, most struggled to demonstrate how innovative compounds for non-communicable diseases will reach these patients.

In total, 40% of products in this analysis are being developed in partnerships. The majority of companies engage in product development partnerships. For seven of them, this covers over 10% of their total pipelines. Companies are also collectively more transparent about the terms and conditions attached, revealing whether they contain pro-access provisions, such as price caps or non-exclusive licensing rights in specified territories.

Approximately 75% of companies are engaged in at least one partnership on access-oriented terms. Six companies have signed access-oriented agreements for more than half of all their relevant partnerships, including product development partnerships and IP-sharing partnerships. These typically involve publicly funded organisations, and mainly target malaria, tuberculosis or neglected tropical diseases. It remains unclear whether partnerships with privately funded organisations include access provisions, as companies remain bound by confidentiality agreements. Nevertheless, with so many companies agreeing to access provisions, there is certainly potential for them to move in this direction when engaging with private partners.

Most companies set high standards in their codes of conduct for clinical trials. Going further, almost one-third have ethical aspects from the Declaration of Helsinki⁵ in their codes of conduct. Codes of conduct generally apply to all trials, in-house and outsourced. However, for outsourced trials, only half of companies provided evidence of having robust auditing and monitoring procedures.

Since 2012, companies have improved significantly in sharing clinical trial data. Many companies have implemented systems for sharing patient-level data with trusted partners. The European Medicines Agency's new policy on data sharing has contributed to this trend.

Product development

R&D is mainly focused on five diseases

Why this matters

There is huge demand for R&D that targets the needs of people living in developing countries: both for new products for certain diseases, and for new versions of existing products that have been adapted for specific populations, different age groups and local conditions.

For each company, the Index determines what proportion of its entire R&D pipeline targets diseases within the scope of

the Index^b, firstly with new compounds and products, and secondly, with new versions of existing products, adapted to local populations and conditions. The Index also looks at how frequently the company drives products through the different phases of its R&D pipeline. It checks whether companies' R&D strategies take relevant health priorities into account and are supported by meaningful targets, sufficient investment and other resources.

All products that target communicable diseases and neglected tropical diseases are included in this analysis. For new products targeting non-communicable diseases and maternal and neonatal health conditions, however, the Index looks for additional evidence that companies specifically target R&D efforts towards people living in relevant countries, for example through registration targets or patent and pricing strategies.

How the companies perform

In total, the companies covered by the Index are developing 327 products that qualify for analysis, of which, some are being developed for multiple diseases. More than half of these (54%) target five diseases: diabetes, lower respiratory infections, hepatitis, HIV/AIDS and malaria.

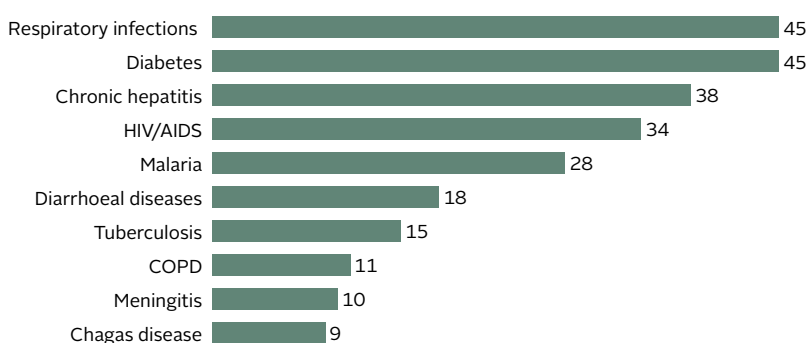
Since 2012, companies have gained regulatory approval for a variety of products targeting 11 diseases or conditions: diabetes, hepatitis, HIV/AIDS, lower respiratory infections, chronic obstructive pulmonary disorder, epilepsy, schizophrenia, meningitis, pertussis, tetanus and tuberculosis.

Companies devote large shares of their pipelines to meeting the needs of patients with diseases in scope and living in countries within scope. For some of the leaders, this reaches as much as 35% of the investigational products in their overall pipeline.

Looking closer, these relevant shares vary when it comes to how and where companies focus their efforts. AbbVie leads when it comes to developing new compounds and products, dedicating more than 25% of its overall pipeline to

Figure 29

Top 10 diseases targeted by the overall industry pipeline



Collectively, the industry is developing 327 products for diseases within scope, including all stages of development. More than half (54%) target the top 5 diseases.

this activity. Johnson & Johnson leads when it comes to adapting existing products, dedicating 25% of its overall pipeline to this. In general, within scope, more companies focus on developing new products than on adapting existing ones to meet local needs.

Comprehensive access-focused R&D strategies still not common

Most companies have an R&D strategy in place that, to an extent, targets diseases within scope. However, only

eight have an R&D strategy that specifically targets multiple disease areas and is supported by specific operationalisation strategies.

More than half of companies provided aggregate figures for their investments in R&D for diseases the Index covers. However, they calculate these figures in various ways. Without an industry-wide standard for such calculations, it remains difficult to assess how companies prioritise relevant R&D activities.

With greater transparency and standardisation, the wider R&D community would be better able to identify and target funding gaps.

Substantial R&D efforts for high-burden communicable diseases

Most companies are developing multiple products for communicable diseases, accounting for the largest proportion (47%) of products included in this analysis. Almost all of these products target just six conditions: HIV/AIDS, malaria, lower respiratory infections, diarrhoeal diseases, tuberculosis and meningitis. Of all products that target communicable diseases, 40% are in early-stage development (discovery and pre-clinical phases).

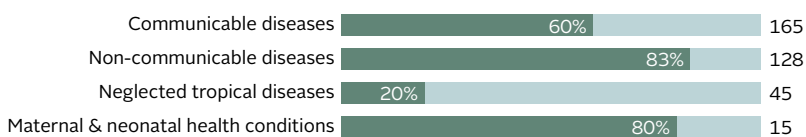
Non-communicable diseases lack implementation strategies

Most companies are also developing at least one product for a non-communicable disease. In total, 36% of all products included in this analysis target this group of diseases, 65% of which target diabetes and hepatitis, of which the latter is linked to cirrhosis of the liver. Conversely, osteoarthritis, epilepsy and nephritis and nephrosis receive little attention. However, for many innovative compounds that target non-communicable diseases, there is no clear strategy for ensuring that they will reach patients living in developing countries. Considering this gap, it is unsurprising that no company has registration commitments for countries within scope for products that target non-communicable diseases.^c

Three companies were able to demonstrate how their R&D efforts for schizophrenia, bipolar affective disorder and unipolar depressive disorders would be accessible to patients living in countries in scope, accounting for only 2% of the overall pipeline. This is of particular concern considering the high prevalence of these diseases globally and the general lack of understanding of local needs.

Figure 30

Proportion of products in clinical trials, by disease category



Compounds can be used for multiple diseases, referred to as multiple indications. Products captured by the Index are being tested for 353 indications in total.

■ Clinical trials (medicines & vaccines)
 ■ Early stage & technology development

Substantial early-stage development for neglected tropical diseases

Twelve companies are involved in product development for the most prevalent neglected tropical diseases (NTDs); in total, 13% of all products included in this analysis target NTDs and are mostly in early-stage development. Promisingly, this includes nine medicines and vaccines in the clinical stage of development that target dengue, rabies, Chagas disease and trypanosomiasis.

Pregnant women and newborns overlooked

Companies collectively are investing marginal efforts in maternal and neonatal health conditions. Only four companies are active in this area:

- Novartis is the only company that is developing products that target maternal sepsis, maternal haemorrhage and hypertensive disorders of pregnancy.
- Novartis and GSK are developing products specifically for neonatal health: to prevent prematurity and infections through maternal immunisation or by prolonging pregnancy.
- AbbVie is the only company that is developing a medicine that is intended to be administered to premature infants directly (for lower respiratory infections).
- Merck & Co. is developing contraceptives.

Demand for product development remains. Research and development of products adapted for pregnant women and neonates is needed in order to

reduce the enormous disease burden on these groups in low income and middle income countries.

Leaders: strong pipelines, clear strategies

The leaders in product development are Johnson & Johnson, AbbVie, Merck KGaA, Novartis, GSK and Sanofi. Their scores are very close to each other, and as a group, they distinguish themselves by dedicating large proportions of their R&D pipelines to patients with relevant diseases in relevant countries. Together, their six pipelines account for 57% of all relevant products being developed.

These strong pipelines are supported by R&D strategies that are clearly linked to global health priorities and supported by robust operationalisation schemes for achieving set targets. This includes having dedicated units that oversee product development for neglected diseases, engage in partnerships and define targets for registration and investment.

Except Novartis, these companies also specify aggregate amounts of R&D investments for most of the diseases covered by the Index.

Compared to other companies in the Index, Johnson & Johnson dedicates the largest share of its overall pipeline to adapting existing products to meet health needs in relevant countries. It also successfully drove the highest number of investigational products from one phase of the pipeline to the

next during the period of analysis, including gaining regulatory approval for HIV/AIDS, tuberculosis, diabetes and hepatitis medicines. Together, these factors push it into the lead in product development.

Close behind, AbbVie dedicates the largest share of its overall pipeline to developing innovative products that target diseases within the Index's scope. GSK, Sanofi and Novartis also dedicate large proportions of their pipelines to innovative R&D products.

Merck KGaA has fewer relevant investigational products than other leaders, yet they account for a significant proportion of its total pipeline. The company also publicly discloses its pipeline beyond the clinical phase, and it was the only company to specify its R&D investments for all diseases within the scope of the Index.

Novartis performs well across all parameters, and of all companies, it has the highest total number of relevant

products in its pipeline. However, it does not provide detailed information about its relevant R&D investments.

The middle group: large pipelines but weaker strategies

Following this group are Bristol-Myers Squibb, Gilead, Eisai, Merck & Co. and AstraZeneca. These five companies also dedicate large shares of their pipelines to developing relevant products. They have potential to strengthen their R&D strategies by including, for example, specific time-bound targets and operationalisation strategies. In addition, Gilead and Merck & Co. did not provide evidence of how much they invest in R&D for diseases within scope. Novo Nordisk, Bayer, Daiichi Sankyo, Takeda and Boehringer Ingelheim also fall into the middle pack, but dedicate smaller shares of their overall pipelines to diseases and countries in scope.

Both Boehringer Ingelheim and Takeda are developing strategies for ensuring that new products for non-communicable diseases (NCDs) reach patients in

relevant countries. As these strategies are not in place yet, most of their NCD products were excluded from this analysis. However, by implementing these strategies, these two companies have substantial potential to improve access to medicine for patients suffering from non-communicable diseases in developing countries.

Laggards have small relevant pipelines

Roche, Pfizer and Eli Lilly lag in product development. Relatively small proportions of their pipelines target diseases relevant to the Index. In addition, Eli Lilly provided little evidence of how its R&D efforts for non-communicable diseases target patients in relevant countries.

Astellas performs poorly in product development due to low disclosure across all parameters. However, it does demonstrate expertise in developing adapted formulations. For example, it is engaged in a partnership to develop a paediatric formulation for treating schistosomiasis.

BEST PRACTICE

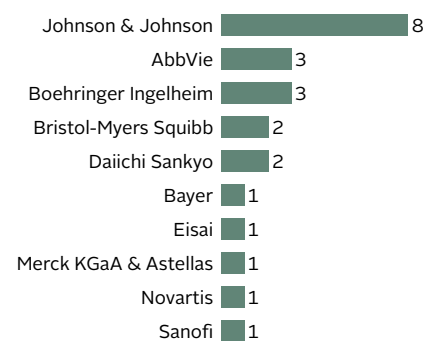
Johnson & Johnson – Adapting products for paediatric use

Children of different ages and weights need differing dosages and dosing forms (such as oral liquids) to ensure effectiveness, safety and compliance.

Of all companies, Johnson & Johnson is adapting the most products for paediatric use that target diseases within the scope of the Index. The company has a strong commitment to targeting unmet needs, and has separate departments for promoting the wellbeing of children: its Janssen Child Health Innovation Leadership Department (CHILD), Paediatric Center of Excellence, Paediatric Advisory Committee and members of its Compound Development teams. Johnson & Johnson is investing approximately USD70 million in 2014 to support paediatric projects of these groups.

- Johnson & Johnson has paediatric medicines in development for HIV/AIDS, hepatitis, diabetes, multi-drug-resistant tuberculosis and soil-transmitted helminthiasis.
- Since 2012, it has gained regulatory approval for a lower-dose tablet for HIV/AIDS and for treating adolescents with schizophrenia with one of its medicines.
- It worked in partnership to ensure its childhood vaccine for meningitis, pertussis, tetanus and hepatitis B could be used in a new delivery device developed for use in remote, resource-limited areas. The device is designed so that community health workers can use it with reduced risk of errors.

Figure 31
Johnson & Johnson is developing most medicines for children



11 companies are developing 23 medicines suited for children.

Partnerships & IP sharing

More R&D partnerships and increased transparency

Why this matters

In recent years, new partnership models have emerged that draw on both public and private funds to pool the risks of R&D and share the benefits.³ As these partnerships become more common, the impact of their terms and conditions on access will also grow.

The Index looks at how and when companies engage in collaborations,

and at whether the underlying R&D contracts include pro-access provisions including, for example, setting price caps, ensuring supply, waiving patent rights, royalty-free provisions and non-exclusive field or territory rights. The Index also examines whether companies have policies for systematically including access provisions while engaging in IP negotiations.

To accelerate early drug-discovery and development, companies can also share their compound libraries and expertise with external parties. The Index looks at whether companies engage in such IP-sharing partnerships to target diseases covered by the Index.

How the companies perform

Companies are developing almost 40% of their relevant products in partnerships. Most of these partnerships target communicable diseases (57%), followed by neglected tropical diseases (21%) and non-communicable diseases (19%). The six conditions targeted most frequently by partnerships are malaria, lower respiratory diseases, HIV/AIDS, hepatitis, diabetes and tuberculosis.

Six companies drive increase in partnerships

Compared with 2012, there has been a 35% increase in the number of relevant product development partnerships and IP-sharing partnerships.^d Nine companies now engage in more partnerships than they did in 2012, with six companies accounting for the majority of the increase; AstraZeneca, Daiichi Sankyo, Eisai, GSK, Novartis and Takeda each engaged in at least five more R&D partnerships than they did in 2012. Conversely, nine companies decreased their number of partnerships since 2012. This may be due to the failure of the compounds in question, to strategic choices or as a result of divestments.

Since the last Index, companies have dramatically increased their transparency around partnerships and their terms and conditions. Overall, more

than half of companies report basing one or more of their product development partnerships on access provisions. Together, these partnerships account for approximately 39% of all product development partnerships. Of the total pipeline, they account for 16% of all product development.

Public partners correlate with access provisions

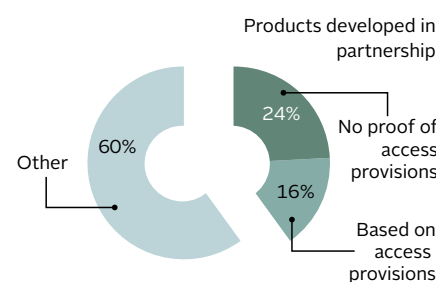
For most communicable diseases, most notably for HIV/AIDS and lower respiratory infections, companies engage with a mix of publicly and privately funded organisations. A large proportion of the private partnerships targeting communicable diseases focus on developing vaccines. Companies provide little evidence that these partnerships are based on access provisions.

For malaria and tuberculosis, companies typically engage in partnerships with publicly funded organisations based on access-oriented terms and conditions. This is also the case for the majority of partnerships targeting neglected tropical diseases.

For non-communicable diseases, there are far fewer partnerships, and companies engage exclusively with other privately funded organisations. Overall,

Figure 32

Almost half of all product development is collaborative



this type of partnership accounts for just 19% of all partnerships. This is to be expected as products for non-communicable diseases typically have functioning markets, at least in developed countries and in the private sector in low income and middle income countries. While this reduces the need for risk sharing via product-development partnerships, it does not guarantee that the resulting products are accessible to the poor or the public sector, especially considering they are often needed for chronic treatment.

Without the involvement of publicly funded organisations, companies are reluctant to disclose the underlying terms and conditions of their

partnership agreements, making it difficult to gauge the accessibility of resulting products.

Leaders agree to access provisions

The best-performing companies in partnerships and IP sharing are relatively transparent about the underlying terms and conditions of their R&D contracts, revealing that they regularly include access provisions. As a result, a large proportion of their partnerships are based on access-oriented terms. The leaders also engage in numerous IP-sharing collaborations.

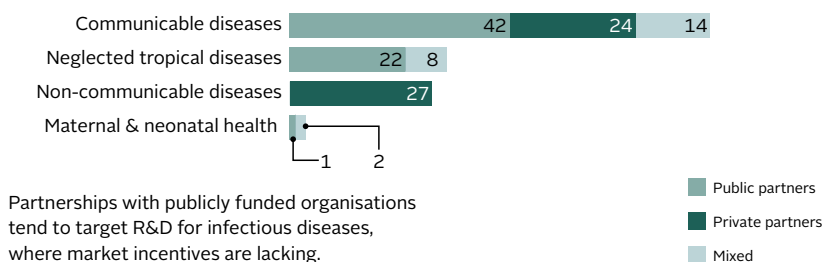
There are eight companies in the leading group: GSK, AbbVie, Merck KGaA, Takeda, Johnson & Johnson, AstraZeneca, Eisai and Novartis.

GSK and AbbVie both develop large proportions of their pipelines in collaboration, and are highly transparent about the related terms and conditions. GSK is the only company that systematically includes access provisions in research contracts for a range of diseases and countries: all projects at its Tres Cantos laboratory in Spain that target tuberculosis, malaria and neglected tropical diseases follow WIPO Re:Search principles, with royalty-free provisions applicable in Least Developed Countries and in materials-transfer or IP-transfer agreements. Other companies can improve by moving in this direction. No company provided evidence of systematically incorporating access provisions into its contracts for a wider range of diseases and countries.

When it comes to IP sharing, AstraZeneca and GSK provided many more external researchers with access to their compound libraries than other companies did. In January 2013, GSK placed information about potential hits for tuberculosis in the public domain, triggering many new research projects. During the period of analysis, AstraZeneca engaged in the most IP sharing through WIPO Re:Search.^a It withdrew from the initiative in September 2013. Seven other companies in the Index

Figure 33

Public partners correlate with greater transparency and access provisions



participate in WIPO Re:Search: GSK, Pfizer, Novartis, Sanofi, Merck & Co., Eisai and Merck KGaA.

Takeda performs well in partnerships and IP sharing, earning it a high position in R&D. It collaborates with three product development partners (PDPs): the TB Alliance, Medicines for Malaria Venture and the Drugs for Neglected Diseases initiative. Takeda is among the leaders when it comes to disclosing the terms and conditions of its partnerships: Takeda joins AbbVie, Merck KGaA, Johnson & Johnson and AstraZeneca in publicly disclosing the access provisions that underpin a number of its partnerships.

Johnson & Johnson, Eisai and Novartis also develop large shares of their overall pipelines in partnership, engage in IP-sharing partnerships and provide evidence of incorporating access provisions in the terms and conditions. However, they did not provide evidence of systematically applying access-oriented principles.

Lack of consistency from middle group

Merck & Co., Gilead, Pfizer, Daiichi Sankyo, Sanofi and Bayer all either develop large proportions of their pipelines in partnership, incorporate access provisions in R&D contracts or engage in numerous IP-sharing partnerships. None of these six companies do all three consistently, and compared with the leaders, they disclose less information about the terms and conditions of their R&D contracts. Merck & Co. stands out for implementing a policy

of systematically incorporating access provisions for certain diseases in its IP agreements.

Roche, Bristol-Myers Squibb and Astellas do not commit to incorporating access provisions, and perform less well in other areas. Roche does not engage in IP sharing, and Bristol-Myers Squibb and Astellas develop just small shares of their pipelines in partnership. Eli Lilly and Bristol-Myers Squibb disclosed only that they engage in public, access-oriented partnerships, instead of disclosing details of the terms and conditions.

The laggards: limited partnerships and less transparency

The laggards are Boehringer Ingelheim and Novo Nordisk. Boehringer Ingelheim reports that it engages in relevant partnerships, but does not disclose the terms and conditions. It also has a comparatively large focus on non-communicable diseases, where there are fewer partnerships and less transparency in general. Its potential lies in ensuring that its in-house developments will be accessible in relevant countries. Novo Nordisk did not report engaging in any relevant R&D partnerships. Drawing on its knowledge and expertise in diabetes care, the company could increase its impact on access to medicine by collaborating with partners with a greater understanding of local needs. Both companies have the potential to increase access to medicine by opening their compound libraries to external researchers looking for potential new hits.

GSK – Partnering for neonatal health

Drug development targeting neonatal health is scarce.

GSK is one of two companies that is developing medicines for neonatal health conditions. It is the only company working in partnership to develop products expressly meant for use in resource-limited settings. Via its partnership with Save the Children, GSK is developing products for neonatal health conditions with an initial focus on neonatal sepsis. Such partnerships enable companies to match their product development expertise with a partner's knowledge of issues on the ground.



^ Via its PRIME project, GSK trains frontline healthworkers and refurbishes health centers such as this one in DRC.

Clinical trial conduct & data transparency

Core group demonstrates higher ethical standards

Why this matters

Companies are responsible for ensuring that their clinical trials are conducted ethically and to high quality standards. When assessing companies in this regard, the Index refers to two documents: the ICH-GCP standards⁴ for good clinical practice and the Declaration of Helsinki⁵.

ICH-GCP was designed with quality assurance in mind and includes basic ethical considerations, such as procedures for gaining informed consent. The Declaration of Helsinki was designed to ensure patient safety and ethical trial conduct. Compared with ICH-GCP, it includes a larger proportion of ethical considerations.

The Index views compliance with ICH-GCP as a baseline for quality assurance, looking for codes of conduct and procedures for monitoring and auditing that align with its require-

ments. As the Declaration of Helsinki is the gold standard for trial ethics, the Index also assesses whether companies comply with that standard.

Increasingly, clinical trials are conducted in multiple locations and regions,⁶ in countries where regulatory oversight may be weak, and by third-party clinical research organisations (CROs). Working with CROs can save companies time and money while bringing local capacity and expertise on board. However, adding layers of management to global clinical trials raises questions about safety and quality.⁷ Oversight is crucial to prevent misconduct.⁸ The Index reports on companies' processes for monitoring compliance and for taking disciplinary action when necessary, for both in-house and outsourced trials. It also examines companies' criteria for selecting CROs.

By sharing patient-level clinical data, companies can improve the efficiency of product development, improve its cost-effectiveness, enable comparative analyses, and help prevent studies from being repeated unnecessarily.⁹ The industry, patients, healthcare professionals, regulators and the scientific community can all benefit if such data-sharing systems are implemented responsibly, with respect for commercial interests and data confidentiality.

In this regard, the Index looks at whether companies share patient-level data with external partners. The Index also measures companies against the standards set out in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards.¹⁰ These standards ensure clinical trials are registered centrally, and that their results are published, regardless of outcome.

How the companies perform

Companies generally set high standards for clinical trial conduct and transparency. All comply with ICH-GCP, with seven moving towards compliance with the Declaration of Helsinki (Novartis, Merck & Co., GSK, Merck KGaA, Eli Lilly, Novo Nordisk and Pfizer). These companies all incorporate two or more aspects of the Declaration of Helsinki into their codes of conduct: including ensuring participants can access experimental drugs post-trial; ethical study design considerations; and compensation in case of injury or other serious adverse events. For comparison, in 2012, multiple companies committed to adhering to ethical aspects of the Declaration of Helsinki, generally without providing specifics.

Novartis, Merck & Co., GSK, Boehringer Ingelheim and Johnson & Johnson are the only five companies that provided evidence of having systems in place for sharing patient-level data with external parties and they comply with the WHO standards for trial registration and publication of results. The Index views such developments as an important step forward for healthcare worldwide.

Signs of movement toward higher ethical standard

A few companies approach the higher standards looked for by the Index for enforcing ethical conduct in clinical trials. They provide evidence of extensive auditing and monitoring procedures for ensuring ICH-GCP compliance for both in-house and outsourced trials. They also have disciplinary procedures in place. However, they generally could not demonstrate how they implemented the ethical considerations they draw from the Declaration of Helsinki.

In 2012, the Index reported that only four companies provided evidence of having procedures for enforcing compliance in outsourced trials. In 2014, ten companies provided strong evidence of enforcing compliance through monitoring and auditing procedures for their trials, regardless of

whether they are conducted in-house or outsourced.

When trial results show that a new product is beneficial and safe, companies can provide trial participants with continued access to the study drug until the new product is on the market. While ten companies demonstrate commitment to such post-trial access, none provided evidence of having provided it in practice. The Index encourages companies to improve transparency concerning the implementation of their policies on post-trial access.

The leaders: systems for ensuring high standards of ethical conduct

Novartis, Merck & Co. and GSK lead in this area, with high transparency about their clinical trials and strong clinical trial codes of conduct.

Their clinical trial codes of conduct go beyond compliance with ICH-GCP to incorporate elements of the Declaration of Helsinki. Furthermore, when selecting CROs, they apply criteria designed to ensure quality assurance and quality control in line with ICH-GCP. In case of violations, these companies also have procedures in place for taking disciplinary action.

These top three companies comply with the standards set out by the WHO for registering trials and publishing results regardless of the outcome. In addition, they have systems in place for sharing patient-level clinical study reports (CSRs) with trusted third parties, such as academics.

GSK and Merck & Co. also provided detailed auditing and monitoring information that shows how they enforce ICH-GCP standards in their trials, whether in-house or outsourced. In addition, they provided evidence of having procedures for taking disciplinary action, also for both in-house and outsourced trials. Novartis, however, could extend its auditing and monitoring procedures to outsourced

trials, in order to improve its oversight of CROs.

Middle rankers slip on data transparency and the Declaration of Helsinki

There is a large middle group with high ethical standards for clinical trial conduct, yet varying performances across other parameters. Toward the top of this group are Merck KGaA, Eli Lilly, Novo Nordisk and Pfizer, which incorporate principles unique to the Declaration of Helsinki in their clinical trial codes of conduct. However, they have lower standards than the leaders when it comes to clinical trial data transparency. Following them, Boehringer Ingelheim, Johnson & Johnson, AstraZeneca and Takeda have codes of conduct that comply with ICH-GCP, but show levels of data transparency similar to that of the leaders.

Bayer, Roche and AbbVie all comply with ICH-GCP and have lower standards of clinical trial data transparency than leaders. Takeda, Roche and AbbVie could also be more transparent about their monitoring and auditing procedures.

Lower ethical standards at the bottom

Six companies lag when it comes to clinical trial conduct and transparency: Sanofi, Daiichi Sankyo, Bristol-Myers Squibb, Eisai, Astellas and Gilead. They all have codes of conduct that comply with ICH-GCP, but lack the level of clinical trial transparency of the leaders. In addition, they are missing either policies for taking disciplinary action or criteria for selecting CROs. Bristol-Myers Squibb and Sanofi stand out due to their data sharing policy, and Sanofi has robust oversight mechanisms that extend to CROs. Daiichi Sankyo stands out due to its procedures for selecting CROs and disciplinary action. Conversely, Bristol-Myers Squibb and Gilead can improve the transparency of their monitoring and auditing procedures.

OBSERVATION

Limited evidence of breaches

In general, the industry has endorsed and enforced ICH-GCP compliance as the baseline for clinical trial conduct. While this shows commitment, it doesn't give any indication as to how effective companies' policies, practices and codes of conduct actually are. To provide this, the Index checks whether companies are involved in lawsuits relating to clinical trial conduct in relevant countries or have been issued regulatory notices or fines. Investigations and legal processes can be very lengthy, so the Index reports on rulings and lawsuits from the past five years.

In countries in scope, evidence of breaches of codes of conduct and legislation is scarce and often limited to high-profile cases. It should be noted that the breaches captured by the Index are also a function of the nature and rigour of the various regional and national legal and regulatory frameworks. As such, fewer breaches are likely to be identified in countries with weak reporting systems and judicial controls.

Notices, lawsuits and fines

Two companies received notices from authorities that supervise ethical clinical trial conduct: Bayer and Sanofi. Both are related to clinical trials conducted in India.

- **Bayer** received a notice for not paying compensation following the deaths of clinical trial participants. Providing compensation due to serious adverse events is included in the Declaration of Helsinki. Bayer's code of conduct does not show evidence of these ethical aspects.
- **Sanofi** received a notice for not reporting safety issues that arose during an outsourced trial. Sanofi has mechanisms in place for enforcing ICH-GCP compliance for outsourced trials. This breach indicates that there is still room for misconduct even when enforcement mechanisms are in place.

One company was fined for a breach of clinical trial conduct:

- **GSK** was fined by an Argentinian court in January 2012 for not following procedures for securing informed consent in a trial of a pneumonia vaccine. The trial involved approximately 15,000 babies from

poor rural areas in Latin America, including Colombia. The fine totalled USD220,000.

Three companies are involved in ongoing lawsuits:

- **Merck & Co.** and **GSK** are both involved in a lawsuit in India concerning studies of their cervical cancer vaccines and whether the studies included adequate safety and efficacy tests. The studies were undertaken by PATH, an NGO.
- **Pfizer** is the subject of a lawsuit related to the Trovan trial that took place in Nigeria in 1996 under Wyeth (later acquired by Pfizer). The latest in a series of lawsuits relating to this trial, it relates to alleged breaches of the original settlement.

In addition to these notices, rulings and fines, there are numerous allegations of violations of ethical clinical trial standards, mainly involving study designs that include unethical placebo groups. However, for these cases, no lawsuits have been brought to date.

BEST PRACTICE

Eli Lilly and Daiichi Sankyo – Actively ensuring ethical study designs

The lack of strong regulatory oversight in countries such as India and South Africa creates an environment in which companies and CROs are left to decide whether clinical trial conduct is ethical or not. A few companies are attempting to standardise highly ethical clinical trial conduct by incorporating aspects of the Declaration of Helsinki into their codes of conduct.

Eli Lilly and Daiichi Sankyo go furthest, having put mechanisms in place to ensure study protocols and designs are ethical. Both have established committees for reviewing study protocols for both in-house and outsourced trials. For example, Eli Lilly's review committees routinely ensure that study protocols adhere to its standards and offer an internal consultation service on ethical study design and conduct.

INNOVATION

Innovation characterised by collaboration and partnership

With its high costs and high risks, the traditional R&D model has historically discouraged companies from developing products specifically for diseases that disproportionately affect patients living in developing countries. To fill the resulting gaps, new models for research and development are needed – models that facilitate R&D

efforts for high-burden diseases in these countries while rebalancing the risks and incentives for the companies that adopt them. The Index captures any innovative, sustainable or open business model that addresses current gaps in product development for diseases within the scope of the Index. To qualify for this analysis, these

models must explicitly target the needs of patients living in countries relevant to the Index. The Index also looks for innovative practices that improve the transparency of patient-level data or facilitate ethical clinical trial conduct in countries within the geographic scope of the Index.

Innovation in product development

GSK is investing GBP25 million (USD41 million) to establish its second Open Lab, which will focus on non-communicable diseases in Africa. These diseases are increasingly seen as the next potential public health crisis in developing countries. Research will aim to understand African variations in non-communicable disease types as well as specific treatment needs.¹¹

GHIT is a new multi-stakeholder collaboration co-established by four Japanese companies – Eisai, Takeda, Daiichi Sankyo and Astellas – together with the Japanese government and the Bill & Melinda Gates Foundation.¹² GHIT is a new funding mechanism that provides funding to three product development partnerships (PDPs): the TB Alliance, the Medicines for Malaria Venture and the Drugs for Neglected Diseases Initiative. Through GHIT, these four companies have significantly improved their contributions to R&D for neglected tropical diseases.

TransCelerate is a new joint initiative, launched in 2012, for accelerating and simplifying drug development processes through collaboration.¹³ Twelve of the companies measured by the Index are involved in TransCelerate, which could have an impact on access to medicine, for example, by making the processes related to clinical trials more efficient. The companies involved are: AbbVie, Astellas, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GSK, Johnson & Johnson, Merck KGaA, Pfizer, Roche and Sanofi.

Innovation in clinical trial conduct and transparency

Eli Lilly has developed a Bioethics Framework that proscribes a higher level of ethical clinical trial conduct than all other companies. It is the only company that supports its clinical trial code of conduct with mechanisms for enforcing the ethical behaviour provisions drawn from the Declaration of Helsinki.

Johnson & Johnson has worked with Yale University to establish an independent external review committee of academics to oversee the sharing of its patient-level data.

For numbered references, see the Appendix.

a WIPO Re:Search is a consortium that aims to build partnerships around companies' intellectual property assets and resources to advance the development of products for neglected tropical diseases, malaria and tuberculosis.

b See the Appendix for the full Access to Medicine Index 2014 Disease Scope.

c See chapter D Pricing, Manufacturing & Distribution.

d Comparison based on analysis criteria from 2012.

D Pricing, Manufacturing & Distribution

Pharmaceutical companies regularly come under pressure to lower their prices for patients living in developing countries, where medicine remains disproportionately out of reach for many. Yet reducing prices from mature-market levels does not guarantee affordability. Affordability depends on who is going to pay – whether it is the patient or another stakeholder in the local healthcare system. In low income countries, up to 90% of people pay for medicine out of their own pockets.¹ Different populations and groups have different incomes and expenses and it is important for pharmaceutical companies to recognise this when pricing their products.

In this chapter, the Index analyses how companies take patients' ability to pay into account when developing pricing, manufacturing and distribution strategies, reporting on: whether companies file for wide and rapid registration in relevant countries, according to need; how companies ensure products are priced equitably, particularly for the poorest population segments; and how companies' manufacturing and distribution practices help ensure quality and price are not compromised as products move along the supply chain (referring specifically to brochure and packaging adaptation, pricing guidelines for sales agents and policies and practices relating to drug recalls).

Methodology evolution in pricing

Following a careful methodology review, the Index no longer captures purely commercial tiered pricing strategies. Instead, it captures pricing strategies that explicitly take societal needs and affordability into account (referred to as 'equitable pricing strategies'). This includes tiered pricing that aims to ensure affordability for the poorest population segment, and single prices or discounts targeted at a specific payer or population segment. The Index only analyses strategies where companies provide a strong, detailed affordability rationale.

Top findings in Pricing, Manufacturing & Distribution

Companies consider affordability for one-third of all relevant marketed products

One-third of products captured by the 2014 Index are covered by equitable pricing strategies that include affordability rationales. This equals 230 out of 700 products captured. In turn, almost one-third of these products (74 out of 230) are targeted towards the poorest population segment.

Greater involvement in equitable pricing, particularly intra-country segmentation

Compared to 2012, more companies commit to or newly engage in equitable pricing, tailoring their prices to different population segments. Two companies have newly implemented inter-country equitable pricing. Yet, the improvement in intra-country equitable pricing is greater, albeit from a lower baseline: three companies newly commit to such strategies, while four have newly implemented them.

Six companies are innovating to improve affordability

Evidence of innovation included a micro-financing project, a differential pricing strategy with a clustered approach to segmentation, micro health-insurance products, quality monitoring in distribution, smaller-dose insulin products, and innovative production techniques, including a soft-chew tablet and semi-synthetic artemisinin production.

On average, products are registered in only a few relevant countries

Individual products are registered in an average of only three low income countries and six of the other countries in scope. Combined, this represents just 17% of the Index's entire geographic scope, and just 8% of low income countries in scope.

Companies lack universal pricing guidelines for sales agents

The majority of companies have yet to set clear, universal pricing guidelines for their sales agents in countries in scope, and most do not monitor mark-ups. Even where guidelines are in place, no company trains its agents on their implementation. No company has guidelines that universally apply to third-party distributors, wholesalers and retailers.

Companies implement stringent drug-recall policies and procedures

In general, the industry commits to consistently high standards in drug recalls: 14 companies have stringent policies on drug recalls that comply with WHO Good Manufacturing Practice (GMP) guidelines in all relevant countries. This is an improvement on 2012, when only three companies reported equivalent policies and country coverage, and a further seven reported policies that covered only some relevant countries.

How the companies perform

The pack is divided into four densely clustered groups, separated mainly by performances in two areas: equitable pricing strategies, and accounting for sales agents' pricing practices. Since 2012, more companies have implemented equitable pricing strategies, with more companies implementing multiple pricing tiers in specific countries.

Leaders target lowest tiers

The leading group comprises six companies: Gilead leads by some margin, followed by AbbVie, Novo Nordisk, Bayer, Johnson & Johnson and Merck & Co. Of these, AbbVie, Bayer and Merck & Co. have all joined this group since 2012, replacing GSK (now 7th) and Novartis (now 13th).

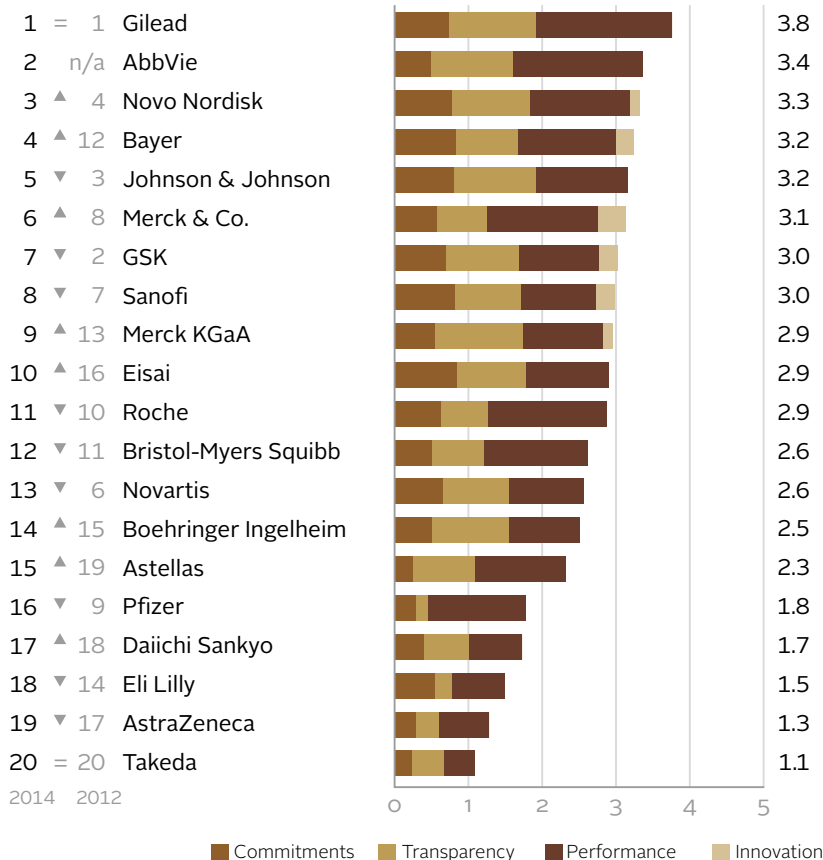
Gilead takes 1st place in this area for the second Index in a row, thanks to its leading performance in equitable pricing and strong performance in other key areas. The company commits to equitable pricing both between countries (inter-country) and within countries (intra-country) and has equitable pricing strategies in place that take affordability into account. Furthermore, by disclosing volumes of sales and price points for relevant products, Gilead indicates it is targeting lower-income population segments in an organised manner.

Gilead is also among the leaders for brochure and packaging adaptation, and issued no drug recalls during the period of analysis. In a change from 2012, Gilead now provides evidence of compliance with WHO GMP guidelines for drug recalls.

In 2nd place, AbbVie has both inter-country and intra-country equitable pricing strategies for its HIV/AIDS products in a large number of relevant

Figure 34

Company Ranking Pricing, Manufacturing & Distribution



countries. Its strategies include an affordability rationale and are targeted towards lower/lowest-income population segments, including preferential pricing for public health systems in some low income countries and lower-middle income countries.

Similarly, Novo Nordisk in 3rd place has both inter-country and intra-country equitable pricing strategies covering some of its diabetes products in the majority of relevant countries. Its strategies include an affordability rationale and are targeted towards the lowest tier. For example, under its differential pricing policy, the company has committed to offering insulin to Least

Developed Country governments at 20% of the price offered in developed markets.

Top six strong in all areas

The six leading companies generally perform strongly in all areas, although Johnson & Johnson is the only one to stand out when it comes to accountability for sales agents' pricing practices.

Regarding equitable pricing strategies, the leaders display varying levels of commitment to inter-country and intra-country equitable pricing. In practice, a relatively high proportion of their relevant products are covered by

equitable pricing strategies that take affordability into account, including for poor population segments. They also disclosed tracer product^a price points and volumes of sales to these population segments. Of the leaders, AbbVie and Merck & Co. join Gilead in issuing no drug recalls during the period of analysis. When drug recalls are required, all six leaders commit to complying with the relevant WHO guidelines.

Merck & Co., Bayer and Novo Nordisk are the only leaders to provide evidence of innovation in pricing, manufacturing and distribution: Merck & Co. leads in innovation due to a unique micro-financing project; Bayer is piloting a new differential pricing model; and Novo Nordisk sells single-cartridge packages of insulin to enable patients to spread the cost of treatment over time. Novo Nordisk has also reduced the unit price of a single vial to only 12% above the unit cost, and has started offering the accompanying insulin delivery device (durable pen) free of charge.^b

Large middle group

The upper-middle group consists of five companies: GSK, Sanofi, Merck KGaA, Eisai and Roche occupy positions 7 to 11. In general, these companies score above average for transparency, as well as for their commitments to inter-country and intra-country equitable pricing and to ensuring that product packaging and brochures are adapted to facilitate rational use.^c

Compared with the leaders, these five have more mixed performances, although they all stand out in one regard or another. GSK has refined its approach to vaccines pricing by increasing the number of pricing tiers. It now has seven tiers (the lowest tier corresponds to countries eligible for GAVI) and bases its tiers on GNI per capita. Sanofi has registered the majority of its products in the majority of relevant countries. Along with Gilead, Merck KGaA leads in new areas of evaluation: the disclosure of tracer

products' price points and of volumes of sales at the lowest pricing tiers for equitably priced products. Eisai has moved up six places since 2012, in part due to its new equitable pricing strategy. Roche is one of the leaders in product registration, having registered the majority of its products in relevant countries.

These five are followed by Bristol-Myers Squibb, Novartis, Boehringer Ingelheim and Astellas. Bristol-Myers Squibb delivers a strong equitable pricing performance in terms of the proportion of products and territories covered; how it takes affordability into account; and for targeting the lowest population segment. Novartis and Boehringer Ingelheim both perform well in disclosure, revealing tracer product price points, volumes of sales at the lowest pricing tier, and how they make registration decisions. Astellas has climbed into this group from 19th position, partly because it improved its disclosure of drug recalls and product registration status.

Laggards slip in all areas

The five lowest ranking companies are Pfizer, Daiichi Sankyo, Eli Lilly, Astra-Zeneca and Takeda. These companies have low scores across all measures. None of the laggards receives credit for innovation in this area.

Biggest risers: Bayer and Eisai

Bayer has risen the furthest, jumping from 12th to 4th position and into the leading group. Compared with 2012, Bayer has a more concrete, specific and comprehensive commitment to inter-country equitable pricing. In addition, it now facilitates the rational use of all its relevant products, rather than a subset, by adapting brochures and packaging. For the first time, Bayer has committed to registering some of its relevant products in low income countries, according to need. Bayer also performed well in one of the new areas of evaluation: it disclosed the volume of sales at the lowest pricing tier for each of its equitably priced products.

Eisai is another notable riser, climbing from 16th place to 10th. The company has performed particularly well in the area of commitments, overtaking all other companies in this regard. For example, compared with other companies, Eisai makes one of the most expansive commitments to equitable pricing: it commits to equitable pricing in relevant countries for all new relevant products going forward. Since 2012, it has newly implemented equitable pricing in one country within the scope of the Index.

Furthest fallers: Pfizer and Novartis

Pfizer and Novartis have dropped the furthest in this area, both falling seven places: Pfizer from 9th position to 16th, and Novartis from 6th to 13th.

For Pfizer, this is in part because it did not score well in new areas of evaluation, including disclosure of tracer price points, volume of sales at the lowest pricing tiers, and the level of targeting and affordability rationale included in its equitable pricing strategies.

Novartis has earned the same score as it did for the 2012 Index, but has dropped rank as other companies have improved their performances. In addition, although Novartis has increased the geographic coverage of equitable pricing, fewer of its products qualify for analysis due to the more stringent evaluation methods employed in the 2014 Index.

Greater diversity and greater involvement in equitable pricing

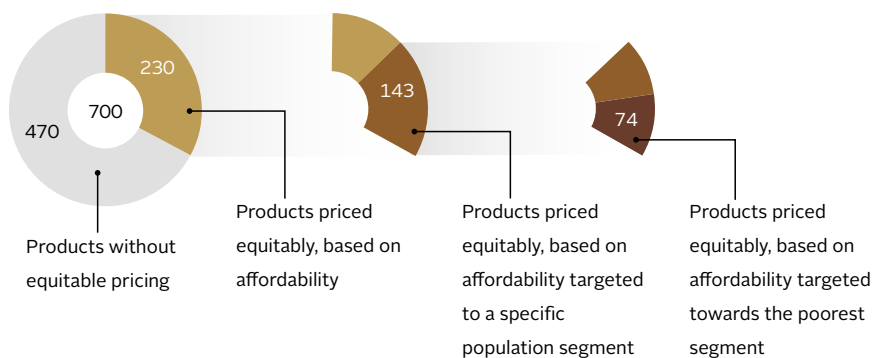
The industry continues to show diversity and greater involvement in the area of equitable pricing, manufacturing and distribution. Compared to 2012, the number of companies that implements equitable pricing has increased from 16 to 18.

Compared with 2012, more companies disclose stronger commitments to equitable pricing, and provide more detail about their equitable pricing strategies: three disclosed commitments to equitable pricing for the first time, while one other (Bayer) made a stronger, more specific commitment in this regard. Such commitments will be particularly relevant when new products enter the market. New areas of evaluation reveal that companies take affordability into account in most of the strategies they classify as equitable. A significant number of these strategies (32% of equitable pricing strategies) target poor population segments, within both low income and lower-middle income countries.

Regarding registration and stringent approval, the data indicate that there has been improvement (the scopes of the underlying indicators have changed since 2012). Fifteen companies now seek stringent approval from special regulatory schemes for the majority of their relevant products that target the diseases covered by these schemes. In addition, 16 companies now register the majority of their relevant products in a large number (>50%) of the countries covered by the Index.

11 companies (AbbVie, Bayer, Daiichi Sankyo, Eisai, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk, Sanofi and Takeda) demonstrate that they have specific targets to register products for certain diseases primarily based on disease burden or prevalence. The diseases in question include diabetes, HIV/AIDS,

Figure 35
Companies consider affordability for one-third of products^d



hypertension, ischaemic heart disease, cerebrovascular disease, lower respiratory infections, lymphatic filariasis, malaria and tuberculosis. Products for family planning are also included. Almost half of the companies, however, do not provide evidence that they have specific targets when making registration decisions.

More, more varied strategies

Compared with the 2012 Index, the 2014 Index has captured a larger number (309) and broader range of equitable pricing strategies for the countries within its scope. This reflects new areas of evaluation^e and the broader geographic scope of the 2014 Index.

In total, for the 2014 Index, companies reported 345 equitable pricing strategies for 263 products. All strategies were assessed to ensure that they did in fact meet the criteria set by the Index of an equitable pricing strategy. Out of these, 309 equitable pricing strategies included an affordability rationale and therefore qualified for our analysis. These covered 230 of the 700 products that qualified for analysis in the 2014 Index (33% of all relevant products).

In turn, almost one-third of these products are targeted towards the poorest population segment (when all marketed products analysed by the 2014 Index are taken into account, this amounts to 11%).

There is still significant room for companies to improve to ensure that existing equitable pricing strategies are targeted towards poor population segments. There is also potential for companies to broaden the application of equitable pricing: for 67% of relevant marketed products, companies do not provide evidence of having equitable pricing strategies in place.

Most strategies set prices per country

In total, 18 companies engage in equitable pricing. Yet there is huge diversity in the range and extent of their activities in this area.

- Companies have between one and more than 80 strategies each, which cover between one and more than 50 products (when each inter-country, intra-country, and other type of strategy is counted separately).
- Companies have equitable pricing strategies for between 8% and 85% of their relevant product portfolio (31% on average).

- Companies have equitable pricing for between 1% and 100% of the countries where they have sales and that are within the scope of the Index (62% on average).

Before analysis, we expected to find a strong positive correlation between the size of a company's portfolio and the number of products for which it has equitable pricing. However, on analysis of the six companies with the largest portfolios (more than 50 relevant products), only two had equitable pricing strategies covering the majority of their portfolios. These companies also had some of the highest proportions of products covered by equitable pricing strategies. The other four companies with large portfolios did not fit this pattern. They had equitable pricing for between 10% and 25% of their relevant portfolios.

Extent of equitable pricing, per portfolio

There is large variation in the coverage of equitable pricing strategies across company portfolios: 13 companies have such strategies for 1-10 products, three for 10-30 products and two for 30-60 products. This is in part due to diversity in company portfolio size. Compared to the 2012 Index, nine companies have increased the proportion of their portfolio for which they have equitable pricing strategies. However, companies of all sizes can still do more.

In 2012, most strategies took the form of inter-country tiered pricing schemes (which set one price per country or cluster of countries). In 2014, these strategies still account for the largest proportion: more than half of all equitable pricing strategies the Index captured were based on inter-country pricing tiers (51%).

Under these schemes, companies set different prices for different countries according to, for example:

- Income level, by GDP or GNI/capita, sometimes adjusted for PPP;
- Country classification by the World Bank, UN, GAVI, PAHO or similar;

- Factors such as disease prevalence, existence of licensing arrangements, level of healthcare or payer infrastructure and economic development; and
- Whether it is in sub-Saharan Africa (which is often treated as a special regional case).

Mixed strategies, which include both inter-country and intra-country segmentation, accounted for approximately 15% of all strategies captured. Strategies with only intra-country segmentation accounted for the smallest portion (6%). Combining these categories, strategies that incorporate intra-country tiers (21%) cover a diverse range of 23 diseases, the most significant being HIV/AIDS, diabetes and chronic obstructive pulmonary disorder.

Intra-country strategies target their pricing tiers to governments, public hospitals, and insurance schemes, as well as to patients directly. They take the form of direct discounts to governments and patients (including not-for-profit and below-cost recovery prices), competition for tenders, negotiations with governments to add products to the national reimbursement list, patient access programmes (including volume-based discounts and patient co-pay cards) and dual brands. In general, companies employ a mix of these strategies across their portfolios.

Innovation beyond pricing tiers

The Index also captured other types of strategies, which account for 28% of the total. Many of these represent innovation, and range from micro-financing; insurance-type initiatives; and financing for wholesalers; to patient-based programmes, which involve increasing patients' ability to pay, rather than reducing prices.

Strategies by disease category

Collectively, companies disclosed an almost equal number of strategies for products for communicable diseases as for non-communicable diseases, comprising 48% and 42% respectively

of all equitable strategies captured. HIV/AIDS has the highest number of equitable pricing strategies (33 out of 230 products) of all conditions within the scope of the Index. This is to be expected considering the large-scale donor financing available from institutions such as the Global Fund, PEPFAR, the World Bank and UNAIDS.

Far fewer strategies apply to products for neglected tropical diseases (3%). Again, to an extent, this is to be expected, as these products are most often the focus of mass-administration donation programmes that aim to eliminate the disease in question.

There are also very few strategies for products for maternal health problems and neonatal infections (7% of all strategies). This is partly because companies in the Index have very few products that target these conditions (7% of total relevant products on the market from all companies' portfolios), which in itself is a reflection of the low priority the industry has assigned to these high-burden conditions.

Gaps in equitable pricing activity

Many products can be used to treat multiple conditions. Taking this into account, the Index has examined per disease the proportion of relevant products that are marketed using equitable pricing strategies. For certain diseases, this reveals clear gaps in the coverage of equitable pricing activity.

Products for neglected tropical diseases are subject to the least equitable pricing activity as they are the focus of mass donation programmes. There is also a gap in pricing activity for non-communicable diseases, particularly for unipolar depressive disorder, schizophrenia, bipolar affective disorder, cerebrovascular disease, epilepsy, diabetes, ischaemic heart disease and lower respiratory infections. In addition, companies target the poorest people in a population with their lowest price tier in only 25% of their pricing strategies for non-communicable diseases. The Index

recognises that the need for a specific product in a specific country depends on multiple factors, such as disease prevalence, product patent status and alternative therapies. However, based on the growing burden of non-communicable diseases in developing countries, this gap is particularly concerning. It is important that companies increasingly ensure that relevant products are affordably priced.

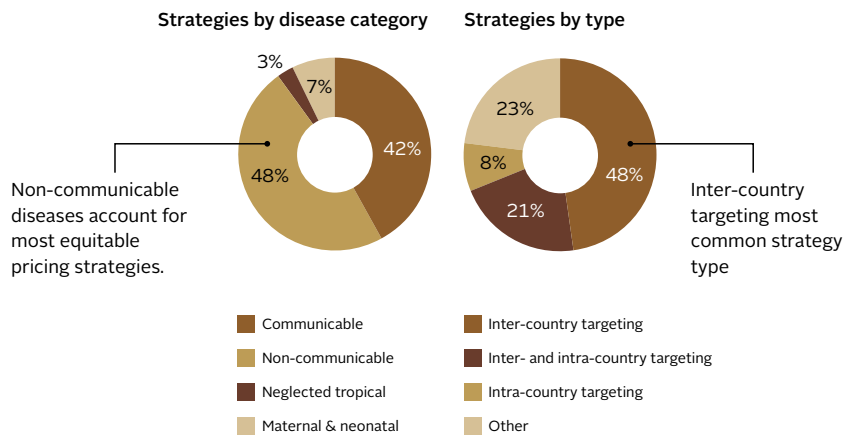
Looking downstream

The majority of companies (17) do not set universal pricing guidelines or provide training for local sales agents, including third-party wholesalers or distributors and retailers. Out of those 17, ten also do not audit or monitor downstream pricing practices.

The majority of companies with tiered pricing strategies adapt packaging for different tiers to prevent lower-priced variants being diverted away from low-income populations. Most companies also facilitate the rational use of certain products by adapting product brochures and packaging to conform with local regulatory requirements. A small group (Bayer, Bristol-Myers Squibb and Roche) go further than regulatory requirements and adapt their packages for specific high-need groups, to address demographic, environmental, language and literacy considerations.

In the area of drug recalls, the majority of companies issued drug recalls for relevant products in relevant countries during the period of analysis. In general, the industry commits to high standards in drug recalls: 14 companies have stringent policies on drug recalls that are either aligned or compliant with WHO Good Manufacturing Practices guidelines for drug recalls in all relevant countries.

Figure 36
Breakdown of equitable pricing strategies



'Targeting' is demonstrated where a company sets out how it segments a market and then implements its strategy based on an assessment of affordability for one or more population segments.

Figure 37
HIV/AIDS products have the most equitable pricing strategies

The top 10 diseases with the most equitable pricing strategies^f

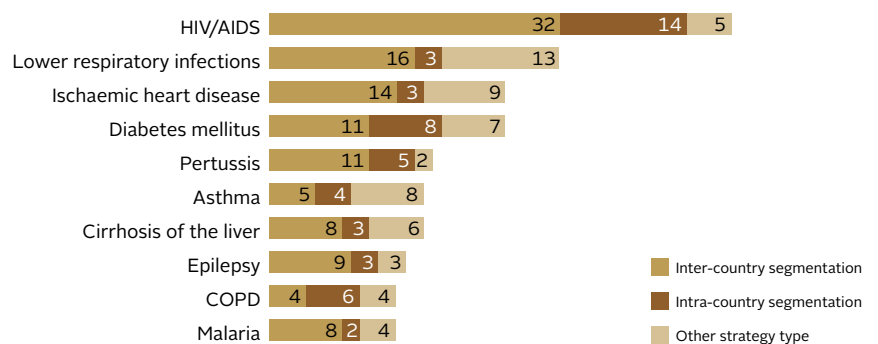
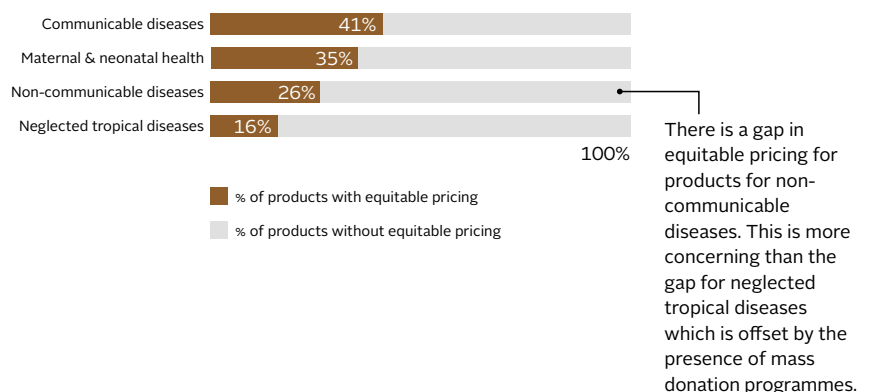


Figure 38
Gap in equitable pricing activity for non-communicable diseases



A new approach to analysing pricing strategies

In 2012, the Index analysed companies' tiered pricing strategies. Specifically, it looked at the proportion of each company's relevant portfolio that was sold via tiered pricing in the countries within scope. The Index also attempted to capture the difference between the price for mature markets and the price for the poorest markets. However, large differences between pricing tiers do not guarantee affordability.

Following a careful methodology review, the 2014 Index no longer captures purely commercial tiered pricing strategies. Instead, it captures pricing strategies that explicitly take societal needs and affordability into account (referred to as 'equitable pricing strategies'). This includes tiered pricing that explicitly aims to ensure affordability for the poorest population segment and single prices or discounts targeted at a specific payer or population segment.

The Index only analyses strategies where companies provide a strong, detailed affordability rationale, for example, for setting and targeting prices toward specific population segments, while taking account of their ability to pay. The Index recognises that companies can employ a range of approaches for the same product in different countries or for different population segments. It looks at how companies customise their strategies based on product and market characteristics and dynamics.

The application of the new methodology has shown that companies are willing to disclose supporting details of their equitable pricing strategies, including: affordability rationales, the poorest population segment targeted, price points for at least some products and volumes of sales at the lowest pricing tiers. Where companies did not clearly provide such detail, their

strategies could not be included in this analysis.

Socioeconomic factors drive equitable pricing strategies

The Index captures many different types of equitable pricing strategies, due to the diversity of products, diseases, countries and companies included in its scope of analysis. It analysed whether pricing strategies were comprehensive, and used price points and volumes of sales as evidence that companies are organised, targeted and deliberate when implementing equitable pricing strategies.

Based on this highly varied data, the Index finds that comprehensive equitable pricing strategies take multiple factors into account and

can be customised to the needs of target population groups in terms of affordability and other socioeconomic factors. Such strategies are the result of companies having deliberately and strategically taken affordability into account.

Table 3

Socioeconomic factors drive equitable pricing strategies To enable access for low-income groups, elements of a comprehensive equitable pricing strategy include:	
A clear set of criteria for determining the population segments to be targeted, including low-income groups (for example, income level, or human development indices)	Understanding of how unit and single-dose prices affect overall cost of treatment (for example, taking treatment duration into account)
Clear tactics for targeting low-income groups (for example, using discounts)	Comprehensive approach to improve health-seeking behaviours (for example, ensuring rational use, patient awareness programmes)
Robust assessment or calculation of affordability for low-income population segments (for example, by using multi-dimensional factors and engaging in affordability research into target segments)	Consideration of supply-side issues (for example, local manufacturing capabilities and ways to reduce cost of production)
Analysis of how price relates to ability to pay for people in specific groups (for example, considering probable mark-ups and reimbursements)	Measures for preventing product diversion from target populations

Product registration and filing for marketing approval

Per-product registration limited to a few countries**Why this matters**

Registration is the first step in making a new product available in a particular country. The Index looks for companies to file for wide and rapid registration in relevant countries, according to need.

Companies can facilitate registration, particularly in countries without strong national regulatory authorities, by applying for stringent approvals, for example (for certain products) WHO

Prequalification, tentative approval from the US Food & Drug Administration or review by the European Medicines Agency. The Index examines whether and how companies follow these steps, and looks at the criteria used to decide where to register products. The Index also captures whether companies have disease-specific, time-bound targets for registering new products in sub-Saharan Africa, low

income countries and/or lower-middle income countries.

As a measure of performance, the Index identifies where companies have registered their products relative to the geographic scope of the Index and disease occurrence. It also identifies what proportion of each company's relevant portfolio has been registered in relevant countries.

How the companies perform

Most companies have applied for stringent approvals for the majority of their relevant products. Since 2012, 13 companies have strengthened or expanded their commitments to registering products in relevant countries. Of these, nine have either made their commitments more specific, or expanded them to include more disease areas. Two companies have newly disclosed commitments where previously they provided none; Roche has improved the timeframe within which it has committed to registering its products in relevant countries, and Novartis has provided a more specific geographic commitment for Africa.

In practice, 16 companies have registered more than 50% of their products in more than 50% of relevant countries. However, four still have not. This could be for a variety of reasons: for example, there may be generic equivalents already on the market, or targeted diseases may not be widely prevalent.

Where are products registered?

On average, companies have registered 76% of their products in at least one country within the scope of the Index.

However, individual products are registered in an average of only three low income countries (8% of all relevant low income countries) and only six of the other relevant countries (9% of countries).

The need for registration is related to disease prevalence and the presence or lack of generic and alternative therapies. For most of the products the 2014 Index captures, this registration need is high. The industry can scale up its efforts to register relevant products in countries in need.

Companies have the potential to improve in this regard, particularly in terms of setting more targets that are more specific, as well as more timeframes for registering their products in countries where need is highest.

Leaders have comprehensive, detailed registration strategies

The best performances in this area come from Novo Nordisk and Roche. Both companies have a comprehensive strategy for registering new products, and provide details of their decision-making criteria. These include needs-based criteria such as epidemiology and disease burden. They have both

set specific targets for registering most of their products for relevant diseases within 12 months of receiving EU approval in relevant low income and lower-middle income countries. To speed up registration, both companies have applied for approval from a stringent regulatory authority for all relevant products.

Furthermore, Novo Nordisk and Roche have disclosed the registration status of the majority of their products, revealing that both companies have registered the majority of their products (relative to overall portfolio size) in the majority of relevant countries.

Bayer, GSK, Johnson & Johnson and Sanofi also perform well in this aspect. These four companies have registered the majority of their products in the majority of relevant countries. They have also provided details of their registration decision-making process and criteria, and have applied for stringent approvals for the majority of their relevant products. They have all committed to registering a sub-set of products for relevant diseases in a subset of low income countries. However, they have not specified a timeframe.

Middle performers' commitments are less specific, less ambitious

Beyond these six companies, performances are more mixed, with companies generally only registering their relevant products in a subset of countries within the Index's scope. In general, although companies commit to registering their products in relevant countries, they do not report specific targets. Their performances are mixed regarding the disclosure of registration criteria and product-level registration status. At the time of data collection, Eisai is the only company that provides no evidence of having registered relevant products in any low income country (although it has done so in certain lower-middle income countries).

Commitments to registration are particularly relevant as they give an indication of companies' intentions to ensure the accessibility of new products in low-income markets.

Lack of commitments from laggards, despite registration activity

The weakest performances in this area come from Eli Lilly and Takeda. In general, these two companies show little commitment to registering their products in relevant countries. Eli Lilly's commitment is limited to lower-middle income countries. Takeda does commit to registering products in a sub-set of low income countries, including sub-Saharan Africa, but has not yet set a specific timeframe. Neither of these companies publicly discloses its decision-making process or criteria for registration, nor do they provide clear evidence of using access-related criteria for making product registration decisions.

In practice, Eli Lilly and Takeda do provide evidence that they register relevant products in countries within the Index's scope. Eli Lilly provides the registration status of all of its relevant products, revealing that they are registered in some low income countries and lower-middle income countries. Takeda provides the registration status for some of its

products, which are registered in a few low income and lower-middle income countries. However, this is a relatively small proportion of relevant countries compared to their peers.

Neither company has filed for stringent approvals, despite having at least two eligible products.

OBSERVATION

Setting timeframes for registration

By setting and disclosing clear timeframes for registration, companies give a clear signal that they plan to make new products available and accessible in certain countries.

3 companies

Novo Nordisk, Roche, Gilead

Novo Nordisk says it aims to provide national authorities in Index countries with its marketing authorisation applications for newly launched products within 12 months of gaining EU approval.

Roche commits to filing for registration in all countries within the scope of the Index within six months of gaining EU or Swiss approval. Its locally based representatives assess the need for registration based on epidemiology, disease burden, market access and available infrastructure. The company uses these assessments to plan and prioritise countries for registration.

Gilead reports that its goal is to register new products in relevant countries as fast as practicably possible. This includes registering new products approved by the FDA or EMA in as many relevant countries as possible within 12 months. It prioritises countries for registration using a tiered approach based on disease prevalence.

OBSERVATION

Basing registration decisions on need and disease burden

Companies base their registration decisions on a wide range of factors. Encouragingly, many companies take patient need and disease burden into account to some extent, as well as health systems and socioeconomic conditions of the countries in question.

8 companies

Bayer, GSK, Johnson & Johnson, AstraZeneca, Boehringer Ingelheim, Merck KGaA, Novartis, Sanofi

Bayer uses the following criteria for its registration strategy: market-size, potential customer base, ease of registration, market attractiveness and access, target price and affordability, highest disease burden, and geographic importance of disease in different countries (for malaria, tuberculosis and contraceptive products).

GSK bases decisions to register products on an assessment of patient needs, the quality of local health systems (i.e., whether patients can be diagnosed and treated), the existence of a regulatory system, and whether, during development, GSK conducted related clinical studies in that country.

Johnson & Johnson prioritises registration decisions based upon high-disease burden, disease prevalence, quality of local healthcare infrastructure, maturity of treatment programmes, the existence of global and/or multilateral programmes, economic vulnerability, and immediate patient need. Prior to the launch of a compound in resource-limited countries, Johnson & Johnson assesses whether a specific access programme is needed.

AstraZeneca generally employs the same regulatory strategy for countries within the scope of the Index as for other emerging and developing countries. Where appropriate, it bases

registration decisions on an assessment of unmet needs.

Boehringer Ingelheim bases its strategy on whether there is a public health need identified by, for example, governments or organisations such as the WHO, UNICEF or UNAIDS, as well as the state of infrastructure in countries in scope.

Merck KGaA evaluates medical need for individual products based on absolute and relative prevalence, diagnosis and treatment rates, and high-risk factors or sub-groups.

Novartis bases decisions on the needs of local health authorities and level of infrastructure including for distribution.

Sanofi bases decisions on unmet medical needs and engages in early registration programmes, focusing on products that have existing approval in other countries.

FOCUS AREA 2

Equitable pricing strategies

More companies tailor equitable pricing strategies to specific groups

Why this matters

Equitable pricing strategies that target specific population segments can help overcome local and global inequalities. Pharmaceutical companies can play a major role here, as they determine and influence the price of medicine along key sections of the supply chain, whether they sell their products to the public or private sectors. Such strategies may comprise tiered pricing schemes, which stipulate different prices for different countries or population segments. They also can take affordability into account by other means, such as by offering volume-based discounts, patient-assistance cards and targeted discounts. The Index recognises that setting the end-price is often beyond the control of the company. Nevertheless, the prices set by companies are important determinants here.

How we measure

In this analysis of equitable pricing strategies, the Index looks at how companies employ equitable pricing strategies for diseases and countries that fall within the scope of the Index. It is important to note that the standards for evaluation have changed since the 2012 Index:

Standards for inclusion: The 2014 analysis included more types of strategies, including tenders, and single-product, single-country discounts, in addition to

conventional inter-country and intra-country equitable tiered pricing.

Standards for exclusion: Pricing strategies that lack evidence of a clear affordability rationale, and/or are not clearly and specifically targeted towards a relevant (low-income) population segment were excluded.

The Index reports on:

- **Inter-country and intra-country equitable pricing**
The Index measures whether companies commit to equitable pricing strategies, either inter-country or intra-country. The Index matches the breadth of each company's commitment against its total geographic reach and relevant portfolio relative to the scope of the Index.
- **The reach of equitable pricing, per company;**
As a measure of performance, the Index also assesses where each company has equitable pricing strategies in place, relative to its entire relevant portfolio and geographic reach.
- **How equitable pricing strategies take affordability into account**
Per company, the Index examines the rationales that underpin these strategies, looking at: proportion of strategies that take affordability into account in general terms; what

factors are included in affordability assessments; and whether strategies target specific population segments or the poorest segment explicitly.

- **Volume of sales at the lowest tier**
For each equitable pricing strategy, the Index asks companies to disclose the volume of sales at the lowest pricing tier of its pricing structure. The proportion of equitable pricing strategies for which a company can provide this information is a measure of its focus on this tier.
- **Price points for tracer products**
The Index also asks companies to disclose price points for a maximum of ten products called tracer products. It does not compare companies based on the price points themselves, only on their disclosure, for the period of analysis (2012 and 2013). This information provides evidence that companies are targeting the lowest tiers in practice.

Although these metrics do not reveal whether products are affordable on the ground, they enable the Index to assess the extent of companies' pricing strategies, and how they are being implemented.

All data on pricing is provided under a blanket non-disclosure agreement and cannot be published or otherwise made available.

How the companies perform

More companies are implementing more equitable pricing strategies in relevant countries for products that target relevant diseases. A total of 18 companies now report having at least one equitable pricing strategy. In 2012, 16 companies reported having at least one tiered pricing scheme.

Increased focus on intra-country tiers

When it comes to inter-country pricing, two companies have newly implemented such strategies: AstraZeneca and Eisai. When it comes to intra-country pricing, the improvement is greater. Four companies have newly implemented them: Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, Merck KGaA. Astellas is the only company not to provide evidence of either committing to or implementing equitable pricing strategies for relevant products.

Across the industry, companies are employing varied and changing pricing strategies for a diverse range of products and countries, and which contain a large variety of methods and mechanisms for taking account of affordability for the poorest population segments.

Evidence of innovation

Companies are also employing novel strategies. For example, several are attempting to add more pricing tiers to target their strategies more toward specific population segments, and are using more relevant factors to define these tiers. Companies are also finding ways of helping patients spread the cost of medicines, either through insurance schemes or by changing the unit size of certain products. Micro-financing is being employed in certain countries in partnership with other stakeholders.

Companies have scope for improvement in the area of equitable pricing, particularly regarding the disease areas they target, proportion of products covered, level of segmentation and

range of countries for which companies have equitable pricing strategies.

A lack of data, a lack of control

When it comes to defining pricing strategies, one size does not fit all – not for products, diseases, geographies nor healthcare systems. Pricing strategies should ideally reflect local conditions and the needs of local communities. In addition, to ensure that medicines reach target populations at target prices, strategies need processes for monitoring mark-ups and for preventing product diversion between tiers.

However, devising such pricing structures and monitoring processes requires data on patients' ability to pay, which are unavailable in many Least Developed Countries. This makes it difficult for companies to appropriately segment their markets. Despite these difficulties, almost all companies are applying segmented pricing in an effort to ensure their products are priced equitably.

Seven companies deliver good performances

The best performance in this area comes from Gilead. The company commits to both inter-country and intra-country equitable pricing. It already has equitable pricing strategies in place that cover some products and the majority of its relevant geographic reach. In general, these strategies take affordability into account using multiple factors, including disease prevalence. For one of its HIV/AIDS and one of its hepatitis B products, Gilead states that the lowest pricing tier covers only production costs and includes no profit margin in a considerable number of countries.

Gilead has fully disclosed its volumes of sales to its lowest pricing tiers for its equitably priced products, as well as the price points for a set of tracer products. Based on these data, and, to an extent, on the fact that it is actively collected, it seems that Gilead is implementing

Figure 39

6 companies have newly implemented inter- or intra-country equitable pricing strategies since 2012

	New strategy
AstraZeneca	inter
Boehringer Ingelheim	intra
Bristol-Myers Squibb	intra
Eisai	inter
Gilead	intra
Merck KGaA	intra

its equitable pricing strategies in an organised manner, including targeting lower-income population segments.

Following Gilead, six other companies deliver good performances: Johnson & Johnson, Novo Nordisk, Bristol-Myers Squibb, AbbVie, GSK and Eisai. These companies have made specific commitments to implementing equitable pricing strategies for the majority of their products in the majority of relevant countries, specifying differing combinations of disease areas and geographic regions.

Going beyond commitments, all of these companies' equitable pricing strategies take affordability into account, including for the poorest population segments. Apart from Eisai, they all have equitable pricing strategies for either the majority of their relevant products or the majority of their relevant geographic areas, and not necessarily for both the majority of products and geographic areas.

As an indication of implementation, all six companies provide some data on their relevant sales volumes, and most also disclose price points for a set of tracer products.

Limited or no strategies from laggards

There are four companies that lag in this area: Astellas, Pfizer, AstraZeneca and Takeda.

Although Pfizer and AstraZeneca both have equitable pricing strategies in place, they only provide evidence that they cover a limited range of relevant countries, and do not provide evidence of targeting the poorest segments of local populations. Furthermore, these companies disclose only limited data about relevant sales volumes, and no tracer product price points. Since 2012, AstraZeneca has implemented inter-country equitable pricing.

Astellas and Takeda have no equitable pricing strategies for any of their relevant products or relevant countries. Since 2012, however, Takeda has made a general commitment broadening access to its products via intra-country equitable pricing. It provides some evidence that it does so for products outside of the scope of the Index in relevant countries.

Astellas remains the only company that has neither committed to nor provided evidence of implementing an equitable pricing strategy within the scope of the Index.

OBSERVATION

Commitments to equitable pricing strategies

Two companies have new commitments to equitable pricing strategies. Sanofi uses equitable pricing for leishmaniasis and schizophrenia.

Sanofi is the only company to provide evidence of using equitable pricing strategies to market products for leishmaniasis and is one of the few to have equitable pricing strategies for schizophrenia (newly in scope).

- Meglamine (Glucantime®) for leishmaniasis: Sanofi charges a single, fixed, low price of USD1.20 for a 5ml ampoule (excluding local taxes and shipping costs) in all low income and middle income countries, including in Latin America, the Middle East, Africa and Asia.
- Chlorpromazine (Largactil®) for schizophrenia: Sanofi applies intra-country segmentation in low income and middle income countries, charging a preferential price to Ministries of Health compared with that for customers from the private sector.

Eisai has a new Global Pricing Policy that applies to all new products and uses both inter-country and intra-country segmentation to set prices in different markets. Based on an analysis of Eisai's late-stage R&D pipeline, this policy can be expected to influence access to medicine in the following disease areas in the short-to-medium term: cirrhosis of the liver, epilepsy and Chagas disease.

Bayer has developed a new differential pricing framework, which is currently in the pilot phase. Its rationale for pricing differentiation is based on a combination of access objectives and commercial objectives. Based on the outcomes of the pilots, Bayer intends to roll out this model in additional countries.

✓ A child in Brazil is treated for leishmaniasis. Sanofi is the only company to use equitable pricing for this disease.



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Brochure and packaging adaptation

Little packaging adaptation – and little momentum

Why this matters

Packaging or brochure adaptation can help ensure medicine is taken correctly, and even by the right person.² For example, the directions for use may be re-written in a local language or for an appropriate literacy level. Adaptations can also help ensure lower-priced variants are not diverted from the low-income patients targeted and sold to wealthier patients able to pay more.

In this section, the Index examines whether brochures and packaging information comply with requirements set by the national drug regulatory authorities. It also asks whether companies go beyond these minimum standards by implementing additional adaptations that target specific local populations.

The Index also reports on whether companies use different packaging for each pricing tier or country, to help prevent product diversion (focusing on products that are both on the 2013 WHO Model Essential Medicines List (EML) and have equitable tiered pricing strategies).³

How the companies perform

There is still room for improvement in this area of analysis, both regarding adaptations to prevent product diversion and to ensure rational use.

The analysis reveals that, for several diseases with many marketed products, companies are adapting packaging for less than 50% of products in order to align with local regulatory

requirements. In total, the brochures and packaging for 37% of all products included in this analysis have not been adapted to facilitate rational use in relevant countries. Regarding product diversion, eight companies are showing the way ahead, routinely adapting brochures and packaging materials for a wide range of products and countries.

All 20 companies can, as a minimum, follow local regulatory requirements for ensuring the rational use of all their products on the market. Ten companies follow regulatory requirements for all products, three of which go beyond local requirements for populations in need. A further five follow local regulatory requirements for the majority of products, while three do so for a subset

Figure 40
Adapting packaging can minimise the risks associated with improper use⁶

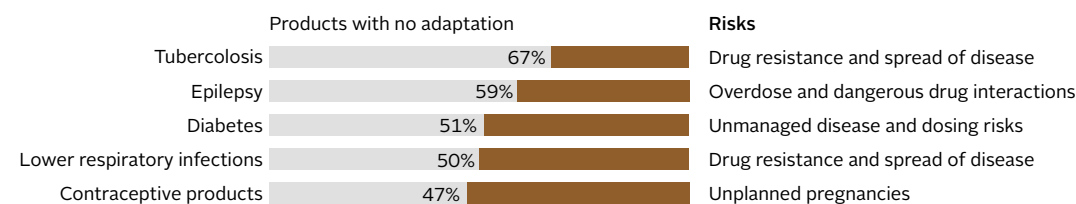
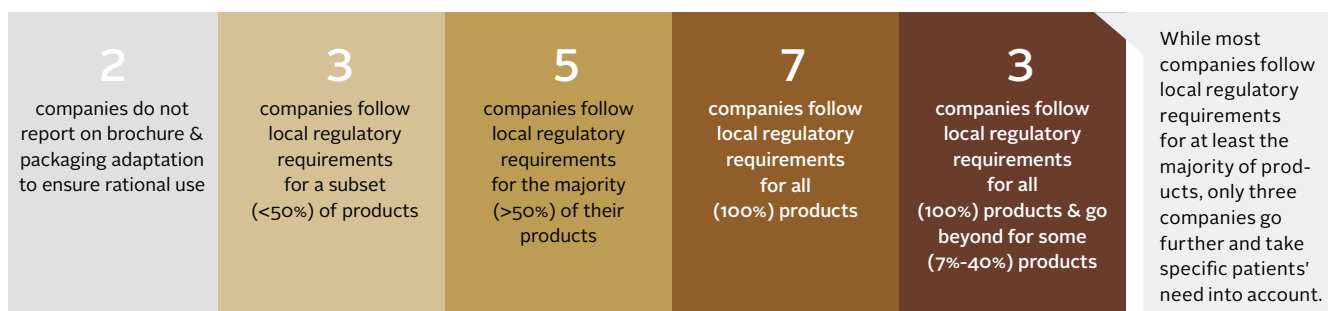


Figure 41
Three companies take specific patients' needs into account



Accountability for sales agents' pricing practices

Broad lack of universal pricing guidelines

Why this matters

Whatever prices companies charge, other parties affect the price patients pay. Their mark-ups can have a significant effect on the product's affordability. Although companies have some ability to influence mark-ups, this is limited by the number of steps between them and the patient, and by local laws and regulations that guard against price fixing.

For example, in countries where there is a free market for medicines, it is

not possible for companies to legally control the resale price charged by distributors. In regulated markets, prices are monitored by governmental authorities, and maximum retail prices are set by regulation. Nevertheless, companies can still provide their sales agents with pricing guidelines, and monitor and audit compliance with these guidelines, other contractual obligations and applicable local laws.

The Index examines whether companies issue sales agents in relevant countries with pricing guidelines, and whether these guidelines also apply to third-party distributors, wholesalers and retailers. The Index also looks for processes and mechanisms including for monitoring mark-ups and sales agents' training, and for auditing sales agents' pricing practices.

How the companies perform

This is generally a low-scoring area. More than half of the companies have dropped in performance due to stricter scoring requirements: pricing guidelines are now only seen by the Index as a baseline for performance.

A lack of attention

The majority of companies have yet to set clear and universal pricing guidelines for their sales agents. Most do not monitor the pricing practices their agents employ. Even where guidelines are in place, no company trains its sales agents on how to implement them. Only a few companies monitor mark-ups. No company has guidelines that universally apply to third-party distributors, wholesalers and retailers. Where companies do issue guidelines and monitor pricing practices, practices vary between companies and types of countries. In part, this is due to differences between supply chains and legal requirements in different countries.

Signs of positive movement

Sanofi satisfies the most criteria here, with widespread use of pricing guidelines for its sales agents. In a change from 2012, it now also

provides evidence and details of global monitoring processes and auditing mechanisms. Johnson & Johnson comes close to this performance: it also has pricing guidelines in place, but audits and monitors compliance to a less specific degree.

Since 2012, Eisai, Astellas and one other company have gone from having no pricing guidelines to having general guidelines in place.

There are opportunities for improvement in this area for uniformly setting pricing guidelines and implementing monitoring and auditing processes for all relevant products' supply chains at national levels (within the limits of companies' influence). In countries where local regulation requires/allows it, companies can set recommended maximum retail prices to control mark-ups. They can also contractually agree on certain provisions and requirements, with distributors, against which companies can monitor and audit performance.

Drug-recall policies and practices

Drug-recall policies consistently meet high standards

Why this matters

Companies are responsible for ensuring products meet high quality standards. When sub-standard products do reach the shelves, the company that produced them must swiftly and effectively recall them and remove them from the market.

The Index views drug recalls as evidence that quality-management

systems are not functioning optimally, and captures evidence of recalls of products targeting diseases in scope, in countries in scope. It looks for companies to commit to drug-recall standards, and to implement stringent drug-recall policies and procedures aligned with WHO Good Manufacturing Practice (GMP) guidelines. The Index

asks whether companies track products, as this can facilitate effective recalls. To raise awareness of potential risks, it also expects companies to publicly disclose where, when and why a drug recall has taken place for both packaging-related and product-quality issues.

How the companies perform

In general, the industry commits to consistently high standards in drug recalls: fourteen companies have stringent policies on drug recalls in all relevant countries. This is an improvement: in 2012, three companies reported equivalent policies and country coverage, and a further seven reported policies with narrower coverage.

In 2014, four companies (Boehringer Ingelheim, Merck & Co., Eli Lilly and Sanofi) provided evidence of tracking products and complying with WHO GMP standards in all relevant countries where their products are available: they provided details of decision-making processes and procedures for investigating and responding to complaints. Only two others (Merck KGaA and Roche) reported product-tracking systems or mechanisms for effective recalls.

Most companies issued product recalls in the last two years, more than 70 in total: twelve companies were involved in recalls related to product-quality issues; one to a packaging-related recall. Seven companies issued no relevant recalls during the period of analysis: Eisai, Gilead, Merck KGaA, AbbVie, Merck & Co., Roche and Pfizer. For five of these (Pfizer, Merck KGaA, Merck & Co., Eisai and Roche), this is an improvement since 2012, when they did issue recalls.

Leaders: no recalls; strict guidelines

The leaders in this area are Eisai and Gilead. Neither has recalled relevant products in relevant countries during the period of analysis. Both have committed to publicly disclosing the details of recalls, should they occur. Eisai and Gilead both apply guidelines for drug recalls in all relevant countries

where their products are available. However, neither has processes for tracking products.

Merck KGaA, AbbVie and Merck & Co. follow close behind. None issued a relevant product recall in the past two years. Merck & Co. and Merck KGaA also have drug-recall guidelines and product-tracking procedures.

Laggards: no public disclosure

Daiichi Sankyo and Bristol-Myers Squibb deliver the weakest performances in this area. Not only did they both issue relevant product recalls during the past two years, they also provided limited evidence compared to peers on the extent to which they comply with WHO GMP guidelines. They do not publicly disclose recalls.

BEST PRACTICE

Eli Lilly – Tracking batches to facilitate recalls

Product recalls must be carried out swiftly and effectively to ensure that unsafe products are removed from the market.

Eli Lilly has an Enterprise Resource Planning (ERP) software to track all

transactions involving its products worldwide. At the time of writing, the company was finalising a module that would enable it to pull relevant information from the ERP software in a timely manner. The intended system is expected to promote a significantly

more efficient recall and market-withdrawal response time.

AbbVie has an IT system in place and Merck KGaA is putting in place an IT system for tracking and monitoring shipments to relevant countries.

INNOVATION

Diversification in innovation on supply and demand sides

By innovating in pricing, manufacturing and distribution, companies have real scope to bring more products at more affordable prices to more people. The Index looks for innovative ways of simultaneously addressing demand- and supply-side issues that affect

Innovation in equitable pricing

Merck & Co. has piloted an initiative in India that combines reduced cost of treatment with a micro-financing option. Called Project Sambhav, the initiative supports patients with no or limited insurance coverage in accessing its hepatitis C medicine and is now under expansion to 11 cities across four Indian states.

Bayer is currently piloting a new differential pricing model that can be considered innovative and unique in the sector. Under this strategy, Bayer bases pricing decisions on a comparatively comprehensive combination of criteria that include assessing local needs and affordability. The company has defined different clusters, based on market type and product type, each with a distinct objective and strategic intent. The rationale for price differentiation is based on a combination of access objectives and commercial objectives.

GSK has entered into a three-year partnership with Barclays with the aim of increasing access to affordable health-care and medicines in Zambia. Interventions and pilots include affordable financing for wholesalers and distributors who are willing to pass savings on to patients, and the development of an around a dollar-a-month micro-health-

pricing; and for new and more efficient technologies, processes or production techniques for manufacturing or distributing products to increase affordability and/or reduce cost without compromising quality.

insurance product that patients can maintain via mobile phone top-ups. The partnership is in an early stage and is planned to run for three years.

Innovation in manufacturing and distribution

Merck & Co. is developing an innovative soft-chew tablet. Because soft-chew tablets can be taken without water, patients do not need access to a clean water supply. In addition, they can be produced using simple formulations and a simple manufacturing process, which reduces manufacturing costs and potentially increases affordability. Merck & Co. has spent approximately USD90,000 on process equipment.

Sanofi has established a large-scale production line for semi-synthetic artemisinin in Italy. It has been established through Sanofi's partnership with PATH and in affiliation with OneWorld Health (both NGOs active in global health). Artemisinin is used to treat malaria, and the botanical supply of this compound is inconsistent. The new large-scale product line will significantly strengthen the artemisinin supply chain, contribute to a more stable price, and ultimately ensure greater availability of treatment. Sanofi

Six companies received credit for innovation in this area in the 2014 Index: Merck & Co. earns the most points, followed by Bayer, GSK, Sanofi, Merck KGaA and Novo Nordisk. Compared with 2012, innovative practices in this area are now more diversified.

plans to produce 50 to 60 tons of artemisinin on the new line each year, starting in 2014. This corresponds to 80-150 million treatments.

Merck KGaA uses heat and humidity sensors to monitor the transportation conditions of all its products shipped from Europe to the rest of world (in its "Temptation Project"). It uses the data collected in a centralised system to ensure product quality, and improve transport routes.

Novo Nordisk has tested the viability of single-dose products for people living in low income countries. The programme began in 2011, with Pakistan as the first pilot country. For use with devices, insulin is normally sold in packs of five cartridges, each containing 300 IU. Novo Nordisk assessed the barriers to access to insulin in Pakistan and began selling its insulin Penfill® cartridges in single-cartridge packages. This enabled patients to spread the cost of treatment over time, making it more affordable. Novo Nordisk also reduced the cartridge unit price to 12% above the unit cost of the vials needed for the vial-and-syringe insulin delivery method. Novo Nordisk also began offering its insulin delivery device (durable pen) free of charge.

For numbered references, see the Appendix.

a Companies were asked for price points for up to ten products that account for highest sales revenue in countries in scope for which equitable pricing strategies are available. These are referred to as tracer products.

b It is not known how long Novo Nordisk will continue to provide the pen free of charge.

c 'Rational use' entails patients receiving the appropriate medicine in the proper dose, for an adequate period of time, and at a cost that is affordable to them and their community.

d 'Targeting' is demonstrated where a company sets out how it segments a market and then implements its strategy based on an assessment of affordability for one or more population segments.

e The 2014 Index measured all equitable pricing strategies, rather than only tiered pricing strategies (as was measured in 2012).

f This graph captures the number of strategies per disease. Each product may have multiple strategies.

g This chart shows the percentage of products without packaging adaptation out of all products captured by the 2014 Index for these 5 diseases.

E Patents & Licensing

One of the more polarising debates in access to medicine relates to patents and centres on whether intellectual property protection stimulates innovation or unduly stifles competition. Where products remain on patent, companies benefit from monopoly rights and, in turn, reduced competition, which can limit access to affordable medicine. There is no guarantee that patent-holders will take low income patients into account when setting prices.

Companies can limit the impact of patent monopolies on low income patients by applying a nuanced approach to IP management and taking steps that support the entry of generic medicine manufacturers. They can refrain from patenting or from enforcing existing patents in certain territories. They can ensure they register products where they are needed. Where generic medicine markets are absent, they can modify prices to stimulate market creation. Where there is market potential, they can enter pro-access licensing arrangements. They can also provide an overview of where patents are active and where they will be enforced (which would support both generic medicine manufacturers and procurement agencies), and disclose whether licensing agreements exist, as well as their terms and conditions.

The ability of a company to pursue certain IP strategies depends on its portfolio and range of on-patent products. Nevertheless, companies with few or no relevant on-patent products can still take a range of actions to support competition from generic medicine manufacturers. For example, they can publicly disclose whether and where patents have expired; denounce patenting tactics designed to extend monopolies; and indicate what their IP approach will be to medicines in their pipelines.

In this chapter, the Index addresses a series of questions about how company approaches to IP-management enable competition from generic medicine manufacturers:

- 1 Do companies pledge not to file or enforce patents in relevant countries?
- 2 Do companies publicly disclose patent status?
- 3 Which companies pledge to engage in licensing or issue formal non-assert declarations?
- 4 How do companies compare in licensing behaviour?
- 5 Which companies are transparent and use access-friendly terms in licence agreements?
- 6 Do companies engage with external brokers?
- 7 How do companies support the TRIPS agreement?

Top findings in Patents & Licensing

Limited support for pro-access IP law, undermined by private policy positions

Publicly, companies generally give only qualified support to the flexibilities intended to protect public health set out in the internationally agreed intellectual property framework (TRIPS).¹

However, even this cautious public stance is undermined by evidence of efforts to lobby against these flexibilities in private.

Early signs that licensing can be expanded to more diseases

The overwhelming majority (93%) of licences identified remain related to antiretrovirals (ARVs) for HIV/AIDS. However, there are early signs that some companies are making steps toward expanding voluntary licensing practices beyond this disease, for example to cytomegalovirus and hepatitis C.

Pro-access licensing agreements increase in number

Since 2012, two more companies have entered licensing arrangements for products for diseases in scope, bringing the total to eight. The Index captured evidence of almost 250 licences relating to diseases in scope. Compared to 2012, a larger proportion of licences include pro-access terms and are publicly available. Innovation is also apparent, with the Medicines Patent Pool playing a key role: for example in the use of tiered royalties in middle income countries.

How the companies perform

Overall, company performance is low in Patents & Licensing. Despite this, a small group of companies exhibit leading performance in licensing practice, including some striking examples of innovation for reaching more middle income countries.

Leaders show innovation, openness, and balance

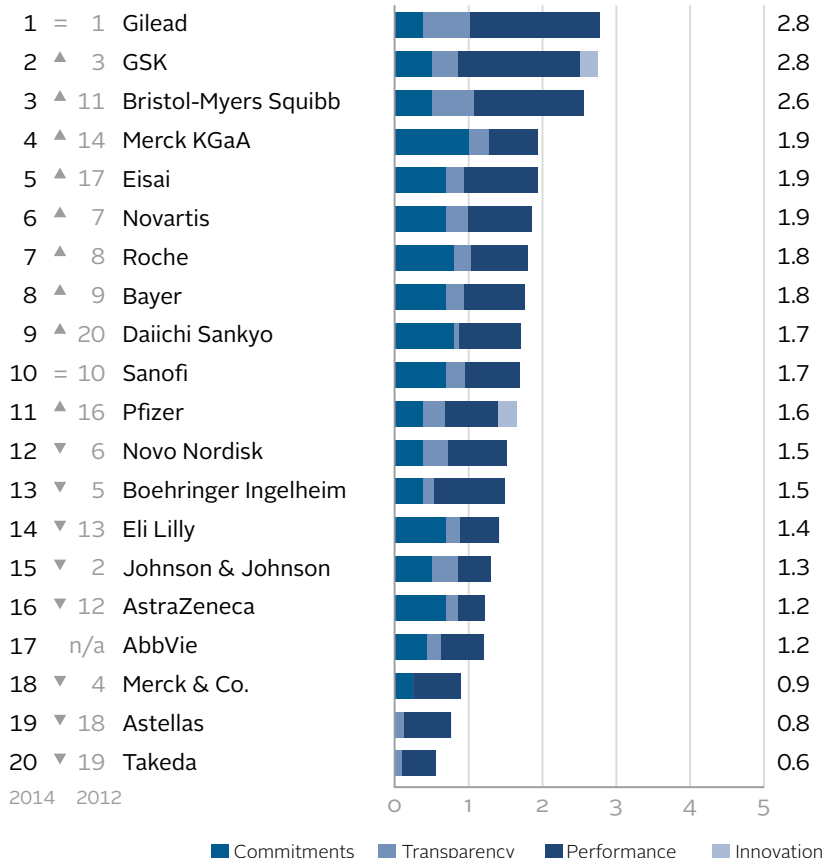
Gilead and GSK lead within this chapter. These companies commit to taking a more balanced approach to IP management, and acknowledge the pressing need for companies to explore new ways of using licensing to improve access to medicine for low income people in middle income countries.

Both companies have patented products that target relevant diseases in relevant countries, and have engaged in voluntary licensing to facilitate the production of generic versions of a comparatively high percentage of them (Gilead: 80%, GSK: 28%).

Both companies engage in licensing bilaterally and through the Medicines Patent Pool. Agreements under the latter cover the broadest geographic scope and include the largest degree of flexibility for licensees. GSK's ViiV Healthcare licences, which also involve Pfizer and were brokered by the Medicines Patent Pool, stand out here. Importantly, both companies have also licensed very new HIV/AIDS medicines with comparatively long patent terms remaining. Gilead, showing best practice, also includes a pipeline ARV in its licensing commitment.

As part of these negotiations, both Gilead and GSK agreed to the terms and conditions of the agreements brokered through the Medicines Patent Pool being published on the MPP's website.

Figure 42
Company Ranking Patents & Licensing



Gilead and GSK both publicly state their support for the TRIPS agreement and Doha Declaration, acknowledging the right of countries to limit patent protection in order to improve access to medicine for their populations. Importantly, the leaders' behaviour appears to be in accord with their public policy positions – with some of their licences, they permit supply to countries that issue compulsory licences.

These two companies could perform better still by further specifying their commitment to engaging in licensing, and whether, how and where they pledge not to file or enforce patents.

Gilead's and GSK's performance in this area is not only a reflection of their readiness to engage in licensing, but also of the number of relevant patented products in their portfolios and of the availability of licensees. Not all companies are able to engage in licensing on the same scale.

Ranking 3rd, Bristol-Myers Squibb also belongs with the leaders. It pledges to refrain from filing or enforcing patents, albeit in a limited range of countries and for a limited range of products. It also engages in licensing agreements for some relevant products. The terms of its agreements brokered by the Medicines Patent Pool are publicly

available, include access-friendly conditions and cover a broader range of countries.

Merck KGaA has climbed ten places to fourth position by demonstrating good practice in other areas: its commitment not to seek or enforce patents covers the widest range of countries among its peers, and it pledges to consider licensing across the widest range of potential products and countries, including both communicable and non-communicable conditions within the scope of its commitment. Merck KGaA also stands out for being the only company to commit to publishing its global patent statuses (which had indeed been made available at the time of writing on the company's website). Merck KGaA is also among the ten companies that have more progressive attitudes towards the TRIPS agreement and the Doha Declaration.

Middle group delivers mixed results

Compared to Gilead, GSK and Bristol-Myers Squibb, the middle pack of companies deliver more mixed performances. Sanofi, for example, which remains in tenth place, has a considered policy on patenting that takes account of the Human Development Index of the country concerned. However, it makes

a limited commitment to disclosing patent status, and only gives qualified support to the TRIPS flexibilities.

Boehringer Ingelheim, in 13th place, discloses limited information about its patenting strategy, but there is supporting evidence that it has issued non-assert declarations in practice (on request), which have been actively used by generic medicine manufacturers. However, the product relating to these declarations is no longer on patent, and the company's transparency concerning the detail of these declarations is limited to disclosure to the Index (as well as to the manufacturers that made the original request). This limits the value of the non-assert declarations for other stakeholders. Similarly, Novo Nordisk, in 12th place, makes a comparatively clear commitment concerning where it patents, but does not make a clear commitment to considering licensing.

Eisai and Daiichi Sankyo are significant risers within this chapter. While this can, in part, be attributed to the application of neutral scoring in some indicators,^a these two companies have shown strong performance in certain areas in 2014. Daiichi Sankyo, for example, has an enhanced commitment

to refrain from patenting in certain groups of countries. Eisai has a clear public stance against evergreening. Neither of these companies were identified as being involved in any IP-related anti-competitive practice.

Laggards lack clear commitment

Astellas and Takeda occupy the bottom positions. Although Astellas and Takeda have relevant patented products, they do not make the same level of commitment to refraining from seeking or enforcing patents in relevant countries. Neither do they commit to engaging in licensing. They take a comparatively conservative stance on the flexibilities set out in the TRIPS agreement.

Johnson & Johnson and Merck & Co. have both dropped substantially since 2012. They both exhibit low levels of disclosure and have weaker policies on patenting in countries of interest to the Index. Although they both engage in voluntary licensing, they do so proportionally less than their peers, and are opaque about the terms of engagement. In addition, they pledge limited support for the flexibilities set out in the TRIPS agreement, which is complicated further by evidence of lobbying.

INDUSTRY

Conservative attitude remains, but movement in licensing

Since 2012, company behaviour has remained static across most areas of investigation. In many areas, companies are maintaining their conservative attitude, particularly when it comes to disclosing patent status in relevant countries. Yet there is some evidence that companies are taking a more considered approach to intellectual property management as it relates to access to medicine.

Notable movement, for example, occurs in licensing: since 2012, companies have agreed to significantly more, and more progressive, licensing agree-

ments, particularly those negotiated with the Medicines Patent Pool.

Of 16 companies that are arguably in a position to issue voluntary licences, eight now provide evidence of doing so – an increase of two since the 2012 Index. The 2014 Index found evidence of almost 250 licences in total. Companies provide more evidence of developing novel licensing strategies, of considering licensing products for conditions other than HIV/AIDs, and of moving into a wider range of countries with different levels of development.

As mentioned, the most novel of these arrangements the Index analysed were negotiated with the Medicines Patent Pool. These include some groundbreaking arrangements that extend favourable licensing terms to more middle income countries in new ways. They also include products with significant patent terms remaining, as well as ones that are still in company pipelines.

Such advances demonstrate that companies are able to manage their intellectual property rights in ways that support access to medicine. In the context of licensing, for example, it

supports the view that patents can be seen as tools that enable their owners to more confidently share intellectual capital with external parties.

Most companies are also involved to some extent in technology transfer. Exceptions include Merck & Co., which does not disclose any information in this regard, while Roche and Boehringer Ingelheim indicated that they had not engaged in technology transfer.

Of those companies with relevant patents in force, the leaders (Gilead and GSK) not only clearly commit to considering licensing, but also issue them in practice, and across a relatively large proportion of their patented products. Importantly, they share the details of the licences publicly, and include access-friendly terms and conditions. The leaders are also prepared to engage with neutral brokers to facilitate licence negotiations. Only one such broker is currently in operation: the Medicines Patent Pool.

Based on an analysis of the licences available for examination, those negotiated via the Medicines Patent Pool provide licensees with the highest level of flexibility and broadest geographic scope.

Limited disclosure

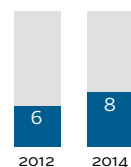
Disclosure remains limited across the board. Over the reporting period, there was no significant improvement compared with equivalent performances in 2012: there was no evidence of companies voluntarily publishing the status of patents in countries within the scope of the Index. Notably, following the end of the reporting period, Merck KGaA disclosed its global patent statuses. This will be taken into account in future Indices.

There is more movement in disclosure around licensing, with some companies sharing greater detail of their bilateral licensing arrangements with the Index and others going further still by publishing complete licences agreed via a third party (the Medicines Patent Pool).

Companies continue to give limited support to the flexibilities afforded to countries in the TRIPS/Doha international framework of IP legislation. Where companies do voice support for these provisions, their words are in general at odds with their behaviour, as many companies continue to attempt to influence the application of those flexibilities in practice. During the period of analysis, most companies

Figure 43

More companies are engaging in voluntary licensing



Out of 20 companies, 16 companies in 2014 have on-patent products within Index scope. 8 now provide evidence of engaging in voluntary licensing for such products, up from 6 in 2012.

were linked via their membership of South African pharmaceutical trade association IPASA to proposals for influencing intellectual property law reform.

Investigating seven key questions

All companies can approach intellectual property in a manner more supportive of access, whether or not they have on-patent products. In the following sections, the Index addresses a series of questions aimed at revealing where companies take a pro-access approach, and where they remain conservative:

- 1 Do companies pledge not to file or enforce patents in relevant countries?
- 2 Do companies publicly disclose patent status?
- 3 Which companies pledge to engage in licensing or issue formal non-assert declarations?
- 4 How do companies compare in licensing behaviour?
- 5 Which companies are transparent and use access-friendly terms in licence agreements?
- 6 Do companies engage with external brokers?
- 7 How do companies support the TRIPS agreement?

ANALYSIS 1

Do companies pledge not to file or enforce patents in relevant countries?

As a baseline, the Index expects companies to refrain from patenting in countries designated by the UN as Least Developed Countries. Internationally agreed guidelines have granted these countries exemptions from protecting patents until at least 2021.² The Index also examines whether companies go beyond this to publicly commit to refrain from patenting in a broader range of countries, including low- and lower middle-income countries.

The 2014 Index identified a wide range of attitudes towards filing and enforcing patents in relevant countries.

Roche and Merck KGaA stand out here: they are the only companies with relevant patented products that pledge not to file or enforce patents in any Least Developed Country, any low income country and most lower-middle income countries.

Variable approaches to patent filing

Two companies have improved their stances since the 2012 Index: AstraZeneca and Daiichi Sankyo.

AstraZeneca previously stated that it would enforce patents in Least Developed Countries. Both now specifically commit to refrain from filing or enforcing patents in certain countries.

Companies that take a more conservative approach to filing and enforcing patents also have relevant products on patent in a subset of countries of interest to the Index. How these companies apply either licensing or pricing strategies to facilitate access is important when analysing their support for access to medicine in general.

Four further companies commit not to file or enforce patents in Least Developed Countries and a subset of low income countries for all products relevant to the Index: AstraZeneca, Bayer, Eli Lilly and Novartis. Eisai, Novo Nordisk and Merck & Co.'s equivalent commitments cover the Least Developed Countries.

Sanofi's commitment in this regard is tied to whether or not a country has a low Human Development Index and it

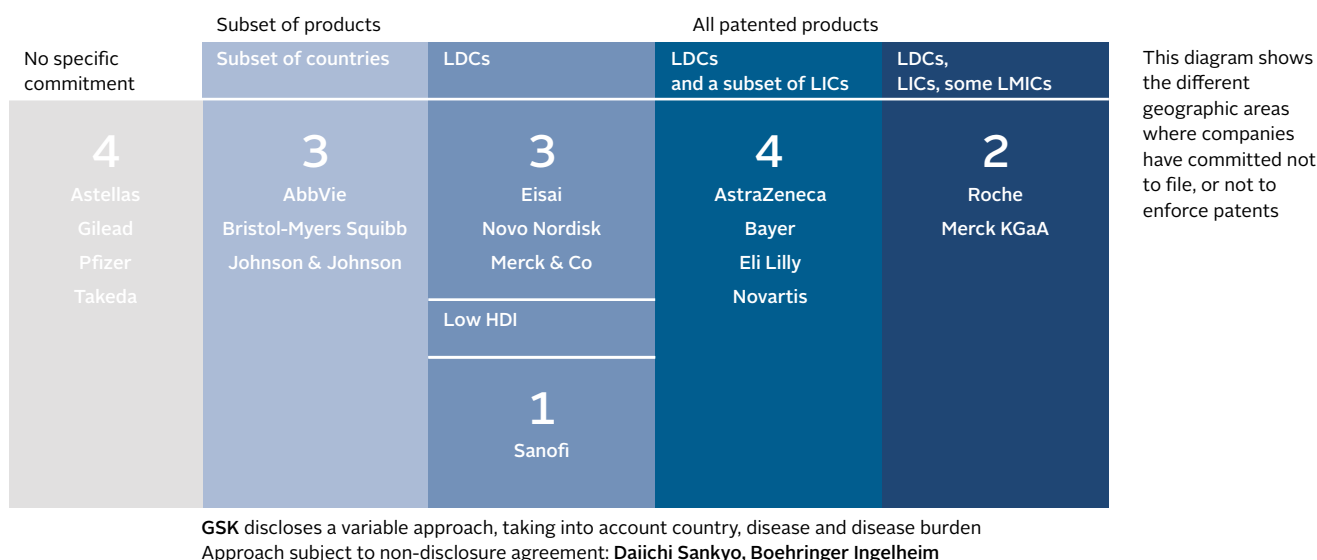
covers all relevant products. According to current data, this covers 46 countries, including almost all Least Developed Countries and several low income and lower-middle income countries.

Conversely, AbbVie, Bristol-Myers Squibb, GSK and Johnson & Johnson take a narrower approach: their commitments apply to a subset of relevant products and subsets of countries.

GSK discloses that its overall approach varies over time and is dependent on the products, countries, and disease burden concerned, among other factors.

The poorer performing companies in this regard are Astellas, Gilead, Pfizer and Takeda. They make no specific commitment not to file or enforce patents in a particular grouping of countries. These companies all currently have at least one patented product relevant in Index countries.^b

Figure 44
Variations exist in company patent filing and enforcement



Do companies publicly disclose patent status?

By disclosing where patents are active, companies give generic medicine manufacturers added clarity on whether to enter a market, and procurement agencies greater confidence as to whether they can deliver generic products in these markets.

Only Bristol-Myers Squibb, Gilead and GSK (ViiV Healthcare) disclose information relating to patent status, and then only limited information for a limited subset of their products. Their disclosure relates to HIV/AIDS products and occurs only in the context of licences negotiated with the Medicines Patent Pool. They do not make this disclosure directly, for example on

their company websites. It is notable in these instances that disclosure of where patents are active goes beyond the countries listed in the licences for supply, and includes the patent status in a range of other countries.

Absence of industry-led transparency in patent status

Performance in this area remains poor compared to equivalent company behaviour captured by the 2012 Index. Companies provide various reasons for not disclosing patent information. Considering the potential positive impact of such disclosure, the Index encourages companies to investigate the feasibility of at least partial disclo-

sure, and/or to clearly disclose the steps interested parties should take to request this information.

Only Merck KGaA stated that it planned to disclose information on the patent status of all its products, including basic information about associated licences it enters into. Merck KGaA has demonstrated that this level of transparency is possible: outside of the period of analysis, it has published patent information on its company website.³ The Index encourages companies to meet and to exceed this level of transparency.

Which companies pledge to engage in licensing or issue formal non-assert declarations and where?

Non-assert declarations and licensing agreements provide generic medicine manufacturers with a high degree of clarity and confidence for engaging in the manufacture and supply of patented products. This analysis looks at whether and where companies pledge to consider issuing licences, and at similar pledges made concerning non-assert declarations.

Merck KGaA stands out, having in place the broadest policy to consider issuing of licences across its entire present and potential product range, including both communicable and non-communicable diseases.

Small group of companies show commitment to licensing

Six companies have policies in place to consider voluntary licensing or non-assert declarations for subsets of their products: Boehringer Ingelheim,

Bristol-Myers Squibb, Gilead, GSK, Johnson & Johnson and Pfizer.

- **Boehringer Ingelheim** commits to considering non-assert declarations for HIV products.
- **Bristol-Myers Squibb** commits to considering non-assert declarations and voluntary licensing for HIV products.
- **Gilead** commits to considering licensing for its HIV and hepatitis products.
- **Johnson & Johnson, Pfizer and GSK** commit to considering licensing for HIV products.

Nine companies commit to considering licensing on case-by-case basis: AbbVie, AstraZeneca, Bayer, Eisai, Eli Lilly, Novartis, Roche, Sanofi and Daiichi Sankyo.

The remaining companies make no specific commitments to considering

licensing or issuing non-assert-declarations. While a public commitment to engage in licensing is welcomed by the Index, and useful for generic medicine manufacturers, actual company engagement in multiple, access-friendly licensing agreements is what counts.

How do companies compare in licensing behaviour?

The Index has analysed whether companies with relevant patented products actually engage in voluntary licensing agreements. The Index makes the assumption that the more a company engages in licensing, with more partners, the greater the potential impact on competition and access to medicine.

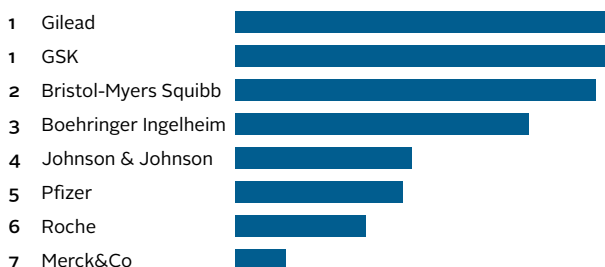
Wide range of licensing behaviour

There are 18 companies with relevant patented products. Eight of them engage in voluntary licensing or issue formal non-assert declarations, issuing almost 250 licences in total. The overwhelming majority (93%) relate to products for HIV/AIDs. However, there are signs this practice can be, and is being extended to other conditions. For example, GSK shows evidence of having issued voluntary licences for products targeting lower respiratory tract infections, measles, mumps and rubella, and Roche for Avian influenza. Roche has indicated through an agreement with the Medicines Patent Pool that it will in future license valganciclovir (Valcyte®),⁴ a product that targets cytomegalovirus (an opportunistic infection associated with HIV/AIDS). In addition, Gilead has agreed licensing terms for sofosbuvir (Sovaldi®) and for pipeline product ledipasvir with seven Indian generic manufacturers for supply in 91 developing countries.⁵ Of all companies, Gilead issues licences for the largest proportion of its relevant products.

Companies with relevant on-patent products that do not engage in licensing: AbbVie, Astellas, Astra-Zeneca, Daiichi Sankyo, Eisai, Merck KGaA, Novartis, Novo Nordisk, Sanofi and Takeda. AbbVie is the only company with ARVs that has not engaged in licensing. It is, however, negotiating licensing terms for paediatric ARV formulations with the Medicines Patent Pool.

Figure 45

Gilead and GSK exhibit leading performance in licensing



This barchart shows the relative performance of the companies who have engaged in voluntary licensing. The ranking is constructed from licensing indicators which measure licensing commitment, transparency of licences, frequency of licensing and licence content.

Table 4

Company licensing profiles

<p>1</p>	<p>Gilead</p> <ul style="list-style-type: none"> • Licences for 80% of relevant patented products. • > 60 licences for 6 products (all for HIV). • Complete licences (both MPP and non-MPP) publicly disclosed. • Broad geographic coverage; pro-access terms. • MPP licence includes pipeline product. 	<p>GSK</p> <ul style="list-style-type: none"> • Licences for 28% of relevant patented products. • > 100 licences for 13 products. • Some complete licences (ViiV Healthcare) publicly disclosed via MPP. • Broad geographic coverage; pro-access terms. • Innovative licence (ViiV Healthcare) includes market segmentation.
<p>2</p>	<p>Bristol-Myers Squibb</p> <ul style="list-style-type: none"> • Licences for 15% of relevant patented products. • 5 licences for 1 patented product (Reyataz). • Complete licence publicly disclosed via MPP. • Licences include pro-access terms. • Immunity from suit agreements for several HIV products. 	
<p>3</p>	<p>Boehringer Ingelheim</p> <ul style="list-style-type: none"> • 8 non-assert declarations^d for 33% of relevant patented products. • 68% of relevant countries included. • Terms (some pro-access) disclosed to the Index. 	
<p>4</p>	<p>Johnson & Johnson</p> <ul style="list-style-type: none"> • Licences for 15% of relevant patented products. • 6 licences for 2 products. • Discloses (near) complete terms of rilpivirine (Edurant®) licences. • Limited evidence of pro-access terms. • Licences agreed prior to FDA approval. 	
<p>5</p>	<p>Pfizer</p> <ul style="list-style-type: none"> • 2 licences (to MPP, via ViiV Healthcare) for 2 products. • Complete licence publicly disclosed via MPP. • Broad geographic coverage; pro-access terms. • Innovative licence (ViiV Healthcare) includes market segmentation. 	
<p>6</p>	<p>Roche</p> <ul style="list-style-type: none"> • 2 licences for 2 products. • Licences for 6% of relevant products. • Partial disclosure of terms. 	
<p>7</p>	<p>Merck & Co.</p> <ul style="list-style-type: none"> • 10 licences for 2 products.^e • Licences for 15% of relevant products. • No disclosure of terms. 	

Which companies are transparent and use access-friendly terms in licence agreements?

Transparency in this area enables stakeholders, including the Index, to investigate the potential of each licence for increasing access to medicine. It should be noted that companies are not always legally able to disclose the terms, even under a non-disclosure agreement with the Index.

Licence agreements can be very restrictive for licensees (generic medicine manufacturers), limiting to whom they can supply and from where they can source, for example, active pharmaceutical ingredients (APIs). However, this does not have to be the case. Licensing agreements can also be based on access-enabling terms.

Third parties key in influencing licensing practice

Companies appear to only fully disclose the terms and conditions when they have been brokered by a third party (i.e., the Medicines Patent Pool). Gilead once again sets itself apart by publishing the details of an additional bilateral licensing agreement on its website.

Whether a licensing agreement has potential to improve access to medicine depends on its terms and conditions^{6,7,8} such as the scale of the any royalties, the geographic scope, and whether it includes restrictions on where the manufacturer may source its APIs.

Pro access terms work in different ways. For example, non-exclusivity clauses ensure that multiple manufacturers are able to agree licences for the same product, supporting greater competition. Other clauses provide greater flexibility to generic medicine manufacturers: regarding, for example, the countries they are permitted to supply to, whether they can terminate components of licences, and whether they are permitted to challenge the validity of the licensor's patents.

Table 5

Pro-access licensing terms	
The Index has identified six licensing terms as important in creating access-friendly licences:	
Non-exclusivity The agreement is not limited to one or more specific generic medicine manufacturers.	Absence of no-challenge clauses Licensees are free to challenge the validity of the licensor's patent)
No restriction on licensees supplying to countries that issue compulsory licences	The ability for licensees to terminate the agreement for any reason at any time
The ability to supply where patents are not in force	The ability to manufacture and source APIs from licensees anywhere in the world
<i>Breadth of geographic scope is also important in determining whether a licence is pro-access.</i>	

Of the licences that are publicly available for scrutiny, those from ViiV Healthcare (GSK, Pfizer) appear to give the greatest amount of flexibility. These included all six terms the Index looks for.

Gilead, Bristol-Myers Squibb and Boehringer Ingelheim follow closely behind, including an average of five of the terms in each of the licences available for analysis.

In terms of geographic scope, the ViiV Healthcare licences (GSK and Pfizer) perform well once again, covering more than 90% of the countries within the scope of the Index. Importantly, this includes many middle income countries.

Bristol-Myers Squibbs' and Gilead's licences cover 86% of relevant countries. Boehringer Ingelheim's non-assert declarations for Nevirapine cover 68% of countries within the scope of the Index.

Although based on a small sample of five companies, this analysis shows companies are willing and able to agree on flexible terms for voluntary licensing. The Index encourages companies to be pro-active in this area.

Do companies engage with external brokers?

The presence of an external broker who can 'pool' patents can be an important mechanism for agreeing transparent, pro-access terms under which generic medicine manufacturers are permitted to manufacture and distribute patented products. Further, in disease areas where fixed-dose combinations are needed, such as in HIV/AIDS, and where multiple companies hold patents on relevant components, pooling patents is particularly important for enabling generic medicine manufacturers to make combination treatments. At present, only one such external broker is in operation: the Medicines Patent Pool (MPP), which currently focuses on HIV/AIDS.

Very few companies with ARVs remain outside the MPP

As shown in other sections of this chapter, licensing activity, as well as the transparency and flexibility of terms and conditions, is highest when a third-party broker is involved, namely the Medicines Patent Pool (MPP). The Index encourages all companies engaged in voluntary licensing to meet the high standards demonstrated in the MPP agreements.

There are nine companies with relevant products: GSK, Johnson & Johnson, Pfizer, Gilead, Bristol-Myers Squibb, Boehringer Ingelheim, AbbVie, Merck & Co. and Roche. At the time of the 2012 Index, Gilead was the only one of these companies to have reached a licensing agreement via the Medicines Patent Pool. Since then, there has been significant movement: Bristol-Myers Squibb, Roche and ViiV Healthcare (Pfizer and

GSK) have all concluded agreements. AbbVie, Boehringer Ingelheim and Merck & Co. were in active negotiations at the time of writing.

Johnson & Johnson is the only company with relevant products that remains both outside the MPP, and not in active negotiations. For two ARVs – darunavir (Prezista[®]) and rilpivirine (Edurant[®]) – Johnson & Johnson engages in limited bilateral licensing agreements with generic medicine manufacturers. However, the terms of the licences have not been made fully available for analysis. During the period of analysis, the company pledged not to enforce patents on darunavir (Prezista[®]) in certain countries. Rilpivirine (Edurant[®]) and etravirine (Intelence[®]), however, are not subject to the same pledge, and the non-enforcement declaration applies only to limited geographic areas.

BEST PRACTICE

Gilead – Including pipeline products within licence agreements

The inclusion of pipeline products within licensing agreements can significantly accelerate the arrival of generic medicines onto the market.

Within licensing agreements reached through the Medicines Patent Pool, Gilead has included pipeline products on several occasions: in 2011 with cobicistat (Tybost[®]), elvitegravir (Vitekta[®]), and with a combination of these products and emtricitabine (Emtriva[®]) in a single pill known as the "Quad." (Stribild[®]). Technology transfer terms were included in the agreement, meaning transfer could be engaged in prior to stringent regulatory approval. As a result, when regulatory approval was finally achieved, access to generic versions could be accelerated.

Earlier in 2014 a similar agreement was reached with the MPP for tenofovir alafenamide. Gilead has also included pipeline product ledipasvir (hepatitis C) within recently bilaterally agreed licences.

How do companies support the TRIPS agreement?

Within the TRIPs framework, WTO-member countries have responsibilities for protecting the intellectual property of organisations that operate within their borders. However, they also have the right to balance these responsibilities with public health priorities.⁹

As in 2012, companies continue to take a conservative stance on TRIPS and the Doha Declaration. Although most are supportive of the agreement overall, very few explicitly endorse specific flexibilities granted to World Trade Organization (WTO) members regarding IP protection legislation. Furthermore, the majority of companies have been implicated in allegations of lobbying or court cases involving the application of TRIPS in certain countries.

Inconsistent company support for TRIPS agreement

The companies are divided into two low-performing groups in this area. The higher-performing group consists of ten companies that provide conservative support to a subset of flexibilities set out in the TRIPS agreement. They do not, for example, completely acknowledge the situations where compulsory licensing is permissible. These companies are: Bayer, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck KGaA, Novartis, Novo Nordisk and Sanofi. Of this group, Eisai, Eli Lilly and GSK are the most supportive of TRIPS flexibilities, explicitly supporting multiple flexibilities.

The remaining ten companies are even more conservative, disclosing either limited, non-specific policies relating to these agreements, or no policy at all. These companies are: AbbVie, Astellas, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, Merck & Co., Pfizer, Roche and Takeda.

Do they support TRIPS in practice?

During the last two years, the majority of companies have at some point acted against the spirit of the TRIPS agreement and Doha declaration. In the most well-known example, members of the Innovative Pharmaceutical Association of South Africa (IPASA) were implicated in a lobbying proposal to delay reform of South African intellectual property legislation. The planned legislation was designed in part to make it easier for South Africa to take advantage of TRIPS flexibilities, such as the right to issue compulsory licences and to engage in parallel importation.

More than half of companies (14) were members of IPASA while this proposal was reportedly under discussion; AbbVie, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk, Pfizer, Sanofi and Takeda.

Roche and Novo Nordisk resigned from IPASA shortly after the allegations were made public, and Novartis released a statement distancing itself from the proposal.^{10,11}

In addition, in 2013, Novartis and Bayer were involved in court cases in India relating to the application of TRIPS flexibilities:

- The patentability of Novartis' cancer drug imatinib (Gleevec[®]) was denied by the Indian Supreme Court on the basis that it was a modification of an existing drug that brought no significant additional efficacy.¹²
- Bayer's challenge against a compulsory licence issued by India was also unsuccessful. The compulsory licence was India's first, and was issued for sorafenib (Nexavar[®]), a liver and kidney cancer medication.¹³

INNOVATION

Tiered royalties bring licensing to more middle income countries

The 2014 Index looked for unique approaches to intellectual property management that take affordability into account. Although such innovation remains scarce, there is evidence of progress in the domain of licensing, led by the Medicines Patent Pool. The

Index welcomes the readiness of some companies to test novel approaches to licensing that will enable the extension of licensing agreements to more middle income countries. This is important because it is the middle income countries where the bulk of the world's

disease burden is concentrated,¹⁴ and because it is also in these countries where companies have typically maintained a more conservative stance on intellectual property management.

Targeting poor patients in richer countries

GSK and Pfizer, via their joint-venture ViiV Healthcare, signed two licensing agreements for HIV drug dolutegravir (Tivicay[®]) with the Medicines Patent Pool.^{15,16} One of these is novel because it segments between public and private markets and introduces a tiered royalty structure in order to enable more middle income countries to benefit from access to generic medicine. This applies in six middle income countries: namely Egypt, India, Indonesia, the Philippines, Turkmenistan and Vietnam. In addition, the licence also covers all countries in Sub-Saharan Africa, Least Developed Countries and low income countries, and allows manufacturers to sell in 50 additional countries. This means the licence could benefit 93.4% of adults living with HIV.

The royalties vary depending on the income level of the countries. In Least Developed Countries, low income countries and sub-Saharan-Africa, licensees can manufacture and sell dolutegravir (Tivicay[®]) without paying royalties. In the six additional middle income countries mentioned, a tiered royalty structure based upon each country's GDP applies, and sales are restricted to public markets (funded by Governments, UN organisations, and NGOs). ViiV Healthcare reserves the right to operate in the private market.

Through its tailored approach to different markets and their ability to pay, this licence has the broadest scope of any licence for an adult medicine examined by the Index.

For numbered references, see the Appendix.

- a Neutral scoring is discussed more fully in the Appendix.
- b Poor performance in patenting commitments should also be read in the light of whether or not, and how broadly, the companies licence their products. (GSK and Gilead, for example, engage in substantial licensing practice across their HIV/AIDS portfolios which cover a broad geographic spread of countries)

- c These agreements were announced on September 15 2014 - outside of the reporting period.
- d Related to nevirapine (Viramune[®]), the compound patent of which has recently expired.
- e It is relevant to note that the patents on efavirenz, which some of these licensing agreements relate to, have largely expired during 2013.

F Capability Advancement

Some of the highest barriers to access to medicine relate to gaps in local healthcare infrastructure and supply chains. Large multinational pharmaceutical companies often have both the know-how and a long-term strategic incentive to help fill these gaps. Companies can draw on their capabilities and expertise to increase the availability of quality-assured, safe and effective medicine and healthcare, while simultaneously helping to build and strengthen future markets.

The Index looks for long-term, systemic company engagement with local stakeholders that is aligned with local needs and aims to strengthen the skills, competencies and abilities of people living in relevant countries, while taking potential conflicts of interest into account. Low income countries generally have the greatest need for capability advancement, consequently the Index places a higher value on activities carried out in these countries.

In general, capability advancement activities are voluntary. In some countries, companies are legally required to invest in local capabilities to some degree (for example in quality management and pharmacovigilance).

Five areas of analysis

Research & Development

Reporting on how companies work with local partners to build capabilities in basic, applied and clinical research.

Quality management in manufacturing

Reporting on how companies are improving local quality management skills, to help ensure locally produced medicines meets (international) quality standards.

Supply chain management

Reporting on how companies are addressing poorly functioning supply chains.

Pharmacovigilance

Reporting on how companies are actively working to strengthen national pharmacovigilance systems.

Activities beyond the value chain

Reporting on how companies are building other local capacities, for example, by training healthcare workers, building health infrastructure and supporting health-awareness or stigma-reduction campaigns.

How the companies perform

Most scores are largely comparable to 2012, although the companies at the bottom are making greater progress. Most companies are building local capabilities in each of the five focus areas and companies are more active in the areas of quality management in manufacturing, supply chain management and pharmacovigilance.

Leaders engage in a long-term systemic manner

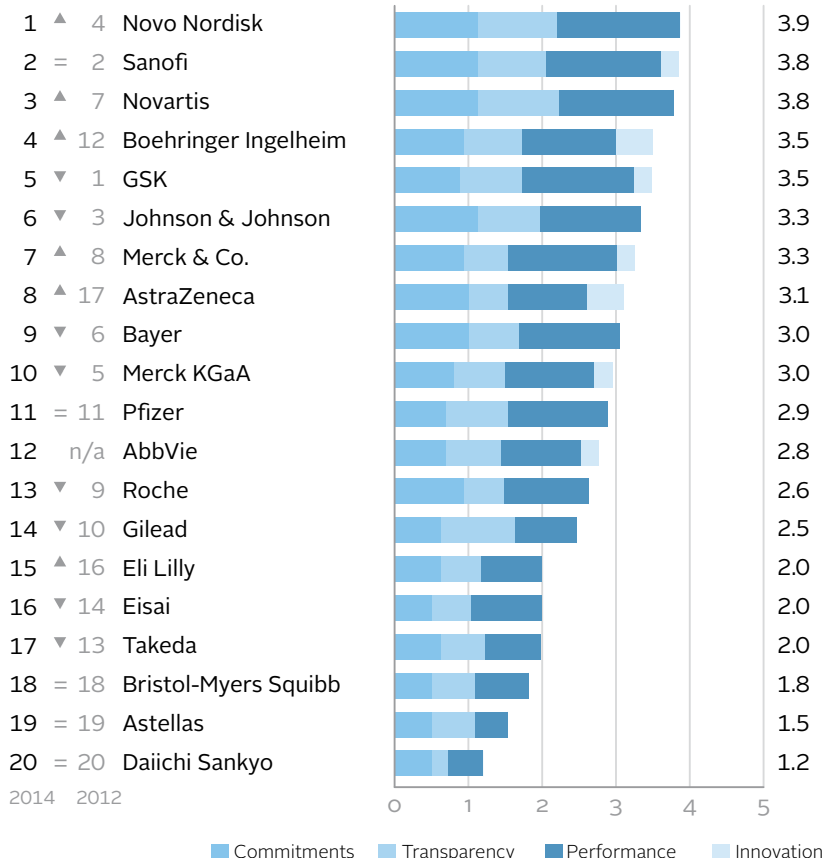
Novo Nordisk, Sanofi and Novartis comprise the leading group. They engage with local stakeholders in a long-term, systemic manner, and are among the leaders in all five of the areas the Index examines.

Novo Nordisk has moved up from 4th to 1st position in this area. It performs particularly strongly in R&D, quality management in manufacturing, supply chain management and areas outside of the value chain. It disclosed clear access rationales for its R&D partnerships in relevant countries. The need for additional capacities is potentially highest in low income countries. Novo Nordisk engages with governments of several low income countries regarding supply chain management and at least one local manufacturer.

Sanofi follows in 2nd place with strong performances in capability advancement for R&D, supply chain management and activities beyond the value chain. It is also innovating: the Sanofi Espoir Foundation is working with the International Confederation of Midwives (ICM) on an online platform for midwives to address maternal and newborn mortality worldwide.

Novartis jumps from 7th place to 3rd, close behind Sanofi, due in part to its leading and improved performance in the area of pharmacovigilance capa-

Figure 46
Company Ranking Capability Advancement



bility building. It is the only company to provide evidence of sharing post-marketing safety reports with authorities in relevant countries beyond legal requirements.

Middle group: less alignment with local needs

The leaders are followed closely by a pack of 11 companies, the majority of which also ranked in the middle group in 2012. Eight of these 11 companies increased their scores since 2012, bringing them closer to the leading companies. These companies are: Boehringer Ingelheim, GSK, Johnson & Johnson, Merck & Co., AstraZeneca, Bayer, Merck KGaA, Pfizer, AbbVie,

Roche and Gilead. In general, they are active in all areas of capability advancement, but do not consistently demonstrate alignment with local needs or structured, long-term engagement with partners. AstraZeneca and Boehringer Ingelheim are both new to the middle group. They are both engaged in large programmes to raise awareness and increase access to healthcare for marginalised communities.

Little activity from one-third of companies

Six companies are ranked toward the bottom: Eli Lilly, Eisai, Takeda, Bristol-Myers Squibb, Astellas and Daiichi Sankyo. These companies are the least

active in capability advancement in all areas, but particularly when it comes to pharmacovigilance, supply chain management and activities beyond the value chain.

Biggest risers: AstraZeneca and Boehringer Ingelheim

Both AstraZeneca and Boehringer Ingelheim rose significantly compared to 2012: up nine and eight places respectively. Both companies showed increased activity in the areas of pharmacovigilance and quality management in manufacturing. In addition, they both expanded large programmes to raise awareness and increase access to healthcare for marginalised communities. Novartis is another big riser, moving up four places with evidence that it has increased its activities in the area of pharmacovigilance.

Furthest faller: Merck KGaA

Merck KGaA falls the furthest (five places from 5th to 10th). Roche, Gilead and Takeda each fell four places. While these companies improved slightly since 2012, other companies overtook them. GSK also dropped four places, losing its leading position in capability advancement in the 2012 Index due to stricter scoring criteria and changes in methodology.^a

Companies build capabilities in 75 out of 106 countries

This map shows the number of companies per relevant country actively contributing to the development of local capabilities in at least one of four areas within the value chain, i.e. R&D, quality management in manufacturing, supply chain management and pharmacovigilance.^b



Figure 47

- ≥ 10 companies active
- 5 to 9 companies active
- 3 or 4 companies active
- 1 or 2 companies active
- no companies active
- country out of scope

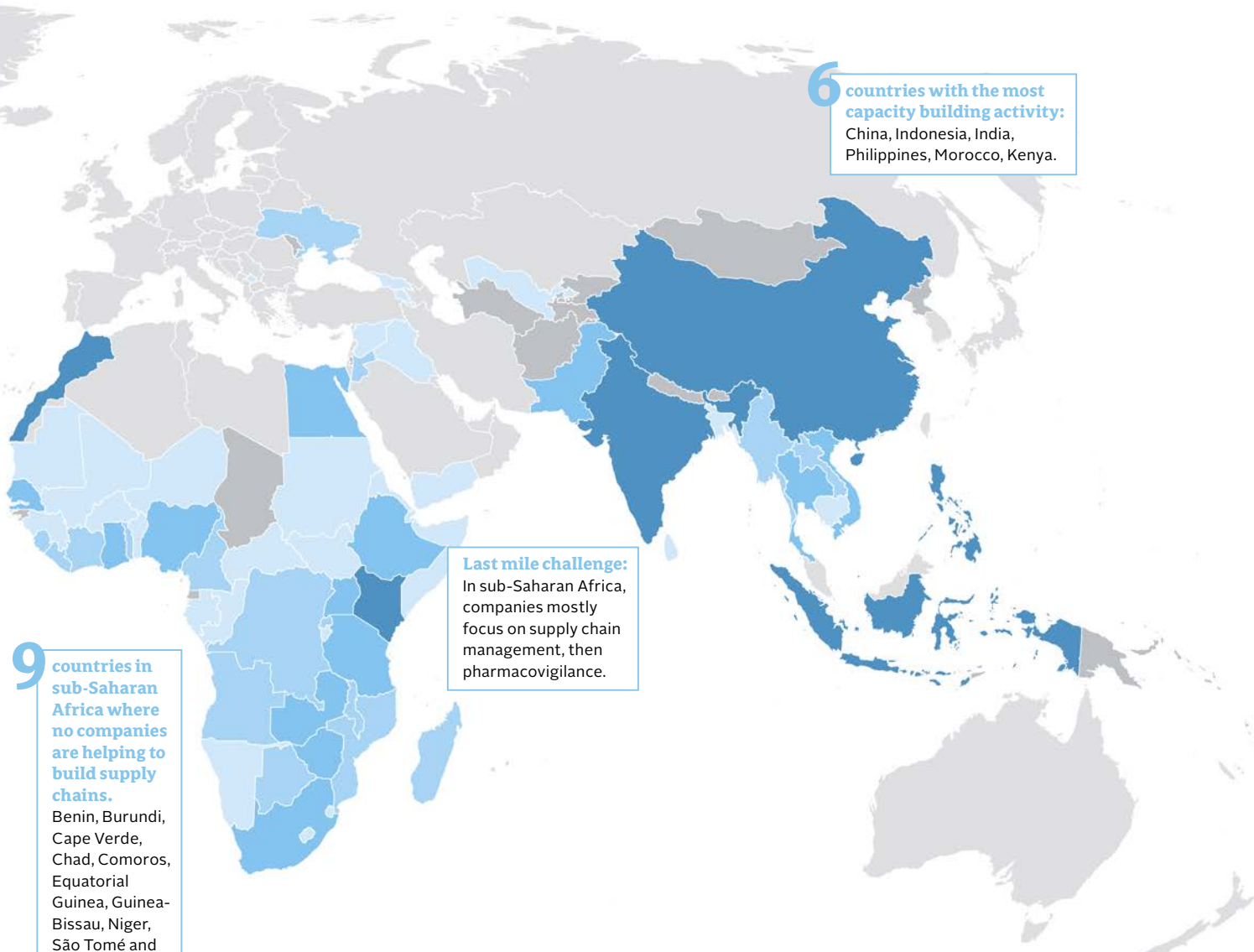
Most companies are building a range of local capabilities

Most companies are building local capabilities in each of the five focus areas. However, their activities are often part of short-term collaborations. Most of their activities relate to quality management in manufacturing, which is to be expected as this is the area where companies carry the most responsibility. Activity in the areas of quality management in manufacturing, supply chain management and pharmacovigilance has increased since 2012.

As in 2012, one-third of companies provided evidence of innovation in capability advancement, particularly when it comes to building capabilities in supply chain management and beyond the value chain.

The industry is actively building capacities within the value chain (i.e., in R&D, quality management in manufacturing, supply chain management and pharmacovigilance) in a wide range of countries. More companies are active in China than any other country within scope:

INDUSTRY

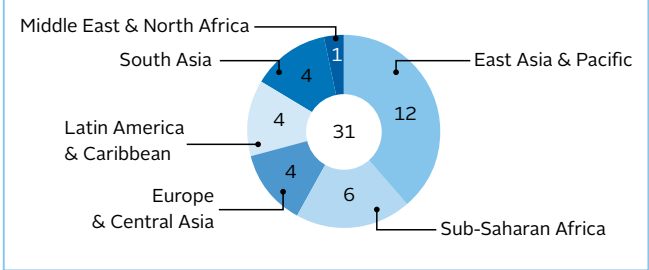


6 countries with the most capacity building activity:
China, Indonesia, India, Philippines, Morocco, Kenya.

Last mile challenge:
In sub-Saharan Africa, companies mostly focus on supply chain management, then pharmacovigilance.

9 countries in sub-Saharan Africa where no companies are helping to build supply chains.
Benin, Burundi, Cape Verde, Chad, Comoros, Equatorial Guinea, Guinea-Bissau, Niger, São Tomé and Príncipe.

31 countries in scope where no companies are building capacities in the four areas linked to the value chain



17 are engaged in capacity building here in at least one area measured by the Index. This is followed by Indonesia, with 13 companies, and India, with 11.

More than two-thirds of companies are active in at least one low income country (companies not active in low income countries are AstraZeneca, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, Roche and Takeda), mainly Kenya, where ten companies are active, Uganda (seven companies) and Ethiopia (six companies).

Research & Development

Almost all companies build local R&D capabilities

Why this matters

Where there is more local R&D capacity, there is a greater chance that new products will be suitable for local people. Through partnerships and involvement with local research institutes or universities, pharmaceutical companies can help build local capabilities in basic, applied

and clinical research. They can fund research projects, build and participate in knowledge-sharing initiatives, or provide training for clinical, scientific or technical researchers and managers, such as data managers and clinical trial managers.

The Index looks at how often companies engage in activities to build local R&D capacity. It also examines whether these activities are long term, and whether they are supported by an access rationale that takes gaps in the local labour market into account.

How the companies perform

In general, the industry is reasonably active in this area. This is to be expected as companies benefit directly from the new products that result from research collaborations. As in 2012, 18 companies engaged in at least one relevant activity. Only two companies provide no evidence of building R&D capabilities in any relevant country. In total, the Index identified 48 separate initiatives for building local R&D capacities, including collaborations with universities and public institutes. Of these initiatives, 11 were long term (≥ 5 years). Companies are most active in China, where eight companies are actively building R&D capacity. Other countries where companies are relatively active are Brazil, Kenya, South Africa and Uganda.

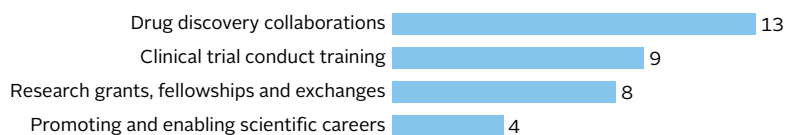
Companies frequently take local needs and labour gaps into account when engaging in this type of activity. Of the 18 companies active in this area, nine provided access rationales for at least half of their collaborations and seven provided evidence of this for all their R&D initiatives.

Boehringer Ingelheim, Gilead, Novartis and Novo Nordisk are in the lead here. These companies all engage in at least one relevant activity, disclosed clear access rationales for their relevant initiatives and had at least one long-

Figure 48

Four main approaches to building R&D capabilities

Number of companies engaging in each activity



term partnership. The laggards are Daiichi Sankyo and Eli Lilly, which provided no evidence of relevant activity.

Companies build R&D capacities in four distinct ways

When it comes to strengthening R&D capabilities, Index analysis shows that companies engage with local stakeholders in four ways:

- **Collaborating on drug discovery with local organisations**, such as universities, hospitals or health authorities. 13 companies are active here: AbbVie, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, GSK, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk, Pfizer and Roche.
- **Providing training on clinical trial conduct**, for example on Good Clinical Practices (GCP), when conducting trials in relevant countries with publicly funded organisations. Nine

companies are active here: Boehringer Ingelheim, Eisai, GSK, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, Novo Nordisk and Sanofi.

- **Providing research grants, fellowships and exchange placements** for researchers, laboratory technicians, managers and students from relevant countries. Eight companies are active here: AbbVie, Astellas, Gilead, GSK, Pfizer, Roche, Sanofi and Takeda.
- **Promoting and enabling scientific careers**, for example by hosting lectures and training workshops, in relevant countries. Four companies are active here: AbbVie, Eisai, Merck KGaA and Novartis.

Quality management in manufacturing

Smaller companies gain on larger peers in building local manufacturing capabilities

Why this matters

The WHO has provided a blueprint in its Good Manufacturing Practices, or GMP, for ensuring that products are consistently produced to high quality standards. With their broad global reach, companies have extensive experience in meeting these international standards. By transferring their knowledge to local manufacturers in low income

and lower-middle income countries, companies can help improve the quality of medicines. In some countries, local governments may require companies to engage in local production as a condition of their operating license.

The Index examines whether companies work with both third-party and

in-house manufacturers in relevant countries to help them implement Good Manufacturing Practices and/or to help build or strengthen quality management systems. The Index looks at, for example, training initiatives, workshops, consultancies and technology transfers.

How the companies perform

All companies commit to supporting in-house and third-party manufacturers in adhering to international manufacturing standards. Collectively, 19 companies provided evidence of 99 relevant engagements with local manufacturers in 19 countries covered by the Index, including training initiatives and technology transfers. Roughly 74% of these were with third-party manufacturers. Only three companies engaged with manufacturers in low income countries, where the need is most likely highest.

Compared to 2012, nine companies have increased activity in this area, eight of which have annual revenues below USD25 billion,^c making them comparatively smaller than other companies in the Index. As such, in

the area of quality management in manufacturing, comparatively smaller companies are gaining on their larger peers (i.e., those with annual revenues above USD40 billion). Only one of these larger companies increased its activities in this area.

Boehringer Ingelheim, Merck & Co. and Novo Nordisk are the best performing companies in this area. They each provided more than five examples of engagements with local manufacturers to improve quality management, including in low income countries. Bayer, GSK, Merck KGaA, Novartis and Roche also support manufacturers in these countries, but provided no evidence of doing so in technology transfers and training initiatives.

At the other end of the spectrum are AbbVie and Bristol-Myers Squibb. AbbVie commits to providing support in this area, but discloses no detailed evidence that it does so in practice. Bristol-Myers Squibb expects third-party manufacturers to adhere to local manufacturing standards and makes no commitment to providing support here. However, it does commit to a technology-transfer support package via the Medicines Patent Pool.

INNOVATION

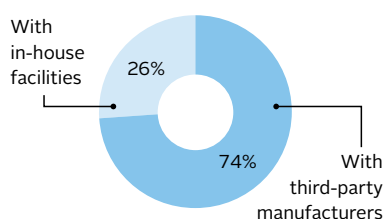
Merck KGaA – Global support for local plant managers

By transferring their knowledge to local manufacturers, companies can help improve the quality of locally produced medicines, and harmonise processes to improve manufacturing efficiency.

Merck KGaA is creating a ‘Virtual Plant Team’ to support its global contract-manufacturing network in achieving and upholding local and global quality standards for manufacturing. Once up and running, this platform will provide local plant managers with support, expertise and regular training in order to harmonise manufacturing standards across all its in-house and third-party manufacturers.

Figure 49

Most technology/knowledge transfers with third-parties



Supply chain management

Most companies active, but few initiatives are long-term

Why this matters

Poorly functioning supply chains can create significant barriers to access. They can increase the risk that health-care providers cannot keep sufficient stocks, lead to over-purchasing and quality deterioration, and facilitate the infiltration of spurious, falsely-labelled, falsified, counterfeit products. It can also lead to the diversion of lower-priced brand variants away from the low-income populations they target. Many organisations are already working to improve pharmaceutical supply chains, and the companies that make the products have much to add to their efforts. Not only would this benefit patients, but the resulting improvements in forecasting and procurement management would also benefit companies.

The Index examines how companies engage with governments and regulators, distributors and stakeholders from up and down the supply chain in order to strengthen local capabilities in supply chain management. Specifically, it looks at whether companies provide on-the-ground training and whether they share information on any of the following six elements of supply chain management:

- **Drug regulation** – strengthening regulatory frameworks
- **Supply chain alignment** – supporting the integration or alignment of processes up and down the supply chain

- **Demand forecasting** – increasing the ability of national and international authorities, distributors and local healthcare providers to estimate demand
- **Stock management** – helping to prevent or reduce stock-outs and product deterioration, and ensure that products remain available
- **Product diversion** – helping to prevent lower-priced brand variants from being diverted toward higher-income populations (at a mark-up) and away from their target market
- **Counterfeiting** – helping to prevent and detect the export, import and smuggling of spurious, falsely-labelled, falsified, counterfeit products.

How the companies perform

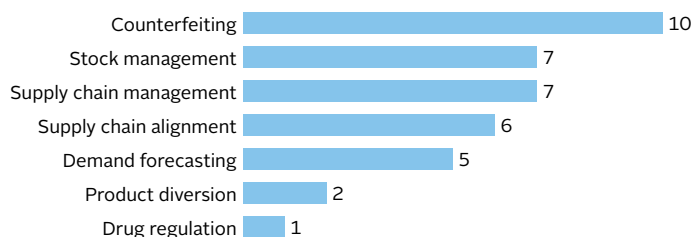
This Index, 17 companies provided evidence of activities to strengthen local capabilities in supply chain management (up from 15 companies in 2012). As in 2012, initiatives regularly cover multiple aspects of supply chain management, yet they are usually *ad hoc* and small scale. Only three companies provide evidence of long-term engagement (≥ 5 years) with relevant partners. Three companies do not engage in capacity building in supply chain management. Collectively, 17 companies cover 67 countries (out of 106 countries in scope), including 24 low income countries. The most companies are active in: China (7); Kenya (6); Nigeria (5).

The majority of the on-the-ground training relates to counterfeiting^d commonly involving teaching government officials how to recognise authentic products. This is followed

Figure 50

Industry mostly focuses on reducing counterfeiting

Number of companies active in on-the-ground training per area of the supply chain



by training on supply chain management, stock management and how to safeguard product quality. Regarding information sharing, companies mostly focus on increasing supply chain alignment and improving demand forecasting, with product diversion receiving the least company attention.

Sharing information to align supply chains

Ten companies are active in this area: AbbVie, Eisai, Gilead, GSK, Johnson & Johnson, Merck & Co., Merck KGaA, Novo Nordisk, Sanofi and Pfizer. They focus on different aspects and employ a range of approaches:

- Working with national governments to study local supply chains and support their redesign
- Working with international and local organisations to improve, redesign or align supply chains
- Engaging with other companies to align demand forecasting and the supply of donated medicines
- Combining technology transfers with the training of procurement agencies

Sharing information to improve demand forecasting

Regarding demand forecasting, companies take a much more homogenous approach. Eight companies share information on this with global agencies (including procurement agencies), national governments and local distributors. Broadly speaking, they either focus on improving stock management systems, or contribute to the exchange and aggregation of relevant data.

Leaders strengthen multiple links in supply chain

Pfizer takes the lead in this area, followed by Merck & Co., Novo Nordisk and Sanofi. These four companies all actively build capacities in supply chain management in three or more of the areas covered by the Index. Pfizer leads because it shares information on the most elements of supply chain management (namely, supply chain alignment, demand forecasting, product diversion, stock management and counterfeiting). Novo Nordisk and Sanofi follow close behind. They both provide evidence of engaging in long-term programmes, but across fewer elements.

The laggards in this area are Astellas, Boehringer Ingelheim and Daiichi Sankyo. These three companies provided no evidence of relevant capacity building activities.

OBSERVATION

Skills transfer to aid detection of counterfeit medicines

Counterfeit or falsified medicines are deliberately and fraudulently mislabelled. They can harm patients because they may include the wrong ingredients, the wrong amounts of active ingredient or come in fake packaging, which may, for example, have misleading directions for use.

Novo Nordisk is working with the Bangladesh government to train staff at its National Drug Control Laboratory on relevant regulations and laboratory techniques. Such activities can help increase a country's ability to detect counterfeit medicines.

GSK has a programme for coordinating donations of scientific equipment by pharmaceutical companies and for ensuring that the skills needed to operate the equipment is transferred to laboratory staff. The company conducts audits to check that equipment has arrived and is being implemented safely. This approach was piloted in Pakistan in collaboration with other companies, the WHO, the Pakistan pharmaceutical industry body, drug regulatory authorities and Ministry of Health. The company plans to expand this programme to African countries.

Merck KGaA works with the Global Pharma Health Fund (GPHF) to support its MiniLabs programme, which provides portable, compact laboratories for conducting rapid, in-the-field verification of drug quality and for the detection of counterfeit medicines. Since 2012, the number of medicines that the MiniLab can test has expanded. The company also provided training seminars and courses on how to use the GPHF MiniLab and participates in external research with the aim of further increasing the variety of medicines that the MiniLab can test.

INNOVATION

Forward integration of supply chains

Forward integration of supply chains involves company collaboration with warehouses, distributors, health facilities and other downstream partners. Sharing of accurate information with these partners in a timely manner can help ensure supply chains function smoothly.

Merck & Co. participated in an innovative pilot led by IntraHealth and funded by the Bill & Melinda Gates Foundation aimed at the forward integration of supply logistics. Under this 'Informed Push Model', trained logistics staff visit health facilities to review inventories in order to plan for the timely restocking of contraceptives. The pilot was conducted in two districts in Senegal, and reduced stock-out percentages for two types of contraceptives from 86% and 57% to 0% in one district. Such a pro-active approach can also free medical staff from logistics planning.

Merck KGaA has developed a software tool that can improve stock management. The tool is integrated with Merck KGaA's order management system, so that customers can enter their orders directly into the company's internal system. This integrated ordering process improves price transparency and reduces lead time and miscommunication. The company has recently tested this tool in Sudan and Ethiopia and plans to expand it to more countries.

OBSERVATION

Alignment of supply and demand

Misalignment of supply (e.g., manufacturers) and demand (e.g., procurers, healthcare facilities) can result in incorrect demand forecasting, long lead times, and, eventually, stock-outs at the health facility level. Collaboration can improve alignment and reduce supply interruptions and stock-outs.

Merck & Co.: During the technology transfer of an ARV, Merck & Co. included training initiatives on supply chain management. In addition, the company has shared best production practices with the Chinese authorities and government officials. This type of activity can improve communication between the supplier and procurer, resulting in fewer supply interruptions.



Merck & Co. - Informed Push Model

A Senegalese health-worker checks stock levels as part of an initiative to improve stock management.



GSK - Vodafone partnership

A healthworker in Mozambique registers an infant's latest vaccination in the partnership's database.

INNOVATION

GSK: GSK is collaborating with Vodafone in Mozambique to assess whether mobile technology can increase vaccination rates. Through SMS messaging, the company aims to encourage mothers to use vaccination services. The pilot also aims to increase accurate demand forecasting and reduce vaccine stock-outs by sending reminders to healthcare facilities to report on vaccine stock levels.



Pfizer - Global Health Fellows

A Global Health Fellow provides on-the-ground assistance to strengthen the supply chain in Nairobi, Kenya.

BEST PRACTICE

Pfizer – Optimizing supply chains

Supply chains are complex, and often unique to specific products and regions. A case-by-case approach that targets multiple aspects up and down the supply chain can improve access to medicine.

Through Pfizer's Global Health Fellows programme, the company has sent its supply chain experts to address breakdowns in the supply chain. Its experts have worked with organisations in Kenya and Tanzania to improve procurement and stock management; to maintain supply chain integrity; and to improve quality control management. For example, Pfizer provided expertise to the NGO Management Sciences for Health to help it develop a master supply-chain plan in Kenya.

The plan defines quality standards for health commodity providers and addresses information needs across the supply chain.

Pharmacovigilance

Majority of companies support national pharmacovigilance systems

Why this matters

Even after a medicine or vaccine has received market approval, much remains unknown about its risks and benefits – particularly when used in certain populations for the first time, or in resource-limited conditions. In mature markets, comprehensive national pharmacovigilance systems ensure medicine use is efficiently monitored and evaluated, and that the results are communicated and acted upon in a timely fashion. However, in many of the countries covered by the Index, such

systems are either lacking or inefficient. Establishing these systems is primarily a government responsibility. Yet companies can make a considerable contribution by drawing on their knowledge and experience of collecting and reporting safety data. The Index looks for companies to engage with local authorities and other stakeholders, when possible, to help establish and support national pharmacovigilance systems. This support could take the form of secondments, consultancy or training.

The Index looks for long-term engagements that are aligned with national or regional plans, and for companies to voluntarily disclose their post-marketing surveillance data to national governments in relevant countries. Such voluntary data sharing can help build strong central information repositories where more robust pharmacovigilance systems are lacking.

How companies perform

Most companies engage in this kind of capability building to some extent: 17 companies (up from 8 in 2012) are active in this area, in a total of 39 countries:

- 11 low income countries;
- 16 lower-middle income countries;
- 12 upper-middle or high income countries.

The highest numbers of companies are active in: China (seven companies), Brazil, Ghana, India and Vietnam (each four companies).

Companies typically engage in training initiatives, roundtables and consultancies with national health authorities. These are mostly conducted *ad hoc* rather than as part of a structured long-term engagement programme. Johnson & Johnson, Sanofi and Merck & Co. stand out for engaging in multiple initiatives, including long-term activities (≥ 5 years). Seven companies take a positive stance towards voluntary data sharing. However, only Novartis provided evidence of engaging in such activity.

Due to local factors, companies are not able to engage in pharmacovigilance capability building in all relevant coun-

tries. Governments play a key role in enabling companies to take on this role. The data captured by the Index indicate that companies are responding to opportunities, although there is scope for improvement, particularly in the voluntary sharing of post-marketing surveillance data.

The leaders in this area are Novartis, Bayer and Johnson & Johnson, followed by Sanofi and GSK. These companies engage with governments on a regular basis and in a wide range of relevant countries.

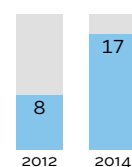
The laggards in this area are Gilead, Takeda and Eli Lilly, which provided no evidence of engaging with governments or other relevant stakeholders to help build national pharmacovigilance systems.

Notable practices

Novartis is the only company that provided evidence of voluntarily sharing post-marketing safety reports with authorities in relevant countries. GSK, Johnson & Johnson and Merck & Co. state that they voluntarily share data but do not provide supporting

Figure 51

Large increase: 9 additional companies contribute to national pharmacovigilance systems



evidence. AbbVie, Bayer and Pfizer indicate they are willing to share safety data beyond legal requirements upon request from authorities.

Merck & Co. is notable for its extensive, long-term collaborations with international partners and local NGOs. For example, the company engages with the African Comprehensive HIV/AIDS Partnership (ACHAP) in Botswana to collect safety data on the company's ARVs.

GSK is piloting a new crowd-sourcing platform: it enables patients in relevant countries to report adverse events using low-tech solutions, such as SMS or telephone calls. GSK aims to roll out this platform in Africa.

Building capacities beyond the value chain

Most companies build capacities beyond the value chain

Why this matters

There are many ways for companies to build local capabilities beyond the value chain. These can be classified into three broad groups: training doctors, pharmacists, lab technicians and other healthcare workers; building health infrastructure, such as laboratories and treatment centres; and supporting health-awareness or stigma-reduc-

tion campaigns. Such activities can improve access to medicine directly, for example by improving and supporting diagnosis and treatment, and indirectly, for example by improving treatment-seeking behaviour.

Conflict of interest can be an issue here, in particular when companies

work directly with patient organisations or healthcare professionals. To identify potential conflicts of interest, the Index asks whether initiatives involve reputable organisations, such as the WHO, established NGOs or governments.

How the companies perform

The industry is collectively building capacities in all areas measured here (training, infrastructure improvement and awareness raising). A total of 16 companies engage in at least one initiative beyond the value chain. Four companies show leadership by

engaging in five or more relevant initiatives: Boehringer Ingelheim, GSK, Novo Nordisk and Sanofi. Companies' initiatives are often disease-specific and often combine elements of training and awareness raising.

At the bottom of the pack, four companies provided no evidence of relevant capability advancement initiatives that met all of the criteria for inclusion: Astellas, Daiichi Sankyo, Eisai and Gilead.



◀ **Sanofi - The Connecting Midwives platform**

Sanofi's platform supports midwives in rural areas. Here, a midwife teaches a young mother in Ethiopia about hygiene.



◀ **AstraZeneca - The Young Health Programme**

A Zambian student from an area impacted by HIV/AIDS learns about sexual and reproductive health.

OBSERVATION

Improving diabetes care with SMS services

Diabetes patients using insulin often require support from health-care providers to better manage their disease and improve disease outcomes.

2 companies

Sanofi, Novo Nordisk

Together with Vodacom, Sanofi has created a support programme for diabetes patients living in Africa. This programme is based around a mobile-phone application that enables patients to interact with their healthcare providers in real time. Once the patient has been introduced to the Vodacom platform in a face-to-face session, they receive regular messages, tips and advice via SMS to help them manage their diabetes. Nurses track patients' progress via a smartphone app, while doctors use a web-based platform. Patients are encouraged to respond to questions regarding their diabetes management via free text messaging.

Novo Nordisk partners with the Copenhagen School of Global Health and Airtel in a similar project, 'SMS diabetes', in Gabon. It provides a free SMS service for patients to use to ask their doctor questions about their diabetes. Patients receive a reply within 24 hours. This approach frees time for the few diabetes specialists in the country.

INNOVATION

Raising awareness among marginalised communities

Educating communities on disease recognition and prevention and on improving healthcare seeking behaviour can have beneficial effects on health and disease outcomes.

AstraZeneca's Young Health Programme focuses on disease prevention and awareness raising among adolescents, and involves Plan International and the Johns Hopkins Bloomberg School of Public Health. It covers four countries within the scope of the Index (Brazil, China, India and Zambia). It is relatively innovative in that it targets marginalised segments of local populations. The programme aims to improve awareness of hygiene, sexual and reproductive health, infectious diseases and environmental harm due to water and air pollution.

Boehringer Ingelheim's Making More Health Initiative (MMH) is a fellowship programme that provides support to individuals who are implementing new ideas for improving health in their communities. These individuals are all members of Ashoka, a network organisation of 'social entrepreneurs', Boehringer Ingelheim's partner in MMH. The aim of the programme is to combine Boehringer Ingelheim's business knowledge and the social knowledge of Ashoka and its members. MMH contains components of capacity building and philanthropy, and covers several countries within the scope of the Index. It is also relatively innovative for its focus on marginalised and stigmatised communities and socially sensitive subjects, such as mental health and sanitation.

INNOVATION

Supporting healthcare providers to improve maternal and neonatal health

Two of the UN Millennium Development Goals aim to reduce maternal and child mortality. Training midwives and tracking disease and outcome rates can contribute to reaching these goals.

The Sanofi Espoir Foundation has set up, in collaboration with the International Confederation of Midwives, a global forum called Connecting Midwives. This online platform allows midwives to share experiences, ideas, projects and innovations, and to propose field projects that aim to reduce maternal and neonatal death or improve maternal and neonatal health in the most underserved areas. The Sanofi Espoir Foundation will provide financial support to ten such local initiatives in 2014.

AbbVie has supported the development of a national neonatal registry for the Philippines, in collaboration with the Philippine Society of Newborn Medicine. In line with national needs, the registry is the first step toward controlling disease among newborns, providing the potential to track disease and outcome rates.

a This analysis is partly based on new and refined indicators. See the Appendix for more information on Scoring Guidelines.

b This analysis excludes regional initiatives for which no separate countries were specified. This equals 5.0% of initiatives.

c Revenues are based on 2013 Annual Reports and cover all business segments. Revenues not reported in USD were converted using exchange rates on 4th September 2014. Within the Index scope eight companies have annual revenues above USD40 billion and 12 companies have annual revenues below USD25 billion.

d This only includes activities relating to improving the skills of local organisations and people working in this field. It does not include implementing anti-counterfeiting technologies, such as overt and covert features, forensic techniques and serialisation.

G Product Donations & Philanthropic Activities

For millions of people worldwide, donation may represent their only chance of gaining access to the medicines they need – particularly if they live in poor, rural and isolated regions where healthcare systems do not function. Pharmaceutical companies have been involved in product donations for many years, and the magnitude and impact of individual programmes on access to medicine can be substantial.

The Index distinguishes between two types of donation programmes: *ad hoc* programmes (which respond to acute, short-term needs, such as emergency situations); and structured programmes (which target specific diseases over a longer period). For all donation programmes, the Index looks for compliance with the WHO Interagency Guidelines for Medicine Donation (Revised 2010).¹

In resource-limited countries or regions, companies can also improve access to medicine through sustainable philanthropy, namely by providing grants for improving local healthcare capabilities. These can be targeted towards prevention and healthcare for certain diseases, or toward healthcare infrastructure improvements and general patient education programmes.

In this Index, more emphasis is placed on strategic and integrated approaches towards donations and philanthropic activities, with a focus on needs-based initiatives and impact assessments that determine effectiveness.

Three areas of analysis

Product donations

Reporting on whether companies engage in product donations that aim to eradicate, eliminate, or control a disease.

Sustainable philanthropy

Reporting on companies' philanthropic activities that align with national and/or international health priorities.

Innovation in donations and sustainable philanthropy

Reporting on innovation in donation and philanthropic activities and approaches that can improve their efficiency and impact.

Top findings in Product Donations & Philanthropic Activities

Neglected tropical diseases are the main focus of donations activities

More than half of the companies in the Index are engaging in structured donation programmes, amounting to 28 programmes in total. Collectively, they target some communicable and non-communicable diseases, as well as ten neglected tropical diseases. The latter stand out for their long-term commitments and wide geographic scopes, frequently covering large proportions of endemic regions. Since 2012, four new structured donation programmes have been initiated.

Philanthropic initiatives are becoming more needs-based

Compared to 2012, more companies are taking a more strategic, needs-based approach to their philanthropic activities. All of the philanthropic activities captured by the Index align with either international health priorities, such as the Millennium Development Goals, or to national health priorities. The best performing companies often have a separate foundation to manage their initiatives, and conform with the best practices identified by the Index.

Majority of companies ensure donation programmes meet high standards

More than half of companies have donation policies that fully adhere to the WHO Interagency Guidelines for Medicine Donations (Revised 2010), with another five companies approaching these standards. Furthermore, most companies that engage in product donations have policies or procedures for ensuring quality along the entire supply chain. Five companies have newly implemented such procedures or policies since 2012.

How the companies perform

The industry performs even better in product donations and philanthropy than in 2012. New structured donation programmes have been initiated, while others have been scaled up. The 2012 London Declaration on Neglected Tropical Diseases has proved a catalyst for action, with many companies subsequently extending their commitments and scaling up efforts to tackle these diseases.

Leaders donate on a large scale

The top six positions are held by Novo Nordisk, Merck & Co., GSK, Merck KGaA, Novartis, and Johnson & Johnson. In terms of scores, these six companies are tightly packed.

Regarding their structured donation programmes, they all deliver top performances across several parameters, including programme value, scale and scope, and on the integration of outcome measures and impact assessments. In addition, these companies are all engaged in numerous sustainable philanthropic activities that adhere to the highest standards examined by the Index. These activities characteristically target local needs, are long term and have specific targets and integrated outcome measures or impact assessments.

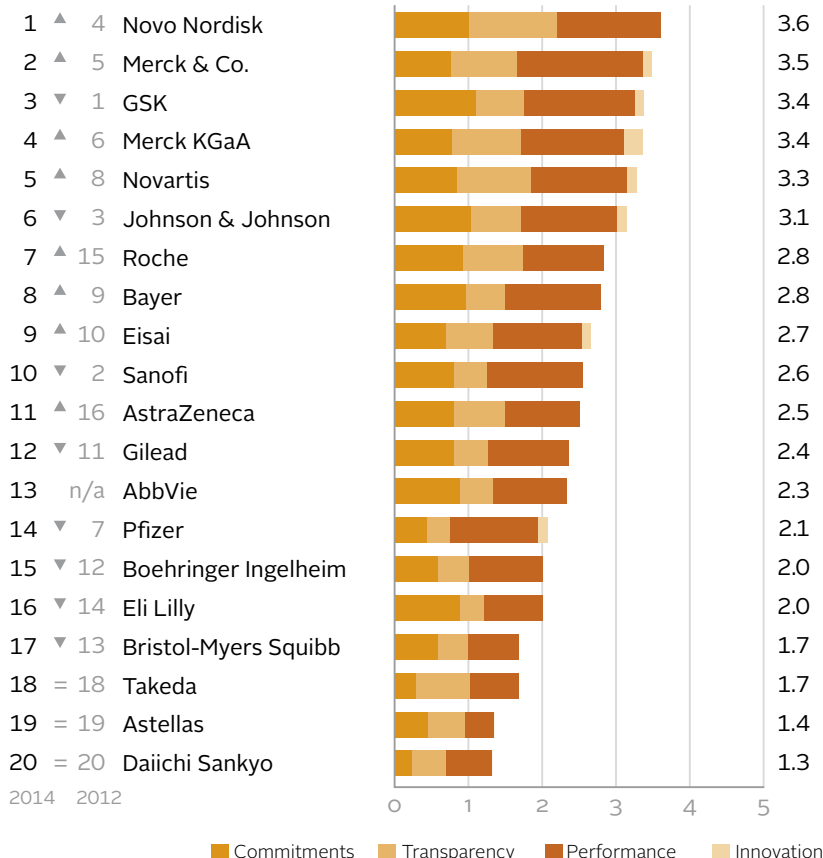
Adherence to the highest standards:

Novo Nordisk

Novo Nordisk is the overall leader when it comes to product donations and sustainable philanthropy. Although its Changing Diabetes in Children programme is not the largest donation programme in terms of scale and scope, the company performs the most consistently across all parameters. Its structured donation programme meets the highest standards set by the Index, including strict adherence to the WHO Interagency Guidelines and a compre-

Figure 52

Company Ranking Product Donations & Philanthropic Activities



hensive monitoring and reporting process. The company is among the leaders in all areas, including philanthropy, and is particularly transparent.

Leaders provide sustainable access for neglected tropical diseases

The next three positions are taken by Merck & Co., GSK and Merck KGaA. All three are very close behind Novo Nordisk and run a large structured donation programme that meets the highest standards set by the Index (donations of ivermectin, albendazole, and praziquantel, respectively). These are all mass-drug administration programmes that are referred to in the 2012 London Declaration on Neglected Tropical Diseases.²

Furthermore, these companies score particularly highly for their commitment level, pledging to support their structured donation programmes until 2020, or until the target disease is eradicated. These companies also perform well in philanthropy.

Merck KGaA provides the most evidence of innovation regarding donation and philanthropy. Together with a partner, it is piloting a study to investigate needs for sanitation to prevent infection with schistosomiasis (in support of its praziquantel donation programme). The pilot is taking place in Senegal and involves people infected with schistosomiasis or living in regions

where the disease is present. The results are due in 2014. Merck KGaA is also one of the members of the NTD Supply Chain Forum, together with GSK, Johnson & Johnson, Pfizer, Merck & Co. and Eisai.³ This is a new collaborative initiative working to improve the delivery of drugs and supplies to more than 70 countries affected by neglected tropical diseases.

Assessing effectiveness

Novartis and Johnson & Johnson take 5th and 6th position respectively. They both stand out for having multiple structured donation programmes. Novartis runs one of the oldest donation programmes, which aims to eliminate leprosy globally, while Johnson & Johnson runs one of the few large donation programmes that targets HIV/AIDS. Neither company, however, demonstrates that it consistently includes impact assessments or outcome measures in its programmes.

Biggest riser: Roche

Roche is the biggest riser in this area, climbing from 15th to 7th position. This is largely because of the wider scope of the Index, which means that its ongoing structured donation programme qualifies for inclusion in this analysis for the first time. It is a smaller-scale structured donation programme that targets hepatitis. It aligns with WHO Interagency Guidelines and includes measures for monitoring the supply chain right up to the patient. Roche would have climbed even higher had it demonstrated long-term commitment and provided a rationale for deciding what level of assistance to provide to each region.

Less consistency from the middle performers

Bayer and Eisai also stand out for the scope and quality of their structured donation programmes. However, they achieved some of the lowest scores for philanthropy, which kept them out of the leader group.

Joining these two in the middle ranks are Sanofi, AstraZeneca, Gilead, and AbbVie. When all parameters are taken

into account, these four companies delivered less consistent performances than the leaders did. Sanofi and Gilead have large, high-value structured donation programmes, and Sanofi is among the leaders in philanthropy. However, Sanofi slips out of the leading group for its lack of transparency regarding its decision-making processes for its structured donation programmes and the specifics of its *ad hoc* programmes. Gilead did not provide evidence of a donation policy, nor evidence that it engaged in *ad hoc* donations. AstraZeneca does not have on-going structured donation programmes, but is among the leaders in philanthropy. AbbVie took over two structured donation programmes from Abbott in 2012. However, it lags other companies when it comes to including outcome measures and impact assessments.

Laggards less involved in large-scale activities

Pfizer, Boehringer Ingelheim, Eli Lilly, Bristol-Myers Squibb, Takeda, Astellas and Daiichi Sankyo occupy the lowest rungs, with a significant spread of scores.

Pfizer has two structured programmes, but does not fully adhere to the WHO Interagency Guidelines and did not provide evidence of conducting impact assessments. Boehringer Ingelheim had a single structured donation programme that was wound up during the period of analysis following revisions to the WHO's treatment guidelines.⁴ Both Pfizer and Boehringer Ingelheim lag in philanthropy. Eli Lilly has two small structured programmes that target diabetes and mental health. The Index encourages the continuation and expansion of these programmes, or a shift to other more sustainable solutions, such as equitable pricing strategies.

Bristol-Myers Squibb, Takeda, Astellas and Daiichi Sankyo do not have ongoing structured donation programmes.

Bristol-Myers Squibb did provide evidence of donating products *ad hoc* for emergency relief while adhering

to the relevant WHO Interagency Guidelines. They also have stringent monitoring policies and procedures for guaranteeing the delivery of their donated products to the intended recipients. Yet, while they disclosed details of these *ad hoc* donations to the Index, they do not make this detail publicly available.

Takeda, Daiichi Sankyo, and Astellas did not provide any evidence that they donated products to relevant countries during the period of analysis. Takeda does have a policy governing product donations that includes elements of the WHO Interagency Guidelines. Astellas provided evidence that its donations in Japan comply with elements from the WHO Interagency Guidelines. However, it does not have a global policy for product donations. Daiichi Sankyo states it does not engage in product donations, as it does not have systems for meeting the standards set by the WHO. If it does donate products in emergency situations, it relies on partner organisations to manage distribution.

High performance in product donations and philanthropic activities

As in 2012, companies perform strongly in this Technical Area. The majority (15) are engaged in long-term structured donation programmes that align with national or international health priorities. In total, 28 such programmes were ongoing during the period of analysis, half of which target neglected tropical diseases, with the rest targeting communicable diseases and non-communicable diseases.

The majority of companies (15) donated products *ad hoc* for emergency relief, typically via humanitarian aid-relief organisations such as the Red Cross, MSF and Project HOPE. During the period of analysis, this included emergency relief for Syrian refugees and people hit by typhoon Haiyan. Only six companies publicly disclose information relating to the type, volume and destinations of the products they have donated *ad hoc* for emergency relief. These companies are Novo Nordisk, Novartis, Roche, Merck KGaA, Bayer and Johnson & Johnson.

All companies in the Index are involved in philanthropic activities in some respect. Eleven are engaged in numerous philanthropic activities that

are supported by substantial levels of commitment and that have clear objectives, integrated outcome measures and impact assessments.

One-third of companies (seven) provided evidence of innovation in this area, in relation to structured donation programmes and with the aim of improving supply chain efficiency, impact on public health, and the involvement of local communities.

High standards in donation policies and practices

The industry continues to set high standards for its product donation programmes. More than half have policies or codes in place that adhere to all aspects of the relevant WHO Interagency Guidelines, including ensuring the quality and usability of their donated products. A further 25% have codes that are partially compliant. Only Daiichi Sankyo and Astellas have no relevant policies or guidelines in place. These companies do not typically donate products outside of Japan. In addition, the majority of companies engaged in donation have policies and procedures in place for ensuring quality along the entire supply chain.

Compared to 2012, five more companies have improved their commitments to ensuring delivery up to the patient by implementing procedures or policies.

In practice, this high compliance means that companies are generally working in collaboration with either the WHO, national governments and/or local stakeholders to align their donation programmes with local needs and health practices. This approach is being applied against neglected tropical diseases, for example, where multiple stakeholders are combining forces to achieve maximum outcomes. Companies can have an even greater impact on public health by integrating their respective donation programmes, thereby addressing multiple disease areas in relevant regions.

Wide scale and scope of structured donation programmes

Many structured donation programmes cover much of the area where the targeted diseases are endemic, especially where neglected tropical diseases are targeted: these programmes typically have wide geographic scopes and are expected to last more than five years.

FOCUS AREA 1

Product donations

Longer commitments and increased efforts in product donations

Why this matters

Structured programmes are defined as gifts that include medicines or vaccines^a that are strategically set up to target local health priorities and aim to control, eradicate, or eliminate diseases within the scope of the Index.^b To qualify for this analysis, programmes must be supported with substantial commitments in terms of

time-scale and resources; ongoing during the period of analysis; active in countries within the scope of the Index; and aligned with national or international health priorities. Donated products that fall outside the disease scope are excluded, despite the fact that they may have a substantial impact on public health (such as the Novartis'

Glivec International Patient Assistance Program).

The Index looks at if and how companies monitor and assess the effectiveness of their donation operations, using either outcome measures (designed to give feedback on the efficiency of supply chains) and/or

impact assessments (designed to give feedback on the programme's impact on public health). For each structured programme, its monetary value and the company's revenue is used to deter-

mine a company's potential capacity to donate. As companies use many different measures to calculate the value of donations, this figure is not used to compare programmes. Instead,

the Index uses each programme's intended duration and geographic scope to categorise it as either a large or small structured programme.

How companies perform

In total, 28 structured donation programmes were ongoing during the period of analysis, four of which were initiated since 2012. Three of these new programmes target neglected tropical diseases and one targets HIV/AIDS.

Increasing access to medicine for neglected tropical diseases

Half of all structured donation programmes target neglected tropical diseases, namely trypanosomiasis, Chagas disease, lymphatic filariasis, leishmaniasis, soil-transmitted helminthiasis, onchocerciasis, schistosomiasis, food-borne trematodiasis, leprosy and trachoma. The majority of these programmes (11) were set up before 2012 and are linked to the 2012 London Declaration on Neglected Tropical Diseases.² These 11 programmes are run by Bayer, GSK, Johnson & Johnson, Merck & Co., Merck KGaA, Novartis, and Pfizer. They all meet the highest standards set by the Index, and all companies involved met the shipment targets set out in the London Declaration.³

Three companies initiated other programmes targeting neglected tropical diseases since 2012: one targets leishmaniasis and was initiated by Gilead; the other targets lymphatic filariasis and was initially set up by Sanofi before being transferred to Eisai in 2013. Eisai has committed to significantly scale it up and started shipping to the WHO in October 2013.

Small-scale donations for malaria, tuberculosis

When it comes to communicable diseases, companies generally engage in smaller-scale donation programmes. There are six such programmes, run by AbbVie, Johnson & Johnson, Merck

Figure 53

Neglected tropical diseases are the main focus of donations programmes

Neglected tropical diseases are the focus of the highest number of structured donations programme, and by far the highest number of large-scale programmes.

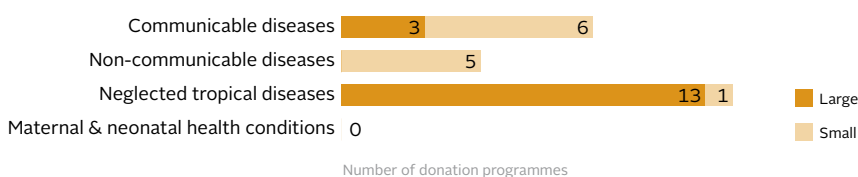
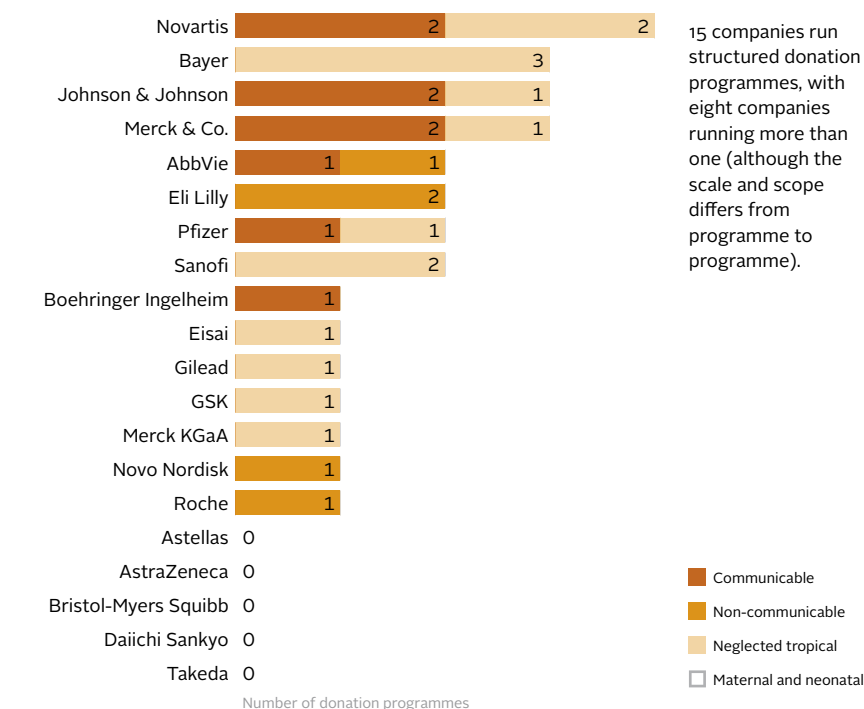


Figure 54

Majority of companies engage in structured donations programmes



& Co. and Novartis. Each one has an extended timeframe and corresponds to national health priorities. They aim to reach specific populations living in relatively small geographic regions, and target lower respiratory infections, malaria, tuberculosis, and HIV/AIDS.

Improved access to antiretroviral medicine

HIV/AIDS is the only communicable disease, as well as the only chronic disease, to be targeted by both small-scale and large-scale programmes. It is the focus of three large-scale programmes in total, run by Boehringer Ingelheim, Johnson & Johnson, and

Pfizer. However, Boehringer Ingelheim wound up its programme in 2013 following revisions to the WHO's treatment guidelines.⁴ Of the other two, one has been initiated since 2012 and provides medicines to children in sub-Saharan Africa (Johnson & Johnson), while the other provides treatment for opportunistic infections related to HIV/AIDS for patients in 63 countries (Pfizer).

Local support for non-communicable diseases

There are no large ongoing structured donation programmes that target non-communicable diseases. However, there are five smaller programmes targeting diseases in this group, namely epilepsy (AbbVie), mental health disorders (Eli Lilly), hepatitis (Roche) and diabetes (Novo Nordisk and Eli Lilly). These programmes aim to reach specific populations living in confined geographic regions where needs are high. They offer temporary relief to patients facing high barriers to access to medicine. Most of these programmes were initiated before 2010: only Roche's programme was launched relatively recently (in 2011).

Maternal and neonatal health conditions not targeted by product donations

There are no structured donation programmes that target maternal and neonatal health conditions. These conditions have high disease burdens that disproportionately affect people in poor, rural areas, making them appropriate candidates for the donation models used to combat neglected tropical diseases. The Index encourages companies to explore opportunities for improving maternal and neonatal health through their existing systems and supply chains for structured donation programmes.

Partners and WHO drive outcomes and impact measurements

Of the 15 companies that engage in structured donations, 11 provided evidence of having monitoring or reporting procedures for measuring

outcomes along the entire supply chain, up to the patient, in all their structured donation programmes. Nine of these companies go further, by integrating health impact assessments into the strategy underpinning some or all donation programmes. For the majority, impact assessments are carried out by independent partners such as the WHO.

The leaders

The leaders in product donations are: Novo Nordisk, Merck & Co., Merck KGaA, Eisai, GSK, Bayer, Johnson & Johnson and Novartis. All structured donation programmes run by the top six companies are supported by measures for assessing outcomes and impact. These measures provide feedback for improving supply chains and the programmes' impacts on public health. The leaders' programmes are managed to very high standards, which helps to guarantee quality. They also include procedures for ensuring donated products reach the intended communities.

The middle group

In the middle group of companies are Roche, Sanofi, Eli Lilly, Gilead, Boehringer Ingelheim, Pfizer and AbbVie.

All of these companies run substantial and worthwhile structured donation programmes. However, when all parameters are taken into account, the leaders deliver stronger, more consistent performances.

The laggards

The lagging companies are: Astra-Zeneca, Bristol-Myers Squibb, Takeda, Daiichi Sankyo and Astellas. None run any structured donation programmes.

The London Declaration: coordinating efforts to combat neglected tropical diseases.

The signing of the London Declaration in 2012,² as a response to the WHO Roadmap,⁵ marked a turning point for millions of patients suffering from neglected tropical diseases. Since then, companies have scaled up their donation programmes enormously. In 2013, the industry donated approximately 1.35 billion treatments – an increase of 35% compared to 2011.³

Ten companies included in the Index endorsed the London Declaration and have committed to donating products: Bayer, Eisai, Gilead, GSK, Johnson & Johnson, Merck KGaA, Merck & Co., Novartis, Pfizer and Sanofi. These companies all run structured donation programmes that together target lymphatic filariasis, trachoma, soil-transmitted helminthiasis, onchocerciasis, schistosomiasis, leprosy, leishmaniasis, Chagas disease, trypanosomiasis and food-borne trematodiasis.

All ten companies fulfilled the commitments they made when signing the London Declaration. As a result, the supply of medicines no longer needs to be a barrier to controlling or eliminating these diseases. The programmes run by Merck & Co., Merck KGaA, and GSK have the highest levels of commitment: the companies pledge to continue their donation programmes until the diseases they target are eliminated.

Due to their large size and scope, these donation programmes require a collaborative approach to ensure that products reach patients. Their implementation and coordination is managed by the United to Combat NTDs consortium, with various stakeholders coming together in a working group (with GSK representing the industry) to enable greater accountability. Progress is monitored using scorecards and milestone tables, facilitating continuous problem solving.³

Timeline of 28 structured donation programmes

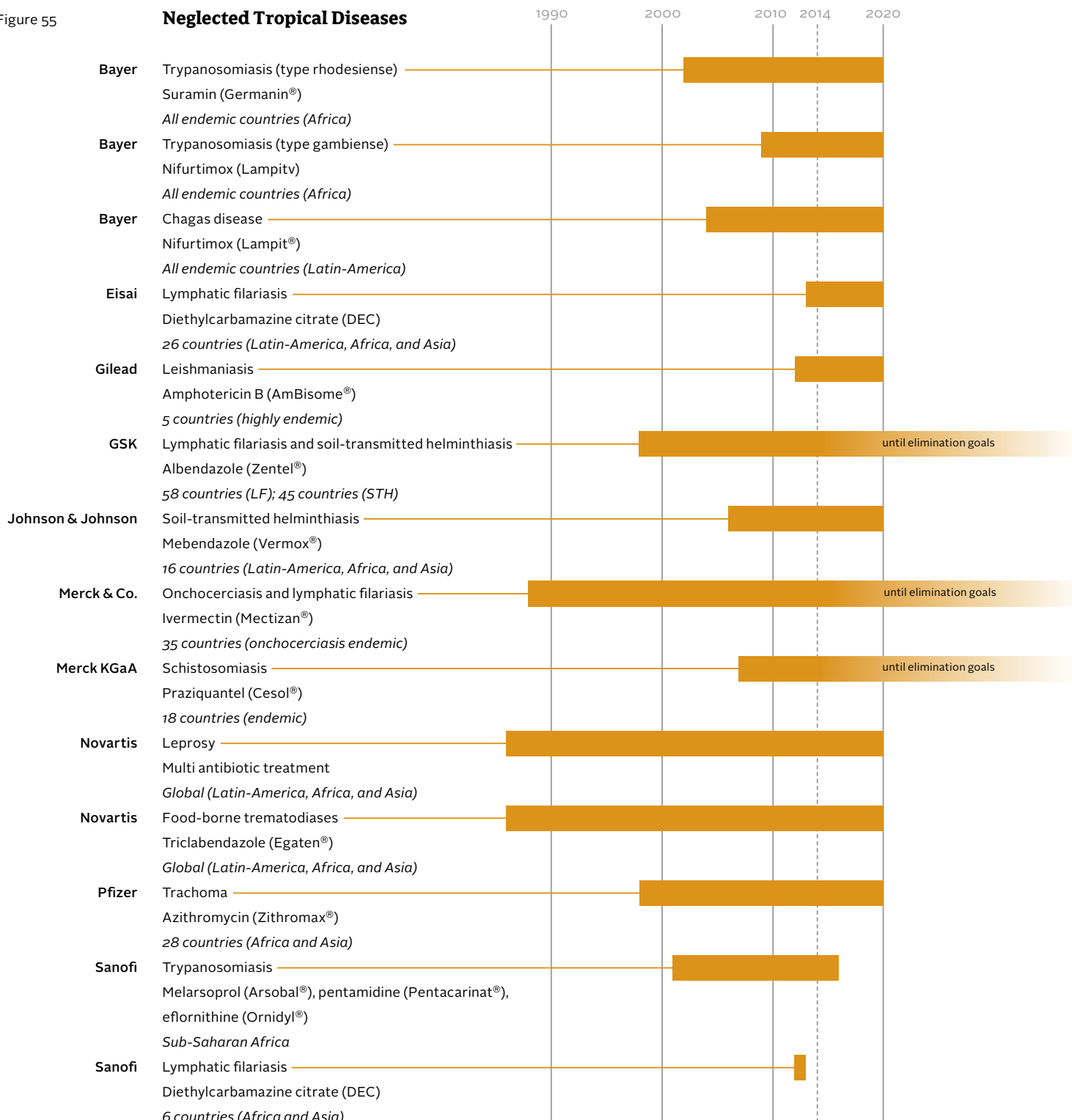
For people living in poor, rural and isolated regions without appropriate healthcare infrastructure, structured donation programmes may provide the only chance of access to medicine. Moreover, conditions typical to these regions make it relatively easy for infectious diseases to spread.

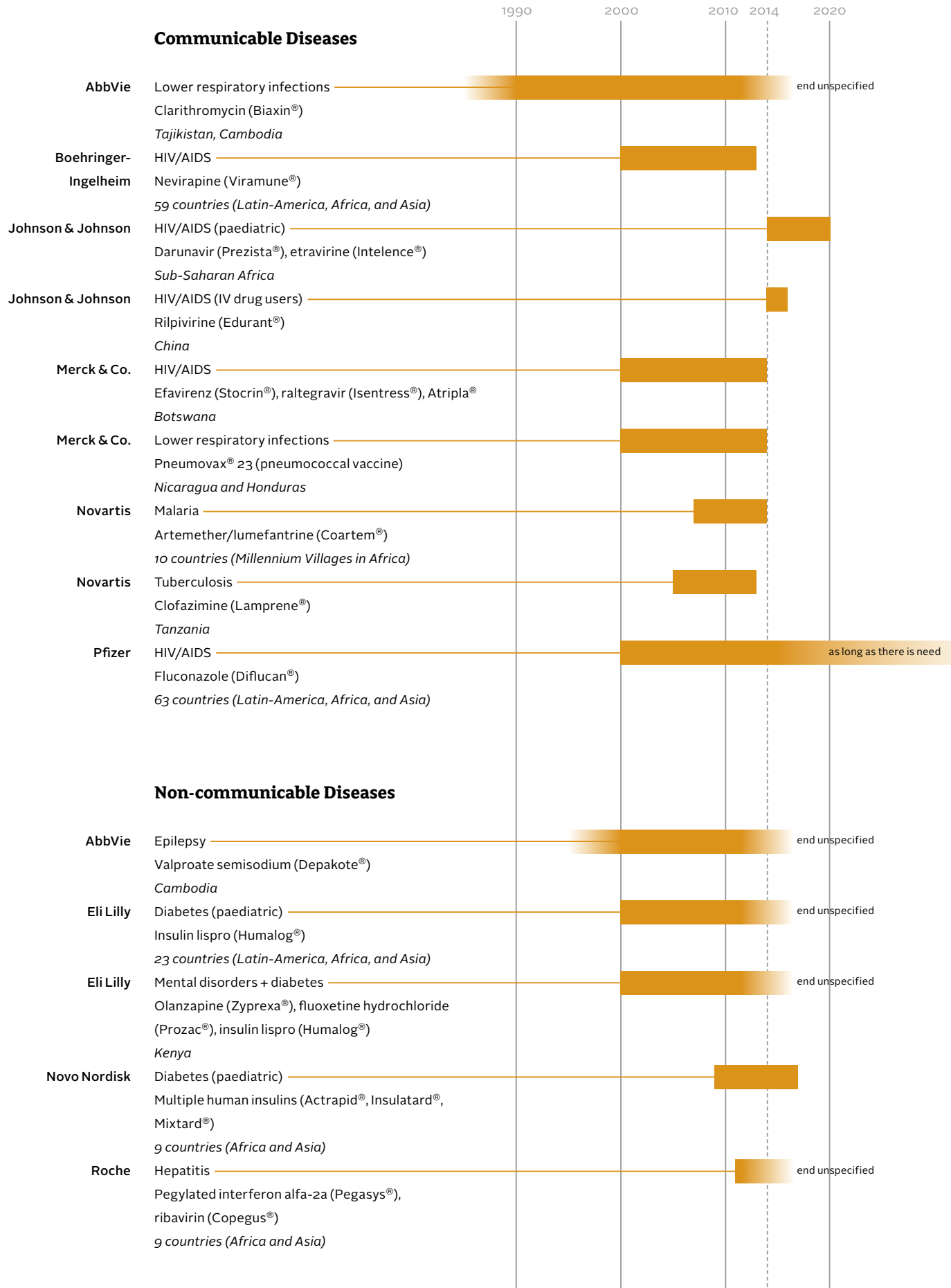
Companies have been engaged in product donations for many years. Some programmes go back as far as the 1980s. Such long-term durations, combined with wide geographic reach and commitments to continue for at least five years or more, make large structured donation programmes an

important mechanism for ensuring access to medicine. Other, smaller scale programmes, which are ongoing in a selection of countries, provide access to medicine for pockets of patients where there is a high need.

Figure 55

Neglected Tropical Diseases





Donation programmes in action

Donation programs aim to control, eliminate or eradicate specific diseases. Medicines are preferably oral, to make them easier to administer correctly, and their use requires acceptance by people in local communities, as well as correct monitoring and diagnosis. It is also important to ensure donated products can reach people in remote areas, packaged in a way that enables health workers to store and administer them appropriately.



◀ Sleeping sickness in Africa

A healthworker screens for trypanosomiasis, as part of Sanofi's donation programme.



◀◀ Helminthiasis in Cameroon

A child in Cameroon receives mebendazole from Johnson & Johnson.

◀ Helminthiasis in Africa

Children in Lomé, Togo, receive albendazole donated by GSK.



◀◀ Trypanosomiasis in Africa

Donations of suramin for trypanosomiasis from Bayer come through the Omugo Health Center in Uganda.

◀ Lymphatic filariasis

Eisai donates Diethylcarbamazine Citrate (DEC), in a programme started by Sanofi.



◀◀ Onchocerciasis in CAR

Merck & Co.'s Mectizan® programme reaches rural Gbatong in the Central African Republic.

◀ Vaccination in Nicaragua and Honduras

Vaccines from Merck & Co. must travel by horseback through the Nicaraguan mountains.



© Chantal Hermans for Merck



© Jon Ryter for Novo Nordisk

« Schistosomiasis in Africa

Determining dosage for schistosomiasis, which Merck KGaA tackles with the WHO.

« Diabetes in Bangladesh

A nurse administers insulin donated by Novo Nordisk to a child with type 1 diabetes in Dhaka.



© Pfizer Inc.



© Bayer Healthcare AG

« Trachoma in Africa

Pfizer donates treatment for this blinding infection in many African and Asian countries.

« Chagas disease in Latin America

Bayer ships donated nifurtimox to El Salvador for further processing.



© Roche



© Christian Flierl / Novartis Foundation

« Hepatitis in Pakistan

Roche supports awareness raising initiatives to encourage screening and prevention.

« TB in Tanzania

Tuberculosis medicine donated by Novartis accounts for 25% of the WHO's annual supply.



© Boehringer Ingelheim



© William Vazquez for AbbVie

« HIV/AIDS in Uganda

A newborn receives a donated HIV/AIDS treatment from Boehringer Ingelheim.

« Epilepsy in Cambodia

Via this hospital in Cambodia, AbbVie's donations reach children with epilepsy or lung infections from rural areas.

Sustainable Philanthropy

Philanthropy aligned with health priorities

Why this matters

The Index looks for philanthropic activities that are sustainable and targeted towards improving local healthcare capabilities and access to medicine in the long term. For example, philanthropic activities can aim to improve healthcare infrastructure, to enhance the capabilities of local organisations, or strengthen disease-prevention or healthcare-promoting initiatives.

To this end, the Index examines whether activities are supported by needs-based, cohesive strategies and long-term commitments. The Index also measures companies' level of disclosure regarding resulting outcomes and impact reports, as well as allocated resources.

To meet the highest standards set by the Index, philanthropic activities

must be long-term, align with national or international health priorities, and include specific targets and integrated outcome measures and impact assessments.

Philanthropy refers to the provision of financial assistance to local organisations. Where other resources are contributed, the Index views this as Capability Advancement.

How the companies perform

In general, companies perform well when it comes to sustainable philanthropy: all companies are involved in philanthropic activities to some extent. The quantity and quality of their activities differs substantially.

The strongest performing companies are involved in numerous initiatives that meet the highest criteria examined by the Index. The leaders often have a separate foundation that manages philanthropic activities in multiple fields and in alignment with international health priorities, such as the Millennium Development Goals. Instead, weaker performing companies are involved in fewer long-term activities without clear targets, outcome measures or impact assessments.

High standards of needs-based philanthropic approaches from the leaders

Seven companies deliver strong performances in this area: Novartis, Novo Nordisk, GSK, AbbVie, Sanofi, AstraZeneca, and Roche. They all take a needs-based, sustainable and long-term approach to philanthropy, and adhere to the best practices set by the Index for philanthropy. Their transparency is also high, as they publicly disclose the outcome measures, impact

assessments and resources associated with the majority of their philanthropic activities.

Novartis: Through its Foundation for Sustainable Development, Novartis is engaged in numerous philanthropic activities that connect to other access initiatives and capacity building projects. Its approach to philanthropy focuses on strengthening local organisations and introducing business tools for planning, implementation and evaluation. Its activities generally focus on improving care for patients with specific diseases or conditions, including malaria, leprosy and tuberculosis. Novartis' initiatives are mainly active in Africa, are all long term (>5 years), have clear targets and include outcome measures. Novartis discloses the resources allocated to these activities.

Novo Nordisk: Through its World Diabetes Foundation, Novo Nordisk supports numerous projects that aim to improve diabetes care, including national diabetes programmes in five African countries. These programmes are very sustainable, due to the involvement of national authorities and long timescales. The World Diabetes Foundation discloses the resources

allocated to all of its activities, as well as their objectives and outcomes. Novo Nordisk integrates its philanthropic activities with its business activities.

GSK: The company invests 20% of its profits from Least Developed Countries in philanthropic activities, which are strongly aligned with national health priorities and designed to have a sustainable impact on local human capital and healthcare infrastructures. In particular, GSK has a strong focus on strengthening local capacity for front-line community-based work. The company partners with international NGOs such as Save the Children and CARE International. The company regularly assesses the impact of its programmes on public health, and discloses aggregate resources allocated to numerous specific projects.

AbbVie: The AbbVie Foundation supports numerous activities, including health education programmes, to improve care for patients with specific diseases, namely hepatitis, HIV/AIDS and neglected tropical diseases. Its approach aligns with national and international health priorities. The company discloses resources and outcome measures for each activity.

Sanofi: The Sanofi Espoir Foundation supports numerous sustainable philanthropic activities. It sets targets and regularly evaluates the health, social, and economic benefits of its activities for the communities involved. These evaluations include progress checks against national and international health priorities. Sanofi discloses in detail the allocated resources and outcomes for all of its activities.

AstraZeneca: The company takes a detailed approach to managing its philanthropic activities, conducting feasibility studies, impact assessments, capacity assessments and sustainability measurements. Its activities align with health priorities and are increasingly focused on non-communicable disease prevention. Through the AstraZeneca Young Health Programme, the company funds a range of activities, from global research and advocacy to education and health skills training, with the aim of improving the health of young people worldwide. AstraZeneca discloses the resources it allocates to philanthropy.

Roche: In its philanthropic activities, Roche focuses on their sustainability. The company aligns its philanthropic efforts with the Millennium Development Goals, and most of its activities are long-term with integrated outcome measures. Its activities relate to many different areas, including disaster relief and local humanitarian organisations that work with disadvantaged populations. Roche discloses the type of resource per activity and outcome assessments associated with the majority of its reported philanthropic activities.

Less sustainability and consistency in the middle group

Following the leading group are Johnson & Johnson, Merck & Co., Astellas, Gilead and Merck KGaA. These five companies are also engaged in numerous philanthropic activities, but tended to drop points for not demonstrating how they track outcomes or

assess impacts, by not disclosing how much they invest in these activities, or by having shorter-term activities.

Johnson & Johnson: Johnson & Johnson is engaged in more than 500 philanthropic activities. They align with national priorities and are mainly centred on the Millennium Development Goals to reduce child mortality, improve maternal health and improve care for patients with HIV/AIDS, malaria and other diseases. However, the company did not provide evidence of systematically integrating outcome measures or impact assessments into its activities.

Merck & Co.: The company focuses its philanthropic efforts on strengthening healthcare systems and building local healthcare capacities (particularly the latter), for example through the Millennium Villages Community Health Worker training programme. However, Merck & Co. does not disclose the allocated resources for all its activities.

Astellas: The philanthropic activities run by Astellas focus on the Millennium Development Goals (MDGs). Although they are not long term, they contribute strategically to achieving the long-term objectives of the MDGs. The company discloses the allocated resources, outcome measures and targets per project.

Gilead: HIV/AIDS is the emphasis of Gilead's philanthropy. It focuses on improving HIV/AIDS care by strengthening healthcare infrastructure and reducing stigma. Gilead's activities include a mobile communications service for healthcare providers. Compared to leading companies, it has fewer long-term strategies. Its activities approach the highest standards set by the Index, but are not long term.

Merck KGaA: Merck KGaA engages in numerous philanthropic activities, some of which are long term. Its approach ensures individual projects align with broader long-term goals, and it disclosed aggregate resources

and outcome measures for some of its initiatives.

Bristol-Myers Squibb: The Bristol-Myers Squibb Foundation manages two initiatives: one that focuses on improving care for patients with hepatitis in Asia, and one that focuses on care for patients with HIV/AIDS in Africa. Called Delivering Hope and Secure the Future, these initiatives involve numerous activities in several countries.

Laggards lack outcome measures and long-term objectives

Bayer, Takeda, Daiichi Sankyo, Boehringer Ingelheim, Pfizer, Eli Lilly, and Eisai lag in sustainable philanthropy. Compared to the leaders, these companies are engaged in fewer long-term activities that generally lack clear objectives or processes for measuring outcomes. Only Boehringer Ingelheim stands out some way, for disclosing aggregate resources and outcome measures for some activities. Bayer and Daiichi Sankyo take a sustainable approach to philanthropy that is evidenced in multiple short-term activities. Pfizer has initiatives to improve human capacity through its volunteering programmes – these qualify for analysis in the chapter on Capability Advancement.

INNOVATION

Increasing localisation to achieve elimination goals

Where donation programmes aim to eradicate, eliminate or control certain diseases, there is an increased need for innovative approaches tailored to overcoming local challenges and infrastruc-

ture limitations. The 2014 Index found evidence of three innovative initiatives that are addressing problems unique to local conditions.

Innovation to decrease disease transmission

Merck KGaA started a pilot study through its Merck Praziquantel Donation programme that involves local communities in Senegal, particularly people infected by schistosomiasis and others living in regions where the disease is present. People can become infected through exposure to infested water, with poor sanitation increasing the risk of infection. Through a partner, Merck KGaA is working to build a better understanding of the processes related to prevention and the need for sanitary solutions.

Novartis has launched an innovative strategy to interrupt leprosy transmission. Leprosy is a disabling and stigmatised disease that mainly affects the poorest of the poor. Its leprosy elimination programme has provided treatment to millions, but its impact has plateaued. To reach its elimination goal, Novartis has developed a new approach that involves early diagnosis and treatment, as well as contact tracing and surveillance, paying more attention to the people close to leprosy patients.



© Paroma Basu/Novartis Foundation

^ A child is examined at a leprosy camp in India, part of Novartis' programmes for leprosy tracking and prevention.

Innovation in product donation supply chain

The **Neglected Tropical Diseases Supply Chain Forum (NTDSCF)** was formed following the signing of the London Declaration on Neglected Tropical Diseases.² It is a new collaborative platform for identifying problems and inefficiencies associated with the supply and delivery of products that have been donated for treating NTDs. A common issue is delays between ports and central warehouses due to custom clearances. Forum members, including DHL, are piloting initiatives to enhance this 'first-mile' distribu-

tion, as well as studies to identify new strategies and planning approaches for 'last-mile' distribution, from central warehouses to the intended communities and patients. 'Last-mile' solutions will be critical in reaching the targets set out in the London Declaration.³ GSK leads this initiative and partners with Johnson & Johnson, Pfizer, Merck & Co., Merck KGaA, and Eisai. NTDSCF members also receive credit in the Capability Advancement chapter.

For numbered references, see the Appendix.

b For the full 2014 index Disease Scope, see the Appendix.

a Donation of other product types, such as diagnostics and vector control products, have been excluded from this analysis, unless integrated with the donation of medicine.

Company Report Cards

The 2014 Access to Medicine Index includes a set of 20 company report cards, which each provide a contextualised analysis of one company's performance in the 2014 Index. This includes a summary of its strengths and weaknesses, any best and innovative practices, as well as the drivers behind changes in its ranking. Each report card includes overviews of the company's portfolio and pipeline, and identifies tailored opportunities for it to increase access to medicine. The report cards are divided into six sections:

Company overview

Graphical overview and explanation of the company's overall Index rank and scores in each area, with a summary of notable new developments and drivers behind changes in its ranking.

Performance update

Update on the company's access-to-medicine performance, including new commitments and new and/or expanded strategies, activities and programs.

Best practices

Overview of all best and innovative practices identified by the 2014 Index for this company. Practices are included here if they: can be considered best in the industry; solve a problem in access to medicine; represent innovation where progress is needed and/or where a clear gap exists; or could potentially have a significant impact in any of the areas measured.

Sales and operations

General description of the company's operations, revenue per region and geographical reach.

Portfolio and pipeline

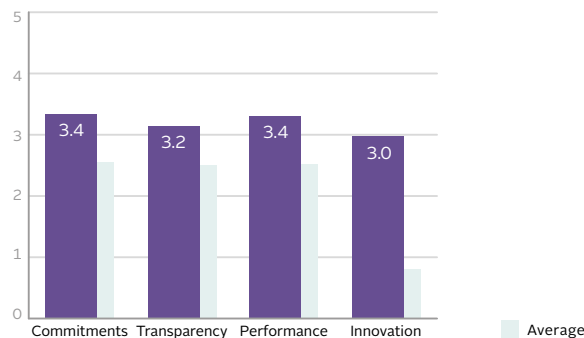
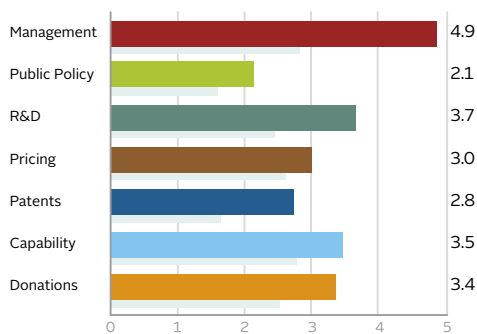
Analysis of the company's portfolio of marketed products and pipeline of R&D products that fall within the scope of the Index, in line with specific inclusion and exclusion criteria (see the Appendix for more information).

Opportunities for improving access to medicine

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.

rank	score
1 st	3.3
1 (2012)	

GlaxoSmithKline plc



Company overview

GSK is in 1st place for the fourth time, performing strongly across the board and with several innovative practices. It has a large relevant portfolio and leads in R&D, dedicating a large pipeline share to diseases in scope. It is developing many products in partnerships based on access provisions. It also participates in numerous IP-sharing partnerships and leads in access-to-medicine management.

GSK no longer leads in Capability Advancement or Pricing, Manufacturing & Distribution. While it has equitable pricing for many relevant products, it does not always provide detailed evidence of how it targets its strategies toward affordability for the lowest tier. GSK also falls in Public Policy & Market Influence, with evidence of multiple breaches.

Performance update

Found in breach of ethical standards multiple times. GSK has been found in breach of marketing standards and legislation multiple times. Allegations also arose of systemic corruption in China during this period. Since then, GSK has been found guilty and fined USD500 million (the conviction occurred outside the period of analysis).

Implementing new compensation system for sales teams. In 2013, GSK announced a new compensation system for sales employees who work directly with prescribing health-care professionals. Instead of individual sales targets, they will be evaluated and rewarded for their technical knowledge, how they support improved patient care and for GSK's overall business performance. GSK aims to have this new system in place in all countries by 2015.

Demonstrates strong oversight of CROs and shares patient-level data. GSK goes beyond baseline standards and incorporates elements of the Declaration of Helsinki in its clinical trial code of conduct. To enforce compliance, GSK has strong monitoring and auditing procedures for both in-house and outsourced trials. It complies with WHO standards for registering trials and publishing results, and has systems for sharing patient-level Clinical Study Reports with trusted third parties (e.g., academics).

Leads in R&D partnerships and IP sharing. GSK engages in a high number of product development partnerships, accounting for the majority of its relevant pipeline. It also engages in numerous IP-sharing partnerships.

Among the leaders in marketing approval/registration policies and practices. The company has registered the majority of its relevant products in the majority of relevant countries. It decides where to register products based on patient needs, local health systems and the existence of a regulatory system.

Has equitable pricing strategies for wide range of products and many countries. It is one of four companies with equitable pricing strategies for the majority of its products in the majority of in-scope countries where it is present. In absolute terms, it has the second-highest number of products with equitable pricing strategies.

Has diverse and over-arching equitable pricing strategies. For example in Least Developed Countries, GSK has capped the prices of patented medicines and vaccines at no more than 25% of the price for the UK or France (provided that it covers manufacturing costs). Plus, GSK has used tiered pricing for vaccines for over 20 years. In 2013, it increased the number of pricing tiers for vaccines to seven, basing price ranges on Gross National Income per capita. The lowest tier corresponds to GAVI-eligible countries.

Advancing adverse-event reporting in Africa. GSK is piloting a crowd-sourcing platform that enables patients to report adverse events using low-tech solutions (SMS, phone calls).

Best practices

■ Implementing Africa-focused business model. In 2014, GSK announced that it will establish a new Africa and Developing Countries business unit which will bring together its commercial and access-related efforts in all sub-Saharan African countries. In high-potential markets, this unit aims to invest for growth; in less-developed markets it aims to support development. The new unit builds on GSK's Developing Countries and Market Access (DCMA) unit.

■ Assigns strong senior sponsorship of access to medicine throughout the company. For example, in its 2012 Corporate Responsibility report, the company published ten 'Health for All' commitments. Each one has a Corporate Executive Team sponsor and lead business owner that works with the business to ensure the commitment is fulfilled.

■ Establishing innovative Open Lab for Africa for NCDs. Building upon its first Open Lab in Spain, GSK is establishing a second Open Lab for Africa. This lab aims to improve understanding of NCD variations seen in the African setting to inform prevention and treatment strategies of NCDs in African patients. Understanding local disease variations is essential to address needs that are specific to Africa.

■ Partnering for neonatal health. In partnership with Save the Children, GSK is developing products for neonatal health conditions with an initial focus on neonatal sepsis. It is a unique partnership in which GSK and Save the Children can combine their expertise and resources to target leading causes of child mortality.

■ Increasing access to affordable financing and insurance. GSK is partnering with Barclays to increase access to affordable healthcare and medicines in Zambia. Initiatives include: affordable financing for wholesalers and distributors willing to pass savings to patients; and the development of an around a dollar-a-month micro health insurance product maintained via mobile phone.

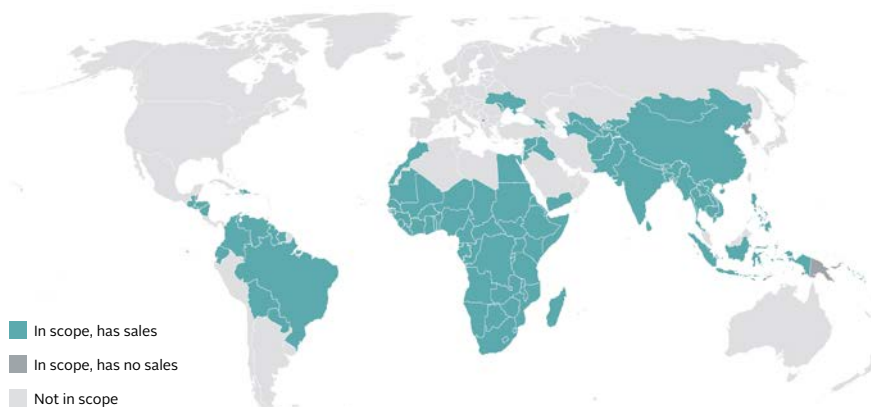
■ Takes a proactive approach to IP management. GSK is one of the leaders when it comes to licensing its patented products, having issued a comparatively high number of licences, some of which are transparent and include pro-access terms. Through ViiV Healthcare and the Medicines Patent Pool, it engages in a novel licensing arrangement that includes tiered royalties based on country income level.

■ Aligning supply and demand to increase vaccination rates. GSK and Vodafone are testing whether mobile technology can help align vaccine supply and demand in Mozambique. The pilot uses SMS to encourage mothers to access vaccination services, and to remind healthcare facilities to report on vaccine stock levels, improving demand forecasting and reducing vaccine stock outs.

Sales and operations

GSK is a diversified company, offering pharmaceuticals, vaccines and consumer healthcare products. It has products for numerous diseases and operates in over 150 countries. Sales in emerging markets account for about 25% of total sales. It holds a 77.4% stake in ViiV Healthcare, a joint venture with Pfizer focused solely on the research, development and commercialisation of HIV/AIDS medicines. It is acquiring Novartis' vaccine business (excluding influenza vaccines) and divesting its marketed oncology portfolio to Novartis. It will create a new consumer healthcare business with Novartis, retaining majority control.

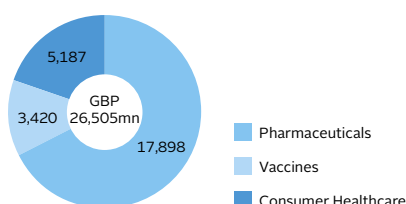
Sales in countries in scope



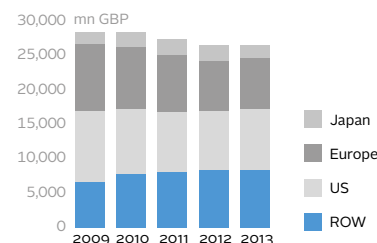
General information

London Stock Exchange
GSK
Headquarters
Brentford, UK
Number of employees
99,451

Turnover by division (2013)



Turnover by region



GlaxoSmithKline plc (continued)

Portfolio and pipeline

Focus

Within the scope of the Index, GSK focuses on infectious diseases and respiratory diseases.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

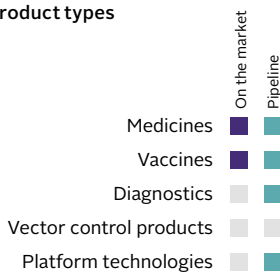
Marketed products

Has medicines and vaccines for 23 diseases in scope, including many childhood vaccines. Its medicines portfolio is strong in respiratory diseases, malaria, HIV/AIDS and antibiotics.

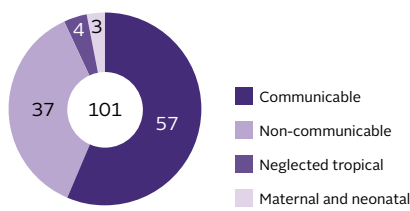
Pipeline products

Its clinical pipeline targets 12 diseases in scope, with a focus on vaccines for lower respiratory infections, malaria, HIV/AIDS and TB. It includes medicines for HIV/AIDS, malaria, cerebrovascular disease, COPD, asthma and diabetes. Notably, it is also developing medicines for neonatal infections and prematurity. Its early-stage pipeline targets neglected diseases.

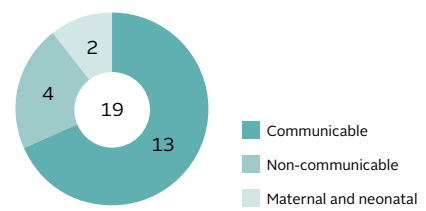
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

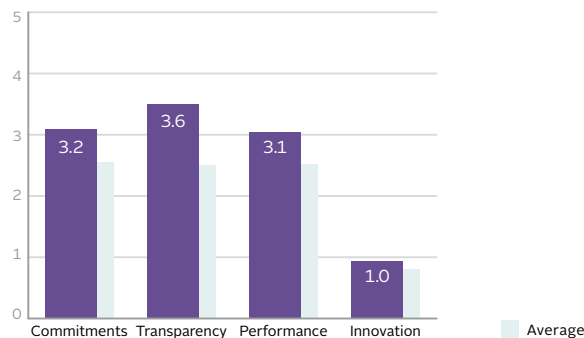
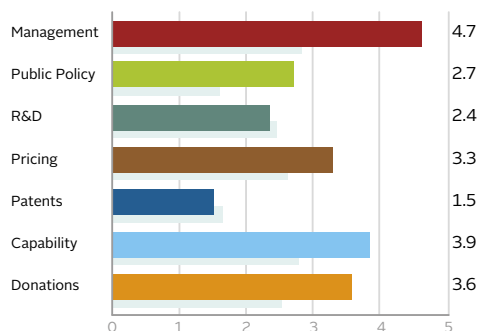
Improve enforcement of anti-corruption and anti-bribery codes of conduct. The company can consider developing strict enforcement measures for its anti-corruption and anti-bribery codes of conduct that apply equally across the breadth of its operations.

Continue to expand equitable pricing, and target the poorest population segments in more strategies. The company has equitable pricing for the majority of its relevant products. For some of its equitably priced products, GSK takes affordability into account and targets the lowest tier. It can expand these practices to all of its products.

Maintain commitment to adapting products for developing countries. There is an opportunity for GSK to fill gaps for much-needed products by maintaining its commitment to adapting products to meet the needs of patients in developing countries: for example, formulations for non-communicable diseases, heat-stable vaccines, and solutions for anti-microbial resistance.

rank	score
2 [▲]	3.0
6 (2012)	

Novo Nordisk A/S



Company overview

Novo Nordisk climbs four places to 2nd place, having risen steadily since 2010. Within the scope of the Index, it addresses diabetes only, but has an integrated strategy for improving access to diabetes care, plus good governance, access management and stakeholder engagement. Compared to peers, it is highly transparent, has robust codes of conducts, and audits compliance in countries in scope.

Plus, its equitable pricing strategies extend across most relevant countries it has a presence in, and it is among the leaders when it comes to rapidly registering new products and applying for stringent approvals. It leads in Donations & Philanthropy and in Capability Advancement. However, it does not commit to licensing and has issued no relevant licences.

Performance update

Integrates access to medicine with core business. Novo Nordisk has renewed its Global Access to Diabetes Care strategy, connecting access to its overall business strategy. It has a new long-term target of reaching 40 million people with diabetes by 2020, including patients at the base of the pyramid. It aims to support the education of healthcare professionals and patients globally, and to promote health for mothers and children. It is overseen by a dedicated senior-level committee.

Took a strong public stance against improper lobbying. Novo Nordisk resigned from the South African Pharmaceutical Industry Association following allegations that IPASA was considering a strategy for influencing South Africa’s intellectual property legislation.

Has robust codes of practice. The company’s codes of ethics are supported by mechanisms for monitoring and enforcing compliance that apply across its operations, and extend to third parties. It provides evidence of auditing compliance with these codes in several Index countries.

Remains a leader in pricing, manufacturing and distribution. The company is one of the leaders in equitable pricing due to its strategies that take affordability for the poorest population segment into account through targeted pricing and product mixes. The company provides insulin to all 49 Least Developed

Countries at a maximum of 20% of the price in the western world. It implements diverse pricing models that are appropriate to local needs in different countries within scope.

Leads in building local capacities. In China, the company engages in multiple public-private partnerships to enhance local R&D capabilities. In Bangladesh, it engaged in technology transfer with a local manufacturer and is training staff from the National Drug Control Laboratory to help detect counterfeit medicines. It is also engaged in several activities, for example to improve cold-chain storage, that aim to build capacities in supply chain management.

Donates to children and meets local needs. It is one of two companies to provide insulin via donations: its Changing Diabetes in Children programme (established in 2009) provides access to care for over 11,500 children with type 1 diabetes in several countries in scope, and includes elements of capacity building. In addition to providing treatment, it meets other local needs. It helps adapt local systems for tracking insulin distribution and to ensure that cold chains function. The programme will run until 2017.

Strongly integrates philanthropy with business activities. Through the World Diabetes Foundation, Novo Nordisk supports numerous projects that aim to improve diabetes care, including national diabetes programmes in five African countries. Its activities are deemed sustainable because they involve national authorities and are long-term.

Novo Nordisk A/S (continued)

Best practices

■ **Expands Base of the Pyramid project.** The project is working toward an integrated approach to diagnosis, treatment and diabetes control for the working poor in developing countries. Since its inception in 2011, it has expanded: it is currently running in India, Nigeria, Ghana and Kenya. The company is working to, for example, establish an effective supply chain, reduce the need to travel for treatment and to build capacity for treating diabetes. It aims to roll the project out in more African countries.

■ **Integrates access-linked incentives into performance management.** It has integrated

access-to-medicine key performance indicators (KPIs), related to its new Access to Diabetes Care strategy, into its formal performance management systems. For example, two access-related KPIs are linked to the company's Long-Term Incentive programme, which is offered to the top-managers (corporate VPs, VPs and Directors).

■ **Strong in stakeholder engagement for diabetes.** Novo Nordisk uses stakeholder engagement to shape its access strategy and to advocate for better diabetes care: e.g., by organising its "Changing Diabetes Leadership

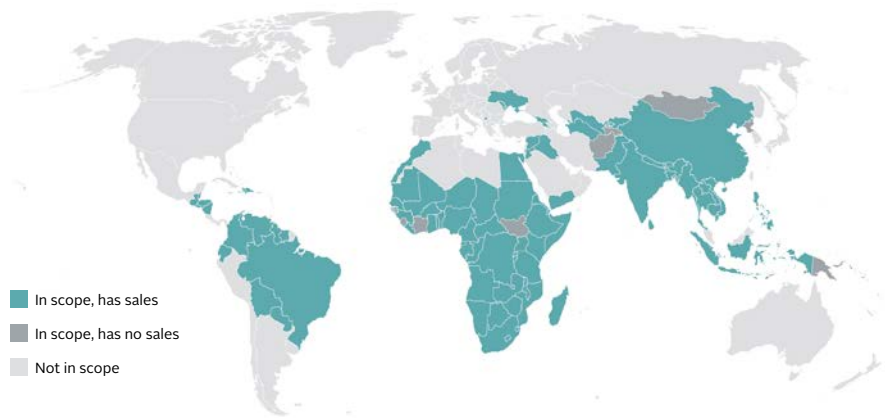
Forums & Policy Roundtables" (international, regional and national gatherings of policy-makers, healthcare professionals and NGOs, among others) to discuss alleviating the burden of diabetes and diabetes care. Since 2005, it has organised 85 such events in more than 30 countries.

■ **Increased affordability of insulin.** One of the leaders in equitable pricing, the company began selling insulin in single-cartridge packages, piloted in Pakistan. This innovative approach to packaging enables patients to spread the cost of treatment over time, making it more affordable.

Sales and operations

Novo Nordisk operates in three business segments: Diabetes Care, Obesity and Biopharmaceuticals. It is a world leader in diabetes care, offering products for type 1 and type 2 diabetes at various stages of progression. It has a broad geographic scope and over 20% of sales come from emerging markets, with a particularly strong position in the Chinese insulin market. To support growth in some of these key markets, the company is investing in building local health-care capacity for providing diabetes care.

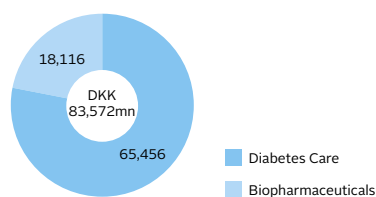
Sales in countries in scope



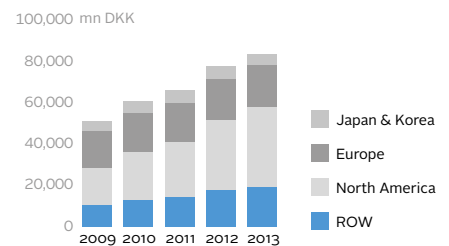
General information

Copenhagen Stock Exchange
NVO B
Headquarters
Bagsværd, Denmark
Number of employees
40,000

Net sales by segment (2013)



Net sales by region



Portfolio and pipeline

Focus

Within the scope of the Index, Novo Nordisk addresses diabetes only.

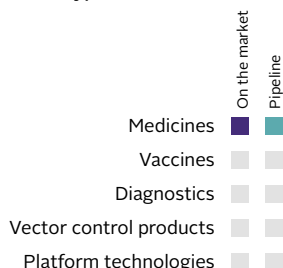
Marketed products

Has medicines for one disease within scope: diabetes. The majority of its medicines are insulins, while others are specifically used to treat type 2 diabetes.

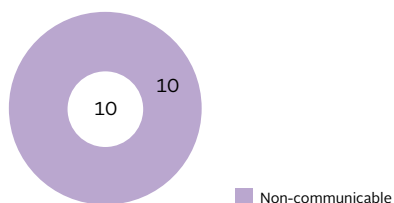
Pipeline products

Within scope, its clinical pipeline targets diabetes, and includes a fixed-dose combination and new formulations that aim to offer clinical benefits. It also has relevant diabetes products in earlier stages of development.

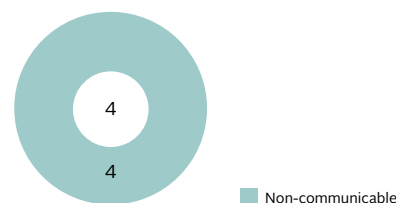
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Continue to develop diabetes treatments suitable for use in resource-limited settings. As a market leader in diabetes care, Novo Nordisk has significant potential to develop diabetes treatments that are more suitable for use in low-income settings, such as heat-stable or oral insulin treatments that would increase compliance. It is currently looking at developing insulin in tablet form.

Extend commitment not to file for patents to a broader range of Index countries. Novo Nordisk continues, as for 2012, to have a clear commitment not to patent in the LDCs. It can consider extending this commitment to generate greater clarity for a wider range of countries in scope.

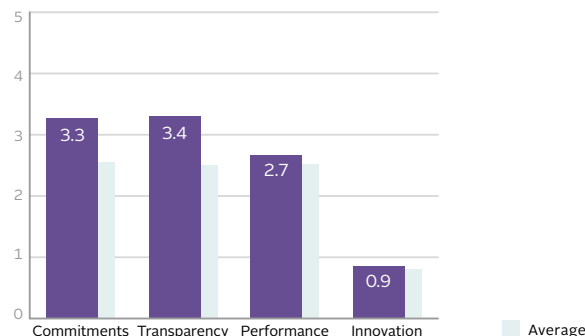
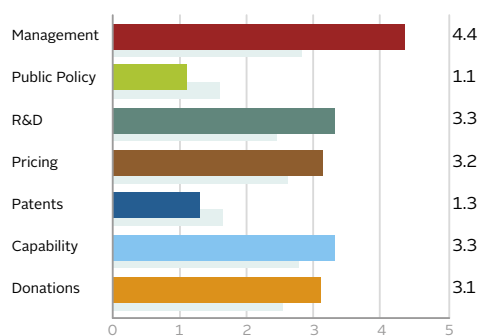
Develop access strategies during R&D process. Novo Nordisk is developing various innovative products for diabetes, but has not provided specific strategies for how they will be made available, accessible and affordable in developing countries, if successful. Novo Nordisk can start taking such factors into account earlier in the development process to ensure access to new products for patients in developing countries.

Extend equitable pricing to more products. Novo Nordisk can expand existing equitable pricing strategies to include a wider range of diabetes treatments.

Consider developing a clear public approach to licensing. It can investigate the potential for licensing its present and future portfolio of patented products as a strategy for supporting access. There is a growing market for diabetes products in many countries in scope. Licensing could prove a viable mechanism to increase access to its newer diabetes products.

rank	score
3 [▼]	2.8
2 (2012)	

Johnson & Johnson



Company overview

Johnson & Johnson falls one place to 3rd, as competition for the top places increases. It is particularly strong in R&D: its relevant pipeline is large and diverse, with significant movement since 2012. Compared to peers, it has greater oversight of its access approach. Its Global Public Health Group manages R&D and access strategies for several diseases in scope. It leads in equitable pricing strategies, with strategies

taking affordability into account and targeting the poorest segment. Johnson & Johnson has newly committed not to enforce its darunavir (Prezista[®]) patents in specific countries, but provided limited evidence of issuing pro-access licences with broad geographic scope. It was found in breach of ethical standards multiple times, including in a country in scope.

Performance update

Establishes group focused on unmet health needs. In January 2014, the company launched Janssen Global Public Health (GPH), responsible for the research, development, delivery and access strategies of pharmaceuticals, diagnostics and services for diseases that impact resource-limited countries and emerging markets.

Found in breach of ethical standards multiple times. Johnson & Johnson has been found in breach of ethical marketing standards and competition law. It was ordered to pay compensation in China following a case (2010) concerning anti-competitive behaviour.

Leads in product development. Johnson & Johnson has an extensive pipeline of products relevant to the Index, with many in clinical development. Since 2012, it has progressed the most products and received the most

regulatory approvals: notably for a first-in-class tuberculosis treatment and a new hepatitis C medicine. It is in the process of globally registering two adapted ARVs.

Engages in comparatively high number of product development partnerships. However, it provides no proof that the majority include provisions for ensuring access.

Leads in equitable pricing strategies. The company's equitable pricing strategies include multiple factors for taking affordability into account, and are targeted towards the poorest population segment. Its pricing model is based on gross national income per capita, at purchasing power parity.

Takes a mixed approach to IP management. Johnson & Johnson newly commits to not enforcing its patent for darunavir (Prezista[®]) in

sub-Saharan Africa and LDCs. It issues limited voluntary licences (for ARV products), with partial disclosure of terms. Licences have a smaller geographic scope and less flexibility than those agreed by peers. It has not yet joined the Medicines Patent Pool.

Remains a leader in building national pharmacovigilance systems. Johnson & Johnson engages with multiple health authorities/governments to help build national pharmacovigilance systems.

Donating to reach children. Johnson & Johnson has two structured donation programmes for children. Children Without Worms targets soil-transmitted helminthiasis, and the company has pledged to scale it up significantly by 2015. Its second programme started in 2014 and provides ARV treatment to children for whom first-line treatment is failing.

Best practices

Engages strategically with local stakeholders. Johnson & Johnson engages with local stakeholders to better understand needs, incorporating findings in access-to-medicine strategies and plans. In Colombia and Brazil, it tailored its approaches following extensive interviews with multiple stakeholder groups.

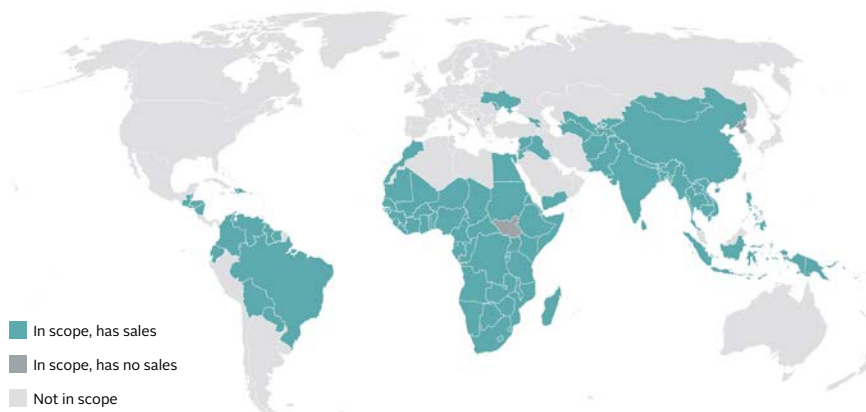
Piloting results-based financing models. The company's GPH group is launching a number of pilots to measuring the economic impact and sustainability of new access and funding models. It is exploring how Developing Impact Bonds and Social Impact Bonds can support healthcare delivery in resource-limited settings.

Developing a large paediatric pipeline. Of all relevant investigational paediatric medicine, Johnson & Johnson has the largest share: including for hepatitis, HIV/AIDS, and multi-drug-resistant tuberculosis. Since 2012, it has gained regulatory approval of one of its medicine for use in adolescents with schizophrenia. It has collaborated to develop a childhood vaccine with a new delivery device for use in remote areas.

Sales and operations

Johnson & Johnson operates in three segments: Consumer, Pharmaceutical, and Medical Devices & Diagnostics. Its pharmaceutical segment offers products in the areas of anti-infective, anti-psychotic, cardiovascular, contraceptive, gastrointestinal, haematology, immunology, neurology, oncology, pain-management, thrombosis, infectious diseases, metabolic conditions and vaccines. It has more than 250 operating companies located in 60 countries worldwide and markets its products in almost all relevant countries.

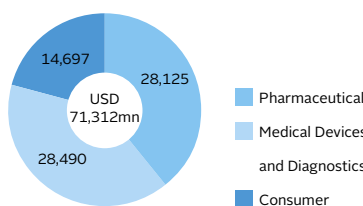
Sales in countries in scope



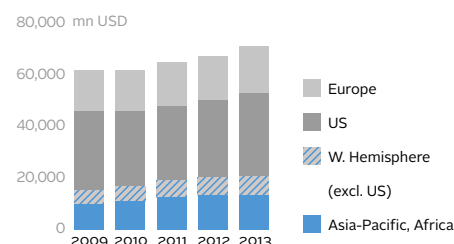
General information

New York Stock Exchange
JNJ
Headquarters
New Brunswick, NJ, US
Number of employees
128,100

Sales by segment (2013)



Sales by region



Portfolio and pipeline

Focus

Johnson & Johnson has a very diverse portfolio and pipeline. It is strong in contraceptives, HIV/AIDS, mental health and hepatitis.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

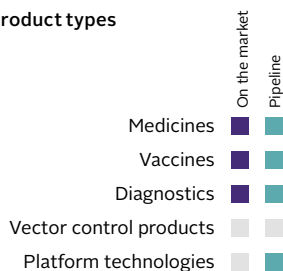
Marketed products

The company has products for 14 diseases in scope. Its medicines focus is on contraceptives, mental health and HIV/AIDS. It also has a first-in-class tuberculosis medicine: bedaquiline (Sirturo®), vaccines for hepatitis B, cholera and typhoid fever and a pentavalent childhood vaccine.

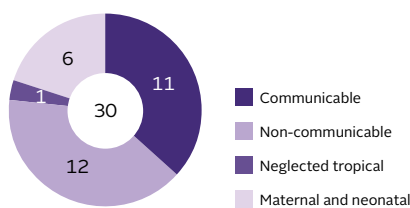
Pipeline products

Its clinical pipeline mainly comprises medicines and targets nine diseases, mainly HIV/AIDS and hepatitis, as well as diabetes, schizophrenia and depression. It is developing vaccines for tuberculosis and rabies, and microbicides for HIV/AIDS.

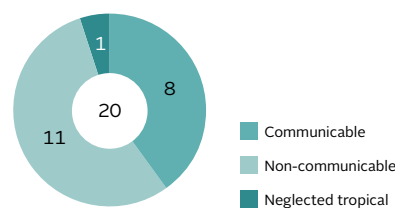
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

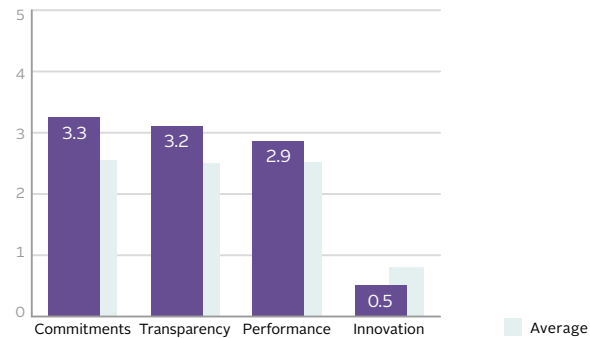
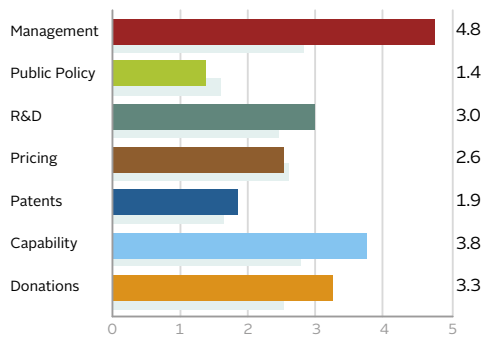
Extend its engagement in licensing. Johnson & Johnson can extend the number, range, scope, and transparency of the licences it issues, based on terms that are designed to facilitate access for poorer patients, including in more middle income country markets. It could also consider engaging in negotiations with the Medicines Patent Pool in order to boost access to the three ARVs in its portfolio (etravirine (Intelence®); rilpivirine (Edurant®); darunavir (Prezista®)) in a wider range of countries in scope.

Develop access strategies for relevant investigational products. The company has an extensive pipeline of products relevant to countries in scope. Many are in the clinical phase of development, meaning that they could reach markets relatively soon. Through its GPH group, the company has significant potential to make them widely available, accessible and affordable. It can develop specific pro-access strategies for product registration, equitable pricing, and patenting and licensing.

Systematically agree to access-oriented terms for product development partnerships. Johnson & Johnson can develop and implement a policy for including a standard set of access-oriented terms and conditions in its research contracts.

rank	score
4 [▲]	2.8
7 (2012)	

Novartis AG



Company overview

Novartis rises three places to 4th. It has significantly improved in access-to-medicine management: in 2012, it approved a new access-to-healthcare strategy that clearly links with its corporate strategy. It has the largest relevant pipeline and is targeting many diseases in scope. It also has two donation programmes that address neglected tropical diseases. It is the only company to voluntarily share pharma-

covigilance data with national authorities. The company is conservative when it comes to waiving data exclusivity rights and was found in breach of ethical standards several times during the period of analysis, but did report taking action against people responsible. It falls in the Pricing, Manufacturing & Distribution area, despite performing well in new areas of pricing disclosure.

Performance update

Strong governance and management of access to medicine. Since 2012, Novartis has approved a new access-to-healthcare strategy and implemented a centralised performance management system for access. It has strong ownership of access-to-healthcare targets. Novartis has also established an Access to Medicine Committee, chaired by the CEO.

Takes public stance against improper lobbying. In a public statement, Novartis distanced itself from the Innovative Pharmaceutical Association of South Africa following allegations that it was lobbying to influence South Africa's reform of IP legislation.

Filling product gaps to improve maternal and neonatal health. Novartis is developing the most products to improve maternal and neonatal health, mainly vaccines targeting neonatal health (some divested to GSK). Others are medicines that target hypertensive disorders of pregnancy and maternal haemorrhage.

Conducting needs-based R&D for infectious diseases. Novartis' pipeline includes many products that target medical needs in low-income countries. This is driven by three of its own research institutes. Its pipeline includes vaccines for meningitis, diarrhoeal diseases and rabies, as well as medicines for malaria, Chagas disease and dengue.

Files for more stringent approvals. Compared to 2012, Novartis has filed for stringent approval from regulatory schemes (WHO pre-qualification, FDA or EMA tentative approval) for a larger proportion of products: this now comprises the majority of its products.

Co-develops e-training on paediatric and maternal care. The tool addresses the integrated management of childhood illness, is globally free of charge and was developed under the WHO strategy to reduce infant and childhood mortality. It was initially adapted for use in Tanzania, Peru and Indonesia, and has

shown promise in reducing training time and costs of scaling up. Novartis is co-developing a similar tool for maternal health.

Supporting national pharmacovigilance plans and sharing safety reports. Novartis leads in the area of capacity advancement in pharmacovigilance, and has worked with health authorities across a wide range of countries. It is the only company to provide evidence of voluntarily sharing post-marketing safety reports with authorities in relevant countries.

Extends commitments to tackling neglected tropical diseases. Novartis has committed to supporting two of its donations programmes until 2020. One aims to control fascioliasis and paragonimiasis; the other to eliminate leprosy and has already helped cure over five million people. It now aims to reach an additional 850,000 people by 2020.

Best practices

Expands business model that addresses health of underserved populations. Through its Social Business Group, Novartis has considerably expanded its "Healthy Family" programme, which focuses on expanding access to medicine, medical professionals and healthcare education for people living at the bottom of the

pyramid. It covers a wide range of products and focuses on prevention and awareness, as well as treatment.

Revising its strategy to interrupt leprosy transmission. To support the goal of eliminating leprosy set out in the London Declaration,

Novartis is revising the strategy of its donation programme. This includes expanding its focus to people surrounding patients in order to minimise further transmission of the disease. It involves early diagnosis and treatment, contact tracing and surveillance.

Sales and operations

Novartis is a highly diversified company, with divisions for pharmaceuticals, generics and vaccines and diagnostics, and offering patented prescription medicines in various areas. Through Sandoz, it offers prescription medicines and pharmaceutical and biotechnological substances. Novartis' focus is currently changing: it is divesting its vaccine business (excluding influenza vaccines) to GSK and acquiring GSK's marketed oncology portfolio. It will sell its Animal Health division to Eli Lilly. It operates in over 140 countries, and about 25% of sales come from emerging markets.

General information

SIX Swiss Exchange

NOVN

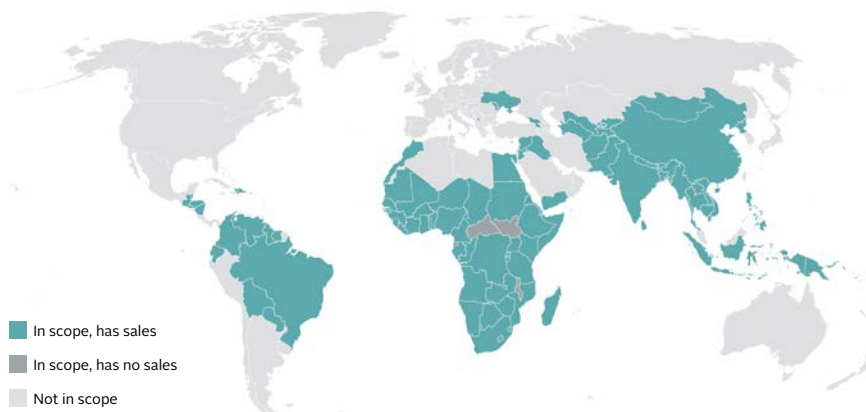
Headquarters

Basel, Switzerland

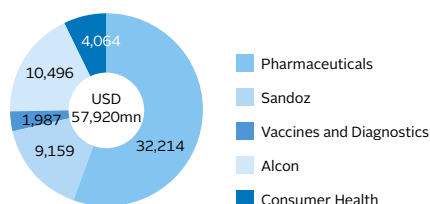
Number of employees

135,696

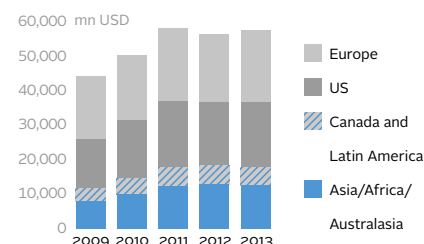
Sales in countries in scope



Net sales by segment (2013)



Net sales by region



Portfolio and pipeline

Focus

Novartis has a large, diverse portfolio and pipeline, covering many diseases, including a focus on maternal and neonatal health conditions. It is divesting much of its vaccine portfolio and pipeline.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

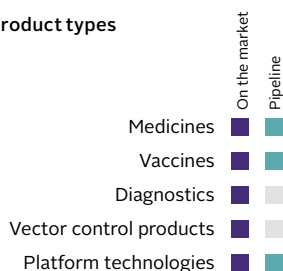
Marketed products

Has products for 34 diseases in scope, mainly medicines, notably for mental health (including epilepsy) and neglected tropical diseases, and a large vaccines portfolio.

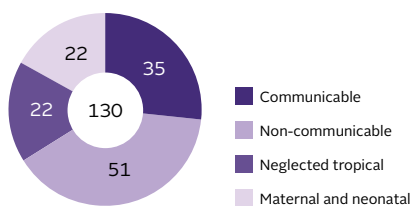
Pipeline products

Its clinical pipeline targets 14 diseases in scope, mainly vaccines for influenza, meningitis and rabies, and medicines for malaria and cardiovascular disease. Earlier stages include medicines for dengue and Chagas disease.

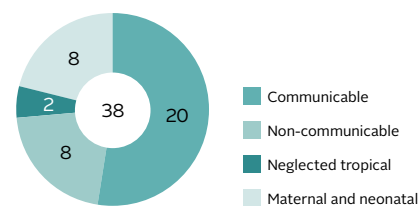
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Measure impact and support the development of access initiatives. Novartis is highly active in setting up new access initiatives and models around the world. Its Malaria Initiative, donation programme for leprosy, and Social Business Group serve as examples for the industry. To increase effectiveness, the company can embed outcome measuring and impact assessments into its initiatives. Novartis' expertise in managing programmes of such large scale, together with its extensive portfolio, creates opportunities to initiate projects focusing on other disease areas.

Continue to develop new medicine for neglected diseases. The divestment of its vaccines business reduces Novartis' focus on infectious diseases. However, it has medicines in development for malaria and neglected tropical diseases, as well as products for maternal and neonatal health conditions. The company can continue to invest in these R&D activities and to maintain and utilise its scientific expertise of its own R&D institutes in this area.

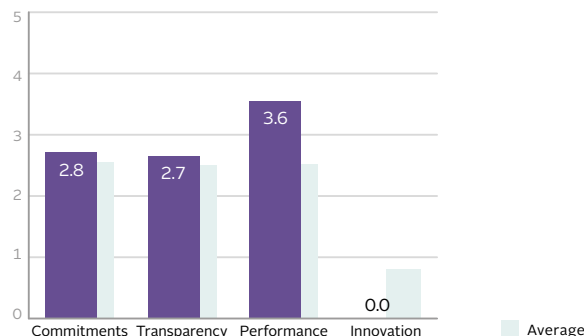
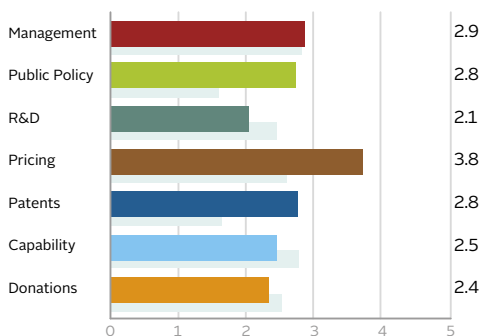
Improve affordability of more products, in more countries. Novartis can expand its equitable pricing strategies to cover more relevant products. Plus, it can ensure its existing strate-

gies specifically target the poorest population segments. It can increasingly leverage the potential of its generics division to ensure its products are affordable and accessible for the poor. Its leading position in biosimilars also offers a way to meet the growing demand for affordable biologics.

Develop a more access-oriented IP strategy. Novartis has potential to develop a more nuanced approach to IP management: for example, by extending its commitment to refraining from patenting in Least Developed Countries to other countries, or by licensing to multiple external partners to boost generic competition.

rank	score
5 th	2.8
5 (2012)	

Gilead Sciences Inc.



Company overview

Gilead is in 5th place for the second time. It remains a leader in IP management and equitable pricing, demonstrated by a range of licences and equitable pricing strategies that take affordability into account. It waives data exclusivity for its HIV/AIDS portfolio. Plus, it is one of only two companies not found in breach of any standards or law during the period of analysis. It tackles leishmaniasis, a neglected tropical

disease, via a structured donation programme. With its new hepatitis C treatment and additional promising candidates in development, it has a unique role to play in making hepatitis treatment available, accessible, and affordable in developing countries.

Performance update

One of only two companies not found in breach of ethical standards. During the period of analysis, the Index found no evidence that Gilead had received convictions or settlements relating to corrupt practice, incidences of bribery, breaches of ethical marketing standards or breaches of competition law.

Innovator in hepatitis C. Gilead has gained regulatory approval for the first of a new class of treatment for hepatitis C. Sofosbuvir (Sovaldi®) is used in the first interferon-free oral regimen. It shows improved efficacy, reduced side effects and improved patient tolerance.

Engages in access-oriented IP sharing. Gilead shares IP relating to tenofovir (Viread®) with CONRAD and the International Partnership for Microbicides to develop microbicides that can prevent sexually transmitted HIV infections.

Newly implements intra-country equitable pricing strategy. Gilead now has equitable pricing strategies that include different prices for the public and private markets of some countries in scope, e.g., for HIV/AIDS products in South Africa.

Leader in drug-recall policy and practices. Since 2012, Gilead has developed more stringent standard operating procedures relating to drug recalls. It also adopted a drug-recall policy that complies with WHO GMP guidelines. It issued no drug recalls in countries in scope during the period of analysis.

Expands licensing, increasing access to HIV/AIDS portfolio. Gilead has expanded its range of licences relating to HIV medicines by actively engaging with different partners to facilitate broader access. Gilead has licensed the largest proportion (80%) of its portfolio, incorporating

access-friendly terms and covering a comparatively broad geographic scope.

Collaborates on global level to improve supply chains. Gilead collaborates with global agencies, such as the Global Fund and the PEP-FAR Partnership for Supply Chain Management, e.g., to help create demand-forecasting tools.

Extends commitments to eliminating leishmaniasis. Gilead now commits to donating 550,000 vials of amphotericin B (AmBisome®) until 2020. Its donation programme runs in highly endemic countries.

Best practices

Sets registration timeframes for new products. Gilead aims to register new products within 12 months of gaining approval from the FDA or EMA in as many relevant countries as possible. It prioritises countries for registration based on disease prevalence.

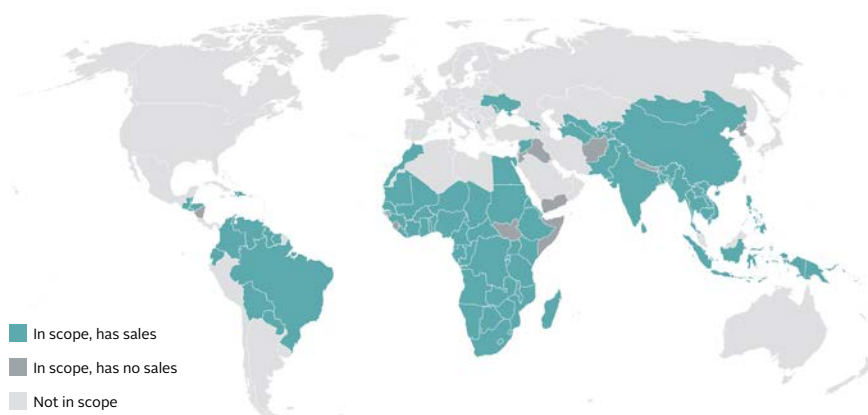
Agrees licensing terms on investigational products. In 2012, Gilead (through the Medicines Patent Pool - MPP) included three investigational HIV medicines within licences. Technology transfer was able to commence during the period of analysis prior to them gaining stringent regulatory approval. These measures enable accelerated access to generic versions. In 2014, Gilead reached similar agree-

ments with the MPP for tenofovir alafenamide, and bilaterally for ledipasvir (hepatitis C).

Sales and operations

Gilead is a biopharmaceutical company that operates through one segment: Human Therapeutics. It originally focused on developing fixed-dose combination antiretroviral treatments, and still specializes in HIV/AIDS treatment. Partly through acquisitions, Gilead is now also present in other therapeutic areas, including liver disease (hepatitis) and serious cardiovascular and respiratory diseases. It has a broad geographic reach, due, at least in part, to its diverse licensing structures.

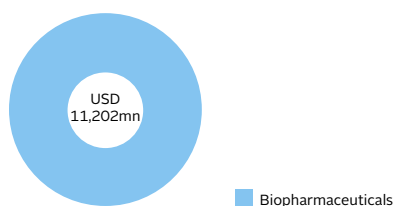
Sales in countries in scope



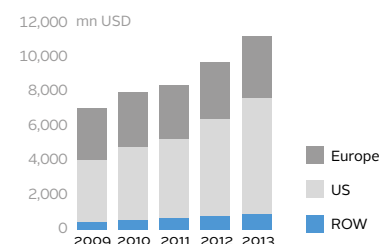
General information

NASDAQ
GILD
Headquarters
Foster City, CA, US
Number of employees
6,100

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Gilead is focused on HIV/AIDS and hepatitis.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

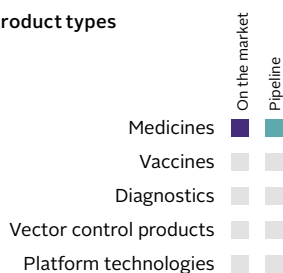
Marketed products

Has medicines for three diseases in scope: HIV/AIDS, cirrhosis of the liver (hepatitis B and C) and leishmaniasis. The majority of its medicines are ARVs for HIV/AIDS. It has a recently approved hepatitis C drug: sofosbuvir (Sovaldi®).

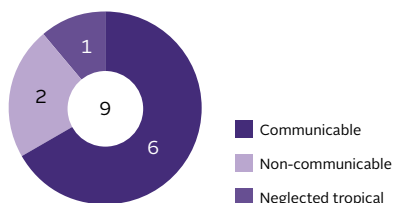
Pipeline products

Its clinical pipeline targets three diseases in scope: it is developing fixed-dose combinations for HIV/AIDS, innovative medicines and fixed-dose combinations for hepatitis, and a medicine for lower respiratory infections.

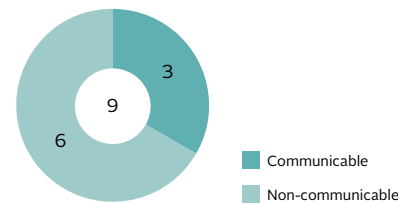
Product types



Products per disease category



Clinical pipeline per disease category



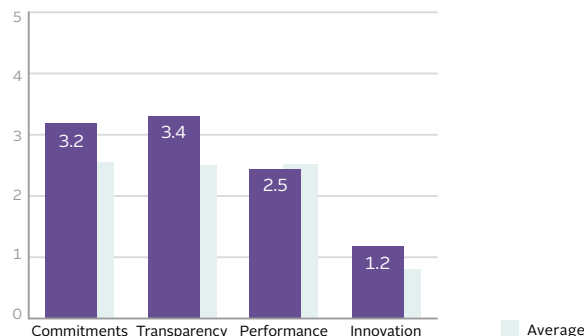
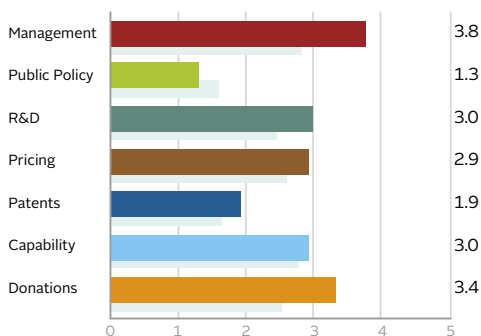
Opportunities for improving access to medicine

Incorporate market segmentation in licensing strategies in middle income countries. Gilead's licences for its HIV/AIDS portfolio do not always cover a broad range of middle income countries. Patients from low-income segments living in these countries often fall outside these access mechanisms. Gilead can consider whether and how licensing can boost access in these markets, e.g., by identifying new approaches to public/private market segmentation.

Expand access to new hepatitis treatment. Through sofosbuvir (Sovaldi®), Gilead has a unique position to improve hepatitis care. In 2014, it agreed a broad licensing strategy with seven Indian manufacturers covering 91 countries, and announced it would offer sofosbuvir to some middle income countries at reduced prices. While the expected price of Sovaldi® in India, for example, is significantly lower than the US price, it is uncertain whether it is affordable. Gilead can consider more clearly how it targets the poor in its pricing strategies, as well as how to expand licensing agreements to include a wider range of middle income countries.

rank	score
6 [▲]	2.8
8 (2012)	

Merck KGaA



Company overview

Merck KGaA rises two places to 6th. It has revised its Access to Healthcare (A2H) strategy and has committed to taking a pro-access approach to IP management and to licensing products in a broad range of countries. It is overall very transparent and has launched new initiatives since 2012, including a pro-access business model in India and an innova-

tive initiative to increase local manufacturing capabilities. It performs strongly in R&D: a substantial share of its pipeline targets local needs for non-communicable diseases, including diabetes and cardiovascular disease, and it has strategies to ensure these medicines will reach patients in relevant countries.

Performance update

Takes multi-dimensional approach to schistosomiasis. This includes: a long-term donation programme that aims to eliminate the disease; strengthening local R&D capacities; developing a new diagnostic tool and paediatric formulation; and piloting local solutions for better sanitation.

Moves from philanthropy-driven to strategic approach. Merck KGaA has significantly revised its A2H strategy: it focuses on R&D for local and unmet needs; strengthening supply chains; assisting patients unable to afford healthcare (among other areas), and is driven by a newly established A2H unit. It revised and broadened its A2H Charter, publicly disclosing its stance on a range of areas, including pricing and IP.

Takes more active approach to dialogue and knowledge-sharing. Through its Merck Access Dialogue Series, Merck KGaA shares information and best practices and assesses, with stakeholders, ways of removing barriers to access. It has hosted dialogues on pricing, intellectual property and supply chains.

Develops tailored marketing code of practice. Merck KGaA has developed internal controls and audits, including 'country compliance officers' in each country of operation.

Aligns R&D strategy with developing country needs. Merck KGaA provides detailed evidence of how its pipeline products for chronic diseases target patients in relevant countries. It is one of the few companies to provide product registration targets. It also

commits to file for registration of most of its products in relevant countries.

Improved targeting of pricing strategies. Merck KGaA now has relevant equitable pricing strategies that include intra-country segmentation. It performs strongly in new areas of disclosure.

Leads in commitment to pro-access IP management. It publicly takes an access-friendly stance on IP management and has policies to determine access to future on-patent products in the widest range of countries. It has committed to not filing for or enforcing patents in a broad range of countries, and considers licensing in several disease categories. Uniquely, it has extended its commitment to products for non-communicable diseases.

Best practices

Piloting pro-access business model in India. The Su-Swastha programme aims to increase access to healthcare products at an affordable price in rural India. It offers community-level meetings and educational health programmes, as well as products based on local needs.

Innovates in distribution to ensure product quality. Merck KGaA uses heat and humidity sensors to monitor transportation conditions of all its products shipped from Europe to the rest of world (in its 'Temptation Project'). It uses the

data collected in a centralised system to ensure product quality, and improve transport routes.

Addressing forward integration of supply chains. It has tested a software tool that can improve stock management in Sudan and Ethiopia. Integrated with Merck KGaA's order management system, it improves price transparency and reduces lead time and miscommunication.

Developing platform to ensure local quality manufacturing standards. Merck KGaA's 'Vir-

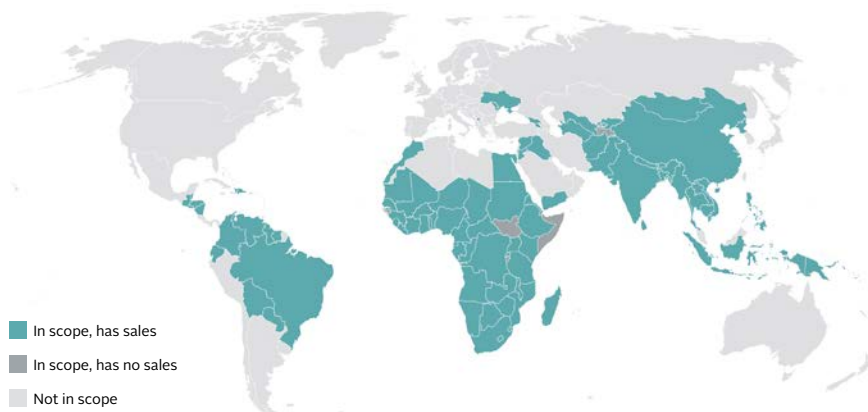
tual Plant Team' will provide support, expertise and regular training to the local third-party plant managers, in order to harmonize manufacturing standards across all its in-house and third-party manufacturers.

Piloting local solutions for better sanitation. As part of its praziquantel donation programme, Merck KGaA started a pilot study in Senegal that aims to build a better understanding of sanitation needs to improve disease prevention.

Sales and operations

Merck KGaA is a diversified company that operates through four divisions: Merck Serono, Consumer Health, Merck Millipore and Performance Materials. Merck Serono provides prescription medicines for treating cancer, multiple sclerosis, infertility, growth disorders, cardiovascular and metabolic diseases and allergies. Through Merck Millipore, it offers tools and laboratory chemicals. Through its partnership with Dr Reddy's, the company is growing in the biosimilars market. About one-third of its sales are generated in emerging markets.

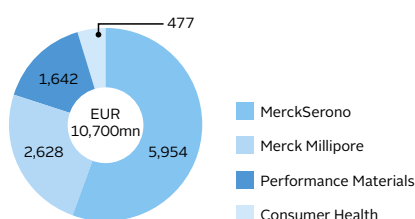
Sales in countries in scope



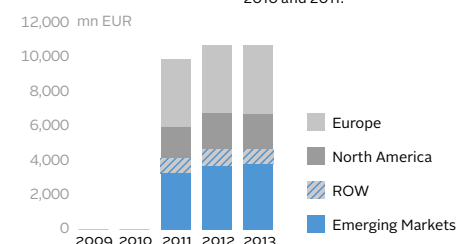
General information

Frankfurt Stock Exchange
MRK
Headquarters
Darmstadt, Germany
Number of employees
38,847

Sales by division (2013)



Sales by region



Portfolio and pipeline

Focus

Within scope, the company focuses on non-communicable diseases. In addition, it has a strong portfolio of antibiotics.

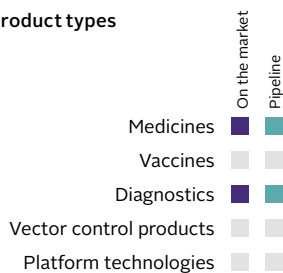
Marketed products

Has products for 16 diseases in scope, mainly medicines for diabetes, cardiovascular disease and antibiotics. Its medicine praziquantel targets three neglected tropical diseases: schistosomiasis, cysticercosis and food-borne trematodiasis.

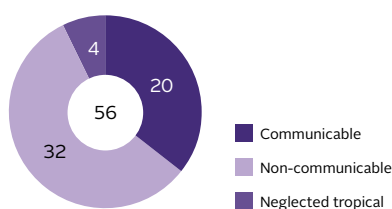
Pipeline products

Its clinical pipeline targets five diseases, including medicines for ischaemic heart disease, diabetes, and osteoarthritis. It is also developing a diagnostic tool for HIV/AIDS and schistosomiasis. In pre-clinical stages it has a paediatric formulation of praziquantel.

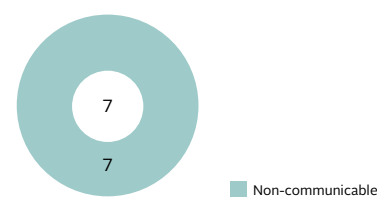
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

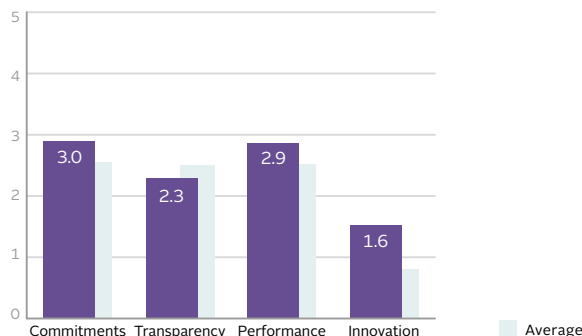
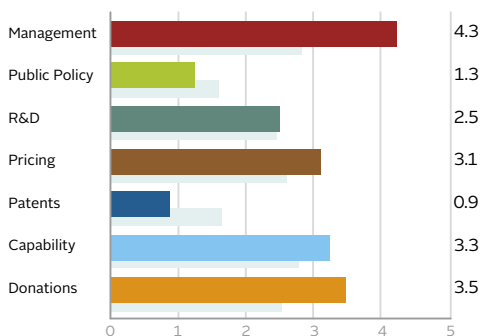
Continue R&D to address local needs. Merck KGaA can continue to focus on adapting existing medicines and developing innovative compounds to meet medical needs in countries in scope. It can continue to integrate the development of medicines and diagnostic tools.

Follow through on pro-access IP and licensing stance. When launching new products, the company can fulfil its pledge not to file for or enforce patents in certain countries and to issue voluntary licences where there is a need and opportunity.

Measure impact of newly launched models and initiatives. Merck KGaA has launched several new models and initiatives that aim to increase access to medicine. By measuring their economic and public health impact, it can determine whether to expand models to more countries and products and whether to turn projects into long-term sustainable programmes.

rank	score
7 [▼]	2.6
4 (2012)	

Merck & Co. Inc.



Company overview

Merck & Co. drops three places to 7th. It performed strongly in donations due to its Mectizan[®] programme, as well as in access-to-medicine management, with a new approach to stakeholder engagement and having embedded access-to-health principles in its operations and strategies. It performs well in the Pricing, Manufacturing & Distribution area. Its performance in Patents & Licensing has dropped, however:

its disclosure is limited, it offers narrow support for the flexibilities set out in the TRIPS agreement, has issued fewer voluntary licences than some peers and is opaque about their terms. In Research & Development, it has been overtaken due to limited movement of compounds along its pipeline, and for not disclosing investments in relevant activities.

Performance update

Has strong governance and management of access to medicine. The company has embedded access to medicine into its governance structures, business strategies and management systems, including in a newly established Emerging Markets Access Committee, responsible for driving its access strategy and implementing its Access to Health Guiding Principles.

Remains only company that is a member of PACI. As in 2012, it is the only Index company in the Index to have joined PACI: the World Economic Forum's Partnering Against Corruption Initiative. It thereby commits to a zero tolerance policy towards bribery and corruption and to establishing an internal anti-corruption programme.

Approaches licensing and data exclusivity with limited access-orientation. Merck & Co. takes a limited pro-access approach to licensing and is opaque about the terms of the agreements it has reached. It discloses no examples where it would waive rights to data exclusivity. Through its membership of the Innovative Pharmaceutical Association of South Africa, it was linked to an alleged attempt to undermine patent reform in South Africa.

A leader in clinical trial conduct and data transparency. The company's code of clinical trial conduct includes elements from the Declaration of Helsinki, with strong monitoring and enforcement mechanisms for in-house and outsourced clinical trials. In 2014, it implement-

ed an online system for researchers to submit requests for access to its clinical trial data.

Has broad scope of equitable pricing strategies. Including new areas of investigation, there is evidence that it has implemented equitable pricing for more products than in 2012. Equitable pricing strategies cover the majority of its products and the majority of countries it has a presence in. It takes numerous factors into account in its pricing decisions.

Commits to eliminating onchocerciasis and lymphatic filariasis. The Merck Mectizan[®] Donation Program started in 1987 and will continue until these diseases are eliminated in all endemic countries.

Best practices

Taking a strategic approach to stakeholder engagement. In 2013, Merck & Co. launched its Strategic Relationship Leads approach in order to enhance its engagement with key external stakeholders regarding HIV/AIDS, hepatitis C, vaccines, family planning and maternal and child health. It also has a dedicated unit for engaging with stakeholders in sub-Saharan Africa and for evaluating and addressing local public health needs that works with governments, international donors and NGOs on the ground to help ensure the delivery of healthcare services, vaccines and contraceptives.

Developing an innovative financing model for hepatitis C. In 2012, Merck & Co. launched a pilot in India to support patients with no or limited insurance coverage in accessing its hepatitis C medicine, peginterferon alfa-2b (PegIntron[®]). The programme offers zero-interest, no-collateral loans to eligible patients, as well as a disease-management option.

Innovating in manufacturing to improve affordability. It is developing a soft-chew tablet that can be taken without water. It may be produced using simple formulations and a simple

manufacturing process, reducing costs and potentially increasing affordability.

Taking an integrated approach to supply chain alignment. The company combined a technology transfer with supply chain trainings, enhancing communication between suppliers and procurer resulting in reduced supply interruptions. It also participated in a pilot to proactively manage contraceptive supply in Senegal to reduce stock-outs.

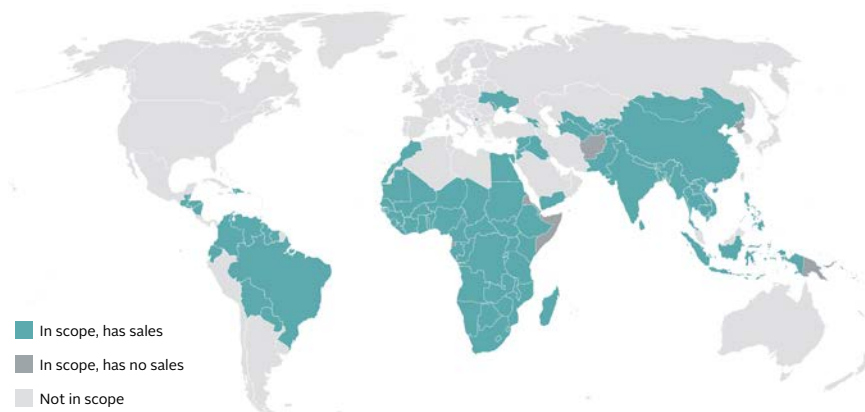
Sales and operations

Merck & Co. develops prescription medicines, vaccines, biologics and animal health products. Its pharmaceuticals and vaccines businesses offer products for diabetes, obesity, women's health, oncology, ophthalmology and immunology, as well as respiratory, cardiovascular, endocrine, inflammatory and infectious diseases. It has various joint ventures and collaborations in India, China, Brazil and South Africa, and an Asia R&D HQ in China. It has increased its focus on emerging markets and about a third of its employees now work in emerging markets. It sold its consumer care business to Bayer in May 2014.

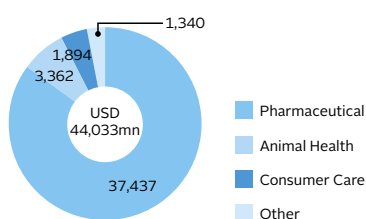
General information

New York Stock Exchange
MRK
Headquarters
Whitehouse Station, NJ, US
Number of employees
76,000

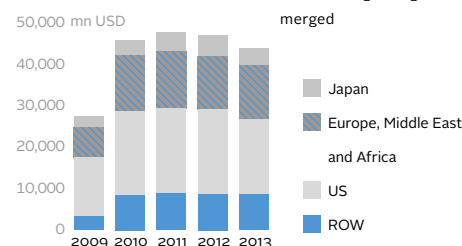
Sales in countries in scope



Sales by segment (2013)



Revenues by region



Portfolio and pipeline

Merck & Co. is diversified with a strong presence in contraceptives and HIV/AIDS.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

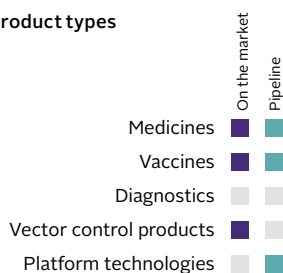
Marketed products

Has products for 16 diseases in scope, with a range of contraceptives, HIV/AIDS products and products for non-communicable diseases, plus a rotavirus (RotaTeq®) and pneumococcal (Pneumovax® 23) vaccine (among others).

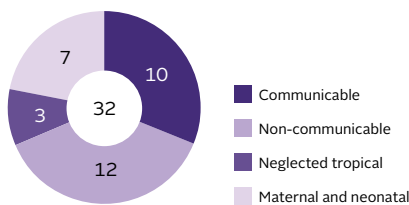
Pipeline products

Its clinical pipeline targets seven diseases, with tetanus and pneumococcal vaccines, medicines for diarrhoeal diseases, HIV/AIDS, diabetes, asthma and Chagas disease, and a notable contraceptives pipeline.

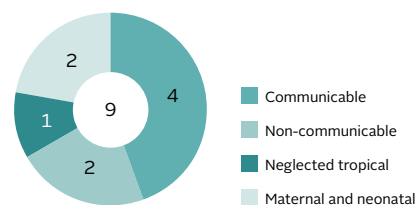
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Expand innovative financing mechanisms and pricing strategies. The company has taken steps to target its equitable pricing strategies toward the poorest segments. If pilots in India can be shown to have positive outcomes and impact, it can further implement these strategies for other relevant products, for more diseases, patients and regions.

Take a more access-oriented approach to licensing. The company can be more transparent about its licensing agreements and can take a more access-oriented approach to licensing its ARVs (efavirenz (Stocrin®); raltegravir

(Isentress®)) through the Medicines Patent Pool. It is currently in negotiations with the MPP regarding potential licences on paediatric formulations of raltegravir. It can also begin discussing licences for other formulations, including efavirenz products.

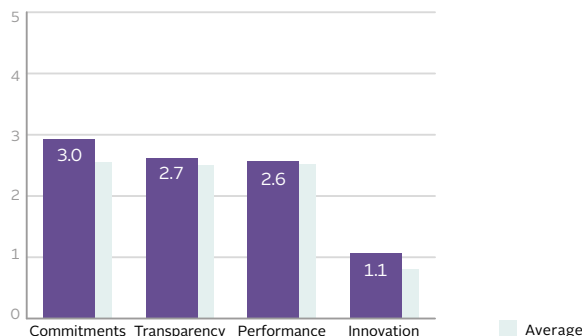
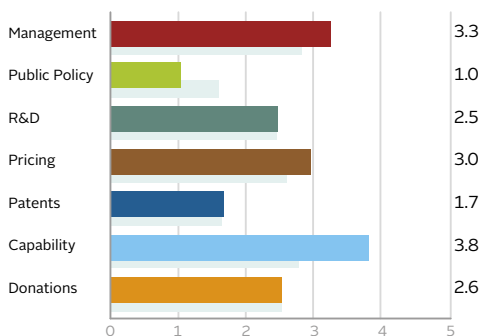
Leverage strong position in reproductive health. The company is committed to developing products that address maternal mortality in resource-limited settings and has adaptive contraceptive methods in late-stage development, including a heat-stable contraceptive ring. Through its Merck for Mothers program, it

addresses family planning and two leading causes of maternal mortality. The company's expertise and products can contribute to improving maternal health in resource-limited settings.

Improve transparency of activities to influence markets. Merck & Co. can increase its transparency regarding activities to influence policy and gain market access in relevant countries. It can extend its current disclosure to include marketing activities and board seats it holds at associations and organisations with relevance to countries and diseases in scope.

rank	score
8▼	2.6
3 (2012)	

Sanofi



Company overview

Sanofi falls from 3rd to 8th place. Despite a broad range of relevant products, it makes comparatively little progress and has lost in the area of transparency. It retains its strong position in Capability Advancement, performing well in all areas, and with an innovative solution for maternal health. In R&D, it is a leader in product development, but is less transparent than others about the terms of its R&D partnerships, with

limited commitment to partnering on access-oriented terms. It drops significantly in Public Policy & Market Influence, with low disclosure of its marketing activities in countries in scope and multiple breaches. Its equitable pricing initiatives cover a limited proportion of its relevant products and countries it has presence in.

Performance update

Has wide range of access initiatives. Notably, this includes initiatives for epilepsy and mental health that focus on cross-sector partnerships and collaborations, training healthcare professionals in diagnosis and treatment, combating stigmatisation and applying preferential pricing policies in a range of countries. Also, it has an initiative focused on paediatric care, with three goals: to develop a portfolio of products adapted for children, strengthen the training of healthcare professionals, and inform the general public about paediatric diseases. It also has initiatives focused on capacity building, neglected tropical diseases, malaria and diabetes.

Taking steps to improve health in resource-limited settings. It engages in IP-sharing partnerships targeting tuberculosis and neglected tropical diseases, and has a vaccine for dengue and a medicine for trypanosomiasis in late-stage development. It contributes to malaria resistance research by providing data to WorldWide Antimalarial Resistance Network.

Has equitable pricing strategies for a relatively narrow proportion of its products. Considering its geographic spread and the size of its portfolio, Sanofi's equitable pricing focus is limited. However, its strategies are targeted towards the lowest tier and apply to diseases where there is limited equitable pricing from the industry, such as leishmaniasis and schizophrenia.

Strongly committed to production and capacity building in Africa. 60% of Sanofi products distributed in Africa are produced locally, shortening supply chains. With the opening of a new production site in Algeria in 2017, it aims to increase this to 80%. It also has a strong focus on building capacities outside the value chain in Africa.

Improves diabetes care with mobile services. Together with Vodacom, Sanofi has created a mobile-phone application that enables diabetes patients in Africa to interact with

their healthcare providers in real time. Patients receive regular messages and advice via SMS and are encouraged to provide information regarding their diabetes management. Nurses and doctors can track patients' progress.

Commits to eliminating trypanosomiasis. Sanofi has a large structured donation programme that aims to eliminate trypanosomiasis by 2020. The medicine it donates is made available where needed, through the WHO.

Best practices

Strengthening malaria medicine supply. Sanofi has established a large-scale production line for semi-synthetic artemisinin. This will significantly strengthen the artemisinin supply chain, contribute to a more stable price and ultimately ensure greater availability of treatment.

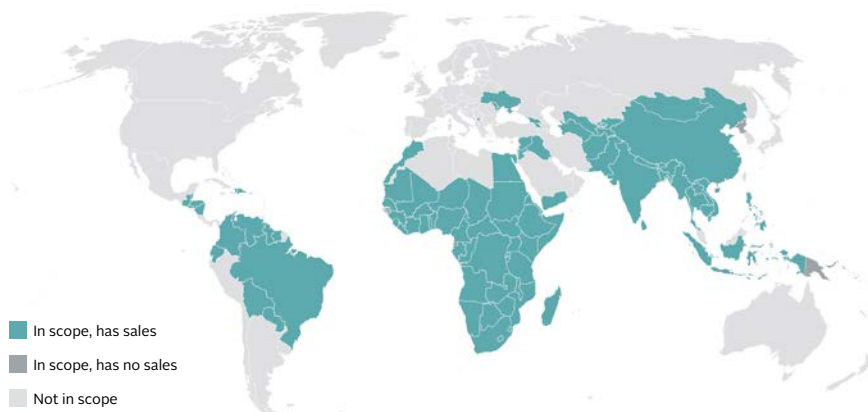
Supporting healthcare providers to improve maternal and neonatal health. The Sanofi Espoir Foundation has set up an online platform called 'Connecting Midwives' in collaboration with the International Confederation of Midwives. It allows midwives to share experiences and ideas and propose field projects to improve

maternal and neonatal health in underserved areas. In 2014, ten initiatives will receive financial support.

Sales and operations

Sanofi is a diversified company that offers prescription- and over-the-counter drugs, including generics, human vaccines and animal health drugs in over 100 countries. Its main areas of research include multiple sclerosis, diabetes, oncology, rare diseases, cardiometabolic diseases, immunology and vaccines. About one-third of its sales comes from emerging markets. The company holds a strong position in the diabetes market and is one of the largest vaccine manufacturers worldwide in terms of sales, through subsidiary Sanofi Pasteur.

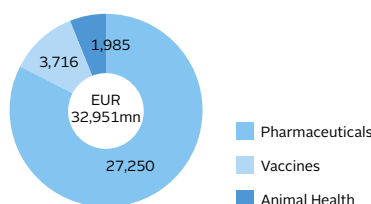
Sales in countries in scope



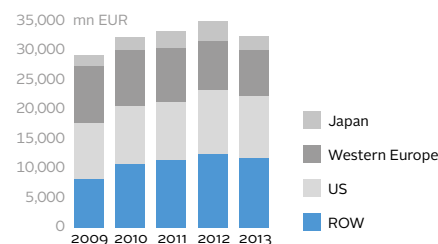
General information

EURONEXT Paris
 SAN
 Headquarters
 Paris, France
 Number of employees
 112,128

Revenues by segment (2013)



Net sales by region



Portfolio and pipeline

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

Focus

Within scope, Sanofi has a large, diverse portfolio and pipeline that focuses on medicines for mental health and diabetes and products for neglected diseases.

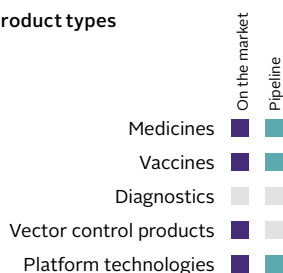
Marketed products

Has products for 26 diseases in scope, mainly medicines, with a strong presence in cardiovascular disease, diabetes, mental health and antibiotics. It has a large range of medicines for neglected tropical diseases, TB and malaria.

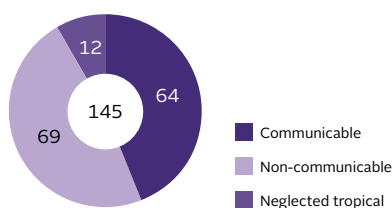
Pipeline products

In clinical stage, Sanofi targets ten diseases in scope including medicines for trypanosomiasis, diabetes and malaria, and vaccines for dengue, HIV/AIDS, TB, meningitis, lower respiratory infections and diarrhoeal diseases.

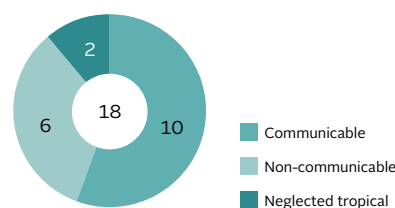
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Include access provisions in more R&D agreements. Sanofi does not commit to systematically incorporating access provisions in R&D agreements: it provides proof that a limited number of R&D partnerships (those targeting malaria, tuberculosis, and neglected tropical diseases) are based on access provisions. It can incorporate these provisions in a broader range of partnerships and diseases.

Develop more specific pro-competitive policies. Sanofi can extend its approach to facilitating competition beyond adherence to relevant competition laws in relevant countries. It can develop policies that support timely market access of generics, e.g., by waiving specific rights to data exclusivity, or developing a clear policy on engaging in voluntary licensing.

The company can increase access to its more advanced diabetes products in lower-income settings through, for example, expanding existing equitable pricing strategies.

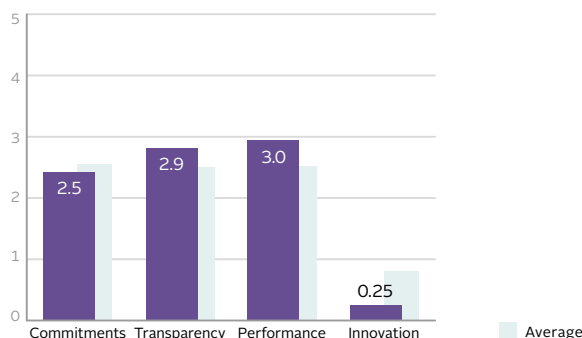
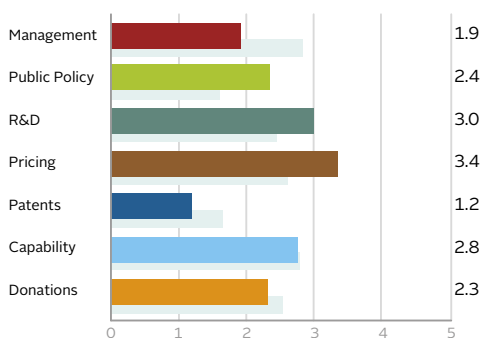
Expand equitable pricing programmes. As it has a broad portfolio of relevant products and a broad geographic spread, it can expand its equitable pricing strategies to include a wider range of products and countries.

Continue developing diabetes products for use in countries in scope. Sanofi is a leader in adaptive R&D for diabetes and can play an important role in developing products and devices that are tailored to local conditions, such as heat-stable insulin or insulin delivery devices.

Leverage strong position in vaccines. Through its large vaccine pipeline and portfolio, Sanofi can play an important role in preventing communicable diseases, including HIV/AIDS, tuberculosis, and dengue. Both for products developed in-house and in partnership, the company can take access into consideration during the development process, for example, by ensuring terms and conditions include access provisions.

rank	score
9	2.6
New in 2014 Index	

AbbVie Inc.



Company overview

New to the Index, AbbVie is in 9th place. It shows promise when it comes to improving access to medicine, particularly as it is among the leaders in developing new treatments for neglected tropical diseases, hepatitis and HIV/AIDS. Its pipeline consists both of products inherited from Abbott, and of new projects, including access-oriented collaborations. AbbVie has considered poorest population segments when

constructing its pricing strategies, but there is room for it to expand this approach to a much greater proportion of its portfolio. It has entered negotiations with the Medicines Patent Pool, however it has no specific policy of engaging in licensing.

Performance update

Provides strong evidence of applying and enforcing marketing code of conduct. AbbVie provides detailed information about its code of conduct for ethical marketing, demonstrating how it is enforced and extended to third parties. It is the only company to report using external parties to audit its code of conduct against corruption and bribery.

Comparatively broad disclosure of lobbying activities. AbbVie discloses board seats and memberships it holds of organisations that can influence access to medicine in countries in scope or that focus on diseases in scope.

Strong commitment to neglected tropical diseases. AbbVie is the only company with a dedicated Executive Council for Neglected Tropical Diseases. It coordinates company efforts regarding neglected diseases, reporting to the Executive Board. AbbVie works with a range of external partners in this area.

Among leaders in pro-access pipeline partnerships and product development. A large share of AbbVie's pipeline is developed in partnerships based on access provisions. It also stands out for sharing compound libraries for screening studies targeting tuberculosis, malaria, and various neglected tropical disease pathogens.

Performs strongly in equitable pricing. AbbVie employs inter-country pricing segmentation across a comparatively broad geographic scope. It also employs intra-country segmentation. When defining segments, it takes account of national income and disease burden. Its equitable pricing strategy takes affordability into account and actively targets poorest population segments.

Low commitment to access-oriented IP management. AbbVie does not specifically commit to not filing for patents in Least Developed Countries, or to considering licensing to support competition. It is, however, negotiating licences with the Medicines Patent Pool.

Does not engage in knowledge- or technology transfers. AbbVie is the only company to not disclose evidence of increasing local production capabilities, either of third-party or its own manufacturing facilities, in countries in scope.

Actively enhances paediatric HIV/AIDS care in Africa. Working with two NGOs engaged in paediatric HIV/AIDS care, AbbVie has helped train more than 21,000 health workers in 17 African countries on the use of ARVs in treatment-naïve patients, pregnant women and children.

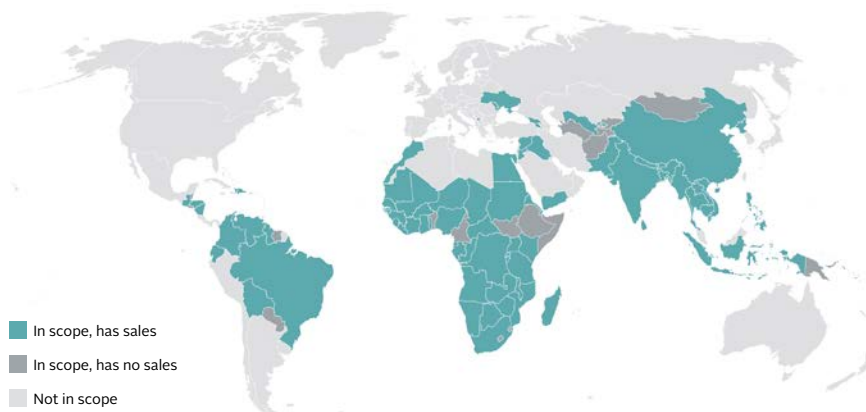
Best practices

Supporting healthcare providers to improve neonatal health. AbbVie worked with the Philippine Society of Newborn Medicine in developing a national neonatal registry in the Philippines. The registry makes it possible to track disease and outcome rates, the first step toward controlling disease among newborns.

Sales and operations

AbbVie became an independent, publicly traded company on January 1, 2013, following the spin-off from Abbott Laboratories, holding Abbott's former research based pharmaceutical business. It has one segment, pharmaceutical products, which focuses on immunology, kidney diseases, hepatitis C, neuroscience, oncology and women's health.

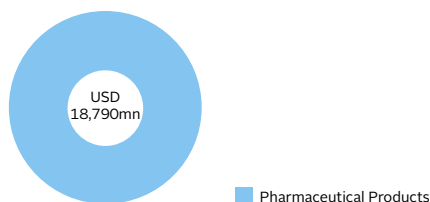
Sales in countries in scope



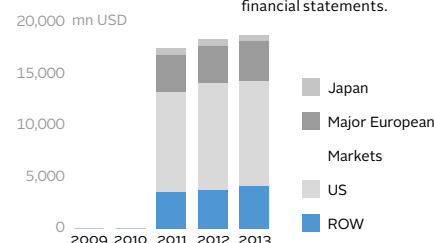
General information

New York Stock Exchange
 ABBV
Headquarters
 North Chicago, IL, US
Number of employees
 25,000

Sales by segment (2013)



Sales by region



Portfolio and pipeline

Focus

Within the scope of the Index, AbbVie focuses on HIV/AIDS and neonatal health, with medicines for hepatitis in development.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

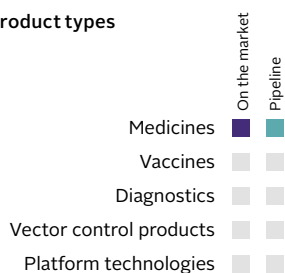
Marketed products

Has products for seven diseases in scope. For communicable diseases, this includes ARVs for HIV/AIDS and an anti-malarial medicine. For neonatal health, it has medicines for respiratory distress syndrome and lower respiratory infections.

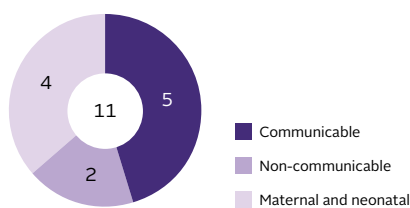
Pipeline products

AbbVie's clinical pipeline targets four diseases in scope, with hepatitis and HIV/AIDS getting most attention. It is developing paediatric medicines for HIV/AIDS and lower respiratory infections, and is involved in R&D for neglected tropical diseases.

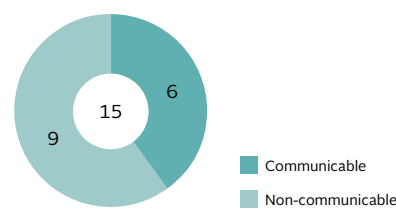
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Centralise and co-ordinate access-to-medicine management. AbbVie is considering developing an executive council responsible for developing, aligning and streamlining a targeted approach to its access-to-medicine strategy and activities. Such stronger oversight could support the integration of the company's access-to-medicine strategy with its business activities, and the development of stronger performance management of its access approach. Especially considering AbbVie's strong relevant portfolio and pipeline, such a change could significantly improve its overall impact on access to medicine.

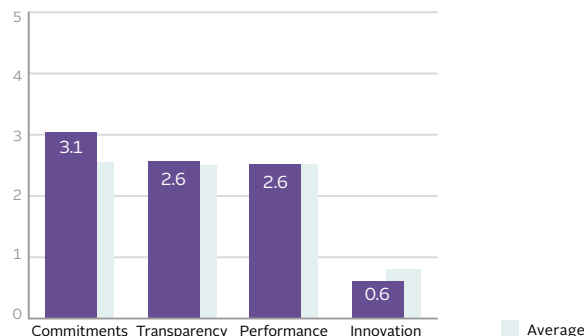
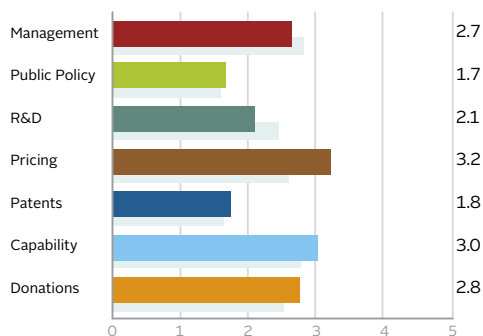
Develop access strategies for relevant pipeline products. AbbVie's pipeline represents a significant proportion of R&D activities captured by the 2014 Index, particularly in hepatitis, and neonatal health. The company can develop strategies ensuring they are as widely available, affordable and accessible as possible once they reach markets.

Expand equitable pricing strategy across portfolio. AbbVie can extend its existing equitable pricing practices to more of its relevant portfolio, particularly to ensure that forthcoming hepatitis treatments are priced equitably.

Engage in licensing. AbbVie has several products that are of significant value to public health, particularly for paediatric HIV/AIDS (lopinavir (Aluvia®/Kaletra®), ritonavir (Norvir®)). Completing licensing negotiations with the Medicines Patent Pool for these products will help ensure they are more widely available. AbbVie can consider expanding licensing to other products where there is generic market potential (particularly for its pipeline products for hepatitis) and develop a clearer, public, approach to licensing in general.

rank	score
10 [▼]	2.5
9 (2012)	

Bayer AG



Company overview

Bayer falls one place to 10th position. Despite maintaining its access-to-medicine management approach, it was overtaken by other companies that implemented new approaches or models. Plus, having received many market approvals during the 2012 Index, its relevant pipeline for the 2014 Index is relatively empty. It does, however, stand out for its equitable pricing strategies. Its commitment to inter-country equitable

pricing is now more concrete, specific and comprehensive than reported in the 2012 Index. Compared to peers, Bayer is more supportive of the Doha Declaration's IP flexibilities, explicitly endorsing several elements. It is also notable for having three large structured donation programmes.

Performance update

Linked to multiple breaches of ethical marketing standards. Bayer has been found in breach of ethical marketing standards multiple times during the period of analysis, and twice in relation to improper marketing practices in South Africa.

Co-developing TB treatment to help limit drug-resistance. Since 2005, Bayer has been co-developing moxifloxacin for shorter treatment regimens for drug-susceptible tuberculosis (patients are more likely to comply with shorter regimens, in turn helping to limit drug resistance). Clinical trial results were expected at the time of writing, with the submission of registration dossiers planned for November 2014. The first sales are expected early 2015.

Adapts packaging to meet local literacy needs. Bayer is one of several leaders in adapting product packaging to meet local needs and

ensure products are used rationally. For malaria and schistosomiasis, it uses a combination of text and pictograms to give directions for use and information about safety and environmental considerations.

Maintains access-oriented approach to family planning. Bayer has strong equitable pricing strategies for several contraceptive products. It also works with multiple partners training healthcare professionals and raising awareness of family planning and contraceptives among women in rural and urban areas of countries within scope. It has expanded these efforts in a broad range of African countries.

Continues to improve national pharmacovigilance systems in Asia. The company continues to work with the WHO Uppsala Monitoring Center and International Society of Pharmacovigilance to support Asian countries

in developing their pharmacovigilance systems. It is among the leaders in building local capabilities in pharmacovigilance.

Increases support for eliminating and controlling neglected tropical diseases. Bayer now commits to eliminating trypanosomiasis and controlling Chagas disease by 2020 (via donations). It is currently also developing a paediatric formulation for Chagas disease. This product could play an important role in treating children with this disease.

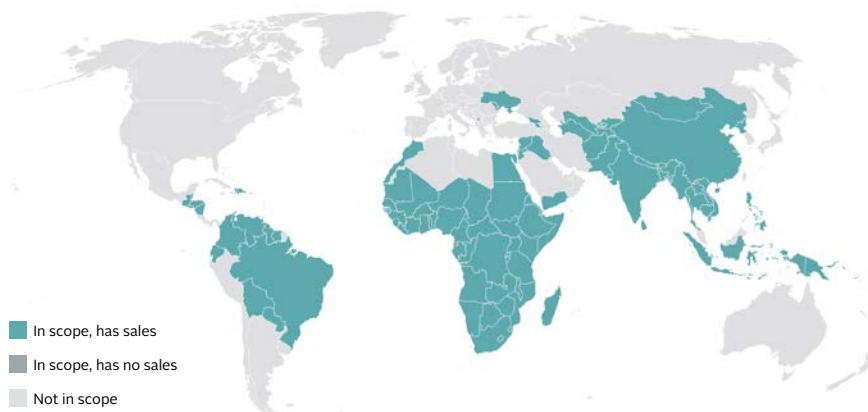
Best practices

Piloting a leading equitable pricing strategy. Bayer is piloting a new differential pricing model that takes into account both access and commercial objectives. It is a leading practice in terms of the level of clustering and the combination of criteria it considers.

Sales and operations

Bayer has three subgroups: HealthCare, CropScience and MaterialScience. HealthCare is divided into consumer health and pharmaceuticals. The latter offers prescription pharmaceuticals, including hormonal contraceptives, haemophilia treatments, anticoagulants, and for multiple sclerosis, cancer, hypertension, diabetes and infectious diseases. CropScience has a broad portfolio of pest-control products, including for controlling and preventing vector-borne diseases. It has a broad geographic presence and over one-third of its sales are in emerging markets. Bayer is acquiring Merck & Co.'s Consumer Care business.

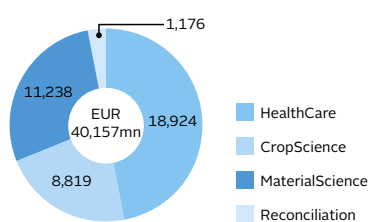
Sales in countries in scope



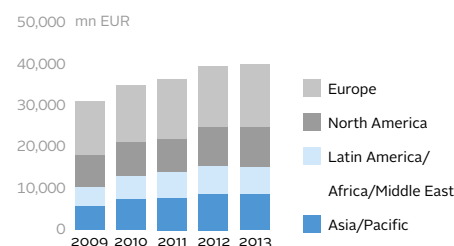
General information

Frankfurt Stock Exchange
BAYN
Headquarters
Leverkusen, Germany
Number of employees
113,200

Sales by subgroup (2013)



Sales by region



Portfolio and pipeline

Focus

Bayer has a strong contraceptive portfolio, with an additional focus on neglected tropical diseases and vector control products.

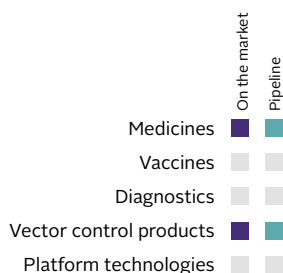
Marketed products

Has products for 13 diseases in scope, mainly medicines. This includes contraceptives and medicines for Chagas disease, trypanosomiasis and schistosomiasis. It has many vector-control products relevant to dengue, malaria and schistosomiasis.

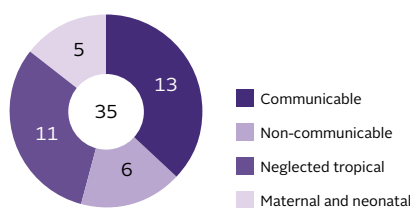
Pipeline products

Within scope, Bayer's clinical pipeline targets two diseases: it has a paediatric medicine for Chagas disease and a medicine for tuberculosis. Plus, it is improving a treated bed-net to provide longer-lasting protection against mosquitos and sandflies.

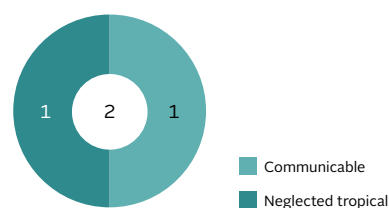
Product types



Products per disease category



Clinical pipeline per disease category



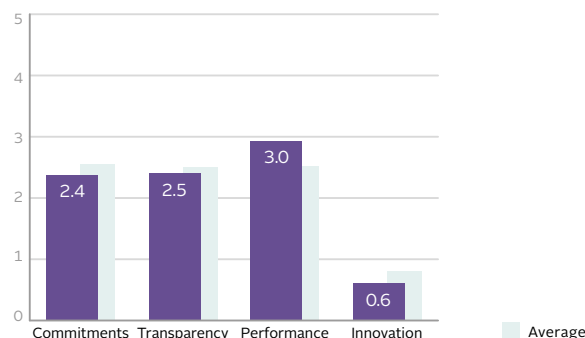
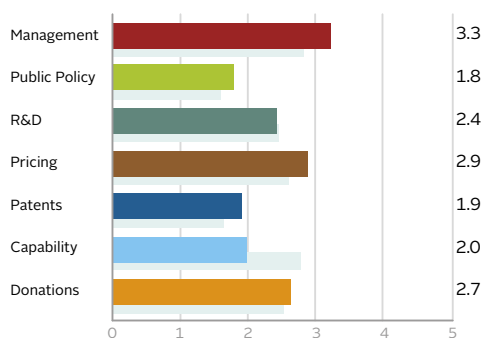
Opportunities for improving access to medicine

Adopt a more access-oriented approach for vector-control products. Bayer has broad expertise with a portfolio that includes both curative therapies and preventive vector-control products. While it already has a comprehensively access-oriented approach for its contraceptive products, it has scope to adopt a more access-oriented approach for its vector-control products. These play an essential role in reducing the global burden of diseases spread by insects. Bayer is already involved in educating and raising awareness among children in rural Africa

on using bed nets. It can apply its knowledge and technological expertise in vector-control products to facilitate innovation. It can also make its vector-control products, including new ones, more widely available and affordable.

rank	score
11 [^]	2.5
15 (2012)	

Eisai Co. Ltd.



Company overview

Eisai rises four places to 11th, driven by improvements in various areas: it rewards specific senior managers for achieving access objectives; in Public Policy & Market Influence, it was linked to fewer breaches than others (none in competition law); it has implemented an equitable pricing strategy in a country within scope; and commits to implementing equitable pricing strategies for all new products

for relevant diseases. It is one of the more supportive companies regarding TRIPS/Doha (although its score is still low), has taken a public stance against the evergreening of patents, and commits not to file for patents in Least Developed Countries. Eisai has a large pipeline of products for neglected tropical diseases.

Performance update

Discloses little about policy positions and lobbying practices. As in 2012, Eisai continues to disclose limited information about policy positions and the scale and scope of its lobbying activities. However, it has improved its disclosure with regard to board seats and memberships of organisations that influence access to medicine in relevant countries.

Pipeline targets relevant diseases. Eisai has achieved considerable movement of relevant products along its pipeline toward more advanced stages of development. It is involved in R&D for a range of neglected tropical diseases, tuberculosis and malaria. A large share of its pipeline products are being developed in partnerships, some of which are based on access provisions.

Improves significantly in equitable pricing commitment and implementation. Eisai now has a Global Pricing Policy that includes both

inter- and intra-country pricing tiers. For the first time, it has implemented an equitable pricing strategy that meets criteria set by the Index.

Develops more supportive stance towards IP. Eisai has a clear public stance against evergreening. It was also not involved in any identified incidences of IP-related anti-competitive practice. In addition, Eisai has a comparatively supportive stance on the public health flexibilities within the TRIPS agreement. However, it has no clear commitment to considering licensing and provides no evidence of engaging in licensing.

More active in building local production capabilities. Since 2012, Eisai has engaged in more knowledge and/or technology transfers with in-house and third-party manufacturers, in relation to quality and manufacturing standards.

Commits to eliminating a neglected tropical disease. In 2012, Eisai took over a donation programme that aims to eliminate lymphatic filariasis by 2020. Eisai has pledged to significantly scale up this programme, aiming to ship 2.2 billion diethylcarbamazine citrate (DEC) tablets to the WHO by 2020. It began shipping treatments in October 2013. The geographic scale of the programme was defined by the WHO, based on elimination targets for lymphatic filariasis. Distribution, storage and administration are periodically reviewed in collaboration with the WHO.

Best practices

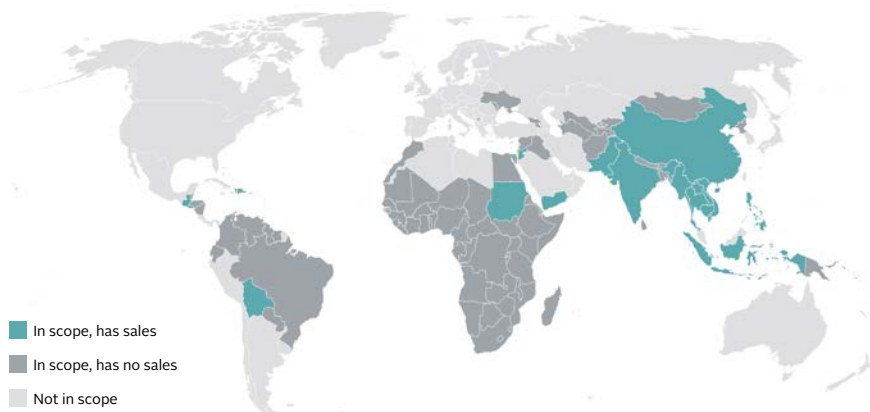
Contributes strongly to R&D for neglected tropical diseases. Eisai is a founding member of the Global Health Innovative Technology Fund (established with other Japanese pharmaceutical companies, the Japanese government and the Bill & Melinda Gates Foundation). Known as GHIT, this is a new scheme that funds early discovery research, including for neglected

tropical diseases. Eisai is also developing a substantial pipeline of medicines and vaccines for leishmaniasis, lymphatic filariasis, and Chagas disease.

Sales and operations

Eisai operates through two segments, with its pharmaceuticals business offering prescription pharmaceuticals, consumer healthcare, diagnostic products and generic medicines. It focuses on oncology, neurology, auto-immune diseases and over-the-counter products. It has a limited presence in countries in scope and has limited sales in countries outside Japan and the US. However, as a proportion of sales overall, sales beyond these territories are steadily growing.

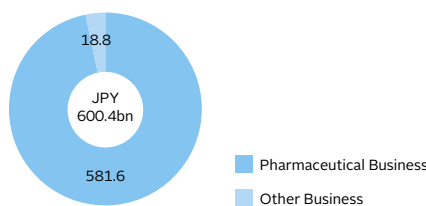
Sales in countries in scope



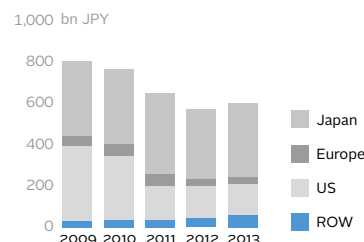
General information

Tokyo Stock Exchange
4523
Headquarters
Tokyo, Japan
Number of employees
10,495

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Within the scope of the Index, Eisai is strong in epilepsy and is diversifying its portfolio to include products for neglected tropical diseases.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

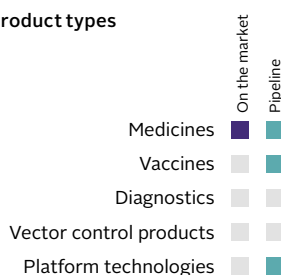
Marketed products

Has medicines for six diseases in scope, with a strong focus on non-communicable diseases, particularly epilepsy. In 2013, it received WHO prequalification for a medicine for lymphatic filariasis.

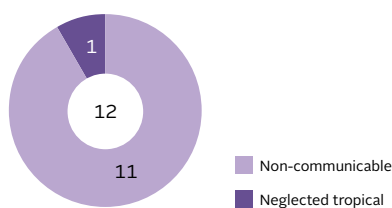
Pipeline products

Its clinical pipeline targets three diseases in scope: cirrhosis of the liver, epilepsy and Chagas disease. It has a large pre-clinical pipeline that includes medicines and vaccines for leishmaniasis, lymphatic filariasis, Chagas disease, lower respiratory infections and malaria.

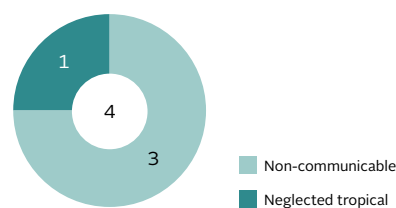
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

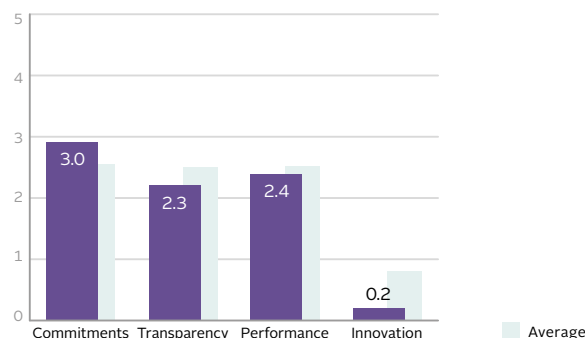
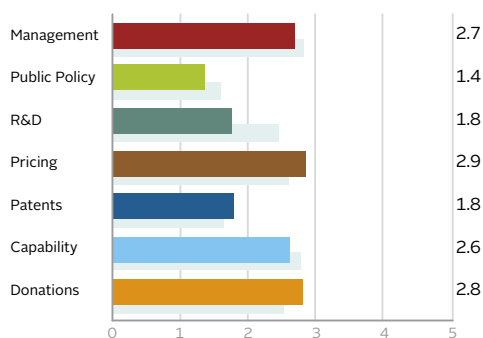
Engage with stakeholders more proactively and strategically. While Eisai already engages with a range of relevant stakeholders, it can do so more proactively and strategically, e.g., to understand risks and opportunities related to access to medicine and to support the implementation of access strategies on a global and local level.

Expand registration plans, develop licensing policies, and implement pricing schemes for pipeline compounds. Eisai is actively developing products for epilepsy, cirrhosis of the liver and a number of neglected tropical diseases. There are several steps it can take to help ensure they become accessible in relevant markets. For example, it can incorporate access provisions in more R&D partnerships and expand the geographic scope of registration targets. Eisai can also develop a policy that sets out when and how it would consider licensing arrangements for current and future on-patent

products. In addition, it can follow through on its commitment to implementing equitable pricing schemes for relevant new products once they reach the market.

rank	score
12 [▼]	2.3
10 (2012)	

Roche Holding AG



Company overview

Roche drops to 12th place. It is developing products for diseases in scope, most notably for hepatitis, yet this accounts for a relatively small share of its total pipeline. Roche reached a unique agreement with the Medicines Patent Pool for a medicine that treats an opportunistic infection associated with HIV/AIDS. Compared to 2012, it has applied equitable pricing strategies to more products. It has

performed well in product donations, as its donation programme targeting hepatitis qualifies for inclusion in the Index for the first time. Roche performs less well regarding Public Policy & Market Influence. Alongside many others, it was found to have breached regulations and standards.

Performance update

Moves closer to integrating access and business strategies. From 2013, all country and regional business plans must have a dedicated access strategy approved at headquarters. In addition, it is establishing a centralised system for tracking access-related metrics.

Took strong public stance against improper lobbying. Roche publicly distanced itself from the Innovative Pharmaceutical Association of South Africa following allegations that it planned to undermine reform of South Africa's intellectual property legislation.

Developing products to meet high unmet needs. Roche has several possibly safer, more efficacious oral hepatitis C medicines in its pipeline (vs. interferon-based regimens). It is also developing an antibiotic and is testing schizophrenia medicines in clinical trials. It is adapting a diagnostic platform that will cut reliance on trained professionals.

Taking affordability into account. Roche has equitable pricing strategies that target the poorest population segments' affordability.

These strategies cover a relatively small proportion of its portfolio, but this has increased since 2012.

Commits to filing for registration of new products in short time-frame. It pledges to register new products in countries in scope within six months of gaining EU or Swiss approval. Roche has local representatives to assess registration need and prioritises based on epidemiology, disease burden, market access and available infrastructure.

Adapts packaging for rational use. Roche donates products via Novo Nordisk's Changing Diabetes in Children programme, and adapts the packaging to help ensure rational use in ten relevant countries. Materials are simple, more illustrative and easy for children and families to understand. This packaging adaptation exceeds requirements set by national regulatory authorities.

Collaborating to improve access to treatment of cytomegalovirus. This virus commonly affects people living with HIV/AIDS, causing

blindness. Roche has reached agreement with the Medicines Patent Pool to lower prices of valganciclovir (Valcyte[®]) in 138 countries. It also commits to negotiating terms for licensing and technology transfer to enable generic production.

Building local diagnostic capacity. AmpliCare, the company's access initiative focused on improving HIV/AIDS diagnostic testing, has enabled the creation of diagnostic centers in Africa and Asia. For example, Roche has established its Roche Scientific Campus in South Africa. Run in partnership with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Campus provides technical and lab-management training, and offers health and scientific education.

Donates to improve hepatitis care. Roche donates several products in nine countries to hepatitis C patients: a diagnostic test and two medicines, peginterferon alfa-2a (Pegasus[®]) and ribavirin (Copegus[®]).

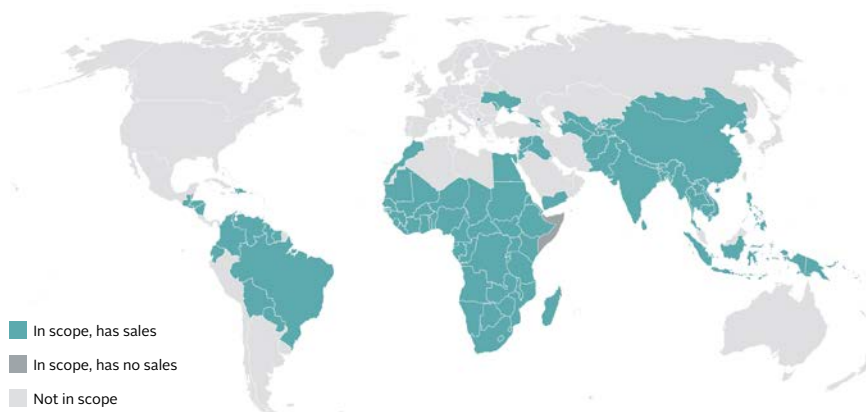
Best practices

The 2014 Index has not identified any best practices from Roche.

Sales and operations

Roche is a leader in *in-vitro* diagnostics, tissue-based cancer diagnostics and diabetes management. Roche has two divisions: pharmaceuticals and diagnostics. It offers medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience, as well as a wide range of diagnostics. It has sales in a significant number of countries in scope, including in Least Developed Countries.

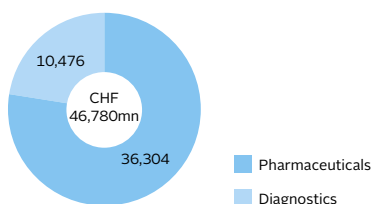
Sales in countries in scope



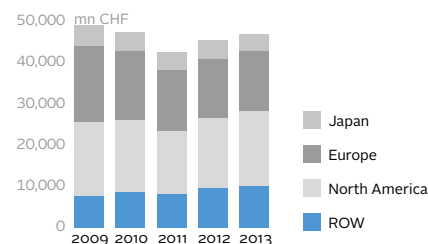
General information

SIX Swiss Exchange
RO; ROG
Headquarters
Basel, Switzerland
Number of employees
85,080

Sales by segment (2013)



Sales by region



Portfolio and pipeline

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

Focus

Within the scope of the Index, Roche has a strong presence in medicines for HIV/AIDS and hepatitis, plus a range of diagnostics.

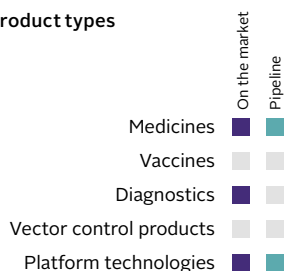
Marketed products

Has products for 14 diseases within scope. Its medicines portfolio is diversified, targeting nine diseases including HIV/AIDS and hepatitis. It has a large focus on diagnostics, mainly for HIV/AIDS, hepatitis and maternal health conditions.

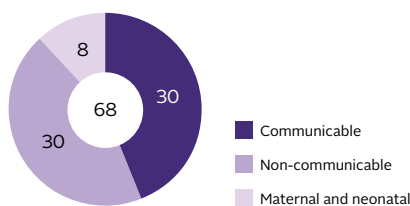
Pipeline products

Its clinical pipeline targets four diseases in scope (mainly medicines for schizophrenia and hepatitis). It is also developing a number of platform technologies, including a diagnostics platform.

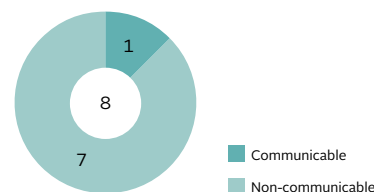
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Ensure wide access to new hepatitis medicines. Roche is developing hepatitis medicines that target a variety of virus genotypes and have different mechanisms of action. If efficacy and safety is sufficient (vs. other recently approved hepatitis medicines), this could enable a range of interferon-free regimens. If they gain regulatory approval, they could lead to a more competitive market with lower prices and increased accessibility. Roche can apply its experience with HIV/AIDS and other products by implementing similar pricing and licensing strategies to ensure these new class hepatitis medicines are affordable and available in sufficient quantities.

Expand implementation strategies during R&D phase. For some investigational products for chronic diseases, Roche lacks implementation strategies that specifically address relevant countries. This includes products for asthma and unipolar depressive disorder. As chronic diseases are on the rise in developing countries, Roche can develop implementation strategies during the R&D stage to ensure coverage of a wider range of countries.

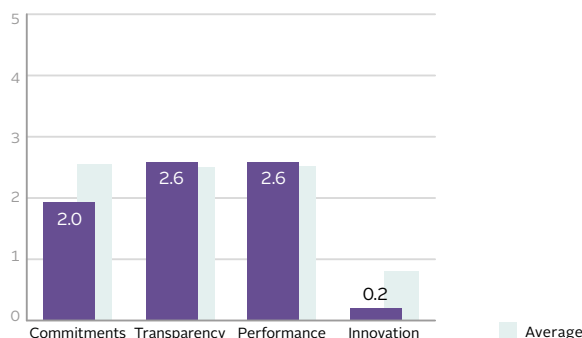
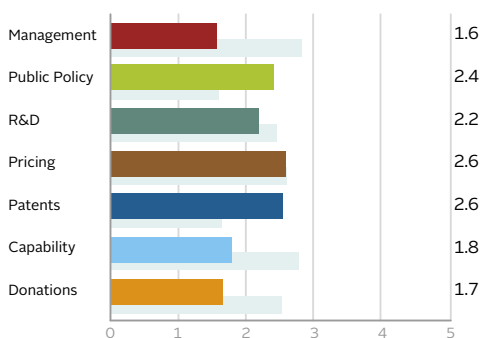
Expand equitable pricing strategies. Roche's existing equitable pricing strategies already take affordability for the poorest population segment into account. The company can expand

these strategies to cover a larger proportion of its portfolio, including technologically advanced medicines.

Expand oncology access structures to other therapeutic areas. Beyond the scope of the Index, Roche is pursuing a range of access-related activities for oncology, e.g., collaborating with healthcare insurance companies in Brazil and China. Roche can engage in similar activities to increase access to medicine in other therapeutic areas.

rank	score
13 [▼]	2.2
12 (2012)	

Bristol-Myers Squibb Co.



Company overview

Bristol-Myers Squibb drops from 12th to 13th place, with a mixed performance. Since 2012, it has disclosed more about its memberships, board seats and payments made to organisations that influence access to medicine. It also negotiated pro-access licences for the ARV atazanavir (Reyataz[®]) with the Medicines Patent Pool. It successfully moved several HIV/AIDS medicines along its pipeline. It has also newly

implemented intra-country equitable pricing. In other areas, it was overtaken by stronger performers: its donations approach remains *ad hoc*, while others engage in structured programmes. Access-to-medicine management lags behind the average, with no evidence that it is embedded in corporate strategy.

Performance update

Entered new IP-sharing partnership. After signing the London Declaration on Neglected Tropical Diseases in 2012, Bristol-Myers Squibb began pooling IP with the Drugs for Neglected Diseases Initiative (DNDi, a not-for-profit product development partnership) to spur drug discovery for leishmaniasis, dengue and Chagas disease.

Moving HIV/AIDS products along its pipeline. Bristol-Myers Squibb devotes a large share of its pipeline to relevant diseases and showed substantial movement of HIV/AIDS medicines to more advanced stages compared to 2012. It moved three antiretroviral drugs from earlier stages of development into clinical development. Plus, it gained stringent approval for paediatric use of atazanavir (Reyataz[®]).

New implementation of intra-country segmentation. For the first time, the company employs intra-country equitable pricing within the scope of the Index. Previously, it only engaged in inter-country arrangements. Within the geographic scope of the Index, it has expanded its equitable pricing strategies to a larger proportion of countries where it is present.

Packaging standards support rational use of medicines. For some products, the company's packaging standards go beyond what is required by national drug regulatory authorities to ensure rational use. For example, blisters are used in countries with a stability need, including the Philippines, Egypt, Brazil, South Africa, Indonesia, Vietnam, China, India, and Thailand.

Facilitating access to atazanavir (Reyataz[®]). The company has reached a licensing agreement with the Medicines Patent Pool covering developing countries. Atazanavir is on-patent, and viewed by the WHO as an important second-line HIV/AIDS treatment. Via the agreement, licensees also gain a technology-transfer package to help ensure quality.

Focuses philanthropy on hepatitis and HIV/AIDS. The Bristol-Myers Squibb Foundation runs two initiatives that both include numerous activities in multiple countries. Delivering Hope focuses on hepatitis B and C in Asia. Secure the Future focuses on developing and replicating sustainable solutions for people living with HIV/AIDS in sub-Saharan Africa. This includes providing technical assistance and transferring skills related to existing community resources.

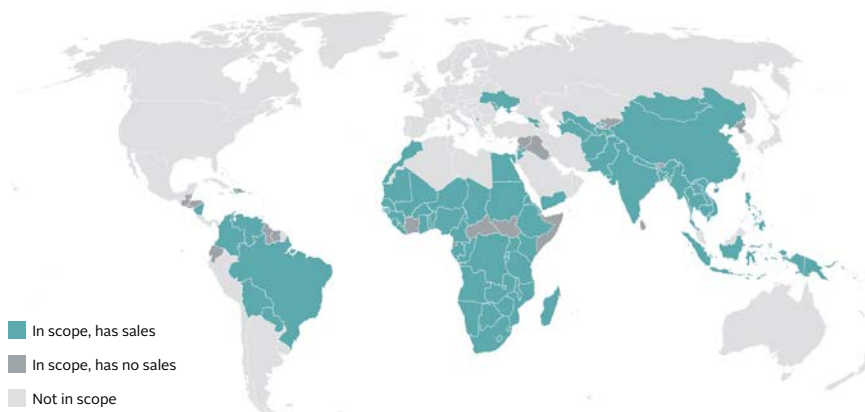
Best practices

The 2014 Index has not identified any best practices from Bristol-Myers Squibb.

Sales and operations

Bristol-Myers Squibb produces biopharmaceuticals, primarily for cancer, cardiovascular disease, hepatitis B, HIV/AIDS, rheumatoid arthritis and psychiatric disorders. In February 2014, it completed the divestment of its share in the global diabetes business that was part of its collaboration with AstraZeneca.

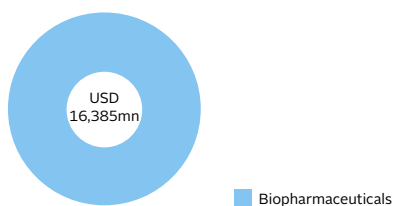
Sales in countries in scope



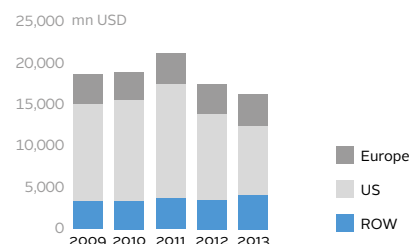
General information

New York Stock Exchange
 BMY
Headquarters
 New York, NY, US
Number of employees
 24,000

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Within the scope of the Index, Bristol-Myers Squibb focuses on HIV/AIDS. Its pipeline includes several new medicines for hepatitis.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

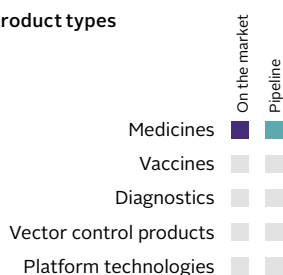
Marketed products

Has medicines for seven diseases in scope, half of which are ARVs for HIV/AIDS. Its portfolio for non-communicable diseases is diversified, including one medicine that can treat bipolar disorder, schizophrenia and depressive disorders.

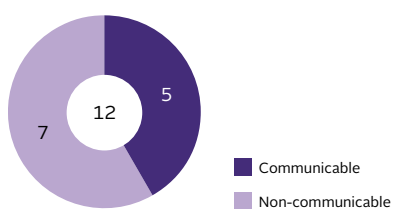
Pipeline products

Its clinical pipeline targets five diseases in scope, mainly hepatitis and HIV/AIDS. It is also developing products for diabetes, diarrhoeal diseases, and nephritis and nephrosis.

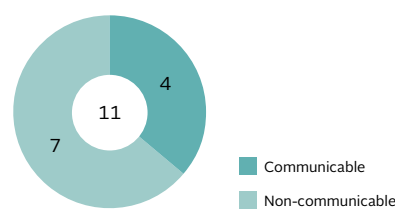
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Develop access strategies for pipeline hepatitis products. Bristol-Myers Squibb has a strong pipeline of hepatitis products. To ensure more patients can access these products as soon as possible, the company can already start developing access strategies, and evaluate the most effective ways to ensure products are affordable in many countries. Strategies could include licensing agreements (building on its licensing experience with atazanavir (Reyataz®)), or a mix of inter- and intra-country equitable pricing strategies, with a strong emphasis on affordability for the poorest population

segments (building on its existing equitable pricing strategies).

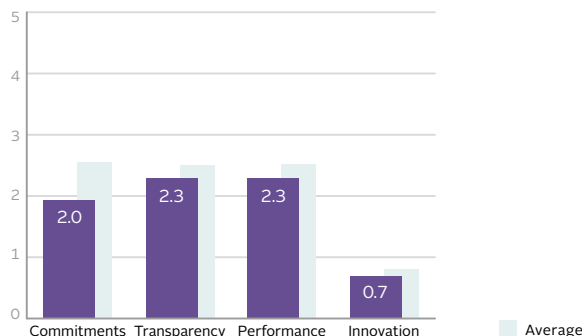
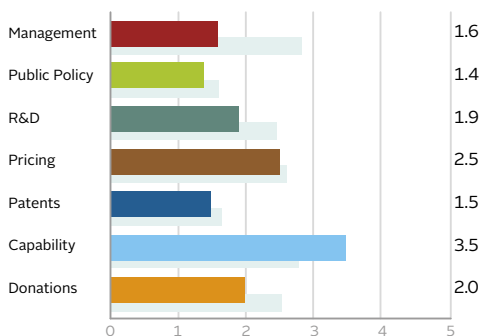
** After the period of analysis, the company launched an access strategy for hepatitis C aimed at addressing need in lower income countries.*

Collaborate on combination therapies. For the HIV/AIDS products in its pipeline, the company can already start considering which partnership (new or existing; with either generic medicine manufacturers or research-based partners) could lead to new, accessible combination regimens of ARVs.

Expand incentives for access-related performance. Employees in the company's Foundation and Global Access programme are already assessed using access-related performance objectives. These objectives could be extended to employees who work in departments outside of these programmes, and tailored to the business activities of those areas.

rank	score
14 [▲]	2.1
17 (2012)	

Boehringer Ingelheim GmbH



Company overview

Boehringer Ingelheim rises from 17th to 14th place, substantially improving its disclosure and widening its access focus beyond HIV/AIDS. It performs strongly in Capability Advancement, particularly in quality management and manufacturing standards, and it has newly implemented intra-country equitable pricing strategies. Yet, in Patents & Licensing, its performance drops: it does not clearly pledge

not to enforce patents in Least Developed Countries, and although it has issued non-assert declarations in the past, it has not made the terms public. It has no clear access-to-medicine strategy or performance management system, and much of its pipeline for non-communicable diseases lacks strategies for reaching patients in relevant countries.

Performance update

■ Widened access approach beyond HIV/AIDS. It has established an internal committee responsible for discussing wider access issues, and is reviewing its access-to-medicine strategy for its products.

■ Improves transparency, still lags behind. Despite disclosing more to the Index, the company remains less transparent than peers on its access-to-medicine strategy, activities and policies. It shares relatively little on policy positions, yet discloses more than in 2012 about memberships held and participation in advisory bodies.

■ Expands equitable pricing strategies. The proportion of its portfolio for which it applies equitable pricing strategies has increased since 2012. Such strategies now cover more products, beyond ones for HIV/AIDS. For the first time in the Index, it applies intra-country equitable pricing strategies.

■ Has new policy and improved disclosure on product recalls. It has provided detailed evidence of its guidelines and policy for product recalls, which align with the WHO GMP guidelines.

■ More active in building local production capabilities. It is among the leaders in building local capabilities in Quality Management Systems and manufacturing standards, and has engaged in multiple knowledge- and/or technology transfers to third-party manufacturers, including in low income countries.

■ Continues to build local research capacities. The company facilitates the training of researchers in Botswana and South Africa, on, e.g., clinical trial conduct, epidemiology and health systems research in relation to HIV/AIDS and respiratory diseases, including tuberculosis.

■ Addressing HIV/AIDS and pregnancy. It works with the Antiretroviral Pregnancy Register to collect safety data on the use of its antiretrovirals by pregnant women. Via its nevirapine (Viramune[®]) donation programme, it treated HIV-positive pregnant women to prevent transmission to their unborn babies. As part of this programme, the company also worked closely with local organisations to enhance local capacity for care and to develop national HIV/AIDS guidelines, policies and activities to reduce stigma. The programme ended in 2013 when WHO treatment advice was updated.

Best practices

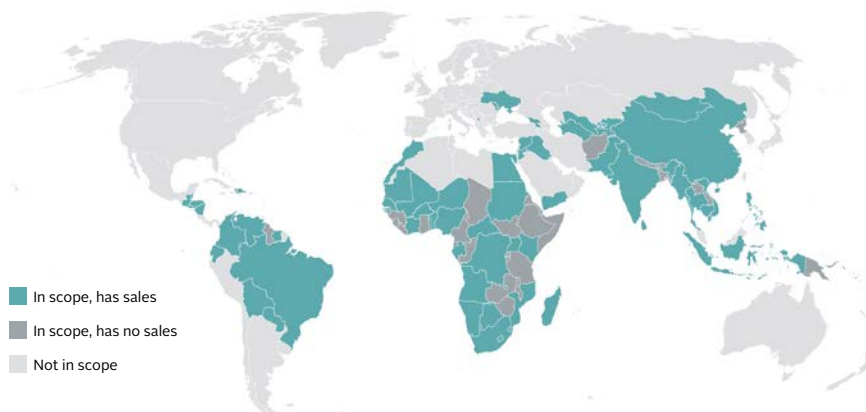
■ Stimulating social entrepreneurship to improve health. Boehringer Ingelheim's Making More Health Initiative (MMH) supports local social entrepreneurs working to improve health in their communities. It is a fellowship programme run with the network organisation Ashoka, contains elements of capacity building and philanthropy, and covers several coun-

tries in scope. It is innovative for focusing on marginalised communities and socially sensitive subjects, such as mental health and sanitation.

Sales and operations

The company has five divisions: Prescription Medicines, Consumer Health Care, Animal Health, Biopharmaceuticals and Industrial Customers. The vast majority of its sales are prescription medicines. It has products for respiratory diseases, cardiometabolic disorders, oncology, central nervous system diseases, immunology and infectious diseases. Over half of its sales are generated in the US, Japan and Germany, yet sales in emerging markets (Russia, Brazil, India, China and Africa) are growing in significance.

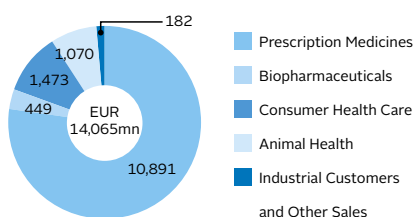
Sales in countries in scope



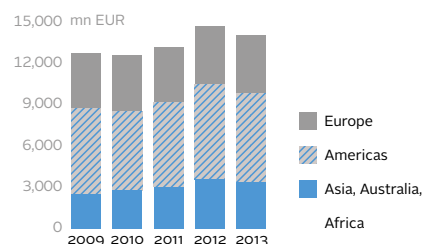
General information

Privately held
Headquarters
 Ingelheim, Germany
Number of employees
 47,492

Revenues by segment (2013)



Net sales by region



Portfolio and pipeline

Focus

Within scope, Boehringer Ingelheim focuses on HIV/AIDS, respiratory diseases and cardiovascular disease.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

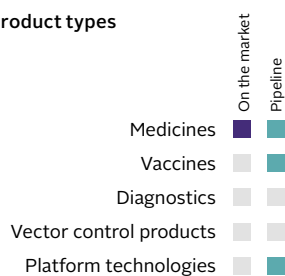
Marketed products

Has products for seven diseases in scope, all medicines. Most are for non-communicable diseases, mainly cardiovascular and respiratory diseases. It has two antiretroviral drugs for HIV/AIDS.

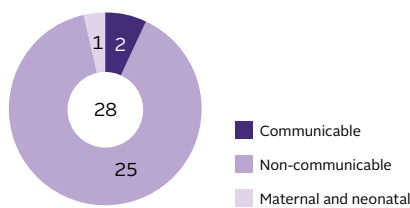
Pipeline products

Its clinical pipeline targets seven diseases in scope, mostly for COPD, diabetes, and HIV/AIDS. It is testing suitability of a number of medicines for use in children, including for cerebrovascular disease and HIV/AIDS. It has invested in the development of a malaria vaccine.

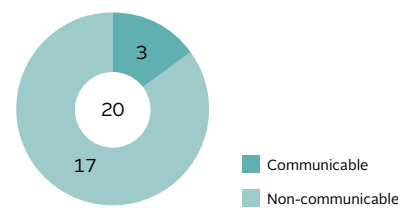
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

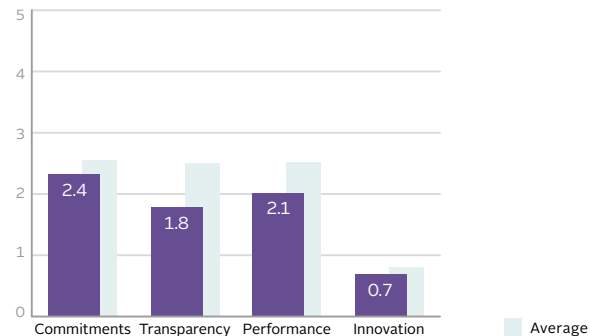
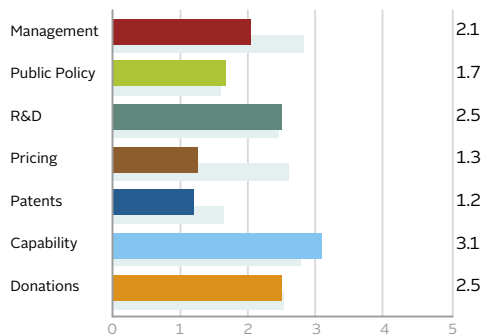
Align access-to-medicine approach with core business. The company can develop a more specific access-to-medicine strategy that is more clearly aligned with its core business and that focuses on improving access to its current and future portfolio. It can also start to formulate more specific targets that both reflect what the company wants to achieve and facilitate the implementation of its access strategy. By implementing performance management systems that include access-related targets, the company can measure and monitor performance and progress.

Take access into account during R&D process. The company is developing a new approach for making new and existing products available. As part of this approach, it can start to take access into account earlier in the product development process. In combination with a broader access-to-medicine strategy and corresponding initiatives, this will help ensure that newly developed products will be available, accessible and affordable in countries in scope. As the majority of its pipeline focuses on non-communicable diseases, the company has particular potential for increasing access to medicine for diseases like asthma, COPD and diabetes.

Build on experience with IP access mechanisms. Boehringer Ingelheim can consider where in its patented portfolio IP access mechanisms can be an appropriate strategy to boost access. It can proactively offer its experience in technology transfer and consider expanding its non-assert declarations to include more countries where patents remain in place for the paediatric and extended-release formulations of this product. It can complete negotiations with the Medicine Patent Pool regarding potential licences.

rank	score
15 [▲]	1.9
16 (2012)	

AstraZeneca plc



Company overview

AstraZeneca rises one place to 15th, improving in several areas. It strengthens its commitment to equitable pricing, and has strong clinical trial codes of conduct. It was linked to no breaches in countries in scope. It has a relevant pipeline for respiratory diseases, and engages in numerous IP-sharing partnerships with access provisions. It states cases where it would waive data exclusivity, and increased its capability

advancement activity. However, it falls in other areas. Its management of access-related performance is weaker than its peers. It has no specific policy on licensing, and has not issued licences for its relevant on-patent products.

Performance update

Supportive of generic market entry for certain diseases. The company commits to waiving rights to data exclusivity for specific diseases within scope, including malaria, tuberculosis, lymphatic filariasis and leishmaniasis.

Engaged in leading number of access-oriented IP-sharing partnerships. During the period of analysis, the company was one of two leaders in this area, with numerous partnerships based on access provisions. However, it withdrew from a large proportion of its IP-sharing partnerships in September 2013, when it ended its participation in WIPO Re:Search. Its remaining partnerships target tuberculosis and neglected tropical disease drug discovery.

Strong enforcement of clinical trial code of conduct, in-house and outsourced. It provides extensive evidence that it has processes for monitoring and auditing the enforcement of its code of clinical trial conduct, including

procedures for managing misconduct for both in-house and outsourced trials.

Implements equitable pricing initiatives. It has equitable pricing strategies for products and countries within the scope of the Index for the first time. At the end of 2012, AstraZeneca established a dedicated team within its International Region business unit (covering all emerging markets and developing countries), which is responsible for its approach to broadening affordability, replicating best practices and expanding the number of programmes in these markets.

Does not engage in licensing, lacks commitment. The company lacks a policy for considering non-exclusive voluntary licences, and provides no evidence of having signed any licensing agreements, despite having relevant on-patent products.

Significantly improves in local capacity building. It has particularly improved efforts to build capacities in quality management systems, manufacturing standards and pharmacovigilance. For example, its Responsible Business Plan explores opportunities to share and use AstraZeneca's pharmacovigilance knowledge and best practices with developing countries.

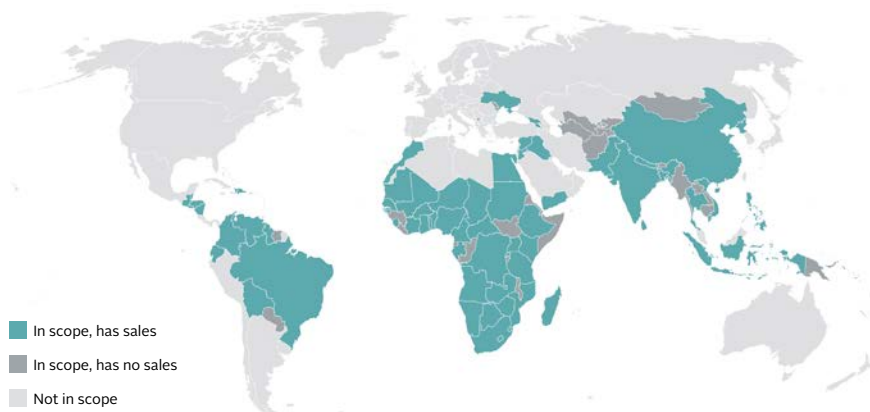
Best practices

Raises awareness among marginalised youth. AstraZeneca's Young Health Programme focuses on awareness-raising and prevention of non-communicable diseases amongst adolescents in marginalized communities in Brazil, China, India and Zambia.

Sales and operations

The company operates through one business segment, biopharmaceuticals, with activities in five main areas: it focuses primarily on cardiovascular and metabolic disease; oncology; and respiratory disease, inflammation and autoimmunity; followed by infectious disease; and neuroscience and gastrointestinal disease. In 2013, revenues rose in emerging markets, with particularly strong growth in China.

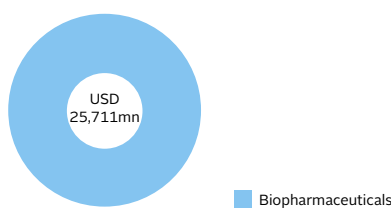
Sales in countries in scope



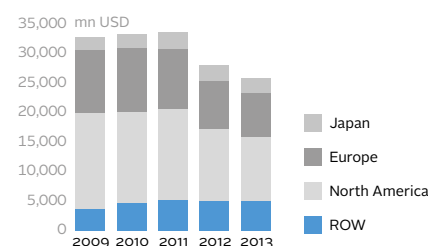
General information

London Stock Exchange
 AZN
 Headquarters
 London, UK
 Number of employees
 51,500

Sales by segment (2013)



Sales by region



Portfolio and pipeline

Focus

Within the scope of the Index, AstraZeneca focuses on respiratory diseases, cardiovascular disease and metabolic disorders.

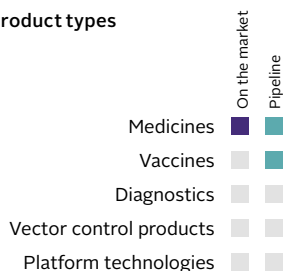
Marketed products

AstraZeneca has medicines for 11 diseases in scope, mostly for non-communicable diseases, particularly cardiovascular and respiratory diseases.

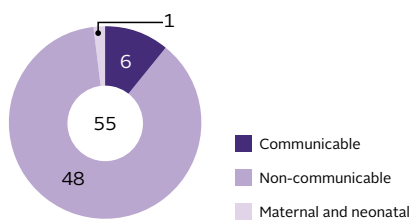
Pipeline products

Its clinical pipeline targets four diseases, mainly respiratory diseases, and includes antibiotics and a vaccine for lower respiratory infections, a medicine for COPD, and a medicine for tuberculosis (including resistant strains). It is also developing medicines for diabetes.

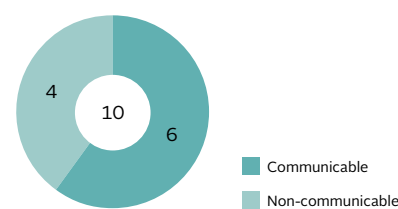
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

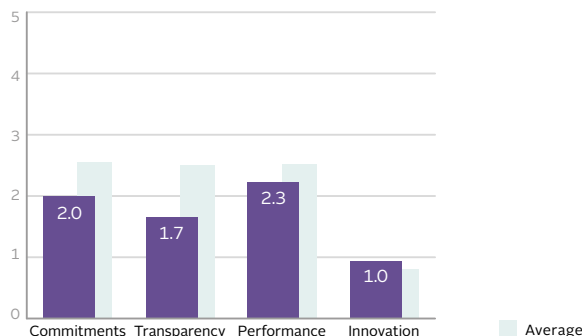
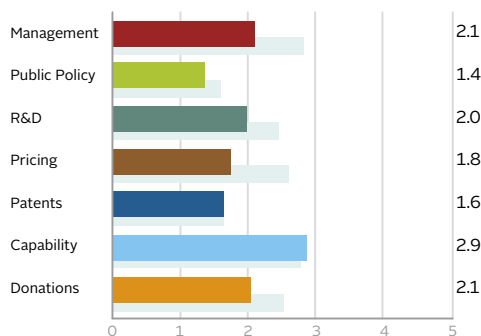
Align business and access-to-healthcare priorities. In April 2013, the company reviewed its Responsible Business Approach and named Access to Healthcare one of its three main strategic responsible business priorities. The company can do more to align its business and access-to-healthcare priorities by formulating additional, more specific access-related goals, targets and key performance indicators. It can also start incentivising relevant performance among employees.

Ensure accessibility of new products for respiratory diseases. AstraZeneca is developing novel treatments for COPD and asthma. However, it could not provide evidence of making provisions for developing countries, where the prevalence of these diseases is rising. The company can impact public health in these countries positively by developing strategies to make these products available and accessible, for example by not filing for patents and taking affordability into account when setting pricing strategies.

Expand access programs for breast-cancer treatment and care to other high-burden diseases. The company has two breast-cancer initiatives in South Africa and Kenya that focus on creating awareness, enabling early diagnosis, improving access to treatment and building effective support networks. It can build on its experience with these programs and implement similar programmes for other therapeutic focus areas, for example, respiratory diseases.

rank	score
16 [▼]	1.9
11 (2012)	

Pfizer Inc.



Company overview

Pfizer falls from 11th to 16th place, driven by a relative lack of progress, particularly regarding R&D and pricing. Pfizer dedicates a relatively small share of its overall pipeline to relevant diseases and countries, with fewer products in development than in 2012. Regarding pricing, its peers have performed well in new areas of disclosure, yet Pfizer has not proved forthcoming. Although it has equitable pricing

for many products, it is not clear whether the majority of its strategies are targeted towards the poorest population segments or take account of whether prices are affordable for these groups. Pfizer has two long-term structured donation programmes.

Performance update

Found in breach of ethical standards, implemented new anti-bribery policy. Pfizer was found in breach of ethical marketing standards multiple times over the period of analysis. In 2012, it settled allegations related to prior incidences of bribery in China, India and Pakistan. In 2013, Pfizer rolled out a new version of its international anti-bribery and anti-corruption policy and procedures, supported by a manual and online interactive training. It also implemented new electronic systems and processes, country by country, which set out regulations and limitations for gift-giving.

Has fewer relevant R&D activities. This is in some cases due to compound failure, in other cases, projects have been handed over to third parties, resulting in a smaller relevant pipeline than in 2012. Pfizer continues to develop medicines for neglected diseases, including for lymphatic filariasis and onchocerciasis.

Has equitable pricing strategies for a wide product and disease scope. Pfizer has the highest number of products with equitable pricing strategies, but it is not clear how targeted they are towards the poorest segment.

Improves support for generic competition. Pfizer increasingly recognises the value of generic competition for access. Through ViiV Healthcare, it has engaged in licensing with the Medicines Patent Pool.

Extends commitment to eliminate trachoma. Pfizer has committed to eliminating trachoma by 2020, by scaling up its donations of azithromycin through the International Trachoma Initiative, or ITI (an independent non-profit organization co-established by Pfizer). ITI has a wide geographic scale, and in 2013, distributed 51.2 million doses. Since the programme began in 1998, 340 million treatments have been donated.

Best practices

Signed novel licensing agreement, boosting ARV availability in middle income countries. The agreement includes tiered royalties based on country income level, and achieves a broad coverage of adults living with HIV/AIDS. The licence has been issued by ViiV Healthcare (Pfizer's joint venture with GSK), which negotiated the licence with the Medicines Patent Pool.

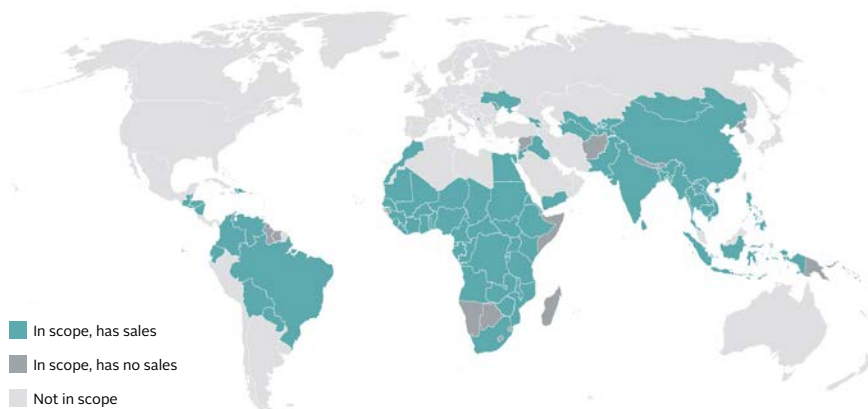
Optimising supply chains. Through its Global Health Fellows programme, Pfizer has sent supply chain experts to Kenya and Tanzania to, for example, improve stock management, maintain supply chain integrity, and improve

quality-control management. It supported an NGO in developing a master supply-chain plan in Kenya. The plan defines quality standards for health commodity providers and addresses information needs across the supply chain.

Sales and operations

Pfizer operates through four segments: Primary Care; Specialty Care & Oncology; Established Products & Emerging Markets and Consumer Healthcare. It offers products for various therapeutic and disease areas including Alzheimer's disease, cardiovascular disease, erectile dysfunction, genitourinary disease, major depressive disorder, pain, respiratory disease and smoking cessation. It holds a 12.6% stake in ViiV Healthcare, a joint venture with GSK focused solely on the research, development and commercialisation of HIV/AIDS medicines. In July 2014, it was announced that Pfizer will acquire Baxter's portfolio of marketed vaccines.

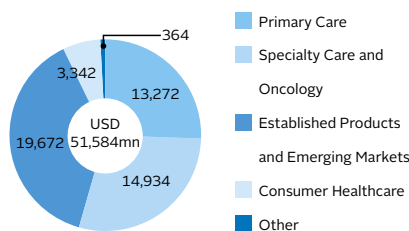
Sales in countries in scope



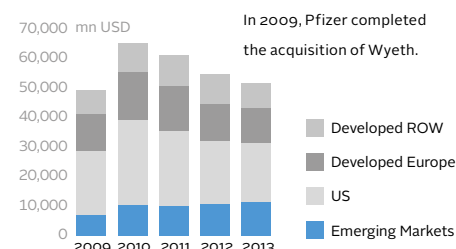
General information

New York Stock Exchange
PFE
Headquarters
New York, NY, US
Number of employees
77,700

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Within the scope of the Index, Pfizer has a large, diverse portfolio. Its pipeline focuses on infectious diseases.

Hepatitis is included under cirrhosis of the liver and counted as a non-communicable disease.

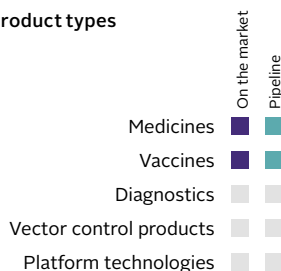
Marketed products

Has products for 21 diseases in scope, mostly medicines, with a strong focus on cardiovascular disease, antibiotics, mental health products (including epilepsy) and HIV/AIDS. Its pneumococcal 13-valent conjugate vaccine (Prevenar 13®) is the world's best-selling vaccine.

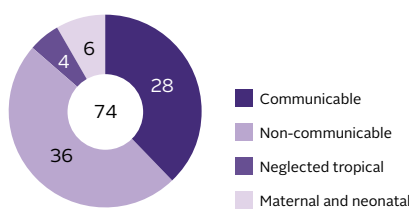
Pipeline products

Its clinical-stage pipeline targets one disease in scope: tuberculosis (including resistant strains). In earlier stages, it has medicines for lymphatic filariasis, onchocerciasis and malaria, and is adapting its pneumococcal vaccine.

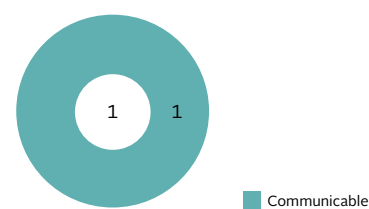
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Improve internal governance and management of access to medicine. Given its broad portfolio of relevant products and wide geographic presence, Pfizer can leverage its existing resources to improve its access-to-medicine footprint and performance in general. Although it has established board-level representation for access-to-medicine issues, it can develop a strong governance structure with executive-level responsibility for access-to-medicine issues. It can also implement a centralised system that monitors access-related performance against set targets.

Improve enforcement of codes of conduct. The company can consider developing stricter enforcement measures for its codes of conduct for ethical marketing and anti-corruption, ensuring they are effective across the breadth of its operations.

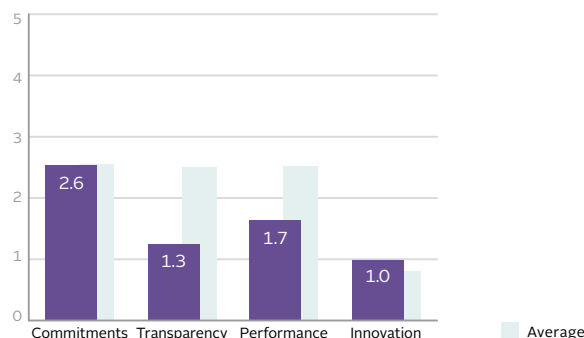
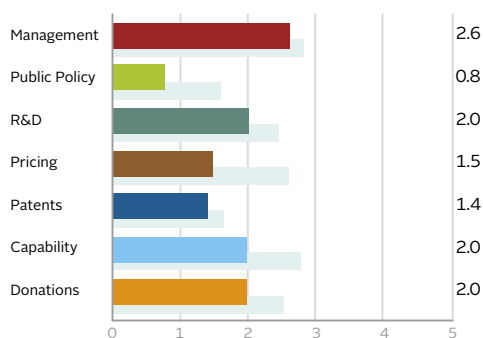
Improve targeting of existing equitable pricing strategies. Although Pfizer has the highest number of relevant products with equitable pricing, it is not clear to what extent these strategies target the poorest population segments. The company can deepen its existing strate-

gies to explicitly target the poorest population segment and to ensure that affordability for this group of patients is taken into account.

Engage in greater range of licensing agreements. Pfizer has on-patent products relevant to countries in scope. Building on its experience with ViiV Healthcare and the Medicines Patent Pool, Pfizer can consider engaging in a broader range of licensing arrangements, to boost access. During negotiations, it can consider including knowledge and technology transfers.



Eli Lilly & Co.



Company overview

Eli Lilly drops three places to 17th, with moderate to poor performance in all areas. It dedicates a comparatively small share of its pipeline to relevant diseases, and engages in equitable pricing for a limited proportion of its products. It is also comparatively less transparent about its pricing practices, the terms of R&D partnerships and relevant policy positions and marketing activities. Nevertheless, in access-

to-medicine management, it has improved since 2012: its new performance-management system includes access-based targets that are linked to the pay of some senior managers. It is the only company to report addressing mental health in sub-Saharan Africa through donations.

Performance update

Assigns cross-functional access team. In 2013, Eli Lilly assigned a team to explore opportunities for expanding access to Eli Lilly's medicines in countries in scope. The team includes representatives from finance, manufacturing, marketing and corporate affairs.

Includes access-related objectives in new performance management system. The access-related objectives link to its Global Health and Expanding Access to People programs. All employees with responsibilities for expanding access have personal access objectives integrated into their performance management plans.

Remains reluctant to disclose influence on public policy and markets. As in 2012, the company does not go beyond legal requirements for reporting lobbying and marketing activities (disclosing financial contributions made in the US, but not in countries within scope).

Subject of settlements or decisions for unethical marketing. One incident involves a settlement with the US government during the period of analysis concerning prior allegations relating to unethical marketing in some countries within scope. Following this, Eli Lilly reports taking corrective action (including disciplinary measures and improving internal controls). Remaining incidents include breaches of ethical marketing standards as monitored by self-regulatory bodies.

Continues to support the development of new TB products. Eli Lilly continues to work with the Infectious Disease Research Institute (IDRI) to develop new drugs for communicable diseases, particularly TB. It has given the IDRI access to 800,000 compounds in its library.

Now adapts packaging to help facilitate rational use. Eli Lilly now adapts the packaging of the majority of its relevant products to align with local regulatory requirements and takes language needs into account.

Continues to increase access to MDR-TB products through capability advancement. Since 2003, Eli Lilly has increased access to its products for drug-resistant TB (MDR-TB), including transferring technology and expertise to manufacturers in China, India and South Africa.

Supporting mental health in Africa. Via its partner AMPATH, Eli Lilly donates products for mental health conditions in Western Kenya, reaching approximately 500,000 people. It donates an anti-depressant and anti-psychotic (among others), for treating, e.g., unipolar depressive disorder, bipolar affective disorder and schizophrenia.

Best practices

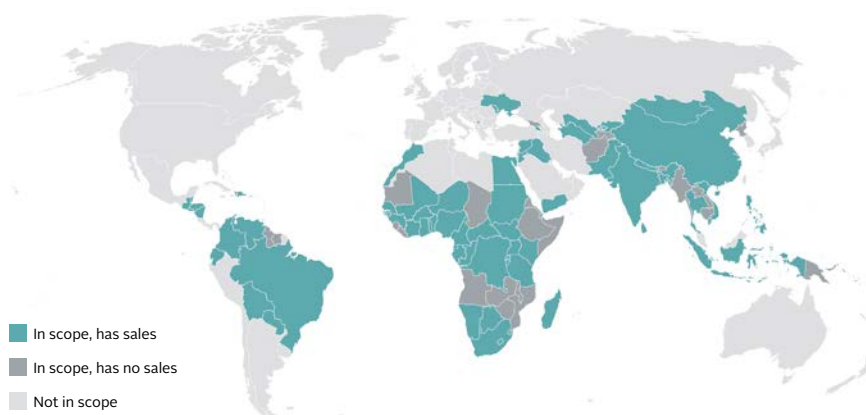
Sets higher standards for clinical trials. Eli Lilly has developed a Bioethics Framework that facilitates a higher level of ethical clinical trial conduct than other companies demonstrate. Its review committees routinely ensure that study protocols adhere to ethical standards drawn from the Declaration of Helsinki, and it has an internal service for consulting on ethical study design and conduct.

Enhancing product recall. Using its existing software that tracks all transactions involving its products globally, Eli Lilly is developing a module for accessing this information more rapidly, resulting in a faster, more efficient recall response.

Sales and operations

Eli Lilly operates through two segments: Human Pharmaceutical Products and Animal Health Products. It has products in the areas of neuroscience, endocrinology, oncology and cardiovascular diseases. It holds a strong position in the diabetes market. In April 2014, it signed an agreement to acquire Novartis Animal Health.

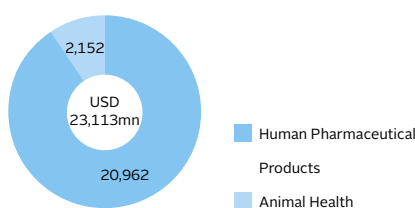
Sales in countries in scope



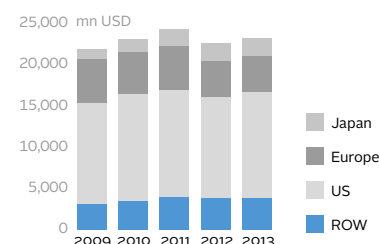
General information

New York Stock Exchange
 LLY
Headquarters
 Indianapolis, IN, US
Number of employees
 39,236

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Eli Lilly has a strong mental health portfolio and is active in diabetes.

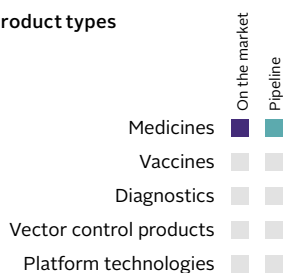
Marketed products

Has medicines for six diseases in scope. Its portfolio for non-communicable diseases includes medicines for mental health conditions and diabetes. It also has a tuberculosis medicine: capreomycin.

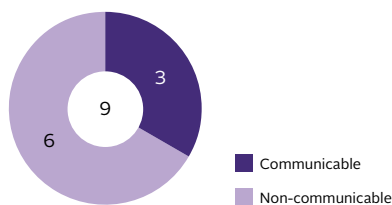
Pipeline products

Within the scope of the Index, its clinical pipeline targets diabetes. This includes four new medicines.

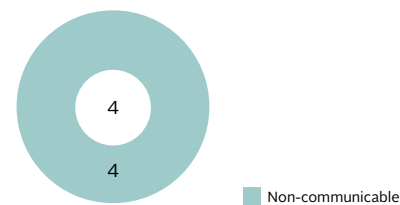
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

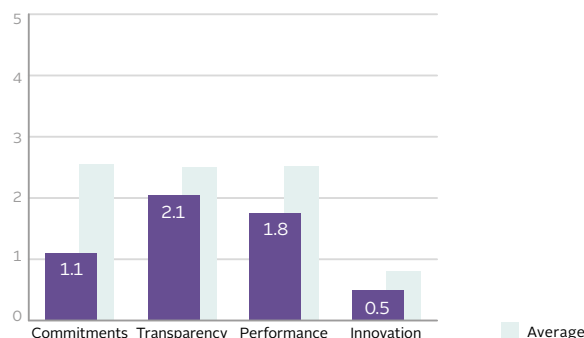
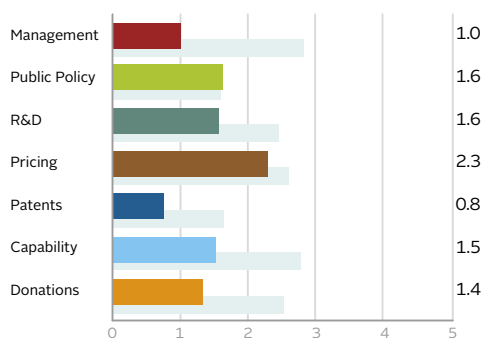
Adapt diabetes products for use in developing countries. Eli Lilly has strong expertise in diabetes drug development. While it has already shown interest in developing products for the Chinese market, it can improve diabetes care across a broader range of developing countries by adapting its diabetes products by targeting the medical needs of the poorest population segments.

Develop access strategies for products in development. Eli Lilly can already begin considering how best to ensure products in development will be accessible to patients in countries in scope, once they reach markets. It could, for example, extend their use of equitable pricing strategies.

Develop and expand sustainable long-term access strategies in addition to donation programmes. Eli Lilly has two important donation programmes that target chronic diseases: diabetes and mental health. While the Index encourages Eli Lilly to continue and expand these programmes, it can also look for opportunities to implement strategies that are more sustainable (such as equitable pricing, or licensing), across a broader range of Index countries.

rank	score
18 [▲]	1.6
20 (2012)	

Astellas Pharma Inc.



Company overview

Astellas rises two places to 18th, partly because it is linked to fewer breaches (none related to competition) than others. It also adapts brochures and packaging to ensure rational use in all disease areas where it is active; its disclosure of product registration status is good; and it actively builds local manufacturing capabilities. However, its activities remain philanthropy-driven. Astellas still has no clear access-to-medicine

strategy, and only manages access issues to a limited extent. It does not clearly commit to equitable pricing, nor takes a pro-access approach to IP: it has not pledged to consider licensing or to refrain from patenting in relevant countries. Astellas did not disclose its relevant pipeline in clinical development.

Performance update

Continues to approach access via philanthropy. Astellas discloses no clear link between its approach to access to medicine and its core business, raising questions about the sustainability of its efforts to increase access to medicine.

Discloses little about its influence on markets. As in 2012, Astellas does not disclose policy positions that could have an impact on access to medicine. It also makes no disclosure of the financial contributions it makes to political organisations.

Increased drug-discovery for neglected tropical diseases. Astellas participates in drug-discovery consortia focused on various neglected tropical diseases, including one addressing Chagas disease, leishmaniasis and trypanosomiasis with Japanese research institutes and the DNDi, a not-for-profit product

development partnership. Astellas is also involved in a drug-discovery partnership for dengue with a Japanese university.

Provides no evidence of a commitment or implementation of relevant equitable pricing strategies. This makes it the only company without at least one of the other.

Has conservative approach to access-oriented IP management. Astellas does not pledge to refrain from filing or not enforce patents in specific countries. Neither does it commit to considering licensing as a mechanism for boosting access to its products. Furthermore, the company offers very narrow support for the flexibilities within the international IP framework (TRIPS).

Engages in technology transfer. An improvement on 2012, Astellas now provides evidence of at least one technology transfer to increase local production capabilities.

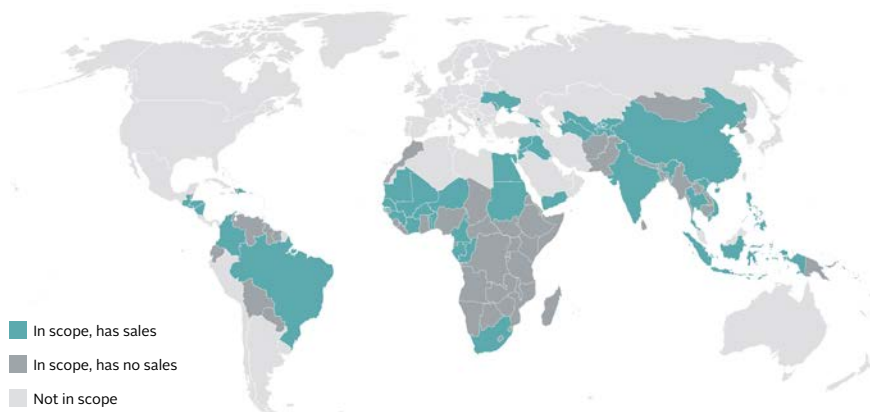
Best practices

Participates in the Global Health Innovative Technology Fund. Astellas provides funding to the GHIT Fund, a new funding scheme for early discovery research for neglected tropical diseases that it co-established with the Japanese government, the Bill & Melinda Gates Foundation and other Japanese pharmaceutical companies. Astellas' role is limited to funding.

Sales and operations

Astellas develops pharmaceuticals, focusing on urology, immunology (including transplantation) and infectious diseases, oncology, neuroscience, diabetes mellitus complications and kidney diseases. It has sales in a limited number of countries within the scope of the Index.

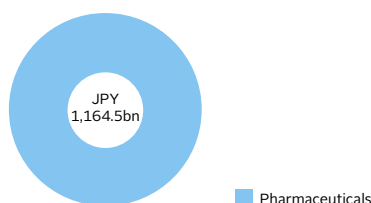
Sales in countries in scope



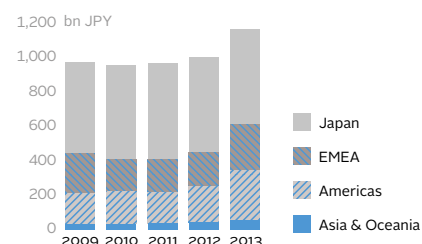
General information

Tokyo Stock Exchange
4503
Headquarters
Tokyo, Japan
Number of employees
17,454

Sales by segment (2013)



Sales by region



Portfolio and pipeline

Focus

The majority of Astellas' overall portfolio and pipeline addresses diseases beyond the scope of the Index. Within scope of the Index, Astellas' focus is on infectious diseases.

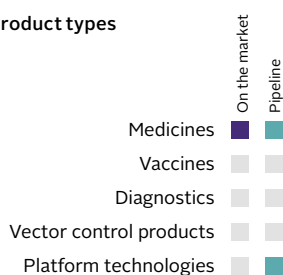
Marketed products

Has antibiotic medicines for two conditions within scope: lower respiratory infections and diarrhoeal diseases.

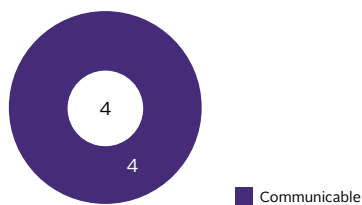
Pipeline products

Astellas did not disclose any relevant medicines or vaccines that are currently in clinical stages of development. Astellas is working in partnership to develop a paediatric formulation for schistosomiasis.

Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Strengthen management of access-to-medicine activities. Astellas can engage employees in its access-to-medicine approach by, e.g., setting company-wide targets; measuring and incentivising relevant activities; and by implementing performance-management systems that include access-related objectives and targets.

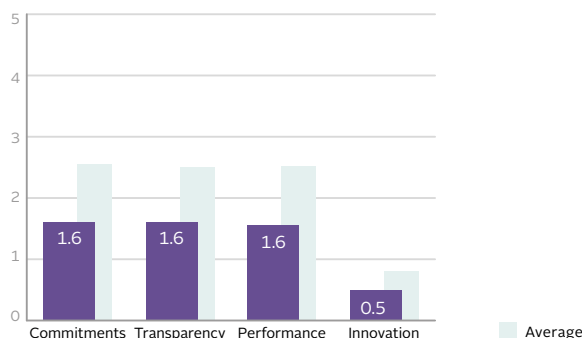
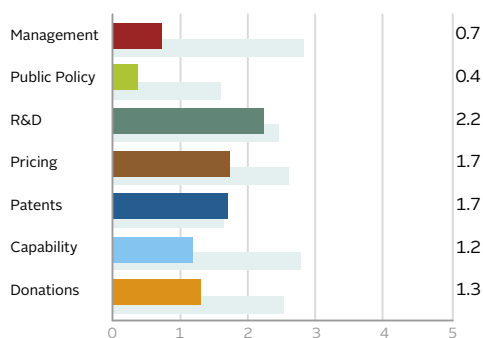
Engage with local stakeholders. Astellas can engage more actively with relevant stakeholders beyond Japan, particularly in countries where it is present, in order to better understand local needs and tailor its activities.

Match portfolio with opportunities to increase access to medicine. Astellas could use several mechanisms to ensure access to its products. Following its peers, it can (commit to) implement equitable pricing strategies. In addition, it can introduce more nuanced IP policies and engage in licensing agreements.

Leverage expertise in adapting existing products. Astellas can help address unmet needs for adapted products, for example paediatric formulations. It can collaborate with additional partners to leverage its expertise in this area (it developed a paediatric formulation of praziquantel with one of its technologies).

rank	score
19 th	1.5
19 (2012)	

Daiichi Sankyo Co. Ltd.



Company overview

Daiichi Sankyo remains in 19th place, despite increasing performance in some areas. It has adopted a more access-oriented approach to IP management, now pledging not to file or enforce patents in a comparatively broad range of countries. The company engages in more R&D partnerships based on access provisions. The Index captured a larger relevant pipeline than in 2012, as its subsidiary Ranbaxy's

pipeline qualified for analysis for the first time (Ranbaxy has since been divested). Although it discloses more, it is not as transparent as peers. It has no clear access-to-medicine strategy, only manages access issues to a limited extent, and its activities remain philanthropy driven.

Performance update

■ Approach remains philanthropy driven.

Daiichi Sankyo's access-to-medicine approach lacks a clear business rationale and has no clear senior-level governance of access to medicine. Its approach to expanding access to health remains very general. Access-related objectives are neither part of the company's performance management systems nor does it have any incentive structure in place for rewarding relevant performance.

■ **Linked to multiple breaches.** Daiichi Sankyo was fined for anti-competitive practices in India during the period of analysis, and was subject to a settlement in the US related to corrupt practices. Both cases concerned Ranbaxy.

■ **Remains only company with no tailored marketing code of practice.** It provides limited evidence of how its internal codes of conduct address ethical marketing: it refers only to

the IFPMA code of conduct, leaving unclear, for example, how it monitors and enforces compliance with these standards by third-party contractors.

■ Improves transparency, still lags behind.

Daiichi Sankyo's transparency in several areas of measurement is below average. For example, while it discloses more patent and registration-related information to the Index than in 2012, its overall disclosure is comparatively poor.

■ **Adopts more access-oriented approach to IP protection.** Since 2012, the company has adopted a more access-oriented approach to IP protection. It now pledges to refrain from filing or enforcing existing patents in a comparatively broad scope of countries. However, it does not publicly support the use of TRIPS flexibilities.

■ More active in building local production capabilities.

Since 2012, it increased its activities building manufacturing capabilities in relevant countries, and engaged in several knowledge- and/or technology transfers to third-party manufacturers in Asia (e.g., provided training at the Center for Research and Production of Vaccines and Biologicals (POLYVAC) in Vietnam).

Best practices

■ **Participates in Global Health Innovative Technology Fund (GHIT)** Daiichi Sankyo is a founding member of the Global Health Innovative Technology Fund (established with other Japanese pharmaceutical companies, the Japanese government and the Bill & Melinda Gates Foundation). Known as GHIT, this is a new scheme that funds early discovery research for neglected tropical diseases. Through GHIT,

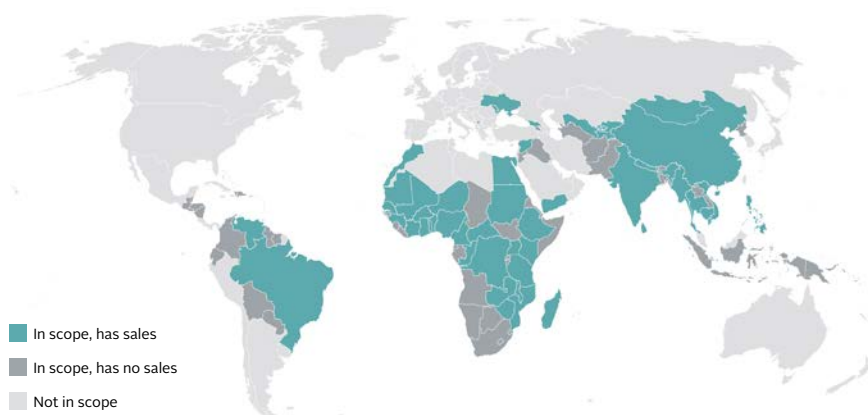
Daiichi Sankyo provides funding, collaborates in research and shares IP.

■ **Has measures to ensure study designs are ethical.** Daiichi Sankyo has established a committee that is responsible for reviewing study protocols for in-house and outsourced clinical trials to ensure ethical conduct.

Sales and operations

Daiichi Sankyo has two business segments: Daiichi Sankyo Group and Ranbaxy Group. The Daiichi Sankyo Group focuses mainly on oncology, cardiovascular and metabolic disorders. It has announced that Ranbaxy will merge (through a share swap) with generic manufacturer Sun Pharmaceutical Industries by the end of 2014, whereby Ranbaxy will be absorbed by Sun Pharma. This move will reduce its exposure to developing countries. Over 60% of Daiichi Sankyo's revenue comes from its home market, Japan.

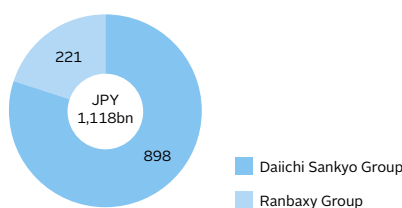
Sales in countries in scope



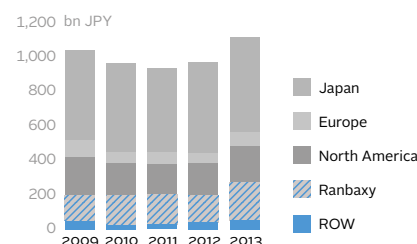
General information

Tokyo Stock Exchange
4568
Headquarters
Tokyo, Japan
Number of employees
32,229

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Within the scope of the Index, Daiichi Sankyo (including Ranbaxy's portfolio and R&D pipeline) is strong in antibiotics and non-communicable diseases.

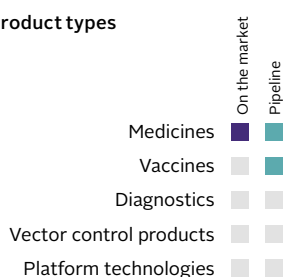
Marketed products

Daiichi Sankyo has products for 11 diseases in scope. For non-communicable diseases, almost half are antibiotics that can treat infections leading to kidney disease. Ranbaxy has a new, synthetic anti-malarial medicine: arterolane+piperazine (Synriam™).

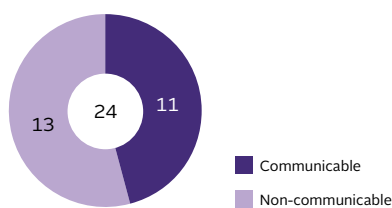
Pipeline products

Its clinical pipeline comprises medicines for eight diseases, mainly non-communicable diseases, HIV/AIDS and malaria. It is developing a broad spectrum antibiotic and has a vaccine for norovirus in early-stage development.

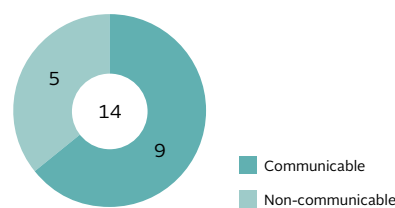
Product types



Products per disease category



Clinical pipeline per disease category



Opportunities for improving access to medicine

Develop more-targeted access-to-medicine strategy. Daiichi Sankyo can assign clearer senior management responsibility for its access-to-medicine strategy and start to set more detailed, time-bound targets and KPIs related to improving access to medicine. Such targets would allow the company to regularly track progress and performance.

Expand local stakeholder engagement beyond philanthropic initiatives. The company can engage with local stakeholders in a more structured way, both to better understand

and address their needs, and to understand its own potential role (and strategic opportunities) for improving access to medicine. E.g., it can collaborate with governments to advance capacities in pharmacovigilance; and it can engage with stakeholders along supply chains to increase efficiencies.

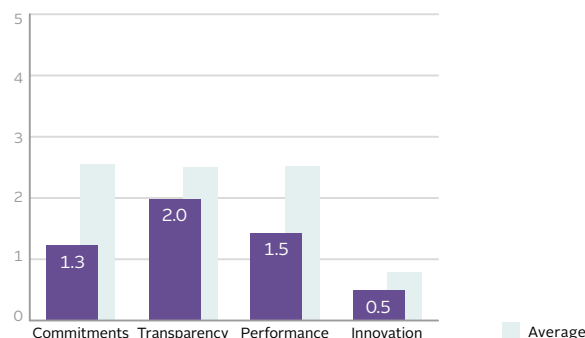
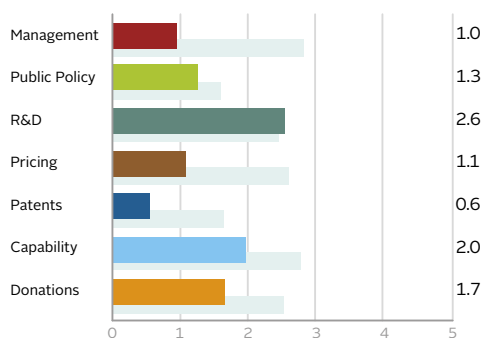
Expand pricing strategies. Daiichi Sankyo can expand its pricing strategies to cover more products (both existing and in its pipeline) and countries it has a presence in. Within its pricing strategies, it can take affordability for the poor-

est segments into account.

Develop product registration plans for pipeline compounds. Daiichi Sankyo has committed to assessing where to register its pipeline products in countries within scope. It can extend these studies and start implementing registration plans that help ensure relevant new compounds for non-communicable diseases become available in countries in scope.

rank	score
20 ^v	1.5
18 (2012)	

Takeda Pharmaceutical Co. Ltd.



Company overview

Takeda drops to 20th place, yet has improved in several areas. It performs well in R&D, with a reasonable pipeline share targeting relevant diseases and it engages in IP sharing and product development partnerships based on access provisions. It newly commits to intra-country equitable pricing, but has not yet implemented such strategies for products in scope. It has a stronger focus on access to medicine than in

2012, but no clear access-to-medicine strategy, managing access issues to a limited extent. It does not take a pro-access approach to IP management, nor pledge not to file for or not to enforce patents in countries in scope. It does not state support for TRIPS flexibilities, nor run donation programmes in countries in scope.

Performance update

Strengthens its internal focus on access-to-medicine issues. Takeda has set up an Access to Medicine working group that aims to build a complete picture of each department's access-to-medicine activities and start monitoring them. It is also considering a range of activities and developing an internal policy on access to medicine. To promote future access-related activities and ensure their successful implementation, the company is establishing a centralised Access to Medicine Office.

Significantly enhanced portfolio for diseases in scope. Takeda has significantly enhanced its product and pipeline portfolios for diseases in scope through partnerships and acquisitions. It shows movement of relevant compounds to different phases of its R&D pipeline since 2012.

Provides limited evidence of monitoring and enforcement mechanisms. While Takeda's clinical trial codes of conduct comply with ICH-GCP, it shows limited evidence of strong oversight of outsourced trials. It also demonstrates limited evidence that company standards for ethical marketing extend to third parties.

Newly committed to intra-country equitable pricing. The company has made a new, general commitment to engaging in intra-country equitable pricing. It already has equitable pricing strategies in place, but not currently for products that fall within the scope of the Index.

Approaches IP and data exclusivity with limited access orientation. The company does not share any instances where it would waive data exclusivity, has not committed to refraining from filing or enforcing patents in countries in scope and does not publicly support the flexibilities as set out in the TRIPS trade agreement.

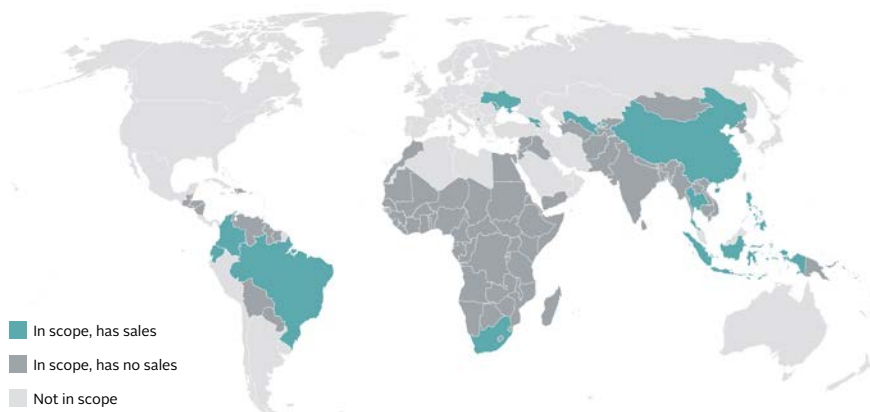
Best practices

Actively involved in drug discovery for neglected tropical diseases. Takeda is involved in a number of GHIT Fund activities with product development partnerships, e.g., collaborations with the Global Alliance for TB Drug Development, with the Medicines for Malaria Venture and with the Drugs for Neglected Diseases initiative. GHIT is a public-private partnership between the government of Japan and other Japanese pharmaceutical companies. It offers a new funding scheme for early discovery research for neglected tropical diseases.

Sales and operations

Takeda provides products in various therapeutic areas, including cardiovascular and metabolic, oncology, central nervous system, respiratory and immunology, and gastrointestinal and genitourinary, as well as vaccines. Through its acquisition of Nycomed, Takeda has significantly expanded its operations and sales in Europe and emerging markets, with particularly strong growth in Russia/CIS, Brazil and China. It recently expanded its presence in the vaccines industry by acquiring LigoCyte Pharmaceuticals Inc. (in 2012) and Inviragen Inc. (in 2013).

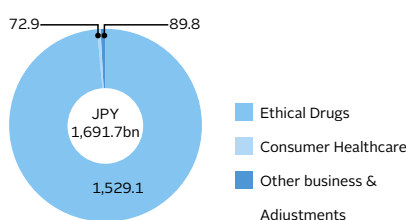
Sales in countries in scope



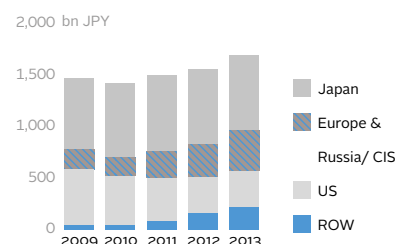
General information

Tokyo Stock Exchange
4502
Headquarters
Osaka, Japan
Number of employees
30,481

Revenues by segment (2013)



Revenues by region



Portfolio and pipeline

Focus

Takeda is strong in diabetes and is strengthening its vaccine portfolio.

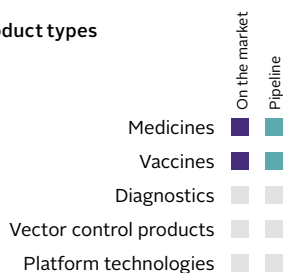
Marketed products

Has products for eight diseases in scope. Its medicines portfolio is strong in the area of diabetes. It also has a small portfolio of childhood vaccines for pertussis, tetanus and measles.

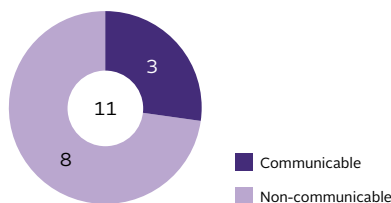
Pipeline products

Its clinical pipeline targets nine diseases in scope. It includes a medicine for malaria and vaccines for pertussis and tetanus. Notably, it also includes a medicine for bipolar affective disorder and a vaccine for dengue.

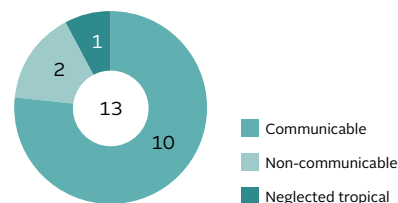
Product types



Products per disease category



Clinical pipeline per disease category



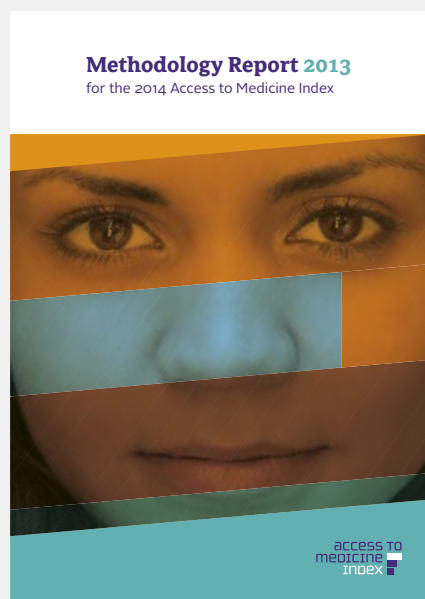
Opportunities for improving access to medicine

Continue internal and external discussion about access to medicine. Through its pipeline and product portfolio, Takeda has much to offer to patients living in developing countries. It can continue its internal discussions about how it can contribute to improving access to medicine and develop a clearer access-to-medicine approach. It has potential to engage with a wider range of stakeholders, who can help build and shape its approach to access to medicine. The company can start to set targets that stimulate the company-wide implementation of a more access-oriented approach.

Develop access-oriented strategies as expansion into emerging markets continues. Since 2012, the company has paid increasing attention to growth in emerging markets and new segments, particularly in the area of vaccines. As yet, its footprint in developing countries remains limited. If Takeda pursues this strategy, and expands its presence in these markets, it can have many opportunities to expand access to medicine. For marketed products, it can expand its commitment and implement equitable pricing strategies for a wider range of products, including for products within the scope of the Index. In addition, it can consider taking a more

access-oriented approach to data exclusivity and IP. For products that are still in development, it can start to consider mechanisms for early access, such as registration targets, to ensure that these products, mainly for diabetes and mental health conditions, become accessible to patients in developing countries soon after stringent approval.

Appendix



Methodology Report 2013

The Methodology Report 2013 is a separate, comprehensive report detailing what and how we measure. It details the review and refinement of the indicators, a process which involved a thorough technical feedback process. Within these appendices, only abbreviated essential components of this process are detailed, alongside the indicators, the scoring guidelines, key references, definitions and acronyms.

Methodology scopes

1 Company Scope

Index 2014 evaluates 20 research-based pharmaceutical companies, 19 of which were included in Index 2012.

Companies included are those with the highest market capitalisation, and product portfolios most relevant to the countries and diseases covered by the Index. Maintaining, as closely as possible, the 2012 list of research-based

companies covered by the Index facilitates comparability and trend analyses over time.

At the beginning of 2013, Abbott's research-based pharmaceuticals business separated into an independent, publicly traded biopharmaceutical company: AbbVie. Given Abbott is no longer part of the research-based pharmaceutical industry, the company is not part of the

2014 Index. AbbVie, however, is a new inclusion for 2014.

As in 2012, generic companies were not captured in the 2014 Index. For the first time, however, companies were allowed to submit relevant data related to their generic subsidiaries.


Table 6 2014 Index Company Scope

Company	Ticker	Stock Exchange	Bloomberg	Reuters	Country	Market Cap* (billion USD)	Revenue** (billion USD)
AbbVie Inc.	ABBV	New York Stock Exchange	ABBV:US	ABBV.N	USA	83.83	18.79
Astellas Pharma Inc.	4503	Tokyo Stock Exchange	4503:JP	4503.T	JPN	26.90	11.47
AstraZeneca plc	AZN	London Stock Exchange	AZN:LN	AZN.L	GBR	74.40	25.71
Bayer AG	BAYN	Frankfurt Stock Exchange	BAYN:GR	BAYGn.DE	DEU	107.67	51.29
Boehringer Ingelheim GmbH	n/a	n/a	n/a	n/a	DEU	n/a	17.96
Bristol-Myers Squibb Co.	BMY	New York Stock Exchange	BMY:US	BMY.N	USA	87.22	16.39
Daiichi Sankyo Co. Ltd.	4568	Tokyo Stock Exchange	4568:JP	4568.T	JPN	12.05	11.01
Eisai Co. Ltd.	4523	Tokyo Stock Exchange	4523:JP	4523.T	JPN	11.29	5.91
Eli Lilly & Co.	LLY	New York Stock Exchange	LLY:US	LLY.N	USA	56.96	23.11
Gilead Sciences Inc.	GILD	NASDAQ	GILD:US	GILD.O	USA	115.23	11.20
GlaxoSmithKline plc	GSK	London Stock Exchange	GSK:LN	GSK.L	GBR	117.65	39.86
Johnson & Johnson	JNJ	New York Stock Exchange	JNJ:US	JNJ.N	USA	258.34	71.31
Merck & Co. Inc.	MRK	New York Stock Exchange	MRK:US	MRK.N	USA	146.52	44.03
Merck KGaA	MRK	Frankfurt Stock Exchange	MRK:GR	MRCG.DE	DEU	36.16	13.67
Novartis AG	NOVN	SIX Swiss Exchange	NOVN:VX	NOVN.VX	CHE	193.43	60.08
Novo Nordisk A/S	NOVO B	Copenhagen Stock Exchange	NOVOB:DC	NOVOB.CO	DNK	90.07	14.30
Pfizer Inc.	PFZE	New York Stock Exchange	PFE:US	PFE.N	USA	196.00	51.58
Roche Holding AG	RO; ROG	SIX Swiss Exchange	RO:SW; ROG:VX	ROG.VX	CHE	219.48	48.53
Sanofi	SAN	EURONEXT Paris	SAN:FP	SASY.PA	FRA	130.08	42.54
Takeda Pharmaceutical Co. Ltd.	4502	Tokyo Stock Exchange	4502:JP	4502.T	JPN	38.04	16.66

* Market cap as at 31 Dec 2013
Japanese companies as at 31 Mar 2014
From Thomson Reuters 2014

** Total 2013 revenue

Exchange rate used from irs.gov, 2013 avg

 Company newly included in the 2014 Index scope

2 Geographical scope

The 2014 Index focuses on 106 countries, adding five new countries in comparison to 2012 – Brazil, Colombia, Ecuador, South Sudan and Venezuela – and removing two – Algeria and the Marshall Islands.

The 2014 Index uses the 2013 World Bank country classifications¹ as the base criteria for

defining its geographical scope. All low income countries (LICs) and lower-middle income countries (LMICs) fall into the Index scope.

The Index also uses the most recent UN Human Development Index (HDI)² to capture further countries which may have lower levels of development despite comparably higher incomes.

In 2014, the Index has added countries that score below 0.55 on the UN Inequality-Adjusted Human Development Index (IHDI)³, recognising that inequality inhibits access to medicine for the poorest population segments.

Table 7 List of countries included in the 2014 Access to Medicine Index – 106 countries

Country	Classification	Country	Classification	Country	Classification	Country	Classification
East Asia & Pacific		Suriname	MHDC	Liberia	LIC	Countries removed since 2012 Index	
Cambodia	LIC*	Venezuela, RB	HiHDI	Madagascar	LIC*	Algeria	HHDC
China	MHDC	Middle East & North Africa		Malawi	LIC*	Marshall Islands	UMIC
Fiji	MHDC	Djibouti	LMIC*	Mali	LIC*		
Indonesia	LMIC	Egypt, Arab Rep.	LMIC	Mauritania	LMIC*		
Kiribati	LMIC	Iraq	MHDC	Mozambique	LIC*		
Korea, Dem. Rep.	LIC	Jordan	MHDC	Namibia	MHDC		
Lao PDR	LMIC*	Morocco	LMIC	Niger	LIC*		
Micronesia, Fed. Sts.	LMIC	Syrian Arab Rep.	LMIC	Nigeria	LMIC		
Mongolia	LMIC	West Bank and Gaza	LMIC	Rwanda	LIC*		
Myanmar	LIC*	Yemen, Rep.	LMIC	São Tomé and Príncipe	LMIC		
Papua New Guinea	LMIC	South Asia		Senegal	LMIC*		
Philippines	LMIC	Afghanistan	LIC	Sierra Leone	LIC*		
Samoa	LMIC*	Bangladesh	LIC*	Somalia	LIC		
Solomon Islands	LMIC*	Bhutan	LMIC	South Africa	MHDC		
Thailand	MHDC	India	LMIC	South Sudan	LIC		
Timor-Leste	LMIC	Maldives	MHDC	Sudan	LMIC		
Tonga	MHDC	Nepal	LIC*	Swaziland	LMIC		
Tuvalu	LDC	Pakistan	LMIC	Tanzania	LIC*		
Vanuatu	LMIC*	Sri Lanka	LMIC	Togo	LIC*		
Vietnam	LMIC	Sub-Saharan Africa		Uganda	LIC*		
Europe & Central Asia		Angola	LHDC*	Zambia	LMIC*		
Armenia	LMIC	Benin	LIC*	Zimbabwe	LIC		
Georgia	LMIC	Botswana	MHDC				
Kosovo	LMIC	Burkina Faso	LIC*				
Kyrgyz Rep.	LIC	Burundi	LIC*				
Moldova	LMIC	Cameroon	LMIC				
Tajikistan	LIC	Cape Verde	LMIC				
Turkmenistan	MHDC	Central African Rep.	LIC*				
Ukraine	LMIC	Chad	LIC*				
Uzbekistan	LMIC	Comoros	LIC				
Latin America & Caribbean		Congo, Dem. Rep.	LIC*				
Belize	MHDC	Congo, Rep.	LMIC				
Bolivia	LMIC	Côte d'Ivoire	LMIC				
Brazil	HiHDI	Equatorial Guinea	MHDC				
Colombia	HiHDI	Eritrea	LIC				
Dominican Rep.	MHDC	Ethiopia	LIC				
Ecuador	HiHDI	Gabon	MHDC				
El Salvador	LMIC	Gambia, The	LIC*				
Guatemala	LMIC	Ghana	LMIC				
Guyana	LMIC	Guinea	LIC*				
Haiti	LIC*	Guinea-Bissau	LIC*				
Honduras	LMIC	Kenya	LIC				
Nicaragua	LMIC	Lesotho	LMIC*				
Paraguay	LMIC						

LIC: Low-income Country
World Bank income classification

LMIC: Lower-middle-income Country
World Bank income classification

LDC: Least Developed Country
UN Human Development Index

LHDC: Low Human Development Country
UN Human Development Index

MHDC: Medium Human Development Country
UN Human Development Index

HiHDI: High Human Development Country with high inequality
UN Inequality-Adjusted Human Development Index

* LDC with WTO membership

■ 5 Countries newly included countries in the 2014 Index scope

■ 2 Countries removed from the Index scope

3 Disease scope

Diseases are included based on their global burden of disability-adjusted life years (DALYs), other WHO classifications, and the relevance of pharmaceutical interventions. Index diseases are defined according to the WHO International Classification of Diseases (ICD-10) codes.⁴

The disease scope for the 2014 Index has expanded from 33 to 47 conditions. Chlamydia is the only new communicable disease; cirrhosis of the liver has been expanded to include chronic viral hepatitis. Schizophrenia and bipolar affective disorder have been added. All cancers remain excluded. All 17 WHO-classified

neglected tropical diseases are covered. In continuing recognition of the importance of protecting maternal and neonatal health from conception through to childbirth, the number of maternal and neonatal health conditions covered by the Index has been increased since 2012.

Table 8 List of diseases included in the 2014 Access to Medicine Index - 47 diseases

Communicable diseases (10)		Neglected tropical diseases (17)		Maternal and neonatal health conditions (8)	
Lower respiratory infections	94.511	Lymphatic filariasis	5.941	Abortion	7.424
Diarrhoeal diseases	72.777	Soil transmitted helminthiasis	4.013	Maternal sepsis	6.535
HIV/AIDS	58.513	Leishmaniasis	1.974	Maternal haemorrhage	4.439
Tuberculosis	34.217	Food-borne trematodiasis	1.875	Obstructed labour	2.882
Malaria	33.976	Schistosomiasis	1.707	Hypertensive disorders of pregnancy	1.888
Measles	14.853	Trypanosomiasis	1.673	Prematurity and low birth weight	44.307
Meningitis	11.426	Rabies	1.462	Birth asphyxia and birth trauma	41.684
Pertussis	9.882	Trachoma	1.334	Neonatal infections and other conditions	40.433
Tetanus	5.283	Dengue	670	Contraceptive methods	NA
Chlamydia	3.748	Cysticercosis	503		
		Chagas disease	430		
		Onchocerciasis	389		
		Leprosy	194		
		Echinococcosis	144		
		Buruli ulcer	N/A		
		Yaws	N/A		
		Dracunculiasis	N/A		
Non-communicable diseases (12)					
Unipolar depressive disorder	65.472				
Ischaemic heart disease	62.587				
Cerebrovascular disease	46.591				
Chronic obstructive pulmonary disorder [COPD]	30.196				
Diabetes mellitus	19.705				
Schizophrenia	16.769				
Asthma	16.317				
Osteoarthritis	15.586				
Bipolar affective disorder	14.425				
Cirrhosis of the liver	13.640				
Nephritis and nephrosis	9.057				
Epilepsy	7.854				

■ 14 Diseases/conditions added to or expanded in the 2014 Index scope

4 Product scope

The product type scope for Index 2014 remains necessarily broad to capture the wide-ranging product types available to support prevention, diagnosis and treatment of Index Diseases in the Index countries.

It draws closely from the definitions provided by the G-Finder 2012 Neglected Disease Research and Development: A Five Year Review,⁵ and remains unchanged from the 2012 and 2010 Indices.

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 intended to prevent HIV.

Therapeutic vaccines

This covers vaccines intended to treat infection.

Preventive vaccines

This covers vaccines intended to prevent infection.

Diagnostics

Diagnostic tests designed for use in resource-limited settings (cheaper, faster, more reliable, greater ease of use in the field) are included.

Vector control products

These include pesticides, biological control compounds and vaccines targeting animal reservoirs. Only chemical pesticides intended for

global public health use and which specifically aim to inhibit and kill vectors that transmit diseases relevant to the Index are included. Likewise, only biological control interventions that specifically aim to kill or control vectors that transmit Index-relevant diseases are included. Only veterinary vaccines specifically designed to prevent animal-to-human transmission of diseases covered by the Index are included.

Platform technologies

Only those products directed specifically at meeting the needs of countries covered by the Index are included. These comprise general diagnostic platforms, adjuvants and immunomodulators, and delivery technologies and devices.

Stakeholder engagement 2013

Between January and October 2013, the Index engaged with a variety of stakeholders to build a more complete, up-to-date view on the changing access-to-medicine landscape.

The goal of this process was to:

- Adjust the methodology to reflect changing global health priorities
- Refine and improve the methodology based on lessons learned from past Indices

Feedback survey and company results calls

In early 2014, the Foundation invited the Index readership, contributors and selected organisations to provide feedback on the development and execution of the 2012 Index. 134 people representing seven stakeholder groups responded.

The foundation also offered all 20 companies evaluated in 2012 the opportunity to give their feedback on Index methodology and results in individual conference calls with the Index team.

Strategic access-to-medicine workshop

In May 2013, company representatives gathered near Amsterdam to discuss how more inclusive business models can be developed to incorporate access strategies into core company business.

Stakeholder dialogue: Ensuring quality and affordable medicines in developing countries

In June 2013, members of the Index team travelled to Accra, Ghana, to host a multi-stakeholder dialogue to discuss two key issues: how to define and measure affordability, and the best ways to monitor safety and quality of medicines.

Investor dialogue

In September 2013, Foundation members attended a series of meetings in Paris with representatives of both mainstream and socially responsible investment firms. The discussions focused on how the Index can be used as a tool for investors to better understand potential risks and opportunities for access to medicine in low and middle income countries.

Technical Subcommittees

Between February and September 2013, the Foundation convened groups of experts to serve as Technical Subcommittees (TSCs) to support methodology enhancement. These committees responded to and advised on various proposals made by the Index team for enhancing the areas of Public Policy & Market Influence; Research & Development; Pricing, Manufacturing & Distribution and Patents & Licensing. Remaining Technical Areas did not convene TSCs, but did consult experts individually.

Expert Review Committee

The Foundation team met with the Expert Review Committee (ERC) in April, June and September 2013. The role of the ERC is to provide the Foundation with strategic guidance with regard to the Index's scope and indicators.

The Access to Medicine Index team remains ultimately responsible for decisions on the final methodology associated with the reporting material, and the findings of the Access to Medicine Index. Following collection of the stakeholder feedback through the aforementioned processes, the methodology was updated by the Access to Medicine Foundation.

Expert Review Committee

- Hans Hogerzeil, *University of Groningen, Switzerland*
- Marja Esveld, *Ministry of Health, The Netherlands*
- Richard Laing, *World Health Organization (WHO), Switzerland*
- Dennis Ross-Degnan, *Harvard University, USA*
- Regina Kamoga, *Community Health and Information Network (CHAIN), Uganda*
- Natacha Dimitrijevic, *Hermes Equity Ownership Services, UK*
- Peter Shelby (2013/2014), *Mario Ottiglio (2014) International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland*
- Dilip Shah, *Indian Pharmaceutical Alliance, India*

Technical Subcommittees

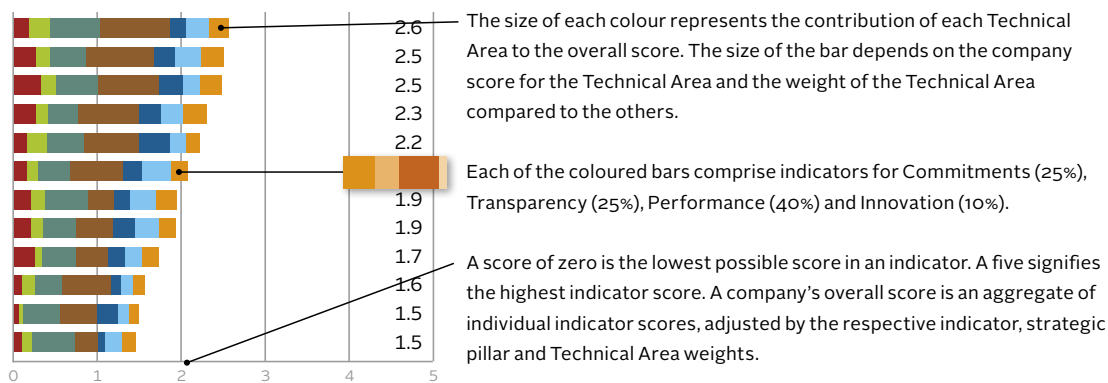
- Public Policy & Market Influence
 - Michele Forzley, *Georgetown University Law Center, USA*
 - Jillian Kohler, *University of Toronto, Canada*
- Research & Development
 - Jennifer Dent, *Bio Ventures for Global Health, USA*
 - Javier Guzman, *Policy Cures, UK*
- Pricing Manufacturing & Distribution
 - Jaime Espin, *Andalusian School of Public Health, Spain*
 - Niranjana Konduri, *Management Sciences for Health, USA*
 - Prashant Yadav, *University of Michigan, USA*
- Patents & Licensing
 - Peter Beyer, *World Health Organization (WHO), Switzerland*
 - Esteban Burrone, *Medicines Patent Pool, Switzerland*
 - Warren Kaplan, *Boston University, USA*

Other sources of feedback

The Access to Medicine Foundation remains open to feedback from other entities willing to provide comments and suggestions. Maintaining openness through engaging and building partnerships with all the stakeholder groups is crucial to the long-term success, legitimacy and impact of the Index.

No single feedback mechanism has disproportionately affected the Index methodology. Rather, the output of the survey, in depth consultations and other feedback processes were studied by the Expert Review Committee. We maximised our efforts to ensure that all the stakeholders receive equal representation in the stakeholder engagement process.

Ranking, scoring and review process



Summary of the scoring process

1 Before inclusion for analysis, the Index team reviewed both marketed products and products in company R&D pipelines. This verification was to ensure they were within the scope of Index 2014 and met relevant inclusion criteria.

Process for R&D pipeline product inclusion

For R&D products, inclusion criteria were applied based upon the disease class the product targets. All products were included for adaptive R&D for all four disease classes, as were innovative R&D products that target either communicable diseases (CD) or neglected tropical diseases (NTD). For innovative R&D products that target non-communicable diseases (NCD) or maternal and neonatal health conditions (MNH), stricter criteria applied for inclusion. For these products, supporting evidence to indicate how the product would be made accessible to people living in countries within scope was required. All R&D had to be ongoing during a part or the entire period of analysis. Following the first submission, companies were asked for clarifications, if needed, to support this verification process. After final submission, all R&D products were evaluated according to this standardised procedure.

Process for market product inclusion

Marketed products also went through a verification process. This was to assess whether they were suitable for use under the disease indication(s) as described by the company, and as covered by the ICD10 codes described in the Methodology Report 2013. Product indications were verified using information from regulatory authorities (such as the FDA and EMA), WHO treatment guidelines, company websites and scientific publications. Any products that remained unclear following

this process were verified with the company. Groups of medicines always excluded were medicines intended for treatment of cancer, painkillers, anaesthetics and supportive medicines without specific indications, such as IV fluids and blood transfusions. Products may be used for multiple diseases in scope. Products were only assessed for diseases listed by the company.

2 Quantitative indicators, such as a company's R&D investment relevant to the Index Diseases from a company's total R&D investments, are adjusted based on total revenues, or other relevant figures indicative of company size, such as the total size of the pipeline. Consistent with the relative ranking approach of the Access to Medicine Index, the adjusted numbers are then scaled for scoring from zero to five.

3 When an indicator is not applicable to a company, neutral scoring is used. Where neutral scoring is a possibility this is indicated in the scoring guidelines. Neutral scoring was applied within the areas of Research & Development; Pricing, Manufacturing & Distribution; Patents & Licensing and Product Donations & Philanthropic Activities. For example, when a company has no structured donation programmes, it receives a lower score in commitment for the relevant indicator. However, for the transparency indicator related to disclosure of the processes and criteria for deciding drug types and destinations, and the performance indicators related to the outcome and impact of structured donation programmes, a neutral score is applied, as the company has already been penalised.

4 Neutral scoring was applied within different Technical Areas using one of three approaches. The approach is determined on

a case-by-case basis per company for each neutrally scored indicator.

- In cases where no other neutrally scored indicators exist for a company within the sub-theme of the indicator in question, a neutral score would be awarded to that indicator comprising a weighted average of all the indicator scores for that company within that subtheme (excluding the indicator which receives a neutral score).
 - For cases where more than one indicator within a subtheme needed to be neutrally scored, a weighted average of all the indicators of all remaining subthemes within the relevant Technical Area for which the company did not have neutral scoring were used as a proxy.
 - For cases where most or all other subthemes within the Technical Area also included indicators that were neutrally scored, the weighted average of the scores of all other Technical Areas that did not have any neutral scoring were applied to the relevant indicator.
- 5 Scoring was carried out based on data from a wide range of information sources, including companies themselves, independent reports, databases from the World Health Organization (WHO), other multilateral organisations and non-governmental organisations, legal databases such as LexisNexis, and news databases such as Bloomberg. Where relevant, publicly available registers were checked, such as the PCPMPA's record of marketing code breaches in the United Kingdom, and equivalent databases in South Africa, the Netherlands and Australia.

6 The final scoring of the companies is the result of a multi-tiered analysis and quality assurance process beginning with scoring by the company 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 Sustainability Technical Area analyst, including an extensive quantitative and qualitative check of each indicator for each company. Finally, a cross-check was performed by the Techni-

cal Area expert from the Foundation team along with each Technical Area expert on the Sustainability team. The project management (PM) team engaged in quality assurance and scoring verification to ensure consistency.

7 A statistical analysis has been carried out on the final scores to check for significant correlations between different indicators and the distribution of scores for each indicator. Based on the analysis of every single indicator, adjustments were made to some indicators' scoring guidelines to ensure maximum variability.

Review process

Following clarification of company data and cross-check of company scores, the Index research team wrote the various sections of the Index report. Each Technical Area was reviewed by at least one member of each of the relevant Technical Subcommittees. Following this initial

review, a member of the Expert Review Committee (Richard Laing) reviewed each Technical Area. Company report cards were reviewed by an external consultant from the investment community. The entire Index was finally reviewed by the chair of the Expert Review

Committee, Hans Hogerzeil. In addition to this, an external editorial review of the entire Index was performed.

Limitations of the methodology

Study Limitations

Limitations exist in every study of this design. Some major limitations specific to this study are discussed here. These and other methodological limitations will be reviewed for the 2016 Access to Medicine Index, as part of the multi-stakeholder Methodology Review process.

Data 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 Expert Review Committee (ERC) during the 2013 Methodology review process, and as published in the Methodology Report 2013.

Although the Foundation recognises that all products, diseases, countries and access and product initiatives are not the same, in general they are treated equally in this study. For example, in R&D, all compounds are treated equally if they meet the inclusion criteria, regardless of their mechanism of action or expected efficacy.

During the period of analysis (1 June 2012 to 30 May 2014), where trend analysis was useful, the Index team compared raw data from 2012 with raw data from 2014. Comparability between companies over successive indices was not always possible or appropriate, especially for new areas of evaluation or where the scoring criteria of an indicator had been refined.

Company comparability

The objective of the Index is to produce a standardised relative ranking of companies' access-to-medicine performances. However, not all companies are the same. Some have large portfolios and pipelines, and a greater

number of patented products of interest to the Index. Some have a comparatively narrow scope of country operations. Others have generic pharmaceutical subsidiaries.

The Index uses various methods to correct for either a company's size or disease coverage, relative to its peers. In indicators that measure quantitative elements (relating to pricing, R&D and patents and licensing), in general, we make adjustments for company size. These are made against the size of the relevant portfolio of products (whether in the pipeline or on the market), the portfolio of patented products, or against company revenue for 2012 and 2013. As an example of adjustment for disease coverage, when evaluating R&D, companies that have a focus on one or two diseases within scope are required to have a higher proportion of their pipelines dedicated to diseases relevant to the Index than companies with more diversified pipelines.

Companies of different sizes also have different capacities to report information. For example, larger companies may not have all data available in a centralised repository/database, and may have more data to report on. This can be further complicated where there are generic medicine subsidiaries to account for.

Companies have idiosyncratic systems for recording and reporting information, which can give rise to complications when comparing the performance of different companies. For example, companies have different mechanisms for calculating the value of donations made and the costs associated with philanthropy. Companies also often have individual ways of categorising information, for example, how different types of

pricing strategies are referred to.

In order to minimise the variability of information sourced from companies, all companies were provided with training on the data submission process. In addition to this, a clarification round was carried out, giving companies an opportunity to provide additional data where there were gaps, inconsistencies identified, or clarifications necessary.

Data availability

Companies are sometimes unwilling or unable to disclose commercially sensitive data, or, if they do, do so only partially. For example, the full contents of voluntary licences are often not shared, nor the content of R&D contracts. Occasionally, where sensitive data could be analysed, complete results could not be published due to legal constraints related to public disclosure (e.g., pricing data). In other cases, collection of very specific data (e.g., R&D investment) which required dis-aggregation, or country-level collection, was not always possible.

While company disclosure has improved significantly in 2014, this issue remains an obstacle to finding and reporting reliable trends and very specific relationships and conclusions in several areas.

Additionally, in some areas it may not be possible to provide a complete picture of the area of analysis due to external constraints on the collection of data. For example, in 2014, settlements and judgements regarding breaches which occurred anywhere in the world were counted when evaluating companies in the areas of ethical marketing, corruption and anti-competitive behaviour. Some breaches

occurred prior to the period of analysis. Even given this expanded scope, it is not possible to be confident that all breaches were captured. Sources of data collection included Lexis-Nexis, Bloomberg, the websites of government departments such as the US Department of Justice, and registers maintained and published by a selection of industry self-regulatory bodies: the UK, the Netherlands, South Africa and Australia. Even given the significantly expanded scope of investigation, we acknowledge that breaches may have occurred which were not captured. We continue to acknowledge that breaches in Index countries are likely to be under-reported.

Similarly, a complete picture of breaches of clinical trial conduct is difficult to capture, due to the absence of a central registry of such information, the fact these incidents are typically not routinely monitored by research ethics committees, and tend not to be prosecuted.

Measuring Outcomes and Impacts

The study as currently designed is not intended to measure the direct impact of companies' access initiatives on patients and other groups. For example, within Capability Advancement, the impact of a company's training activities is not measured. Alternative measures are used as proxies for patient access or considerations of impact. For example, within Product Donations & Sustainable Philanthropy, while the Index does not look at whether or not a company's programme is, in practice, effective, we evaluate whether or not impact evaluation is part of the company's approach to donation activities. Within Pricing, Manufacturing & Distribution, disclosure of the volume of sales achieved to specific population segments is taken as a proxy measure of the success of an equitable pricing strategy in reaching target patients.

Indicators and Scoring Guidelines

The Scoring Guidelines are scaled according to either current industry practice based on the spectrum of evidence provided (i.e., a score of 5 represents the best that the companies are currently doing, and a score of 0 or 1 represents

the least they are currently doing) or according to stakeholder expectations (i.e., a score of 5 represents good practice and a 0 represents behaviour below minimum acceptable standards).

A General Access to Medicine Management

A.I Commitments (25%)

A.I.1 Governance: management structures

55%

- The company has a governance system that includes direct board-level responsibility and accountability for its access to medicine initiatives for Index countries.
- 5 The company has a board-level process and representation and an executive committee or an executive role (such as a VP).
 - 2,5 The company has a board-level process and representation and a director.
 - 1 The company has board-level representation but no director or executive.
 - 0 No representation in the company's senior governance bodies.

A.I.2 Stakeholder engagement

45%

- The company commits to work with relevant stakeholders, including universities, patient groups, local governments, employees, local and international NGOs and peers with the aim of improving access to medicine.
- 5 The company has a strategy and platform for outreach to relevant stakeholders and there is strong evidence of stakeholder engagement for most of its access initiatives.
 - 4 The company has a strategy and platform for outreach to relevant stakeholders and there is strong evidence of stakeholder engagement for some of its access initiatives.
 - 2,5 The company has a broad strategy and platform for outreach to relevant stakeholders and provides some evidence of relevant stakeholder engagement.
 - 1 The company has some stakeholder engagement but there is no evidence of a strategy and platform for outreach to relevant stakeholders.
 - 0 The company has no relevant stakeholder engagement.

A.II Transparency (25%)

A.II.1 Strategy: policies & practices

50%

- The company reports on its access to medicine strategy and discloses its overall rationale for its access to medicine activities.
- 5 The company publishes publicly available information on its access to medicine strategy, including policies and activities; rationale; long-term objectives; short-term targets and performance (either as part of its annual report/CSR report or a separate report) AND the access strategy is part of a wider corporate strategy.
 - 4 The company publishes publicly available information on its access to medicine strategy, including policies and activities; rationale; measurable targets and performance (either as part of its annual report/CSR report or a separate report) AND the access strategy is part of a wider corporate strategy.
 - 3 The company publishes publicly available information on its access to medicine strategy, including some information on policies and activities; rationale; objectives AND some information on short-/long-term targets and performance (either as part of its annual report/CSR report or a separate report).
 - 2 The company publishes publicly available information on its access to medicine strategy including policies and activities and long-term objectives but no information on short-term targets or performance (either as part of its annual report/CSR report or a separate report).
 - 0 The company does not include any of the above information in its public reporting.

A.II.2 Strategy: policies & practices

50%

- The company discloses goals and targets (both qualitative and quantitative) and performance measures for its access to medicine practices related to the Index countries.
- 5 The company discloses qualitative AND measurable quantitative targets AND performance measures AND progress for most of its relevant access initiatives.
 - 4 The company discloses 3 out of 4 of the above criteria for most of its relevant access initiatives.
 - 2,5 The company discloses 2 out of 4 of the above criteria for most of its relevant access initiatives.
 - 1 The company discloses long-term objectives for its relevant access initiatives.
 - 0 The company discloses none of the above.

A.III Performance (40%)

A.III.1 Governance: management structures, performance management & incentives

40%

- The company has a performance management system including quantitative targets to implement and monitor its access to medicine strategy in the Index countries.
- 5 The company has a centralised performance management system that uses quantitative and qualitative measures to collect data and appraise performance across its global operations.
 - 2,5 The company has a broad performance management system but progress is not monitored on a regular basis AND/OR not centralised.
 - 1 The company has qualitative and quantitative targets for its access to medicine strategy but no specific performance management system.
 - 0 The company does not provide any evidence of managing and measuring access to medicine performance.

A.III.2 Stakeholder engagement

- 25%** Senior management participates in public debate and engages with different stakeholder groups with the goal of dialogue and knowledge sharing aimed at improved access to products for the Index Diseases in the Index countries (the company organises/ facilitates/ hosts relevant conferences, symposia, workshops etc. attended by senior management).
- 5 The company (including senior management) plays a significant role in dissemination of knowledge (for example an agenda development role/ participation on organising committee) at more than 10 reputable* conferences/ symposia/ workshops/ meetings/ working groups.
- 4 The company engages in 5 - 10 of the above.
- 2.5 The company engages in 2 - 4 of the above.
- 1 There is no evidence of more than 1 of the above.
- o The company does not provide any evidence of the above.

* Reputable events are considered to be those which feature strong representation from organisations such as governments, major international agencies, regulatory bodies, foundations, academia, PPPs/PDPs and NGOs.

A.III.3 Governance: performance

- 25%** **management & incentives**
- The company has internal incentive structures to reward effective delivery of initiatives that improve access to medicine in the Index countries for the Index Diseases.
- 5 The company has an HR/ performance management strategy and supporting processes, and provides clear evidence of financial and non-financial incentives for relevant performance of directors and senior management.
- 2.5 The company has a broad HR/ performance management strategy and supporting processes which provide financial and non-financial incentives for relevant performance and there is evidence that this is active.
- 1 There is some evidence of internal incentive structures for relevant performance for employees working on access initiatives.
- o The company does not provide any evidence that it provides incentives for relevant performance.

A.III.4 Strategies, stakeholder engagement

- 10%** The company has a system in place to incorporate external and local (market) perspectives on access to medicine needs in the development and implementation of access strategies.
- 5 The company has a system in place to incorporate local stakeholder

perspectives in the development and implementation of its access strategies and there is evidence that this is structural.

- 2.5 There is some evidence that the company includes local stakeholder perspectives in the development and implementation of its access strategies, however, there is no evidence this is structural.
- o There is no evidence of local stakeholder engagement when developing and implementing access strategies.

A.IV Innovation (10%)**A.IV.1 Innovation in general access to medicine management**

- The company has contributed to the development of innovative business models that meet the needs of patients in Index countries.
- 5 The company has developed a financially sustainable innovative model that focuses on the needs of the poor.
- 4 The company has adopted or expanded a financially sustainable innovative business model that focuses on the needs of the poor.
- 2.5 The company has developed an innovative model, however, there is limited evidence concerning its (financial) sustainability.
- o No innovative models identified in this area.

B Public Policy & Market Influence

B.I Commitments (25%)**B.I.1 Endorsement of competition**

- 35%** The company commits to endorse and support competition and to refrain from anti-competitive practices or pursue arrangements with generic medicine manufacturers that might delay their market entry in the pharmaceutical markets in the Index countries for products related to the Index Diseases.
- 5 The company publicly discloses its commitment related to competition with its peers (both research-based and generic manufacturers) which endorses competition AND commits not to adopt practices that hamper competition AND explicitly commits not enter into arrangements with competitors or generic medicine manufacturers for delayed product entry to the market.

- 4 The company publicly discloses its commitment related to competition with its peers (both research-based and generic) which endorses competition AND commits not to adopt practices that hamper competition.
- 2.5 The company discloses to the Index its commitment related to competition with its peers (both research-based and generic) which endorses competition AND commits not to adopt practices that hamper competition.
- 1 The company publicly discloses a general statement in support of competition.
- o The company does not make any policy statements in this area.

B.I.2 Non-pursuit of data exclusivity**25%**

- The company's policies and practices surrounding data exclusivity do not impede access for products related to the Index Diseases in the Index countries.
- 5 The company systematically commits not to utilise or to waive data exclusivity laws for all its products related to Index Diseases in Index countries.
- 4 The company commits not to utilise / commits to waiving its right to data exclusivity periods for specific conditions and/or diseases in Index countries.
- o No policy statement on data exclusivity / negative stance on data exclusivity.

B.I.3 Ethical marketing**20%**

The company commits to enforce a code of conduct regarding ethical marketing practices for all sales agents and local third party distributors and contractors consistent with its own internal standards and any existing industry standards.

5 The company has processes in place to monitor marketing practices and enforce ethical marketing codes of practice by all its sales agents (third party distributors*) in the Index countries, which includes auditing of the agent's practices.

2,5 The company has specific ethical marketing codes of practice for all its sales agents (third party distributors) in the Index countries, but has no auditing, monitoring or enforcement mechanisms.

o The company has no provisions in place with regards to the marketing behaviour of its local sales agents.

*Third parties include local distributors, sales agents, wholesalers, clinics and pharmacies, faith based hospitals, pharmacy retail units/chains, private health facilities, transport providers, customs service providers, contract research organisations, public affairs, events companies or marketing contractors, consultants, etc.

B.I.4 Anti-bribery/anti-corruption**20%**

The company commits to proactively engage in fighting corruption through its internal anti-bribery and anti-corruption codes of conduct, external commitments and memberships.

5 The company has internal and/or external auditing of its anti-bribery/anti-corruption codes AND has all of the following:

- a) is a member of the World Economic Forum's Partnering Against Corruption Initiative (PACI)
- b) is a signatory to the UN Global Compact
- c) has a code of conduct that addresses anti-corruption which specifically applies to all employees, agents and intermediates
- d) has board level ownership/direct responsibility for ethics and compliance of anti-bribery/corruption practices
- e) has whistle-blower facilities and protection policies.

4 The company has internal and/or external auditing of its anti-bribery/anti-corruption codes and has 4 out of 5 of the above.

3 The company has internal and/or external auditing of its anti-bribery/anti-corruption codes and has 3 out of 5 of the above.

2 The company has no internal and/or external auditing of its anti-bribery/anti-corruption codes but has demonstrated at least 3 of above.

1 The company has no internal and/or external auditing of its anti-bribery/anti-corruption codes but has demonstrated at least 2 of the above.

o The company makes none of the above commitments.

B.II Transparency (25%)**B.II.1 Lobbying****15%**

The company is transparent about its lobbying positions, political contributions and positions it seeks to promote where it has an impact on access to medicine in Index countries, either directly or indirectly.

5 The company is publicly transparent with regard to its lobbying activities and public policy positions and political (financial) contributions impacting access to medicine in Index countries.

4 The company is transparent upon engagement with regard to its lobbying activities, its public policy positions and its political (financial) contributions which have an impact upon access to medicine in Index countries.

3 The company is publicly transparent with respect to either relevant lobbying activities, or its political contribution, or its public policy positions which have an impact upon access to medicine in Index countries.

2 The company is transparent upon engagement with regard to either its lobbying activities, or its political (financial) contributions or its public policy positions which have an impact upon access to medicines in Index countries.

1 The company discloses (publicly or upon engagement) its public policy or lobbying positions which have an impact upon access to medicines in Index countries via a general statement.

o The company is not transparent or makes no statement with regards to transparency in its lobbying activities or political (financial) contributions or public policy positions which have an impact upon access to medicines in Index countries.

B.II.2 Influence**15%**

The company discloses membership and financial support of trade associations, think tanks, interest groups, or other organisations, including any potential governance conflict of interests, through which it might advocate its public policy positions at regional, national or international levels where relevant to access to medicine in the Index countries.

5 The company discloses its financial support and membership of all institutions of all the named categories* for the Index countries.

4 The company makes detailed transaction level disclosure on payments made to different stakeholders, but provides no Index Country reporting.

2,5 The company makes partial disclosure in this area OR provides aggregate figures only.

o The company makes no disclosure in this area.

*Categories include: trade associations, think tanks, interest groups, or other organisations.

B.II.3 Influence**10%**

The company discloses its board seats at industry associations and advisory bodies related to health access issues for the Index Diseases and the Index countries.

5 The company publicly discloses through its own channels all the board seats and memberships that it holds in different organisations/institutions related to access to medicine in the Index countries including in organisations operating in the Index countries.

3,5 The company discloses upon engagement or on third party websites, all the board seats and memberships that it holds in different third party institutions related to access to medicine in the Index countries including in organisations operating in the Index countries.

2,5 The company makes partial disclosure of memberships (publicly or otherwise) that it holds in different third party institutions related to access to medicine in Index countries, including organisations operating in Index countries.

o The company makes no disclosure in this area.

B.II.4 Endorsement of competition

30% The company discloses policies related to competition in areas such as data exclusivity, patent extensions or other arrangements with generic companies that might delay their market entry for Index products in the Index countries.

5 The company publicly and precisely discloses its stance on competition and has provided evidence of promoting competition in ways such as data exclusivity waivers, arrangements with generics companies which support their market entry, etc.

2,5 The company publicly and precisely discloses its stance on competition but provides no evidence of any pro-competitive activities.

o The company makes no disclosure in this area.

B.II.5 Ethical marketing

20% The company publicly discloses detailed information regarding its marketing and promotional programmes in the Index countries, such as payments to or promotional activities directed at physicians or other key healthcare professionals or opinion leaders.

5 The company publicly discloses detailed information related to pharmaceutical marketing and promotional programmes in the Index countries. For example, payments made to physicians and methods for incentivising healthcare providers, pharmacies, key opinion leaders, and others. This includes decentralised activities and third party sales agents.

4 The company discloses upon engagement information related to pharmaceutical marketing and promotional programmes in the Index countries. For example payments to physicians and methods for incentivising healthcare providers, pharmacies, key opinion leaders, and others.

2,5 The company discloses on engagement its policy approach for pharmaceutical marketing in Index countries without disclosing exact contribution figures and performance information in this area.

o The company makes no disclosure in this area.

B.II.6 Ethical marketing, anti-bribery/**10% anti-corruption**

The company voluntarily discloses all information regarding its breaches of internal and internationally recognised codes of conduct for ethical marketing, lobbying, bribery and/or corruption in any country in the last two years, including litigations related to marketing practices in the Index countries.

5 The company publicly discloses detailed, current information (i.e., location, time, year) in its annual report, including cases which occurred in the Index countries, in relation to breaches of the following codes of conduct: IFPMA Ethical Marketing Guidelines, DHHS Code of Conduct, PhRMA Code of Conduct; EFPIA codes of conduct; WHO ethical criteria and relevant anti corruption codes such as PACI and the UN Global Compact.

4 The company discloses detailed, current information of the above, but only on engagement.

3 The company publicly discloses minimal or aggregate numbers related to breaches as outlined above as part of its annual report.

2 The company discloses minimal or aggregate numbers related to the breaches or litigations outlined above, but only on engagement.

o The company makes no disclosure in this area.

B.III Performance (40%)**B.III.1 Lobbying, ethical marketing,****35% anti-bribery/anti-corruption**

The company has been in breach of any national or international codes of conduct in any country in relation to lobbying, ethical marketing and/or bribery and corruption.

5 The company has not been the subject of any settled cases.*

2 The company has been the subject of at least one litigation/challenge in a non-Index Country with negative ruling/settlement with payment or regulatory proceeding with a fine.*

1 The company has been the subject of several litigations/challenges in non-Index countries with negative rulings/settlement with payment or regulatory proceedings with fines.*

o The company has been the subject of at least one litigation/challenge in an Index Country with negative ruling/settlement with payment or regulatory proceeding with a fine.*

**Pending cases and allegations are not considered breaches. If a ruling is appealed, the most recent verdict is taken into consideration.*

B.III.2 Endorsement of competition

35% There is evidence* of the company's anti-competitive behaviour** that impacts access to medicine based on fines or litigation records during the past two years.

5 The company has not been the subject of any settled cases.***

1 The company has been the subject of a challenge/litigation in non-Index countries with negative rulings/settlement with payment or regulatory proceedings with fines.***

o The company has been the subject of at least 1 litigation in an Index Country with negative rulings/settlement with payments or regulatory proceedings with fines.***

**Evidence to refer to fines or reports/controversies.*

***Excluding all IP anti-competitive practices.*

****Pending cases and allegations are not considered breaches. If a ruling is appealed, the most recent verdict is taken into consideration.*

B.III.3 Lobbying, ethical marketing,**10% anti-bribery/anti-corruption**

Part a – The company has taken disciplinary action against third parties or employees who violate its code of conduct for ethical marketing or lobbying and anti-corruption.

Part b (qualitative-no scoring) – The company has established stringent enforcement mechanisms for disciplinary action against third parties or employees that violate its codes of conduct for ethical marketing or lobbying and anti-corruption.

5 The company has clearly defined enforcement processes and disciplinary measures with regards to lobbying/corruption and/or marketing, and there is no evidence of violations.

2,5 The company has clearly defined enforcement processes and disciplinary measures and provides evidence that disciplinary action has been taken for lobbying/corruption and/or marketing violations, with disclosure made that action was taken.

1 The company does not have clearly defined enforcement processes and disciplinary measures and/or

its codes of conduct do not apply to third parties.

- o The company has abrogated its own internal whistleblower policy, for example, retaliating against an employee for whistleblowing action; or has not taken disciplinary action with regard to violations.

B.III.4 Lobbying

- 20%** Is there evidence that the company lobbies national or regional governments, or other companies and their trade associations, either directly or through third parties, to adopt additional measures to protect intellectual property and/or patent systems beyond the minimum standard outlined in the TRIPS agreement (e.g. data exclusivity, etc.)?
- 5 There is no evidence that the company directly or through any of

its trade associations or industry groups has engaged in lobbying activities for TRIPS + measures.

- 1 There is at least one incident where the company directly or through any of its trade associations or industry groups has lobbied for TRIPS + measures.
- o The company directly or through any of its trade associations or industry groups has more than one instance of lobbying for TRIPS + measures.

B.IV Innovation (10%)

B.IV.1 Innovation in public policy & market influence

100% The company has adopted an innovative (unique in the sector), sustainable approach to improving ethical business performance and interactions in Index countries in areas relevant to

increasing access to medicine such as marketing, advocacy, lobbying, anti-corruption, and pro-competition.

- 5 The company has adopted innovative (unique in the sector) approaches to promoting ethical, pro-competitive and anti-corruption behaviour in relation to Index Disease products in Index countries, and supports this with evidence of progress and/or the human or financial resources invested.
- 2,5 The company has adopted innovative (unique in the sector) approaches to promoting ethical, pro-competitive and anti-corruption behaviour in relation to Index Disease Products in Index countries but does not disclose progress or resources inputs.
- o No innovative initiatives identified in this area.

C Research & Development

C.I Commitments (25%)

C.I.1 Innovative and adaptive R&D for Index Diseases

40% The company commits to carry out research focusing on the development of both innovative and new remedies for the Index Diseases and adaptive new formulations of its existing products for the Index Diseases with the goal of improving access to medicine in the Index countries.

- For companies that have only one or two Index disease focus: tiers 1 and 3 are not applicable, scored according to tiers 2 and 4 or 5.
- 5 The company makes specific commitments supported with a strong rationale (alignment with health priorities) and specific operationalizing strategies (including responsibilities of partners), including measurable time-bound targets, in multiple disease areas related to the development of relevant innovative and/or adaptive products.
 - 4 The company makes specific commitments supported with a strong rationale (alignment with health priorities) and specific operationalizing strategies (including responsibilities of partners) in multiple disease areas related to the development of relevant innovative and/or adaptive products.
 - 3 The company makes a specific commitment as above, but only in a few

disease areas.

- 2 The company makes specific commitments supported with a strong rationale (alignment with health priorities), OR has specific operationalisation strategies in place, in multiple disease areas.
- 1 The company makes a general commitment in a few disease areas.
- o The company makes no commitments in this area.

C.I.2 Collaborative R&D

30% The company commits to ensuring equitable access to products successfully developed through R&D partnerships.

- 5 The company systematically commits to policies for inclusion of access-oriented principles in research contracts in all relevant countries, for all relevant diseases in relation to the intellectual property generated in partnerships (i.e. either waives all rights over the IP generated or explicitly encourages affordable, timely and high quality supply to relevant populations).
- 3,5 The company systematically commits to policies for inclusion of access-oriented principles in research contracts in a subset of relevant countries in relation to the intellectual property generated in partnerships for a subset of relevant diseases (i.e. either waives all rights over the IP generated or

explicitly encourages affordable, timely and high quality supply to relevant populations).

- 1,5 The company applies principles of access-oriented research contracts in relation to the intellectual property generated in partnerships for a subset of relevant products in only a subset of the relevant countries on an *ad hoc* basis.
- o The company makes no commitments in this area.

C.I.3 Clinical trial conduct

30% The company commits to compliance with quality assurance and control, plus ethical standards when conducting clinical trials in Index countries, consistent with codes such as Good Clinical Practice and the Declaration of Helsinki (regardless of whether the trials are conducted in-house or through a third-party, e.g. CRO).

- 5 The company provides evidence that it has policies in place in relation to
 - a) selecting third parties
 - b) application of codes of conduct consistent with the Declaration of Helsinki
 - c) ensuring compliance with Good Clinical Practice
 - d) has procedures in place for taking disciplinary action against any violations.
- 3,5 The company provides evidence

that it has policies in place in relation to

- a) selecting third parties
- b) ensuring compliance with Good Clinical Practice
- c) has procedures in place for taking disciplinary action for any violations.

- 1.5 The company provides evidence that it has policies in place in relation to 2 out of 4 above-mentioned elements (from score 5).
- 1 The company provides evidence that it has policies to ensure compliance with Good Clinical Practice.
- o The company makes no commitments in this area.

C.II Transparency (25%)

C.II.1 Resources towards R&D

30%

- The company discloses the resources dedicated to its research and development activities conducted in-house and/or in collaboration for Index Diseases suitable for Index countries.
- 5 The company discloses investments for all Index Diseases for which it carries out R&D.
 - 3.5 The company discloses investments for a subset of Index Diseases for which it carries out R&D.
 - 1.5 The company discloses investments for one or a minority of Index Diseases for which it carries out R&D.
 - 1 The company discloses its aggregate investments for Index Diseases, without specifying targeted disease areas.
 - o The company makes no disclosure in this area.

C.II.2 Collaborative R&D

30%

- The company discloses the licensing details pertaining to its research collaborations related to the Index Diseases (with regard to Intellectual Property rights, access provisions etc.).
- 5 The company publicly discloses the existence and mandate of all relevant collaborations plus included pro-access provisions (e.g. non-exclusivity in fields/territories, royalty free provisions, waivers of patents, price caps, commitments to ensure sufficient supply).
 - 4 The company publicly discloses partial information on the existence and mandate of its relevant collaborations and provides partial details of pro-access provisions relating to at least one of its collaborations.
 - 3 The company partially publicly discloses the existence and mandate of its relevant collaborations and discloses the included pro-access

provisions on an engagement basis.

- 2 The company discloses the existence of relevant collaborations plus included pro-access provisions for the majority of its agreements on an engagement basis.
 - 1 The company discloses the existence of relevant collaborations on an engagement basis.
 - o The company makes no disclosure in this area.
- NS Companies without relevant partnerships receive a neutral score.

C.II.3 R&D for Index Diseases suitable to Index countries' needs

10%

The company discloses its research pipeline related to both in-house research and collaborations targeting Index Diseases (where disclosure is not legally required).

- 5 The company publicly discloses its a) research and development pipeline (phase 1, 2 and 3), for all products, with diseases/indications specified) plus b) areas of basic/pre-clinical activity for all relevant diseases and products related to its in-house and c) collaborative research, and d) technology development.
- 4 The company publicly discloses three of the above four elements of its R&D pipeline.
- 3 The company publicly discloses two of the above four elements of its R&D pipeline.
- 2 The company publicly discloses one of the above four elements.
- 1 The company discloses on an engagement basis only.
- o The company makes no disclosure in this area.

Corrected for companies without relevant collaborations or technology development

C.II.4 Clinical trial data

30%

- The company discloses information and results of all of its clinical trials conducted in Index countries, regardless of the outcome and whether the trial was conducted in-house or through a third-party (e.g. CRO).
- 5 The company a) discloses all relevant country-conducted clinical trials (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: trial registration in an ICMJE approved registry and result disclosure within one year, and b) has a mechanism/

process in place for sharing clinical trial data with qualified third parties (e.g. universities).

- 4 The company a) discloses all relevant country-conducted clinical trials (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: trial registration in an ICMJE approved registry and result disclosure within one year, and b) has a positive stance towards clinical trial data transparency.
- 3 The company a) discloses all relevant country-conducted clinical trials (in-house or by CROs) to a standard not lower than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: trial registration and result disclosure OR b) discloses the majority of trials to a standard not lower than the WHO 2005 standards and has a mechanism/process in place for sharing clinical trial data with qualified third parties (e.g. universities).
- 2 The company registers trials and publicly discloses to a similar (or slightly lower) standard than that recommended in the WHO's 2005 Technical Consultation on Clinical Trial Registration Standards, with respect to: trial registration and results disclosure, but there is no evidence that this applies to all trials.
- 1 There is no evidence that disclosure goes beyond legal requirements.
- o The company makes no disclosure on either issue detailed above.

C.III Performance (40%)

C.III.1 Resources towards R&D

15%

- Portion of financial R&D investments dedicated to Index Diseases out of the company's total R&D expenditures.
- 5-1 Each company's R&D investments for diseases within scope is divided by total R&D investments. Revenue-standardised number (2012 & 2013) is scaled across all companies and scored.
 - o The company makes no disclosure in this area.

C.III.2 R&D for Index Diseases suitable to Index countries' needs

20%

Share of research pipeline reflecting 'new molecules' for Index Diseases including in-house and collaborative research.

For companies that have multiple Index disease focus:

- 5 The share of the company's pipeline dedicated to new molecules for relevant diseases is greater than or equal to 25% of its total pipeline.
- 4 The share of the company's pipeline dedicated to new molecules for relevant diseases is between 15-25% of its total pipeline.
- 3 The share of the company's pipeline dedicated to new molecules for relevant diseases is between 10-15% of its total pipeline.
- 2 The share of the company's pipeline dedicated to new molecules for relevant diseases is between 5-10% of its total pipeline.
- 1 The share of the company's pipeline dedicated to new molecules for relevant diseases is less than 5% of its total pipeline.
- o The company has no molecules/ activity with respect to R&D for relevant diseases.

For companies that have only one or two Index disease focus:

- 5 The share of the company's pipeline dedicated to new molecules for relevant diseases is greater than 50% of its total pipeline.
- 4 The share of the company's pipeline dedicated to new molecules for relevant diseases is between 25-50% of its total pipeline.
- 2.5 The share of the company's pipeline dedicated to new molecules for relevant diseases is between 10-25% of its total pipeline.
- 1 The share of the company's pipeline dedicated to new molecules for relevant diseases is less than 10% of its total pipeline.
- o The company has no molecules/ activity with respect to R&D for relevant diseases.

C.III.3 R&D for Index Diseases suitable to 20% Index countries' needs

Share of research pipeline and products registered reflecting 'adapted products or new technologies' specific to an Index Disease and an unmet need in an Index Country, including in-house and collaborative research.

For companies that have multiple Index disease focus:

- 5 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is greater than or equal to 25% of its total pipeline.
- 4 The share of the company's pipeline

dedicated to adapted products and technologies for relevant diseases is between 15-25% of its total pipeline.

- 3 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is between 10-15% of its total pipeline.
- 2 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is between 5-10% of its total pipeline.
- 1 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is less than 5% of its total pipeline.
- o The company has no adapted products/technologies with respect to R&D for relevant diseases.

For companies that have only one or two Index disease focus:

- 5 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is greater than 50% of its total pipeline.
- 4 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is between 25-50% of its total pipeline.
- 2.5 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is between 10-25% of its total pipeline.
- 1 The share of the company's pipeline dedicated to adapted products and technologies for relevant diseases is less than 10% of its total pipeline.
- o The company has no adapted products/technologies with respect to R&D for relevant diseases.

C.III.4 Collaborative R&D

10% R&D partnerships in which the company has been involved, with the aim of developing products or formulations for Index Diseases specifically targeting access issues in Index countries (adjusted for the number of molecules in the company's research pipeline).

For companies that have multiple Index disease focus:

- 5 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is greater than or equal to 25%.
- 4 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is between 10-25%.
- 2.5 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is between 5-10%.

- 1 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is less than 5%.
- o The company has no active relevant product development collaborations during the survey period.

For companies that have only one or two Index disease focus:

- 5 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is greater than 50%.
- 4 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is between 25-50%.
- 2.5 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is between 10-25%.
- 1 The share of the company's relevant pipeline that is developed in collaboration for relevant diseases is less than 10%.
- o The company has no active relevant product development collaborations during the survey period.

C.III.5 R&D for Index Diseases suitable to 5% Index countries' needs

Number of candidates relating to Index Diseases moving through research and development life cycle from early research phases to more advanced phases.

- 5-1 For each company, its R&D pipeline submitted in Index 2012 was compared with its R&D pipeline submitted for Index 2014 to determine the number of medicines and vaccines that progressed to different stages in each company's pipeline, as a proportion of the company's total R&D pipeline. Progress from discovery to pre-clinical, pre-clinical to clinical and from clinical to regulatory approval is weighted, scaled and scored.
- o The company did not provide evidence of molecules progressing through the pipeline.

C.III.6 Collaborative R&D

10% The company provides evidence that the terms and conditions of its research collaborations are conducive to improving access to Index Disease products in the Index countries for the individuals with significant financial barriers to access.

- 5 All agreements in relation to the company's relevant research collab-

- orations have pro-access provisions included in the terms and conditions.
- 4 More than 50% of the company's agreements in relation to the company's relevant research collaborations have pro-access provisions included in the terms and conditions and the company has provided evidence of engagement in other access-oriented partnerships (of which terms and conditions are non-disclosed).
- 2.5 Fewer than 50% of the company's agreements in relation to the company's relevant research collaborations have pro-access provisions included in the terms and conditions and the company has provided evidence of engagement in other access-oriented partnerships (of which terms and conditions are non-disclosed).
- 1 The company has been engaged in partnerships with access-oriented organisations (e.g. WIPO Re: Search, PDPs), without providing evidence of pro-access terms and conditions.
- o The company has been involved in partnerships, but there is no evidence of engagement in access-oriented partnerships.
- NS Companies without R&D partnerships in scope receive a neutral score.

C.III.7 Clinical trial conduct

- 5%** Has the company been the subject of any breach of international codes or lawsuits related to its clinical trial practices in the Index countries during the last five years?
- 5 The company has not been the subject of any regulatory notices or legal cases related to its clinical trial conduct.
- 4 The company has been the recipient of a couple of regulatory notices.
- 3 The company has been the subject of one or two legal cases (without a ruling) or more than two regulatory notices were issued to the company.
- 2 The company has been the subject of one or two legal cases (with negative rulings) but no precedent-setting cases.
- 1 The company has been the subject of at least one significant legal case (with negative ruling) that could set a precedent.
- o The company has been the subject of several significant legal cases and at least one major* case with a negative ruling.

For companies with no operations in relevant countries the score will be 5. For each of the above scores it is assumed: the case was with respect to its

*clinical trial conduct, the case occurred in a relevant country, the legal case, or regulatory notice occurred in the last 5 years and it was brought against the company itself or one of its third-parties for whom it was legally responsible. *Major' is defined as possibility to set a precedent.*

C.III.8 IP sharing

- 10%** The company provides evidence of sharing its intellectual capital (e.g. molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g. WIPO Re: Search, CDD, OSDD) that develop products for Index Diseases on terms most conducive to access to medicine for the Index countries.
- 5-1 The total number of instances of the company providing third-party access to its relevant disease-related intellectual property on access-orientated terms during the survey period is divided by total company revenue in 2012 and 2013. The number of IP sharing instances is divided by revenue and scaled across all companies.
- o The company did not provide evidence of IP sharing.

C.III.9 Clinical trial conduct

- 5%** The company provides evidence of ensuring compliance with Good Clinical Practice and the Declaration of Helsinki when conducting trials in Index countries, regardless of whether the trial was conducted in-house or through a third-party (e.g. CRO).
- 5 The company provides evidence that it
- has measures to comply with the Declaration of Helsinki
 - audits and monitors clinical trial conduct to comply with ICH-GCP
 - where relevant, applies processes for disciplinary action for any violations of guidelines/codes of practice for BOTH in-house and outsourced trials.
- 4 The company provides evidence that it
- audits and monitors clinical trial conduct to comply with ICH-GCP
 - where relevant, applies processes for disciplinary action for any violations of guidelines/codes of practice for BOTH in-house and outsourced trials.
- 2.5 The company provides evidence that it audits and monitors clinical trial conduct to comply with ICH-GCP for BOTH in-house and

outsourced trials OR provides general statements on auditing and monitoring procedures and procedures for disciplinary actions for any violations of guidelines/codes of practice.

- 1 The company makes a general statement concerning monitoring or auditing its clinical trial conduct.
- o The company provides no evidence of monitoring or enforcement of ethical behaviours for in-house or outsourced clinical trials.

C.IV Innovation (10%)

C.IV.1 Innovation in R&D

- 100%** The company has adopted innovative (unique in the sector), sustainable or open business models to further the global R&D agenda for the development of products for Index Diseases.
- 5 The company has provided evidence that it invested in designing new innovative (unique in the sector) R&D approaches or business models, including open approaches to IP, for relevant diseases with significant potential to improve ATM and has demonstrated significant resources and progress.
- 4 The company has adopted innovative (not unique in the sector) R&D approaches or business models, including open approaches to IP, for relevant diseases with significant potential to improve ATM and has demonstrated significant resources and progress.
- 2.5 The company has adopted innovative (not unique in the sector) R&D approaches or business models, including open approaches to IP, for relevant diseases with significant potential to improve ATM, but did not provide evidence of dedicated resources and progress.
- 1 The company is involved in a collaborative, industry-wide effort to develop new common R&D approaches or business models for relevant diseases with significant potential to improve ATM.
- o No innovative initiatives discovered for the company in this area.

D Pricing, Manufacturing & Distribution

D.1 Commitments (25%)

D.1.1 Equitable pricing strategies

25%

The company commits to implement equitable inter-country pricing models for the products related to the Index Diseases in the Index countries to ensure affordability.

- 5 The company commits to apply inter-country equitable pricing models in all the countries it operates in which are relevant to the Index, for all its products relevant to the Index.
- 4 The company commits to apply inter-country equitable pricing models in the majority of relevant countries for a majority of its relevant products.
- 3 The company commits to apply inter-country equitable pricing models in a majority of relevant countries for at least one of its relevant products or for a majority of relevant products in at least one relevant country.
- 2 The company commits to apply inter-country equitable pricing models to at least one product in a small number of relevant countries.
 - 1 The company makes a general commitment to implement inter-country equitable pricing.
 - o The company makes no commitments in this area.

D.1.2 Equitable pricing strategies

20%

The company commits to implement equitable intra-country pricing models for the products related to the Index Diseases in the Index countries to ensure affordability.

- 5 The company commits to apply intra-country equitable pricing models in all the countries relevant to the Index it operates in, for all its products for diseases relevant to the Index.
- 4 The company commits to apply intra-country equitable pricing models in a majority of relevant countries for the majority of its relevant products.
- 3 The company commits to apply intra-country equitable pricing models in a majority of relevant countries for at least one of its relevant products.
- 2 The company commits to apply intra-country equitable pricing models to at least one product in a

small number of relevant countries.

- 1 The company makes a general commitment to implement intra-country equitable pricing.
- o The company makes no intra-country equitable pricing commitments.

D.1.3 Accountability for sales agents'

20% pricing practices

The company adopts clear policies to control the pricing practices of its local sales agents with the aim of improving affordability and accessibility of the products.

- 5 The company has pricing guidelines for its local sales agents (third party wholesalers and distributors) AND the company has a pricing monitoring process including mark-up monitoring, training and audit mechanisms for all its products relevant to the Index in countries it operates in.
- 4 In addition to pricing guidelines, the company has a pricing monitoring process including mark-up monitoring and training OR audit mechanisms for its sales agents (third party wholesalers and distributors) for some relevant products and relevant countries.
- 3 The company has general pricing guidelines for its sales agents and monitors mark-ups.
- 2.5 The company has general pricing guidelines for its sales agents but does not monitor mark-ups.
 - 1 The company provides evidence of monitoring mark-ups but does not have pricing guidelines.
 - o The company has no pricing guidelines, and does not monitor pricing practices or markups applied by local sales agents.

D.1.4 Drug recalls

10%

The company has in place the policies, procedures and resources needed to carry out effective drug recalls (product and packaging) in the Index countries where it operates.

- 5 The company provides evidence of compliance with WHO GMP guidelines* for drug recalls in all countries relevant to the Index where its products are available, AND commits to achieve the highest possible standards AND has processes to track products to ensure effective recalls.
- 4 The company provides evidence of

compliance with WHO GMP guidelines for drug recalls as described above in all relevant countries where its products are available AND it commits achieve the highest possible standards BUT does not have processes to track products to ensure effective recalls.

2.5 The company provides evidence of compliance with WHO GMP guidelines for drug recalls in some of the relevant countries where it makes its products available and commits to achieve the highest possible standards.

- 1 The company has general guidelines for drug recalls and provides evidence of tracking procedures
- o The company makes no commitment in this area.

**WHO GMP guidelines includes written procedures describing the action to be taken, including the need to consider a recall in the case of a complaint concerning a possible product defect; processes for an investigation and evaluation of a complaint; and appropriate follow-up action, possibly including product recall; storage of recalled products; periodic evaluation of recall processes.*

D.1.5 Brochure & packaging adaptation

10%

The company commits to needs-based (facilitation of rational use) brochure and packaging adaptation for its products destined for Index countries (at least equal to local regulatory requirements).

- 5 The company discloses that its product brochure and packaging information is consistent with that approved by the country's drug regulatory authority for all of the relevant diseases for which its products are sold AND for some products its product brochures and packaging information go beyond those required by the country's drug regulatory authority, with the aim of facilitating rational use for societies in need, at various levels of the health system.*
- 4 The company discloses that its product brochure and packaging information is consistent with that approved by the country's drug regulatory authority for all of the relevant diseases for which its products are sold, with the aim of

facilitating rational use.

- 3 The company discloses that its product brochure and packaging information is consistent with that approved by the country's drug regulatory authority for the majority of the relevant diseases for which its products are sold, with the aim of facilitating rational use.
- 2.5 The company discloses that its product brochure and packaging information is consistent with that approved by the country's drug regulatory authority for a sub-set (or one) of the relevant diseases for which its products are sold, with the aim of facilitating rational use.
- o The company makes no disclosure in this area or has no packaging adaptation to facilitate rational use.

**Including at point of dispensing and at use level*

D.I.6 Filing for marketing approval/ registration

15%

The company commits to file for marketing approval or product registration of its products for the Index Diseases in the Index countries in need.

- 5 The company has specific targets to register most of its products for diseases relevant to the Index in Sub-Saharan Africa and all Low-Income Countries within 12 months of market launch.
- 4 The company has specific targets to register most of its products for relevant diseases in Sub-Saharan Africa and all Low-Income Countries but has committed to no timeframe.
- 2.5 The company has committed to register a sub-set of its products for relevant diseases in a subset of LICs but has committed to no timeframe.
- 1 The company has committed to register its products for relevant diseases in LMICs.
- o The company makes no commitment to register its products for relevant diseases in countries relevant to the Index.

D.II Transparency (25%)

D.II.1 Equitable pricing schemes

30%

The company discloses the volume of its sales to the lower tiers covered under equitable pricing programs to ensure affordability.

- 5 The company discloses the volume of sales covered by equitable pricing programmes to the lowest tier for all of its products relevant to the Index.
- 4 The company discloses a subset

of the above information such as regional or representative figures for all of its relevant products OR discloses full volume data for the majority (greater than 50%) of relevant products.

- 3 The company discloses a subset of the above information such as regional or representative figures for the majority (greater than 50%) of its relevant products OR discloses full volume data for a subset (less than 50%) of relevant products.
- 2.5 The company discloses a subset of the above information such as regional or representative figures for less than 50% of its relevant products.
- o The company has equitable pricing strategies for products and countries relevant to the Index, but makes no disclosure in this area.

NS Companies without any relevant equitable pricing strategies receive a neutral score.

D.II.2 Equitable pricing schemes

35%

For equitably priced products relating to the Index Diseases in the Index countries, the company discloses target prices for the lower tiers and how it determines these prices.

- 5 Companies with multi-product equitable pricing: The company discloses details of how it takes affordability of the lowest tier of each pricing strategy into account for all of its products relevant to the Index covered by equitable pricing programmes AND discloses the price point offered to the lowest tiers* for all relevant tracer products covered by equitable pricing programmes. Companies with single product equitable pricing: The company discloses FULL details of its equitable pricing strategy AND discloses the price point offered to the lowest tiers* for its product.
- 4 Companies with multi-product equitable pricing: The company discloses details of how it takes affordability into account for the majority of its relevant products covered by equitable pricing programmes AND discloses the price point offered to the lowest tiers for the majority of relevant tracer products covered by equitable pricing programmes. Companies with single product equitable pricing: The company discloses SOME details of its equitable pricing strategy AND discloses the price point offered to the lowest

tiers for its product.

- 2.5 The company discloses details of how it takes affordability into account for the majority of its relevant products covered by equitable pricing programmes AND discloses the price point offered to the lowest tiers for a subset of relevant tracer products covered by equitable pricing programmes.

- 1 The company discloses details of how it takes affordability into account for its equitable pricing strategy sufficiently for all of its relevant products covered by equitable pricing programmes but does not disclose the price point offered to the lowest tiers for any products covered by equitable pricing programmes.

o The company has equitable pricing strategies for products and countries relevant to the Index, but makes no disclosure in this area.

NS Companies without any relevant equitable pricing strategies receive a neutral score.

**The lowest price point within a company's equitable pricing structure. This price is offered to the poorest segment (i.e., to the poorest population group within a country, or to the poorest country (or countries) within a larger group of countries). This includes the price at which products are sold to the public sector within a poor country or sales to LICs and/or LDCs.*

D.II.3 Filing for marketing approval/ registration

25%

The company discloses its decision-making process regarding registration (marketing approval) and also the status of marketing approvals for each product related to Index Diseases in the Index countries.

- 5 The company publicly discloses the criteria used in its decision making process for obtaining marketing approval and discloses the registration status of almost all its products for relevant diseases in relevant countries.
- 4 The company publicly discloses the criteria used in its decision making process for obtaining marketing approval and the registration status of the majority of its products for relevant diseases in relevant countries.
- 3 The company publicly discloses at least partial criteria AND partial information about the registration status of the majority of its

- products for relevant diseases in relevant countries.
- 2.5 The company publicly discloses the criteria OR partial information about the registration status of its products for relevant diseases in relevant countries.
- 2 The company discloses the criteria used in its decision-making process for obtaining marketing approval and the registration status of all its products for the relevant diseases in relevant countries on engagement.
- 1 The company discloses partial information concerning the above areas on engagement.
- o The company makes no disclosure in this area.

D.II.4 Drug recalls

10%

- The company publicly discloses information about the drug recalls and breaches it has been involved in related to drug quality issues in the Index countries.
- 5 The company publicly discloses the date, location and the reason for drug recalls it has been involved in during the period of analysis and how it responded to the recall in an integrated accessible way.
- 3.5 The company publicly discloses the mentioned data in aggregate format only.
- 2.5 The company discloses detailed information on engagement.
- 1 The company discloses aggregated information on engagement.
- o The company provides no disclosure with regard to product recalls or the company has had drug recalls but does not disclose them to the Index.
- NS Companies without any drug recalls during the period of analysis receive a neutral score.

D.III Performance (40%)

D.III.1 Equitable pricing strategies

20%

- Do the company's equitable pricing programmes for products relating to Index Diseases cover all or a significant percentage of Index countries?
- 5 At least 75% of the company's market within the scope of the Index is covered by equitable pricing programmes for at least 75% of products related to diseases relevant to the Index.
- 4 Between 50-75% of the company's relevant market is covered by equitable pricing programmes for at least 75% of relevant products OR

- at least 75% of the company's relevant market is covered by equitable pricing programmes for between 50-75% of relevant products.
- 2.5 Less than 50% of the company's relevant market is covered by equitable pricing programmes for greater than 75% of relevant products or greater than 75% of the company's relevant market is covered by equitable pricing programmes for less than 50% of relevant products.
- 2 Less than 50% of the company's relevant market is covered by equitable pricing programmes for between 50-75% of relevant products or between 50-75% of the company's relevant market is covered by equitable pricing programmes for less than 50% of relevant products.
- 1 Less than 50% of the company's relevant market is covered by equitable pricing programmes for less than 50% of relevant products
- o Less than 5% of the company's relevant market is covered by equitable pricing programmes for less than 5% of relevant products
- NS Companies without any relevant equitable pricing strategies receive a neutral score.

D.III.2 Equitable pricing strategies

20%

- Does the company take into consideration needs-based affordability when making pricing decisions for relevant products targeted at the poorest population segments* in relevant countries?
- 5 Companies with multi-product equitable pricing: At least 75% of equitably priced products both target the poorest segment and take into account affordability for this segment.*
Companies with single product equitable pricing: Has a single product in multiple countries relevant to the Index that both targets the poorest segment and takes into account affordability for this segment.*
- 4 Companies with multi-product equitable pricing: At least 50% of equitably priced products relevant to the Index both target the poorest segment and take into account affordability for this segment
Companies with single product equitable pricing: Has a single product in one relevant country that both targets the poorest segment and takes into account affordability for this segment.
- 3 Companies with multi-product

- equitable pricing: Less than 50% of the company's equitably priced products both targets the poorest segment and takes into account affordability for this segment
- 2 Companies with multi-product equitable pricing: The majority of the company's products have equitable pricing that takes into account affordability and is targeted.
Companies with single product equitable pricing: Has a single product that takes into account affordability and is targeted.
- 1 Companies with multi-product equitable pricing: The majority of products take into account affordability and a subset of products are targeted.
Companies with single product equitable pricing: Has a single product that takes into account affordability.
- o Companies with multi-product equitable pricing: None of the company's equitably priced products are targeted.
- NS Companies without any relevant equitable pricing strategies receive a neutral score.
- *The lowest-income population segment within a given country, or the poorest country (or group of countries) worldwide. The poorest segment a company sells a product to may be a lower-income population segment, and not the lowest-income segment within a country.*

D.III.3 Filing for marketing approval/

15% registration

- Has the company attempted to register (obtain marketing approval for) its products for Index Diseases in the Index countries in need?
- 5 The company has registered the majority of its products (relative to company portfolio size) in the majority of countries in scope on a needs-basis.
- 4 The company has either registered the majority of its products in some relevant countries or has registered some of its products in the majority of relevant countries on a needs-basis.
- 3 The company has registered at least half of its products in at least half of the relevant countries on a needs-basis.
- 2.5 The company has either registered at least half of its products in a few relevant countries or has registered a few of its products in at least half of the relevant countries.

- 2 The company has registered less than half of its products in less than half of relevant countries.
- o The company's makes no disclosure in this area, or the company's registration efforts were less than the above indicating that the company's behaviour in this area may be a barrier to access.

D.III.4 Drug recalls

- 20%** Have drug recalls occurred due to product or packaging quality issues in the Index countries for products produced by the company, its licencees or other manufacturing partners during the past two years? If so, how has the company dealt with them?
- 5 There is no evidence that the company or any of its licensee/manufacturing partner(s) have issued product recalls related to quality issues during the past 2 years in any of the countries relevant to the Index.
 - 2.5 There is no evidence that the company has issued drug recalls but there are cases of its licensee/manufacturing partners issuing drug recall(s) due to quality issues in relevant countries were discovered OR the company has issued drug recalls due to packaging issues, not due to quality issues.
 - 1 The company makes no disclosure in this area OR has issued drug recalls but dealt with them rapidly and effectively.
 - o The company has issued drug recall(s) related to quality issues with company produced products in relevant countries during the past 2 years.

D.III.5 Filing for marketing approval/ registration

- 10%** The company files for WHO Prequalification list, tentative approval of US Food and Drug Administration, European Medicines Agency or other stringent regulatory authority approval for its eligible products for the Index Diseases.
- 5 The company has applied for any of the following stringent approvals: WHO Prequalification, tentative approval from the US Food and Drug Administration or European Medicines Agency (Article 58) for all of its qualifying products.
 - 4 The company has applied for any of the mentioned approvals for the majority of its qualifying products.
 - 2.5 The company has applied for any of

- the mentioned approvals for some of its qualifying products.
 - o The company has not filed for any of the mentioned approvals but has eligible products.
- NS Companies without relevant products eligible for stringent approvals receive a neutral score.

D.III.6 Equitable pricing schemes

- 15%** Do products for Index Diseases destined for Index countries for which tiered pricing is used have special packaging or other distinct markers to prevent product diversion?
- 5 All products for which the company has equitable tiered pricing and which are on the 2013 WHO Model Essential Medicines List (EML) are tagged or packaged differently and all products not on WHO EML that have tiered pricing are packaged differently for the poorest segment.
 - 4 At least 75% of equitable tiered pricing products that are on the EML are tagged or packaged differently BUT relevant products not on the EML that have tiered pricing are not packaged differently.
 - 2.5 Less than 50% of relevant products on the EML are tagged or packaged differently.
 - 1 Less than 20% of relevant products on the EML are tagged or packaged differently.
 - o The company does not have special tagging or packaging for any of its products and has equitable tiered pricing.
- NS Companies without relevant products with tiered pricing receive a neutral score.

D.IV Innovation (10%)

D.IV.1 Innovation in equitable pricing

- 50%** The company has introduced innovative approaches (unique in the sector) to equitable pricing which help with sustainable delivery of the products for Index Diseases to individuals in the Index countries who face the highest financial barriers to access.
- 5 The company has adopted innovative (unique in the sector) business models related to pricing and affordability of products relevant to the Index, countries within the scope of the Index, which are expected to result in increased affordability and accessibility of these products, including sustainable financing mechanisms and pricing schemes that ensure products reach target consumers at target

prices. Only innovative projects for which either progress made, or human and/or financial resources are disclosed are taken into consideration.

- 2.5 The company has adopted innovative (unique in the sector) business models related to pricing and affordability of Index Diseases products in Index countries but NO progress or inputs disclosed.
- o No innovative initiatives discovered in this area.

D.IV.2 Innovation in manufacturing & distribution

- 50%** The company has introduced innovative approaches (unique in the sector) to manufacturing and distribution of products for the Index Diseases which may help with sustainable delivery of such products for the Index Diseases in the Index countries.
- 5 The company has adopted innovative (unique in the sector) manufacturing & distribution practices related to increasing affordability and availability of products relevant to the Index, countries within the scope. Only innovative projects for which either progress made, or human and/or financial resources are disclosed are taken into consideration.
 - 2.5 The company has adopted innovative (unique in the sector) manufacturing & distribution practices related to increasing affordability and availability of Index Disease products in Index countries but NO progress or inputs disclosed.
 - o No innovative initiatives discovered in this area.

E Patents & Licensing

E.I Commitments (25%)

E.I.1 Patent filings

50%

The company commits to not file for or enforce patents related to its products for the Index Diseases in LDCs, LICs and LMICs.

5 The company makes a general commitment not to patent, to abandon existing patents or to issue non-assert declarations on all IP relating to products for Index Diseases in all Least Developed Countries (as defined by the United Nations), LICs (as defined by the World Bank) and LMICs.

4 The company makes a general commitment not to patent, to abandon any existing patents or to issue non-assert declarations on all IP relating to products for Index Diseases in all LDCs, LICs, and most LMICs.

3 The company makes a general commitment not to patent, to abandon any existing patents or to issue non-assert declarations on all IP relating to products for Index Diseases in LDCs or LICs.

2 The company makes a general commitment not to patent, to abandon any existing patents or to issue non-assert declarations on IP relating to products for Index Diseases for a sub-set of its products in LDCs and LICs.

1 The company makes a general commitment not to patent, to abandon any existing patents or to issue non-assert declarations on IP relating to relevant products for Index Diseases in certain regions (such as Sub-Saharan Africa)

o The company makes no commitment in this area.

E.I.2 IP strategies

50%

The company commits as part of a wider access-oriented strategy to issue non-exclusive voluntary licensing (NEVL) or binding non-assert declarations (NAD) for manufacturing and supply of the patented product.

5 The company has in place a policy to engage in non-exclusive voluntary licensing that is pro-access* with qualified manufacturers for products for Index Diseases for which third party production is deemed conducive to increased affordability and accessibility or to use binding non-assert clauses for

exclusive voluntary licensing (EVL), demonstrating the engagement of its legal/IP team on such matters.

4 The company has in place a policy to consider non-exclusive, voluntary licensing with pro-access* terms or binding non-assert declarations, demonstrating that such tools have been considered by its legal/IP team.

3 The company has in place a policy to consider voluntary licensing for a sub-set of its products but does not mention their non-exclusive nature and not for all products.

2.5 The company does not have in place a policy to consider voluntary licensing but has equitable pricing for Index Disease products for the Index countries or it considers it as an option where it is appropriate.

o The company has neither commitments regarding non-exclusive pro-access licensing nor equitable pricing in place for pharmaceutical products related to the Index Diseases for the Index countries.

**No challenge, ability to supply to country issuing compulsory license, ability to supply where no patents in force, termination for any reason at any time, ability to manufacture and source APIs from any licensee.*

E.II Transparency (25%)

E.II.1 TRIPS flexibilities

25%

The company discloses its explicit support of usage of TRIPS flexibilities based on the Doha Declaration on TRIPS and public health.

5 The company discloses explicit support for the Doha Declaration and usage of the following TRIPS flexibilities (compulsory licences, parallel imports, bolar provisions, and exemptions for least developed countries) in relation to the Index countries.

4 The company discloses support for the Doha Declaration and the majority of the above-mentioned items.

3 The company discloses support for two of the above-mentioned items.

2 The company discloses support for one out of the above-mentioned items.

1 The company discloses support for one out of the above-mentioned

items, but company is indirectly involved in negative lobbying through membership of industry associations.

o The company makes no disclosure of support for the Doha Declaration, makes a statement in support of the Special 301 Watch List, or evidence of lobbying against the use of TRIPS flexibilities (either directly or indirectly through trade associations or lobbying groups).

E.II.2 Patent filings

45%

The company discloses the patent status of its products for the Index Diseases in the Index countries.

5 The company publicly discloses the patent status for all patents for all the products concerning Index Diseases in all the Index countries.

3 The company makes partial public disclosure of patent status for some products.

o The company makes no public disclosure about patent status.

E.II.3 IP strategies

30%

The company discloses detailed information about the voluntary licensing activities it is engaged in and its binding non-assert clauses for products related to the Index Diseases for the Index countries (such as licence duration, licence territory, technology transfer, etc.).

5 The company publicly discloses complete information regarding the terms* of its voluntary licences for all relevant Index Disease products.

4 The company publicly discloses complete information regarding the terms* of its voluntary licences for a subset of its relevant Index Disease products.

3 The company publicly discloses partial information on the terms* for a subset of its licensees and products.

2 The company discloses all relevant information about the licences it has issued for a subset of products, on engagement only.

1 The company discloses partial information on a subset of products on engagement only.

o The company makes no disclosure in this area.

NS Companies without any voluntary licences receive a neutral score.

**Including the name/location of the licensee, the exclusive/non-exclusive nature of the license, includes manufacturing as well as distribution, license duration, territory, scope/application, TT agreements and conditions, royalty terms, pricing clauses, production information (supply units), where APIs can be sourced, No challenge clauses, ability to supply to country issuing compulsory license, ability to supply where no patents in force, termination for any reason at any time.*

E.III Performance (40%)

E.III.1 IP strategies

- 20%** Does the company actively engage in issuing multiple non-exclusive voluntary licences and/or use legally binding non-assert declarations/clauses for the Index countries for its products related to the Index Diseases?
- 5 The company has issued more than or equal to five non-exclusive voluntary licences and/or non-assert declarations to generic manufacturers for more than 80% of its relevant products for Index Diseases.
 - 4 The company has issued less than five non-exclusive voluntary licences and/or non-assert declarations to generic manufacturers for between 25-100% of relevant products for Index Diseases.
 - 3 The company has issued less than five non-exclusive, voluntary licences and/or non-assert declarations for less than 25% of its products.
 - 2 The company provides some evidence of non-exclusive, voluntary licensing activity.
 - o The company has relevant patented products but has not issued any non-exclusive voluntary licences.
- NS Companies without any patented products receive a neutral score.

E.III.2 Technology transfer

- 20%** Does the company have technology transfer agreements that accelerate and facilitate generic product development?
- 5 The company has technology transfer agreements in place, either as know-how agreements or as part of its licensing agreements, and provides evidence of all of the following: quality assurance terms, no additional royalties, opt-out clauses and are public health oriented.
 - 4 The company has technology transfer agreements in place, either as know-how agreements or as part

of its licensing agreements, and provides some evidence of the following: quality assurance terms, no additional royalties, opt-out clauses and public health oriented.

- 3 The company has technology transfer agreements in place but makes no disclosure around the terms.
 - o The company has no technology transfer agreements in place.
- NS Companies without any patented products receive a neutral score.

E.III.3 IP strategies

- 20%** The company supports patent pools such as The Medicines Patent Pool for development of new/adaptive remedies for the Index Diseases in the Index countries.
- 5 The company has concluded licensing agreements with the MPP for relevant products in its portfolio which reach all relevant populations in Index countries.
 - 4 The company has concluded licensing agreements with the MPP for products in its portfolio which reach relevant populations in 90% of Index countries.
 - 3 The company has concluded licensing agreements with the MPP for at least one relevant product for a subset of Index countries OR has made a formal commitment to the MPP to enter into licensing agreements for a relevant product.
 - 2.5 The company is in negotiations with the MPP.
 - o The company has not engaged in negotiations with the Medicines Patent Pool.
- NS Companies without any HIV products on-patent receive a neutral score.

E.III.4 IP strategies

- 20%** Are the contents of the non-exclusive voluntary licensing and/or legally binding non-assert declarations/clauses access-oriented for its products related to the Index Diseases in Index countries?
- 5 For companies with voluntary licences in place, the licences (where they were able to be examined) include all five of the designated access-oriented clauses*.
 - 4 For companies with voluntary licences in place, the licences (where they were able to be examined) include four of the five designated clauses.
 - 3 For companies with voluntary licences in place, the licences (where

they were able to be examined) include three of the five designated clauses.

- 2.5 For companies with voluntary licences in place, the licences (where they were able to be examined) include two of the five designated clauses, or the company does not have applicable licences.
 - 1 For companies with voluntary licences in place, the licences (where they were able to be examined) include one of the five designated clauses.
 - o For companies with voluntary licences in place, the licences (where they were able to be examined) do not include any of the above access-oriented provisions, or the company has not disclosed the information.
- NS Companies without any voluntary licences receive a neutral score.
- *No challenge, ability to supply to country issuing compulsory license, ability to supply where no patents in force, termination for any reason at any time, ability to manufacture and source APIs from any licensee.*

E.III.5 IP strategies

- 20%** Is there evidence that the company employs an IP strategy that is conducive to access to affordable products for Index Diseases in the Index countries (e.g. actively engage in pro-competitive approaches by avoiding anti-competitive practices such as evergreening, thicketing, protection of research tools etc.)?
- 5 No evidence is found that the company is involved in IP-related anti-competitive practices in relation to access to medicines.*
 - 3 Evidence is found that the company is involved in IP-related anti-competitive practices that restrict access to medicines,* but the company has provided evidence of supporting pro-competitive IP policies and practices.
 - o The company has been involved in anti-competitive IP related practices*.

**Including patenting in Least Developed Countries; evergreening of products for Index Diseases to protect new applications for use that extend their patented life; creating patent thickets to deter R&D in certain technological areas related to Index Diseases; extending patent application dates to prevent public disclosure; anti generic campaigns; using patent challenge clauses in licenses;*

interventions at regulatory agencies to delay generic registrations; advocacy tactics to undermine public confidence in generic products and acting against usage of TRIPS flexibilities by the Index countries based on the Doha Declaration on TRIPS and Public Health).

E.IV Innovation (10%)

E.IV.1 Innovation in patents and licensing 100%

The company has engaged in innovative (unique in the sector), sustainable programmes aimed at decreasing the impact of the exclusivity conferred by patent protection that could result in

increased affordability and accessibility of medicine to individuals with financial barriers to access (e.g. adopted innovative socially responsible licensing practices aiming at increased effectiveness of its licensing programmes).

- 5 The company has adopted innovative, sustainable programs aimed at decreasing the potential public health impact of the exclusivity conferred by patent protection (decreased affordability, for e.g.). For (e.g., adopted innovative pro-access licensing practices aiming at increasing the effectiveness of its licensing programs) and supports

this with evidence of progress and/or the human or financial resources invested.

- 3 The company has adopted innovative, sustainable programs aimed at decreasing the potential public health impact of the exclusivity conferred by patent protection (decreased affordably, for e.g.), but does not disclose progress or resource inputs.
- o No innovative initiatives discovered in this area.

F Capability Advancement in Product Development & Distribution

F.I Commitments (25%)

F.I.1 Capacity building in QMS and manufacturing standards 50%

The company commits to assist Index Country manufacturers in building quality management systems aimed at achieving international quality standards (e.g. FDA, EMA, WHO Good Manufacturing Practices or recognised national certifications) and ensure that local staff employed at in-house facilities operating in Index countries follow the same standards.

- 5 The company demands quality standards from its third party manufacturers AND in-house facilities in low income countries and commits to provide them with the training and tools needed to maintain drug quality consistent with international standards.
- 4 The company commits to all of the above except only in respect of Index countries which are not low income countries.
- 3 The company either provides quality training & tools as listed above or demands specific quality management requirements as listed above from its third party manufacturer or at its in-house facilities.
- 2 The company makes a broad commitment, but provides no detailed information on how third-party manufacturers and/or in-house facilities are supported.
- o The company makes no such commitment.

F.I.2 Capacity building in pharmacovigilance 50%

The company commits to support the development and/or implementation of national pharmacovigilance programmes in the Index countries.

- 5 The company commits to and is found to have > 2 examples of engagement with local stakeholders to support and establish national pharmacovigilance systems in at least one Index country, including disclosure of detailed mechanisms OR human or financial inputs (including training, consultancies, secondments; inputs to development of national programme).
- 4 The company commits to and is found to have one or two examples of engagement with local stakeholders to support and establish national pharmacovigilance systems in at least one Index country, including disclosure of detailed mechanisms OR human or financial inputs as above.
- 2.5 The company has provided evidence such as a detailed approach towards supporting national pharmacovigilance programmes OR human or financial inputs as above in at least one Index country.
- 1 The company has provided evidence of internal pharmacovigilance in one or more Index country.
- o The company does not engage in pharmacovigilance in Index countries.

Emphasis here is on national pharmacovigilance programmes (vs. global programmes).

F.II Transparency (25%)

F.II.1 Capacity building in pharmacovigilance 25%

The company discloses details of its capability advancement activities related to the development and/or implementation of national pharmacovigilance programmes and the company discloses post-marketing surveillance data to Index Country governments.

- 5 The company discloses information about the financial OR technical OR human resources dedicated to its in-house activities and collaborations aimed at improving national pharmacovigilance systems in the Index countries AND the company discloses post-marketing surveillance data to Index Country governments where not legally required, and provides examples.
- 3.5 The company discloses information about the financial OR technical OR human resources dedicated to its in-house activities and collaborations aimed at improving pharmacovigilance systems in the Index countries.
- 2.5 The company discloses its approach to improving national pharmacovigilance systems in Index countries but no disclosure related to human or financial resources.
- 1 The company discloses information about its internal pharmacovigilance in Index countries.
- o The company makes no disclosure in this area.

Emphasis here is on national pharmacovigilance programmes (vs. global programmes).

F.II.2 Capacity building in QMS and manufacturing standards 25%

The company discloses details of its local in-house facilities' quality standards and details of contracts with local manufacturers (including licencees and contract manufacturers) that evidence obligations to maintain good quality standards similar to those it applies internally in developed countries or at least consistent with international standards such as the FDA, EMA and/or WHO Good Manufacturing Practices.

- 5 The company discloses details of how it ensures QMS for its products produced in Index countries (ICs), both in-house AND through third-parties through provision of detailed evidence such as audit data, review process, (parts of) contracts, etc.
- 3.5 The company discloses details of how it ensures QMS for its products produced in ICs as above except only in respect of in-house facilities.
- 2.5 The company makes a general statement about how it ensures QMS for its products produced in ICs, both at in-house facilities and through third-parties.
- 1 The company makes a general statement about how it ensures QMS for its products produced in ICs, except only with respect to in-house facilities.
- o The company makes no disclosure in this area.

F.II.3 Capacity building in R&D 25%

The company discloses details of its partnerships/collaborations with Index Country public sector research institutes or universities evidencing how they aim to create local research capacity and product development for Index Diseases.

- 5 The company discloses evidence of an access rationale* for all its capacity building Public-Private-Partnerships (PPPs)
- 2.5 The company discloses evidence of an access rationale* for at least half of its capacity building PPPs.
- o The company makes no disclosure in this area.

*An access rationale is a statement of how the company aims to increase local R&D capacities through this partnership

F.II.4 Capacity building in supply chain management 25%

The company discloses details of how it is transparent with other stakeholders across the supply chain to enhance local capabilities by preventing product diversion, stock-outs, counterfeiting, information gaps and improving demand forecasting and drug regulation.

- 5 The company discloses details of how it improves capacity building in Index countries (ICs) by sharing information across the supply chain and is found to do so in at least 5 elements of the supply chain* .
- 3.5 The company discloses details of how it improves 3 - 4 elements of supply chain capacity building in ICs by sharing information across the supply chain.
- 2.5 The company discloses details of how it improves 1- 2 elements of supply chain capacity building in ICs by sharing information across the supply chain.
- o The company makes no disclosure in this area.

*The six elements of the supply chain captured by the Index are preventing drug diversion, implementing anti-counterfeiting measures, preventing stockouts, improving demand forecasting, supply chain alignment and drug regulation

F.III Performance (40%)

F.III.1 Capacity building in QMS and manufacturing standards 20%

Is there evidence that the company assists local Index Country manufacturers or in-house manufacturing facilities to achieve international good manufacturing standards* in the Index countries through training or technology transfer?

* Such as FDA, EMA or the WHO Good Manufacturing Practices or equally recognised national certifications.

- 5 The company has conducted >5 training workshops or consultancies and/or technology transfers across Index countries with the aim of achieving compliance with WHO GMP or equivalent internal standards including in at least one low income country.
- 4 The company has provided at least 2-4 training workshops or consultancies and/or technology transfers in at least one Index country with the aim of achieving compliance with WHO GMP or equivalent internal standards in Index countries.

- 2.5 There is evidence of one example of training workshops or consultancies and/or technology transfers in at least one Index country with the aim of achieving compliance with WHO GMP or equivalent internal standards in Index countries.
- o The company provides no examples of activities in this area.

F.III.2 Capacity building in R&D

20% Is there evidence that the company participates in local partnerships with public sector research institutes or universities in the Index countries with the aim of increasing local capacity for health research (including clinical trials capacity) and product development?

- 5 The company has >5 active long-term (>5 year) engagements in capacity building initiatives with local research institutions such as building clinical trials capacity* OR other research capacities** OR human capital development*** OR funding initiatives such as sponsorships.
- 4 The company is engaged in 5 of the above-mentioned initiatives (<5 years) with the aim of transferring research capacity to Index country organisations AND/OR <5 long-term initiatives.
- 2.5 The company is engaged in 2-4 of the above-mentioned initiatives (<5 years) with the aim of transferring research capacity to Index country organisations.
- 1 The company is engaged in one of the above-mentioned initiatives (<5 years) with the aim of transferring research capacity to Index country organisations.
- o The company provides no examples of activities in this area.

*E.g., training in data management, ethical review board management, software provision.

**E.g., transferring hardware and know-how through training, conferences, exchanges, secondments, co-authorship of papers.

***Human capital development includes training of technicians/pharmacists/other technical skills, including community-level trainings.

F.III.3 Capacity building in supply chain management

20%

The company is engaged in programmes/partnerships with Index Country governments (e.g. MoH/procurement, logistics and distribution agencies) and other distributors to develop locally appropriate supply chain capabilities with the aim of improving affordability, accessibility and quality of the delivered Index Disease products.

- 5 The company is engaged in at least 5 programmes/partnerships with Index country governments and/or other distributors in Index countries to develop locally appropriate supply chain capabilities* OR at least one long-term (>5 years) collaboration to achieve the same.
- 4 The company is engaged in 2-4 programmes/partnerships with Index country governments and/or other distributors to develop locally appropriate supply chain capabilities.*
- 2.5 The company is engaged in at least one programme/partnership with Index country governments and/or other distributors to develop locally appropriate supply chain capabilities.*

- o The company provides no examples of activities in this area.

**Supply chain capabilities include efforts to prevent product diversion, deterioration, stock outs or counterfeiting and improve overall forecasting and procurement management.*

F.III.4 Capacity building in pharmacovigilance

20%

The company is actively engaged in developing and implementing national pharmacovigilance-related programmes in the Index countries.

- 5 The company is engaged in >2 active long-term engagements (>5 years) with leading institutions in country* to build pharmacovigilance capacity according to a national/regional plan, with the aim of improving the effectiveness of pharmacovigilance systems in a large number of relevant countries where it operates.
- 4 The company is engaged in two active long-term engagements as listed above.
- 3 The company is engaged in one active long-term engagements as listed above.
- 2 The company is engaged in *ad hoc* activities (e.g. providing resources/

infrastructure/materials) to support the implementation of pharmacovigilance systems, for only specific disease areas or products or a sub-set of countries.

- o The company provides no examples of activities in this area.

**Leading institutions may include: national pharmacovigilance committees, health and drug regulatory authorities, local pharmaceutical representatives, health services and decision making agencies.*

F.III.5 Initiatives to build other capacities

20%

The company carries out other initiatives (where there is no conflict of interest) with potential for improving capacity of Index Country organisations to address access to medicine in those countries.

- 5 The company shows evidence of 5 or more examples of activities involving reputable* international or national organisations and/or contributing money to a fund run by reputable organisations that run programmes which build other capacities outside the pharmaceutical value chain, and where conflict of interest is fully absent.
- 3.5 The company shows evidence of 2-4 examples of activities as above.
- 2.5 The company has one example of activities as above.
- o The company provides no examples of activities in this area.

** For example, the WHO, iNGOs, or local NGOs.*

F.IV Innovation (10%)

F.IV.1 Innovation in capability advancement

100%

The company has introduced innovative (unique in the sector) approaches to local capacity advancement, working with Index Country organisations to improve the quality and accessibility of products for Index Diseases.

- 5 The company has adopted innovative (unique in the sector) approaches to local capacity advancements in quality and supply chain management (including securing pharmaceutical supply-chain, demand forecasting, pharmacovigilance, and local quality management) and/or research & product development capacity and/or capacities beyond the value chain with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.

- 2.5 The company has adopted innovative (unique in the sector) approaches to local capacity advancements in quality and supply chain management (including activities described above) and/or research & product development capacity and/or capacities beyond the value chain but does NOT disclose progress or resources input.
- o No innovative initiatives discovered in this area.

G Product Donations & Philanthropic Activities

G.I Commitments (25%)

G.I.1 Drug donations

10%

- The company commits to comply with the WHO Guidelines for Medicine Donations – Revised 2010 in the Index countries for all its drug donation activities.
- 5 The company has both a donation policy and makes a commitment to respect the WHO Guidelines for Medicine Donations - Revised 2010 OR commits to ALL of the core components of the guidelines:
 - a) meeting local needs (national treatment policies, essential medicines list)
 - b) participatory approach (communication and collaboration)
 - c) optimised drug donation quality (formulation, GMP standards, matching expiry dates)
 - d) appropriate labelling, packaging and shipment
 - e) affordable value setting and supply chain costs coverage, in all its donations activities, AND is a member of Partnership for Quality Medical Donations (PQMD)
 - 4 The company has a donation policy AND makes a commitment to either respect the WHO Guidelines for Medicine Donations - Revised 2010 OR commits to ALL of its core components above, but is NOT a member of the PQMD.
 - 2.5 The company's commitment in this area is partial or conditional or based on an internal code equivalent to the WHO Guidelines for Medicine Donations - Revised 2010 and contains at least three of the five areas of the guidelines as outlined above.
 - o The company has not committed to respect the WHO Guidelines for Medicine Donations - Revised 2010.

G.I.2 Drug donations

30%

- The company commits to ensuring that donated products are administered to patients in the Index countries.
- 5 The company has a) stringent regular monitoring processes or reporting policies (e.g. financial, supply chain, storage, administration monitoring/reporting) to ensure that the product donations which are donated directly or through intermediaries reach the targeted communities in need, based on

standards set out in the WHO Guidelines for Medicine Donations - Revised 2010 AND b) has internal monitoring/reporting procedures in place to ensure delivery to the intended patients.

- 4 The company has both a) stringent regular monitoring processes or reporting policies (e.g. financial, supply chain, storage, administration monitoring/reporting) to ensure that the product donations which are donated directly or through intermediaries reach the targeted communities in need, based on standards set out in the WHO Guidelines for Medicine Donations - Revised 2010 AND b) rely on trusted partners that guarantee delivery to the intended patients AND reporting is requested (e.g. financial, supply chain, storage, administration). NB: if company only donates through the WHO, tier 5 applies.
- 3 The company has policies to ensure that the product donations which are donated directly or through intermediaries reach the targeted communities in need, based on standards set out in the WHO Guidelines for Medicine Donations - Revised 2010, but has not demonstrated that there are any monitoring or reporting procedures in place.
- 2.5 The company has internal monitoring/auditing procedures in place to ensure delivery to the intended patients, but no policies in place to ensure that the product donations which are donated directly or through intermediaries reach the targeted communities in need.
- 2 The company does not have a policy to ensure delivery to the intended patients but illustrates examples of monitoring performance and certifying that the donations activities carried out on its behalf incorporate standards set out in the WHO Guidelines for Medicine Donations - Revised 2010.
 - 1 The company has a guideline for its donations programmes and donation management intermediaries but does not regularly monitor performance and certify the donations activities carried out on its behalf.
 - o The company makes no commitments in this area.

G.I.3 Sustainable philanthropy

30%

- The company commits to and explains its rationale for investing in health infrastructure-related philanthropic projects (outside of the standard value chain) in the Index countries and their relevance to long-term sustainable access to medicine in Index countries.
- 5 The company has a sustainable, long-term approach to supporting health care infrastructure/capacity advancement in Index countries, set out in specific statements of its strategic approach, which a) is integrated with other activities of the company b) targets local public health needs, c) has specified objectives and d) contains outcome and/or impact assessment.
 - 4 The company has a sustainable, long-term approach to supporting health care infrastructure/capacity advancement in Index countries, set out in specific statements of its strategic approach, which a) targets local public health needs, b) has specified objectives and c) includes outcome and/or impact assessment.
 - 3 The company has a sustainable, long-term approach to supporting health care infrastructure/capacity advancement in Index countries, set out in specific statements of its strategic approach, which a) targets local public health needs and b) has specified objectives.
 - 2 The company has an approach for philanthropic activities in Index countries, but specific evidence which indicates sustainability and targeting of local public health needs are not provided.
 - 1 The company discloses only a general statement in this area without providing details on the areas of its strategic focus or rationale for infrastructure building or objectives.
 - o The company's philanthropic activities are not focused on bringing about sustainable, long-term change in the target Index countries.

G.I.4 Single-drug donations

30% The company commits to delivering single-drug donation programmes, in line with the WHO Guidelines for Medicine Donations – Revised 2010.

- 5 The company commits to >2 single-drug donation programmes AND commits to follow the WHO Guidelines for Medicine Donations - Revised 2010 or all of the following 5 conditions: a) meeting local needs (national treatment policies, essential medicines list), b) participatory approach (communication and collaboration), c) optimised drug donation quality (formulation, GMP standards, matching expiry dates), d) appropriate labelling, packaging and shipment, e) affordable value setting and supply chain costs coverage.
- 4 The company commits to 2 single-drug donation programmes AND commits to follow the WHO Guidelines for Medicine Donations - Revised 2010 or all of the 5 conditions stated above.
- 3 The company commits to 1 single-drug donation programme AND commits to follow the WHO Guidelines for Medicine Donations - Revised 2010 or all of the 5 conditions stated above.
- 2 The company commits to single-drug donation programmes but does not declare that this is the preferred mode of making drug donations or all of the conditions stated above.
- o No evidence of any commitment to single-drug donation programmes.

G.II Transparency (25%)

G.II.1 Drug donations

40% The company discloses the process and criteria for deciding the drug types and destinations for its single-drug donation programmes in the Index countries.

- 5 The company publicly discloses details about drug donation selection criteria including drug types and volumes for ALL of its single-drug donations programmes carried out directly by the company or through intermediaries in the relevant countries for the relevant diseases.
- 2.5 The company publicly discloses details about drug donation selection criteria including drug types and volumes of some of its single-drug donations.
- 1 The company discloses details about drug donation selection

criteria including drug types and volumes of its single-drug donations on an engagement basis only.

- o The company did not provide information nor disclosed upon engagement.
- NS Companies without single-drug donation programmes receive a neutral score.

G.II.2 Drug donations

40% The company discloses detailed information about the type, volume and destination of products that are part of its multi- drug donation programmes donated in the Index countries.

- 5 The company publicly discloses the type, volume and destination (organisation or country) of products that are part of multi-drug donation programmes donated in Index countries.
- 4 The company publicly discloses two of three of the items above.
- 3 The company publicly discloses one of three of the items above.
- 2 The company discloses the equivalent of score 5 on engagement basis only.
- 1 The company discloses the equivalent of score 3 or 4 on engagement basis only.
- o The company makes no disclosure in this area.
- NS Companies without any donation programmes receive a neutral score.

G.II.3 Sustainable philanthropy

20% The company discloses the amount of resources dedicated to and achievements resulting from its philanthropic activities in the Index countries.

- 5 The company discloses a) resources and b) outcome measures or impact assessments for all of its philanthropic activities (e.g. improved allocation of public resources; improved capabilities in sector including numbers of qualified personnel to complete tasks; improved hardware to enable tasks to be undertaken).
- 4 The company discloses a) resources and b) outcome measures or impact assessments for the majority of its philanthropic activities (e.g. improved allocation of public resources; improved capabilities in sector including numbers of qualified personnel to complete tasks; improved hardware to enable tasks to be undertaken).
- 2.5 The company discloses a) resources

at the aggregate level and b) outcome measures or impact assessments for a subset of its philanthropic activities OR the company discloses resources only for each of its philanthropic activities.

- 1 The company discloses resources of its philanthropic activities in aggregate format only.
- o The company makes no disclosure in this area.

G.III Performance (40%)

G.III.1 Drug donations

25% The company monitors outcomes and impact of single-drug donation programmes during the reporting period.

- 5 The company provides evidence of integrating impact assessments on public health (e.g. number of patients reached, epidemiology) into its drug donation program(s) (external or in-house evaluations), and evidence of monitoring and auditing delivery of supply units until the end user, for all drug donation programs.
- 4 The company provides evidence of integrating impact assessments on public health (e.g. number of patients reached, epidemiology) into a subset of their drug donation program(s) (external or in-house evaluations), and evidence of monitoring and auditing delivery of supply units to the recipient(s) for all drug donation programs.
- 3 The company provides evidence of monitoring and auditing outcome measures beyond its own supply chain for all drug donation programs.
- 2 The company provides evidence of monitoring and auditing delivery of supply units to the end user for a subset of drug donation programs, and until delivery to recipient(s) for other drug donation programs.
- 1 The company provides evidence of monitoring and auditing outcome measures along its own supply chain for all drug donation programs.
- o The company has single-drug donation programmes, but does not provide evidence of outcome/ impact assessment.
- NS Companies without single-drug donation programmes receive a neutral score.

G.III.2 Drug donations

25% The value of donated products which were donated based on targeted, needs-based strategic donations programmes to the Index countries during the period of analysis (single-drug donations adjusted for the company size).

- 5 - 1 Divide value of single-drug donations during Index period by company total revenue 2012 & 2013. Revenue-standardised number is scaled and scored.
 - o The company did not provide the value of its single-drug donation programme(s).
- NS Companies without single-drug donation programmes receive a neutral score

G.III.3 Drug donations

25% The scale and scope of donated products to the Index countries during the period of analysis.

- 5 The company has multiple long-term (> 5 years - unlimited) single-drug donation programmes that are strategically set up for eradication or control of Index Diseases, for which there is a public health need that aligns with national or international health priorities (corrected for company size).
- 4 The company has one long-term (> 5 years - unlimited) single-drug donation programmes that is strategically set up for eradication or control of Index Diseases, for which there is a public health need that aligns with national or international health priorities (corrected for company size).
- 3 The company has at least one or more long-term single-drug donation programme(s) (> 5 years) that reach only a subset of patients in Index countries.
- 2 The company has at least one or more single-drug donation programme(s) that reach only a subset of patients in Index countries for a short duration (< 5 years).
- 1 The company has multi-drug donation programme(s) that comply with the WHO Guidelines for Medicine Donations - Revised 2010.
- o The company has no product donation programmes.

G.III.4 Sustainable philanthropy

25% There is evidence that the company's philanthropic activities (excluding drug donation programmes) are aligned with and support implementation of national health system development plans and stated health priorities in the Index countries.

- 5 The company provides evidence of multiple (>10) philanthropic activities that a) are explicitly linked to national and/or international health priorities, b) are long-term engagements, c) have specific objectives AND d) the company provides evidence of outcome measures or impact assessment (in-house or outsourced) for some activities.
- 4 The company provides evidence of 1-10 philanthropic activities that a) are explicitly linked to national and/or international health priorities, b) are long-term engagements, c) have specific objectives AND d) the company provides evidence of outcome measures or impact assessment (in-house or outsourced) for some activities.
- 3 The company provides evidence of multiple (>10) short-term philanthropic activities that a) are explicitly linked to national and/or international health priorities and b) have specific objectives that support a strategic longer term objective specified by the company.
- 2 The company provides evidence of 1-10 philanthropic activities that a) are explicitly linked to national and/or international health priorities, b) are long-term engagements OR support a strategic longer term objective specified by the company.
- 1 The company provides evidence of short-term philanthropic activities that a) are explicitly linked to national and/or international health priorities.
- o The company provides no evidence that philanthropic activities are related to national and/or international health priorities.

G.IV Innovation (10%)**G.IV.1 Innovation in product donations**

50% The company has introduced innovative (unique in the sector), sustainable and impactful approaches to managing drug donations, which may result in increased effectiveness and efficiency.

- 5 The company has designed and implemented innovative (unique in the sector) approaches to managing product donations with significant potential to improve access to medicine and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has implemented innovative (unique in the sector) approaches to managing drug donations but does NOT disclose progress or resources inputs.
- o The company has no innovative initiatives discovered in this area.

G.IV.2 Innovation in sustainable philanthropy

50% The company has introduced innovative (unique in the sector) approaches to philanthropic programmes to make it more sustainable and linked to better health outcomes in the Index countries, which may result in sustainable health improvements.

- 5 The company has designed and implemented innovative (unique in the sector) approaches to philanthropic programmes in relevant countries which may result in sustainable health improvements and supports this with evidence of progress and/or human or financial resources invested.
- 2.5 The company has implemented innovative (unique in the sector) approaches to philanthropic programmes in relevant countries which may result in sustainable health improvements but does NOT disclose progress or resources inputs.
- o The company has no innovative initiatives discovered in this area.

Abridged Summary of Academic and Technical Sources in the Methodology Development and Data Analysis of Index 2014

■ Introduction

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- 4 AstraZeneca "AstraZeneca to acquire Bristol-Myers Squibb share of global diabetes alliance assets" Web. 23 Oct. www.astrazeneca.com/Media/Press-releases/Article/20121218--AstraZeneca-acquire-Bristol-Myers-Squibb-share-global-diabetes-alliance-assets/
- 5 Daiichi Sankyo "Announcement Regarding Merger Between Sun Pharma and Daiichi Sankyo's Subsidiary Ranbaxy and Resulting Change in Subsidiary" Web. 14 Oct 2014. www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006111.html
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- 16 WTO "The least developed get eight years more leeway on protecting intellectual property" 12 June 2013. Web. Oct 14 2014. www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm
- 17 CPTech "Pharmaceutical company lawsuit (42 applicants) against the Government of South Africa (ten respondents)" Web. 23 Oct 2014. <http://www.cptech.org/ip/health/sa/pharmasuit.html>
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■ Product & pipeline analysis

- 1 Shantanu N, Edith H "New technology needs for non-communicable diseases in developing countries: a landscaping study" Results for Development Institute 2012. Web. 24 Oct, 2014. www.healthresearchpolicy.org/assessments/new-technology-needs-noncommunicable-diseases-landscaping-study

■ General Access to Medicine Management

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Definitions

For the sources used in determining these definitions, please contact the Access to Medicine Foundation.

Access provisions/Access orientated terms and conditions

[Working definition, used for analysis]

A provision to ensure that public health needs are taken into consideration during the R&D phase. A pro-access R&D agreement will have explicit terms embedded within it that facilitate availability, accessibility and affordability for patients in Index countries (e.g., non-exclusivity in specified territories, price caps, licensing strategies, supply guarantee, waiving patent rights, royalty-free provisions).

Access rationale (for R&D capacity building)

[Working definition, used for analysis]

A statement of how the company aims to increase local R&D capabilities and address local labour market gaps through its public-private partnerships (PPPs) in Index countries.

Adaptive research/products

[Working definition, used for analysis]

Adapting existing/registered New Chemical Entities (NCEs), New Biological Entities (NBEs) or other relevant medicines, therapeutic and preventative vaccines, diagnostics, vector control products and microbicides to address an unmet need in the Index countries e.g., new demographic segments (e.g., infants/children, pregnant women), environmental conditions (e.g., heat-resistant formulations), or new formulations (e.g., fixed-dose combinations).

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 stock availability, based on the explicit needs of a country. Donations made during emergency situations, such as conflict situations and natural disasters, are included here.

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.

Anti-competitive practice

Any practice by a company or group of companies that has, is intended to have, or is likely to have, the effect of restricting, distorting or preventing competition in order to maintain or increase their market position and/or profits. Anti-competitive behaviour leads to disadvantage or detriment of competitors, customers and suppliers such that higher prices, reduced output, less consumer choice, loss of economic efficiency and misallocation of resources (or combinations thereof) are likely to result.

Balanced scorecard

A strategic planning and management system that is used to align business activities to the mission, vision and strategy of the organisation, improve internal and external communications, and monitor organisation and business unit performance against strategic goals.

Beyond the (pharmaceutical) value chain

[Working definition, used for analysis]

Activities beyond the scope of the company's normal operations and distribution channels.

Breaches

Acts that are in violation of or non-compliant with laws, rules, guidelines or codes.

Breaches of clinical trial conduct

Acts that are in violation/disregard of or non-compliant with laws, rules, guidelines or codes.

Clinical-stage development

Clinical-stage development refers to medicines, microbicides and vaccines that are under investigation in one or more of the clinical trial phases. These phases in medical research and drug development generate safety and efficacy data in humans.

- Phase I: In these studies a study health intervention (e.g., medicine) is investigated in a small group of healthy volunteers. This phase is to determine the safety profile of the intervention (and how medicines can be metabolised and excreted).
- Phase II: In these initial studies a study medicine is investigated in a small group of patients to determine efficacy to treat a specific condition and determine safety profiles.
- Phase III: During this phase the efficacy and safety of a health intervention (e.g., medicine) is studied in different large patient populations. Different doses are tested and its efficacy and safety are compared to other therapeutic agents. When favourable results are demonstrated in this phase, regulatory approval for marketing can be obtained.

- Phase IV: These are studies that are conducted after market approval. Typically, they investigate risks, benefits and optimal use in a large population.

Code of conduct

Statement of principles, values and rules that establishes a set of expectations and standards on responsible practices by an organisation, government body, company, affiliated group or individual. This includes minimal levels of compliance and disciplinary actions for the organisation, its staff and volunteers

Competition law

Competition law seeks to promote or maintain a competitive marketplace by regulating anti-competitive behaviour by companies. In the sphere of pharmaceutical regulation, competition law can often involve different actions taken by companies to delay or hamper the entry to market of generic competition.

Compulsory licence

A formal ruling set by law or arbitration by a government to allow a third party (e.g., pharmaceutical manufacturer) to produce a patented product or use a patented process without needing to obtain consent of the patent owner.

Conflict of interest

A situation where a professional or a company has a vested interest that creates a risk that professional judgement or actions will be unduly influenced. The interests at stake could be, for example, money, status, knowledge or reputation.

Data exclusivity

Protection of originator pharmaceutical company's data preventing other parties from using these data for a commercial purpose. Concretely, this protection prevents generic product manufacturers from proceeding to clinical trials and health authorities from evaluating generic product market authorisation applications during this period.

Data transparency

Sharing patient level clinical study reports (CSRs) with trusted external parties (e.g., universities, research institutes). This refers to sharing data for research purposes only.

Declaration of Helsinki

A set of principles regarding human experimentation developed for members of the medical community. This code of conduct is for ethical clinical trial conduct, and essential principles revolve around respect for the individual and the right to make informed decisions. It aims to protect the rights and wellbeing of the individual participating in human research. The Declaration of Helsinki was initially adopted in 1964 as a reaction to the lack of a general accepted code of conduct for human research and is frequently updated (last update: 2013).

Doha Declaration (on the TRIPS Agreement and Public Health)

An agreement between governments affirming that the TRIPS agreement should not prevent TRIPS member countries from protecting public health interests. The Doha Declaration (14 November 2001) clarified the flexibilities of TRIPS member states in navigating pharmaceutical patents. It granted member states the right to grant compulsory licences; to determine what constitutes a national emergency or extreme urgency; and that each member is free to establish its own regime for the exhaustion of intellectual property rights.

Drug diversion

Channelling lower-priced medicines from developing countries into developed countries or from lower-income segments to high-income segments, or from public to private sector, within a country.

Drug recall

Actions taken by a company or medicine regulatory authority to remove from the market products or batches of products that are found to be either defective or potentially harmful. Recalls include those due to both packaging and quality or safety issues. The Index captures those recalls of products that are subject to GMP standards, i.e., medicines, vaccines, microbicides and other medicinal products for human use.

Early-stage development

Early-stage research and development refers to discovery and pre-clinical research.

- Discovery research: Basic research and screening methods (target identification, target validation, target to hit, hit to lead, and lead optimization).
- Preclinical research: Research aimed at assessing potential efficacy and toxicity prior to testing a product. Typically, both *in vitro* and *in vivo* tests are performed. During *in vitro* tests data is collected to determine chemical and biological properties of products in an isolated laboratory setting. When results are positive, *in vivo* tests are used to determine toxicity and ability to treat or prevent a particular disease or symptom in living animals.

Equitable pricing

[Working definition, used for analysis]

A targeted pricing strategy that ensures the poor gain access to medicine by affordable pricing that is locally appropriate, implemented on a case-by-case basis.

Ethical clinical trial conduct

Guidelines regarding ethical and scientific quality standards for designing, conducting, recording, and reporting findings from trials that involve participation of human subjects. Rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society. Principles from Good Clinical Practice and the Declaration of Helsinki, among others, are used as guidelines to guarantee ethical clinical trial conduct

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.

Evergreening

Patent clusters around an existing medicine is patenting of new forms or other minor variations of existing products that have no additional therapeutic value and display limited inventiveness. This can be used to prolong patent protection in an inappropriate manner, creating a negative effect on access to medicines, as well as on further innovation – a strategy referred to as ‘evergreening’. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) defined evergreening as a term popularly used to describe patenting strategies “when, in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term”.

False Claims Act

The False Claims Act is a piece of federal legislation in the US which imposes penalties on people or companies who defraud government programs. In the pharmaceutical sector, there have been several large scale settlements agreed under this Act for activities involving off-label promotion, amongst other things.

Forward integration (of the supply chain)

Integration of processes down the supply chain, for example through collaboration with warehouses, distributors, health facilities and other downstream partners.

Good Manufacturing Practices (GMP)

Guidelines for ensuring that products are consistently produced and controlled according to

quality standards. It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. WHO has established detailed guidelines for GMP. Many countries have formulated or harmonised their own requirements for national GMP, often based on WHO GMP.

Healthcare infrastructure

Basic physical and organisational structures needed to deliver health care. This extends from healthcare-related services provided to communities, hospitals and other healthcare-related facilities.

Impact assessment

Evaluating the effects that a policy, programme or activity has on the health of a population, and the distribution of those effects within the population. This includes the effect on patient outcomes, epidemiology, healthcare infrastructure and other effects that relate to public health. It can include also wider socio-economic impacts. It can be performed by a company or by a third party.

Innovative research/products

[Working definition, used for analysis]

Development of New Chemical Entities (NCEs), New Biological Entities (NBEs) or other medicines, therapeutic and preventative vaccines, diagnostics, vector control products, and microbicides.

Inter-country equitable pricing

A targeted pricing scheme that differentiates prices between countries and takes into account affordability of the poorest countries.

International Conference on Harmonisation Guideline for Good Clinical Practice (ICH-GCP)

An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. GCP is set up by The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that aims to harmonise technical requirements for registration of medicines for human use globally.

Intra-country equitable pricing

A targeted pricing scheme where a company has different pricing tiers within a country based on the socioeconomic profiles of different population segments, taking into account affordability for the poorest segments in the country.

IP sharing partnerships*[Working definition, used for analysis]*

Sharing of intellectual property (e.g., compound libraries, patented compounds, processes or technologies) by a company to an external party (e.g., WIPO Re:Search, DNDi, MMV, TB Drug Accelerator) that use the IP for R&D targeting Index Diseases.

Key Performance Indicator

Quantifiable measures that are used to measure progress against set goals and targets and/or critical success factors.

Licensing agreement

A contract in which the patent holder allows the contracting party to use the patent, either against a payment of royalties or free of charge for a defined period of time.

Lobbying

Any activity carried out to influence a government or institution's policies and decisions in favour of a specific cause or outcome. Direct lobbying occurs via communication with a legislator, legislative staff, legislative body or government employee who may participate in the formulation of legislation. Grassroots lobbying is an attempt to influence legislation by encouraging the public to contact legislators about a specific issue. Even when allowed by law, these acts can become distortive if disproportionate levels of influence exist.

Lowest pricing tier*[Working definition, used for analysis]*

The lowest price point within a company's equitable pricing structure. This price is offered to the poorest segment (i.e., to the poorest population group within a country, or to the poorest country (or countries) within a larger group of countries). This includes the price at which products are sold to the public sector within a poor country or sales to LICs and/or LDCs.

Medicines Patent Pool

An organisation that aims to increase access to priority HIV medicines. It invites patent holders to negotiate licences allowing other to develop adapted formulations or sell generic version of patented medicines in developing countries. It sub-licenses to other manufacturers to develop, produce and sell medicines under strict quality assurance.

National pharmacovigilance systems

Nationwide systems or projects (in Index countries) to establish and support a database of adverse drug reactions for informed regulatory decision making; and to improve the rational and safe use of medical drugs, the assessment and communication of the risks and benefits of drugs on the market, and the education of patients. A comprehensive national pharmaco-

vigilance system should include efficient surveillance, effective communication methods, and collaboration with the relevant stakeholders to ensure pharmacovigilance activities are incorporated.

Non-assert declaration

A legally binding commitment that contains an explicit set of conditions, including permitted actions and designated territories, for which the patent owner commits not to enforce patent rights. This allows for a generic version of a patent protected product to be produced in a resource-limited setting.

Off-label promotion

Off-label use is defined as use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the FDA approved label. It is a violation of the False Claims Act (in the US) for pharmaceutical companies to promote pharmaceuticals for off-label use.

Outcome measures*[Working definition, used for analysis]*

Evaluating measures that are related to operationalisation of a donation programme. This includes quality control along the entire supply chain from manufacturing site to recipients and from recipients to the end-user. Reporting or monitoring are common procedures for evaluating outcome measures. Outcomes can be measured by the company or provided by recipients of the donated products.

Parallel importation

Import of a patented or trademarked product from a country where it is marketed, usually to obtain a lower price.

Partnering Against Corruption Initiative (PACI)

A voluntary multi-stakeholder initiative set up under the banner of the World Economic Forum. It aims to address corruption through raising business standards and seeking company commitment to meet certain standards of behaviour.

Patent

An intellectual property right providing an inventor with a legal monopoly to prevent others from making, using, or selling the new invention for a defined period of time, subject to a number of exceptions. Also includes the obligation to publish the invention. A patent does not automatically mean the product is safe for consumers or that it can be supplied. Patented medicines still have to go through rigorous testing and approval before they can receive market authorisation.

Performance management systems

Formal and informal mechanisms, tools, processes and networks used by organisations to manage and reward performance in line with corporate and functional strategies and goals. This includes performance measurement, i.e., collecting, analysing and reporting information regarding the performance of an individual, group or organisation in order to track progress towards set goals.

Performance measures

Indicators used to assess progress towards set goals and targets.

Period of analysis*[Working definition, used for analysis]*

For the 2014 Index, the time period for which data will be analysed covers fiscal years 2012 and 2013, where company activities must be ongoing between June 2012 and the end of May 2014, as this is the cycle of the Index. Programmes that have ended before June 1st 2012 are not included. Additionally, any activities that were already assessed in the 2012 Index will not be scored as innovative or new in relevant indicators. The Index team assesses most recent policies, codes and stances, up to final submission.

Pharmacovigilance

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Medicines need to be monitored, and any adverse drug reactions need to be remedied in a timely manner through pharmacovigilance systems.

Poorest segment*[Working definition, used for analysis]*

The lowest-income population segment within a given country, or the poorest country (or group of countries) worldwide. The poorest segment a company sells a product to may be a lower-income population segment, and not the lowest-income segment within a country.

Price point*[Working definition, used for analysis]*

The price of a product at a particular point in the supply chain. For example, wholesaler/ex-factory/ex-manufacturing/pre-tax/list price/marginal cost/Maximum Retail Price, etc.

Pro-access*[Working definition, used for analysis]*

An adjective to ensure positive provisions that address public health needs. A pro-access licence will have explicit terms embedded within it that ensure timely medicine development and market registration, safe and acceptable products delivered to populations who need them.

Product development partnership

Research and development of compounds/products performed jointly by more than two parties where knowledge and/or expertise and resources are shared towards one or more common goals. This could involve academic institutions, government agencies and divisions, pharmaceutical companies, biotechnology companies and other public or private organisations.

Product donation programmes

[Working definition, used for analysis]

Gifts of products (medicines and vaccines only) that are ongoing during the period of analysis. These are subdivided into structured donation programmes and *ad hoc* donation programmes.

Rational use

The scientifically sound use of medicines. Rational use requires that patients receive the appropriate medicine, in the proper dose, for an adequate period of time, and at a cost which is affordable to them and their community.

Special 301 Watch List

The Special 301 Report is prepared annually by the Office of the United States Trade Representative (USTR) under Section 301 as amended of the Trade Act of 1974. The reports identify trade barriers to US companies and products due to the intellectual property laws, such as patents, in other countries. The annual report contains a 'Priority Watch List' and a 'Watch List', identifying countries whose intellectual property regimes are deemed of concern to US companies.

Spurious, falsely-labelled, falsified, counterfeit products

The term counterfeit medical product describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Substandard batches of or quality defects or noncompliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting. Medical products (whether generic or branded) that are not authorised for marketing in a given country but authorised elsewhere are not considered counterfeit.

Stringent approval

Positive opinions or tentative approval for medicines used exclusively outside the ICH region, under any of the following special regulatory schemes are recognized as stringent approval:

- Article 58 of European Union Regulation (EC) No. 726/2004
- United States FDA tentative approval (for antiretrovirals under the PEPFAR programme)

- Similarly, the WHO Prequalification Programme works in close cooperation with national regulatory agencies and partner organizations, with the aim of making quality priority medicines (for diseases such as HIV/AIDS, malaria, tuberculosis and for reproductive health, amongst others) available for the benefit of those in need.

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 based on long-term, targeted donation programmes based on country needs, usually targeted to control, eliminate, or eradicate a disease.

Subsidiary

[Working definition, used for analysis]

A company that is owned or controlled by another firm or company; subsidiaries include firms in which a company owns more than 50% of the outstanding voting stock, as well as firms in which a company has the power to direct or cause the direction of the management and policies.

Sustainable philanthropy

[Working definition, used for analysis]

Providing grants to other organizations to improve local healthcare capabilities. It includes the donation of financial assistance only.

Technology Transfer

The process by which any party gains access to another party's technical information or know-how and successfully learns and absorbs it into its research, development or manufacturing processes.

Tiered pricing

A pricing scheme where a company adapts product prices based on the purchasing power of consumers in different geographic or socio-economic segments. Tiered pricing that takes into account affordability of medicines and other products for low-income segments is a form of equitable pricing.

Tracer product

[Working definition, used for analysis]

Products that account for highest sales revenue in relevant countries covered by the Index for which equitable pricing strategies are available.

Trade association

An organisation founded and funded by companies from a particular industry, through which companies can collaborate with each other on activities such as standardisation, lobbying, education, and other areas.

Trade Related Aspects of Intellectual Property (TRIPS) Agreement

A multilateral agreement that was issued to protect Intellectual Property rights around the world under international rules, where all countries must make patents eligible for pharmaceutical products and processes. The World Trade Organization's TRIPS Agreement covers five broad issues:

- How basic principles of the trading system and other international intellectual property agreements should be applied
- How to give adequate protection to intellectual property rights
- How countries should enforce those rights adequately in their own territories
- How to settle disputes on intellectual property between members of the WTO
- Special transitional arrangements during the period when the new system is being introduced.

TRIPS Flexibilities

In the context of public health, these typically refer to the flexibilities within the TRIPS Agreement confirmed by the Doha Declaration (2001) that allow WTO members to implement TRIPS in a "manner supportive of WTO members' right to protect public health...", and to use the measures within TRIPS for this purpose. For example, countries may permit manufacturers to use a patented invention to obtain marketing approval before expiry of the patent and without the permission of the patent owner.

United Nations Global Compact (UNGC)

A UN administered agreement that encourages businesses to align with ten principles of responsible behaviour, including fighting corruption. However, it is not a performance-assessment tool, and is not enforceable.

Voluntary licence

A contract through which the patent holder allows permits the contracting party to use the patent.

Whistleblower

An informant who exposes wrongdoing by a company that threatens public interest, such as neglect or abuse, within an organisation, either internally or publicly, in the hope of stopping it.

WHO Prequalification

A service provided by WHO to assess the quality, safety and efficacy of certain medicinal products (mainly for HIV/AIDS, TB, malaria and reproductive health).

Acronyms

ABPI	Association of the British Pharmaceutical Industry
ACHAP	African Comprehensive HIV/AIDS Partnership
AIDS	Acquired Immuno Deficiency Syndrome
AMPATH	Academic Model Providing Access to Healthcare
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral drug
COPD	Chronic Obstructive Pulmonary Disease
CROs	Clinical Research Organisations
DNDi	Drugs for Neglected Diseases initiative
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EML	WHO Model Essential Medicines List
FDA	Food and Drug Administration (US)
GHIT	Global Health Innovative Technology Fund
GAVI	Global Alliance for Vaccine Immunization
GCP	Good Clinical Practices
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
GNI	Gross National Income
HIC	High-income country [World Bank]
HIV	Human Immunodeficiency Virus
ICH-GCP	International Conference on Harmonisation guideline for Good Clinical Practice
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IP	Intellectual Property
IPASA	Innovative Pharmaceutical Association of South Africa
KPI	Key Performance Indicator
LDC	Least Developed Country [United Nations]
LIC	Low-income country [World Bank]
LMIC	Lower-middle income country [World Bank]
MDG	Millennium Development Goals
MDR-TB	Multidrug-resistant Tuberculosis
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NEVLS	Non-Exclusive Voluntary Licences
NGO	Non-governmental organisation
NCDs	Non-communicable Diseases
NTDs	Neglected Tropical Diseases
NTD-SCF	Neglected Tropical Diseases Supply Chain Forum
PAHO	Pan American Health Organization
PACI	Partnering Against Corruption Initiative
PEPFAR	President's Emergency Plan for AIDS Relief
PhRMA	Pharmaceutical Research and Manufacturers of America
PDP	Product Development Partnership
PPP	Public-Private Partnership
R&D	Research and Development
TRIPS	Trade Related Aspects of Intellectual Property Rights
UMIC	Upper-middle income country [world bank]
UN	United Nations
UNGC	United Nations Global Compact
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
UNAIDS	Joint United Nations Programme on HIV/AIDS
TB	Tuberculosis

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access to
medicine
FOUNDATION

Access to Medicine Foundation
Scheepmakersdijk 5a
NL-2011 AS Haarlem
The Netherlands

W www.atmindex.org
E info@atmindex.org
T +31 (0)23 533 91 87