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Access to Medicine Index flags slowing momentum, especially in LMICs

The Access to Medicine Foundation, has recently released an Index ranking and evaluating 20 of the world's leading pharmaceutical companies according to their efforts to expand access to their products for people living in low-and middle-income countries. The 2024 Index highlights that, despite progress in several areas, the overall momentum has slowed compared to the previous Index

Every two years, the Access to Medicine Index evaluates 20 of the world's leading pharmaceutical companies according to their efforts to address access to medicine for people living in low- middle-income countries (LMICs), where access gaps are the greatest. By ranking companies on their performance on priority access-to-medicine topics across three Technical Areas: Governance of Access, Research & Development (R&D), and Product Delivery, the Index aims to identify Best Practices, track progress, and highlight where critical action is needed to address shortcomings. In this ninth iteration of the Index, Novartis ranks as the top company for the first time, followed closely by GSK, which has previously been in first position across all Index reports.

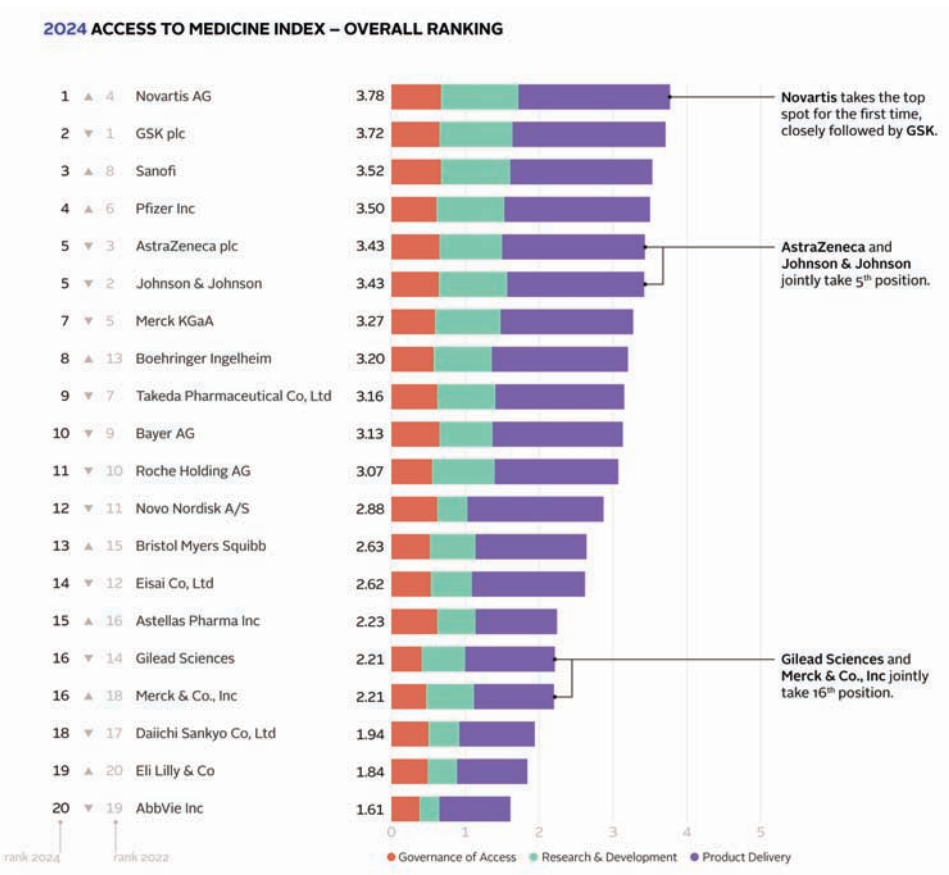
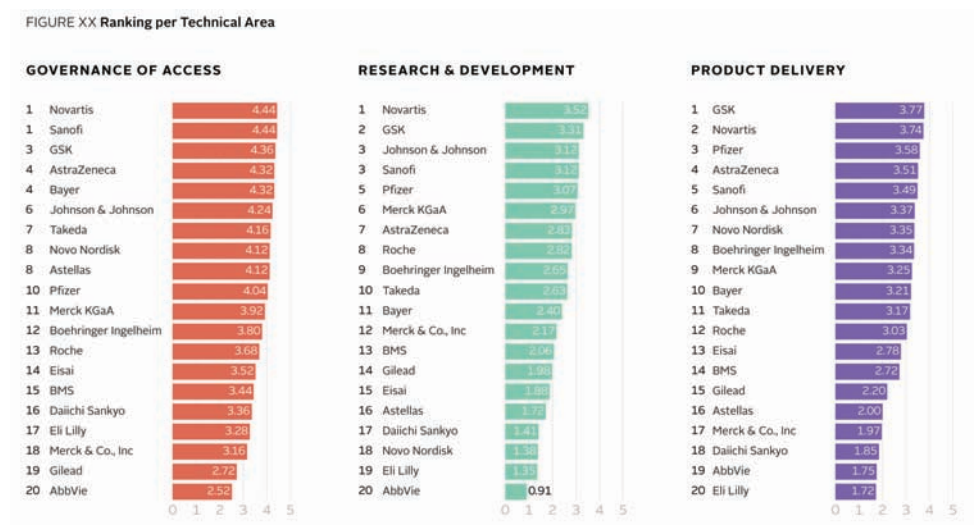


FIGURE XX **Ranking per Technical Area**



How do the companies compare in 2024?

◆ **Novartis and GSK stand out as the two leaders:** Novartis (1st) and GSK (2nd) rank within the top three performers across all three Technical Areas, with Novartis leading in Governance of Access and Research & Development (R&D). The company has robust governance structures in place and demonstrates how it puts policy into practice. For example, Novartis implements a process to measure patient reach (as assessed in Governance of Access) and demonstrates an increase in the number of patients reached through access strategies for its products assessed by the Index within Product Delivery. In addition, Novartis performs well in R&D access planning for both communicable and non-communicable diseases (NCDs), where it has robust plans in place, with broader country coverage compared to peers. GSK demonstrates strong performance across the board, leading in Product Delivery, with a particularly strong performance in access strategies and licensing. It continues to have the largest priority pipeline in comparison to peers, with R&D access plans in place for most pipeline candidates.

◆ **Just behind the leaders, four companies rank as high performers Sanofi, Pfizer, AstraZeneca and Johnson & Johnson**, ranked 3rd to 5th respectively, rank above average in all Technical Areas, leaving little separation between them in terms of overall performance. Sanofi (3rd) and Pfizer (4th) have re-entered the top five, after dropping out in the previous Index. Sanofi leads in Governance of Access (alongside Novartis) and performs strongly in R&D, with a diverse pipeline of projects for NCDs and priority diseases. Both Sanofi (3rd) and Pfizer (4th) stand out for engaging in large-scale inclusive business models to reach vulnerable populations, namely the Sanofi Global Health Unit and the Pfizer Accord for a Healthier World. AstraZeneca and Johnson & Johnson are tied in 5th place, both performing strongly overall. AstraZeneca performs strongly in Governance of Access and Product Delivery, demonstrating Best Practice in measuring the outcomes of its access strategies and its

process for tracking the number of patients reached. Johnson & Johnson performs well in R&D, with access plans for all late-stage candidates – although its number of priority pipeline candidates has fallen significantly since the previous Index. Within Product Delivery, it performs well in health system strengthening and supply chain strengthening..

◆ Eight middle-performing companies show strengths in certain areas, but lack consistency in their performance across all Technical Areas

Merck KGaA (7th) performs well in R&D; despite a decreasing priority pipeline, it still has access plans in place for all late-stage candidates. It has an above average performance in Governance of Access and Product Delivery. Boehringer Ingelheim (8th) is one of the biggest risers, ranking in the top ten for the first time, due to strong performance in capacity building and health system strengthening initiatives. Additionally, it has also strengthened its strategy to ensure a continuous supply of medicines in low- and middle-income countries (LMICs). Takeda (9th) has a comprehensive access-to-medicine strategy integrated within its overall corporate strategy, as assessed within Governance of Access. It has R&D access plans and access strategies for marketed products; however, they tend to focus on a limited number of LMICs. Bayer (10th) rounds out the top ten, demonstrating a strong performance in Governance of Access and has access strategies for its products across different income classifications; however, data on the outcomes of some of these strategies is limited. Bayer demonstrates Best Practice, alongside Roche (11th), for registering its products widely in LMICs. Although Roche has a large pipeline predominantly focusing on NCDs, it lacks access plans for some of these projects. Novo Nordisk (12th) performs well in Product Delivery, implementing equitable access strategies in LMICs and reporting the outcomes of these strategies, although it has a comparatively small pipeline

FIGURE 1 **Industry performance across Governance of Access**

Across the industry, strong performance is seen in the priority topics of governance and strategy and responsible business practices, but there is room for improvement in measuring and reporting patient reach.

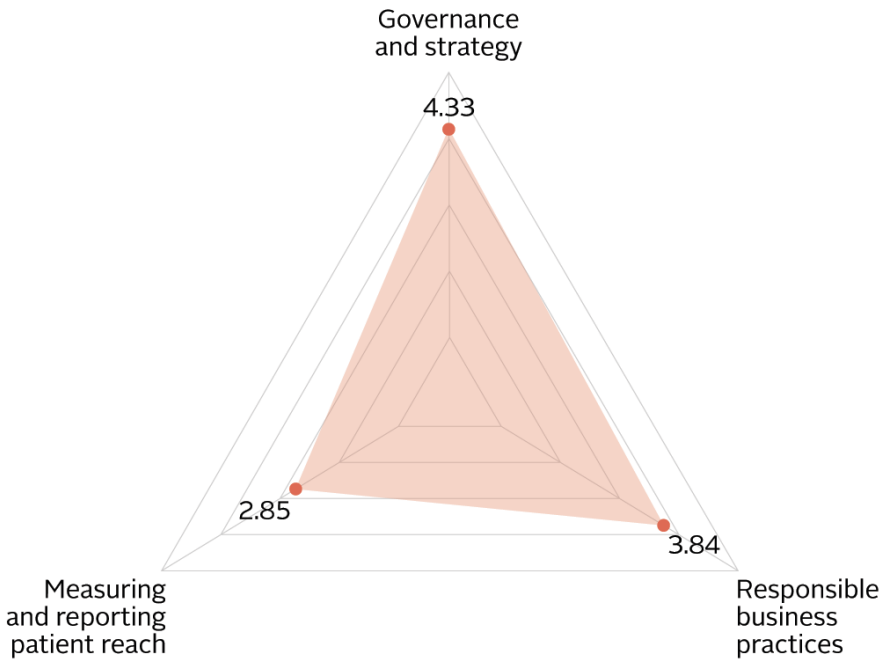
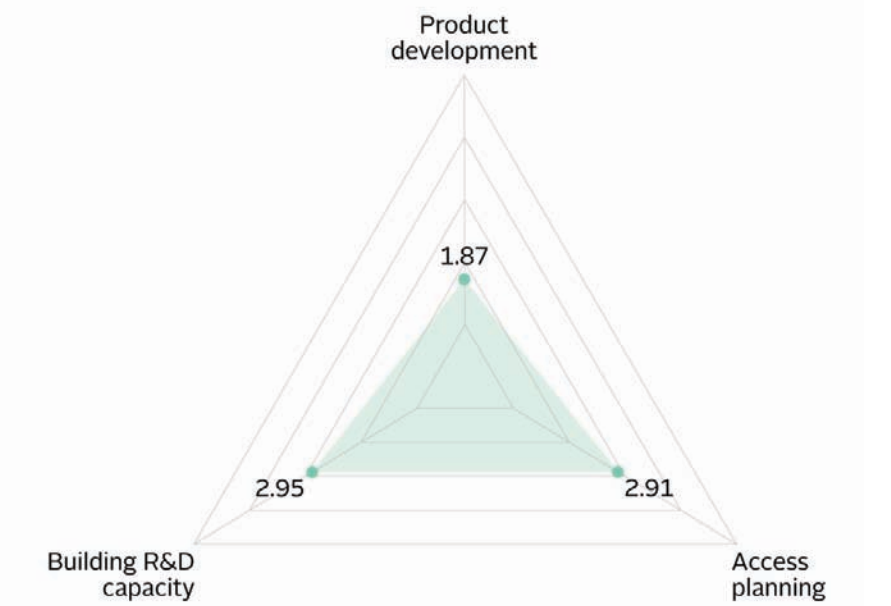


FIGURE 2 **Industry performance across Research & Development**

Across the industry, companies have a relatively poor performance for developing products to target diseases analysed by the Index. Some companies perform well in R&D capacity building and access planning but the geographic reach of plans is limited.



compared to other companies. Bristol Myers Squibb (13th) has recently launched an inclusive business model to improve access to its innovative therapies in low-resource settings but falls behind other companies in Governance of Access. Eisai (14th) continues to perform strongly in long-term product donations and in R&D for priority diseases but many of its late-stage pipeline projects do not have an access plan.

◆ Six low-performing companies make up the bottom ranking, with below-average performance across most of the Technical Areas

Astellas (15th) has a consistent performance in Governance of Access, where it has a robust set of controls to promote ethical conduct and mitigate risk but falls behind its peers in R&D and Product Delivery. Gilead and MSD, (tied in 16th), both perform well in voluntary licensing and supplying products through supranational mechanisms. However, they fall short in terms of Governance of Access and access planning for R&D projects. Daiichi Sankyo (18th) performs well in health system strengthening; however, it remains in the lower ranks of all Technical Areas. Eli Lilly (19th) rises one spot, newly engaging in technology transfer for some of its products, but still ranks in the lower tiers in all Technical Areas. AbbVie (20th) performs poorly across all areas and is the only company that did not share any processes for measuring and reporting patient reach.

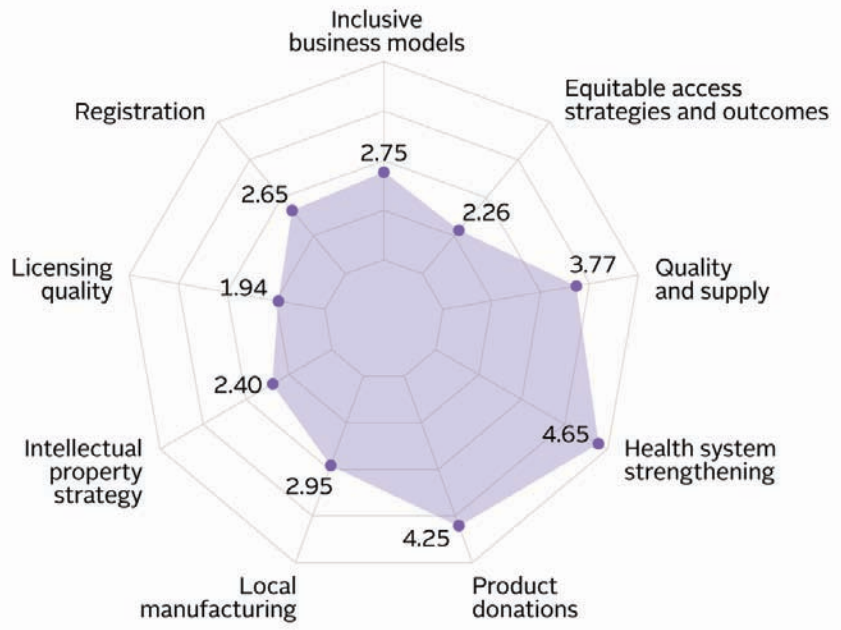
Industry performs well on policy, but lags in practice

The 2024 Access to Medicine Index shows an overall stagnation in pharmaceutical companies' efforts to improve access to their essential healthcare products across low- and middle-income countries (LMICs), which is evidenced by uneven progress across the Technical Areas assessed by the Index. Companies are maintaining comprehensive policies and promising commitments to expand access, with the Index identifying specific initiatives from several companies aimed

at addressing chronic gaps in underserved regions. However, progress in the implementation of these initiatives is somewhat limited. Notably, with the increased emphasis on assessing the outcomes of companies' policies and practices in the 2024 Index, there has been a global decrease in performance across the 20 companies. This indicates that, although leading companies are making efforts to bridge the gap in equitable access, there is still a considerable way to go in achieving the United Nations Sustainable Development Goal of universal health coverage through equitable access to affordable essential medicines and vaccines. An overall industry analysis across the 15 priority topics within the three Technical Areas – Governance of Access, Research & Development (R&D) and Product Delivery – unpacks companies' performance in more detail, revealing where companies perform strongly and where progress needs to be accelerated.

FIGURE 3 **Industry performance across Product Delivery**

Companies perform well in health system strengthening, product donations, and quality and supply. However, performance is lower in local manufacturing, intellectual property strategy, registration and inclusive business models, with even greater gaps in licensing quality and equitable access strategies.



◆ Governance of Access

Overall strong industry performance and emerging efforts to measure patient reach

As companies continue to prioritise access to medicine in LMICs within their corporate strategies, it is encouraging to see that most companies (17) now cover all therapeutic areas within their access-to-medicine strategies (14 did this in the 2022 Index). An additional company now also demonstrates direct board-level responsibility for access, bringing this total up to 17 from 16 in 2022. While corporate policies and practices inform the activities and initiatives companies undertake to expand access to their healthcare products, it is also important to ensure that these activities are supported by processes that can measure the impact they have on patients. Consequently, for the first time, this Index iteration also assessed how companies measure and report on patient reach, finding that 19 of the 20 companies report processes and 17 publicly report the resulting numbers. While some of these processes can be further refined by, for example, considering different contexts and scenarios; working closely with partners to collect and report on-the-ground data; and improving collaboration and knowledge sharing among industry peers, these findings illustrate encouraging steps from industry. (See figure 1)

◆ Research & Development

Beyond improving access to their existing products, companies also hold the key to developing products that can address unmet healthcare needs. However, the 2024 Index finds that companies are increasingly shifting away from addressing priority R&D gaps for diseases, such as malaria and tuberculosis, which pose a disproportionate disease burden in LMICs. This is reflected by a shrinking priority pipeline (253 projects versus 367 in the previous Index) and fewer new priority R&D projects added to the pipeline (93 projects compared to 151 in the previous Index).

In addition, companies are increasingly focusing their corporate strategies and, consequently, their R&D efforts on diseases that are not covered by the Index. Industry performance on access planning varies – with 14 of 20 companies having systematic policies to plan for access for all pipeline candidates from Phase II onwards. However, only four companies – Boehringer Ingelheim, Johnson & Johnson, Merck KGaA and Takeda – were found to have implemented this policy for all late-stage candidates. Despite a high proportion of pipeline candidates having access plans in place, an increased focus on the quality and geographic scope of these access plans in the 2024 Index analysis revealed considerable gaps. Specifically, companies only plan to make their pipeline candidates available in six countries in scope on average (out of a total of 113), meaning people in many LMICs will face delays in accessing the latest innovations once they reach the market. The gap is even greater in the quality of access plans for NCDs, where less than half of plans include any additional considerations beyond commercial plans for registration.(See figure 2)

◆ Product Delivery

Strong efforts in health system strengthening and quality and supply, but stagnation in voluntary licensing.

Companies have shown a strong performance in health system strengthening and quality and supply, with wide engagement in quality health system strengthening initiatives, and fulfilling most criteria for mechanisms to ensure continuous supply of medicines, such as managing buffer stocks and strengthening supply chains. Similarly, most companies have policies to facilitate product donations, and 11 companies are engaging in long-term donation programmes for neglected tropical diseases.

Company performance varies significantly in product registration; while several companies have demonstrated their ability to register their products in a broad number of countries (see Best Practice on p.xx), almost half of products analysed (49 per cent, 87/179) are not registered in any of the countries with the highest disease burdens. Moreover, companies are five times more likely to register their products in an upper-middle-income country (UMIC). Similarly, companies' equitable access strategies and outcomes are skewed towards UMICs, with 61 per cent of the products assessed still lacking access strategies in low-income countries (compared with 65 per cent in the 2022 Index). This marginal improvement is reflective of some companies expanding coverage in the 113 LMICs covered by the Index, but still leaves many patients living in low-income countries and least-developed countries without access. Encouragingly, many companies did report outcomes of their access strategies to the Index, with patient reach data shared for 74 per cent of the access strategies assessed. However, few companies shared the numbers of the eligible patient population, which is crucial for determining whether those in need are benefiting equitably from these access strategies. (See figure 3)

Notably, there has been a trend in companies developing and launching inclusive business models over the last five years, with wide-reaching commitments to expand access for neglected populations. However, the 2024 Index finds that the implementation of the newly established models are still in early stages, and implementation of the older, more established models is currently limited

There are several ways in which the companies analysed in the Index can harness their vast resources, expertise and knowledge to increase the availability of their innovative products in LMICs, including in those where they do not have commercial presence. For example, voluntary licensing, particularly undertaken alongside technology transfers, can be a powerful mechanism for improving local availability in LMICs. However, companies' performance in voluntary licensing has stalled. While the

2022 Index showed companies' willingness to engage in voluntary licensing, the number of new agreements has fallen from six in the 2022 Index to just two in the 2024 Index. This is despite the fact that seven of the 20 companies currently have products in their portfolios for which voluntary licensing would be a viable option. Notably, most companies provided evidence of at least one technology transfer initiative to local manufacturers, with leading companies engaging in multiple technology transfers and other local manufacturing capacity building initiatives; lower-performing companies have not demonstrated any evidence of such efforts.

With regards to their intellectual property strategy, 18 of the 20 companies have policies in place, whereby they agree not to file or enforce patents in low-income countries and/ or least developed countries (this stood at 17 in the previous Index). This provides greater certainty to international drug procurers and generic medicine manufacturers when planning the supply of generic products. However, no companies list patent information for all products in scope on their websites.

The road ahead: Future challenges and opportunities for access to medicine in LMICs

In analysing companies' performance in the 2024 Index, this report sets out practical steps that companies should now take to provide affordable access to more people living in low- and middle-income countries (LMICs). These recommendations are also informed by trends, developments and overarching opportunities within the current global health landscape that will be pivotal for companies and their partners in working towards closing persistent equity gaps. The Foundation will continue to monitor pharmaceutical companies' actions against this backdrop, and how they address the challenges and opportunities that could have a significant impact on public health in LMICs.

◆ **From pipelines to patients: Products in development that could be game-changing for global health**

The 20 companies in scope of the Index hold the key to some of the most promising innovations to improve health outcomes of people worldwide. Typically, pharmaceutical products are developed to target more lucrative markets and, as a result, are often poorly matched to the needs of LMICs, with R&D trends increasingly shifting towards precision medicine and advanced therapies. However, several candidates that are currently in companies' pipelines could yield the potential to reduce the burden of some communicable diseases that disproportionately affect people in LMICs.

◆ **Respiratory Syncytial Virus (RSV)** causes the deaths of 100,000 children each year, 99 per cent of which occur in LMICs. Until recently, no effective prevention or treatment for RSV existed.1 However, the recent approvals of Pfizer's Abryvso (a maternal vaccine) and AstraZeneca/Sanofi's Beyfortus (a prophylactic monoclonal antibody for infants) offer new hope of preventing unnecessary deaths. In addition to these recent approvals, Merck & Co., (MSD) has an investigational prophylactic monoclonal antibody (clesrovimab) in development that has also shown promising results in clinical trials.

◆ **HIV treatment | Gilead's** lenacapavir is a long-acting six-monthly injectable drug that has shown overwhelming efficacy in clinical trials for HIV prevention and is already approved for the treatment of HIV. Equitable access to affordable long-acting injectables to treat and/or prevent HIV could prove game-changing in the fight against the disease. In October 2024, Gilead announced that it had signed non-exclusive voluntary licensing agreements with six manufacturers to make and sell generic lenacapavir (subject to regulatory approval) in 120 LMICs.

◆ **Tuberculosis** remains the leading infectious disease killer globally, responsible for 1.25 million deaths in 2023.3 GSK is currently developing ganfeborole (GSK3036656), an antituberculosis agent, with a novel mechanism of action, which could be impactful in addressing drug-resistant strains of the disease.

◆ **Malaria | Novartis** has several pipeline candidates addressing the emerging threat of artemisinin-resistance of malaria in adults and children, including its Phase III study, which investigates a combination of ganaplacide (an antimalarial with a new mechanism of action), with a new formulation of lumefantrine optimised for once-daily dosing.

In addition to developing new products such as these, which can address unmet health care needs, it is crucial that companies plan for access in LMICs during R&D to expediate access after product approval. In doing this, companies must prioritise equitable and affordable access in countries that face the highest burden of disease so that the impact on public health can be maximised.

Capitalising on regulatory harmonisation in Africa to broaden access in overlooked countries

After a product proves successful in clinical trials, registration through a regulatory agency serves as a critical step for access to quality assured healthcare products for patients. The 2024 Index found a gap in product registration in Africa, identifying that 43 per cent of innovative product approved within the past five years have not been registered in any African countries. In 2024, 27 African countries ratified the African Medicines Agency (AMA) treaty, with more African Union members expected to follow.4 The establishment of the AMA – which aims to harmonise regulatory procedures in Africa to improve access to safe, quality-assured medicines across the continent – provides an opportunity for companies to engage with an entity that will coordinate the evaluation of prioritised medicinal products in Africa.5 In addition, streamlining regulatory processes through the AMA could help facilitate more clinical trials in African countries, where populations are currently underrepresented in clinical research.

Accelerating current efforts to reach vulnerable populations

Companies are increasingly adopting 'inclusive business models' (IBMs) to improve and provide sustainable access to their products for neglected populations, including those in low-income countries. In the last five years, Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi have launched IBMs with comprehensive approaches to addressing underserved or unserved populations' access needs. However, implementation is currently limited and the degree of transparency on outcomes and progress varies across companies, making it challenging to assess their impact. As companies increasingly adopt IBMs, it is vital that companies transparently report the progress in implementing these models, particularly the number of patients reached. Not only will this help ensure accountability towards commitments tied to these models, but it can help facilitate the adoption of such models by more companies.

Ensuring sustainable supply in countries where companies have shifted operations

Over the past two years, some companies have shifted their operating models in some African markets, discontinuing direct operations and moving to a third-party distribution model, largely due to economic factors. GSK has made this transition in Kenya and Nigeria*, and Sanofi has done so in Nigeria. Although this shift does not mean the companies no longer supply their products in these markets, it may impact the availability and affordability of essential health products, particularly as the supply of medicines transitions to third-party distribution. The continuity of affordable access for patients in these countries now hinges on the effective implementation of this distribution model, making it crucial for companies to streamline distribution channels and prioritise the maintenance of robust and reliable supply chains.

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In October 2024, GSK entered a partnership with the Federal Government in Nigeria to strengthen local production.

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