

KEY FINDING 1: INCLUSIVE BUSINESS MODELS

Pharma companies are taking steps to address access in low-income countries, but significant gaps remain

- ▶ Several pharmaceutical companies are prioritising low-income and least developed countries within their inclusive business models, with this trend rising.
- ▶ Some companies are including large swathes of their product portfolios in these models, with wide-reaching commitments to deliver these products to patients.
- ▶ However, implementation of these models is currently limited, and transparent reporting on how many patients are truly being reached is lacking.

The pharmaceutical companies analysed by the Access to Medicine Index have systematically been expanding access to their essential products in several low- and middle-income countries (LMICs)*, but many populations – especially those living in low-income countries – remain largely overlooked by companies' access strategies. This was highlighted in the 2022 Index, with the 2024 Index still finding that far fewer products, for example, are covered by access strategies in low-income countries (39%) than in lower-middle-income countries (76%) and upper-middle income countries (85%).

Historically, most medicines and vaccines have reached people in low-income countries via companies' donations programmes or through donor-driven supranational procurement. While these strategies can (and are) addressing some of the gaps in these countries, more comprehensive, tailored and inclusive approaches are required to successfully address chronic access issues for vulnerable patients in the long term.

2019 – 2024: Early steps from certain companies

Over the last five years the Index has identified steps by some companies to cover more countries and products as part of their efforts to expand access. Five companies in particular have developed and launched inclusive business models with comprehensive approaches to facilitate access to their products for neglected populations, including those in low-income countries and least developed countries.

Overall, these five companies' models distinguish themselves in that they aim to reach underserved or unserved populations in LMICs that traditional business models have failed to cover. They focus on partnerships to tackle access barriers, with long-term plans for scalability to include additional countries and products and include long-term aims to generate a sustainable source of revenue.

Five models that aim to expand access in low-income countries**

- 2019 Novartis's Sub-Saharan Africa Business Unit
- 2021 Novo Nordisk's iCARE
- 2021 Sanofi's Global Health Unit
- 2022 Pfizer's Accord for a Healthier World
- 2024 Bristol Myers Squibb's Accessibility, Sustainability, Patient-centric, Impact, Responsibility and Equity (ASPIRE)

These five companies are taking various approaches to operating their inclusive business models, including the types of strategies they use to reach neglected populations. However, they all involve companies' selling and supplying either a set of products or their entire portfolio – for which they implement specific affordability strategies that can be tailored to specific settings across and within LMICs. This includes tailored pricing commitments, inter-country, as well as intra-country pricing, which Bristol Myers Squibb, Novartis and Sanofi facilitate through second brands. In addition, these models have also been developed to suit local health systems and address comprehensive access barriers, such as health system capacity and supply chain constraints.

Collective geographic coverage of the five models includes all low-income and least developed countries

As set out in the accompanying map on the next page, the commitments tied to the models from Bristol Myers Squibb, Novartis, Novo Nordisk, Pfizer and Sanofi cover 102 countries, collectively. This includes all 48 low-income countries and/or least developed countries analysed in the Index, 32 of which are in Africa. These countries make up about 13% of the global population, and a 2021 estimate finds that 35% of the total population in these countries were living below the international extreme poverty line of USD 1.90 per day.¹

*The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

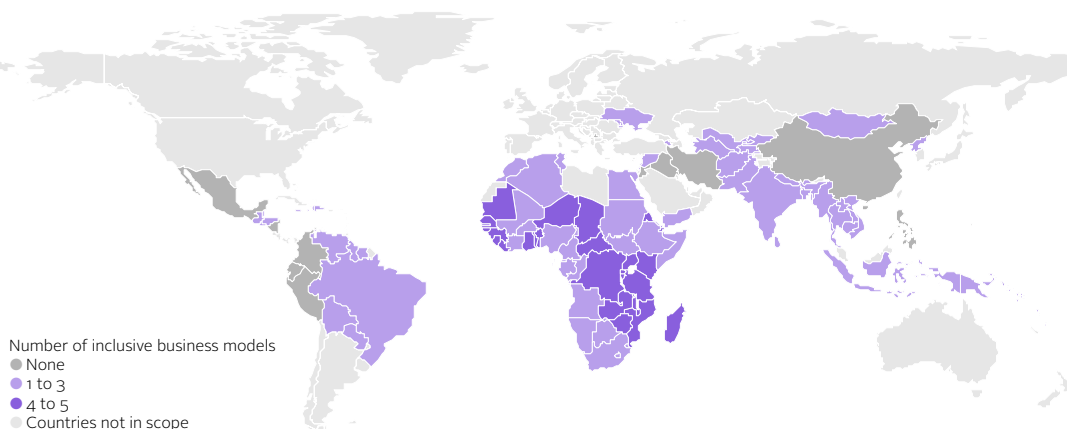
income groups classification. Likewise, the terms LIC and UMIC refer to low-income countries and upper-middle income countries.

**In May 2024, Bayer announced the launch of its Global Health Unit. The full

strategy, product and geographic scope have yet to be disclosed, therefore it was not assessed as part of the 2024 Index cycle.

FIGURE 1 Countries where companies have committed to operating their inclusive business models

Across the five inclusive business models, companies commit to making their products available in 102 countries. At least one model covers each of the 48 low-income countries and/or least developed countries in its commitments.



Products offered within the five models are mainly for non-communicable diseases

The range of products covered by these inclusive business models varies among companies, but all include products traditionally excluded from strategies targeting low-income and least developed countries. Bristol Myers Squibb, Novartis, Novo Nordisk, and Sanofi include select items from their global portfolios, while Pfizer offers all the on- and off-patent products that the company currently has global rights to, as well as future products.

Portfolios offered under these models mostly consist of products indicated for non-communicable diseases (NCDs), accounting for 73% of all products (see Figure 2). This includes both older treatments and newer on-patent medicines typically not covered by companies' access strategies in low-income countries. These portfolios encompass both small molecules and biologics, such as monoclonal antibodies for some companies. While not an exhaustive list, these are some of the NCDs covered:

- All but one model includes oncology products, such as products indicated for leukaemia, breast cancer, colorectal cancer, lung cancer, ovarian cancer and multiple other cancer types.

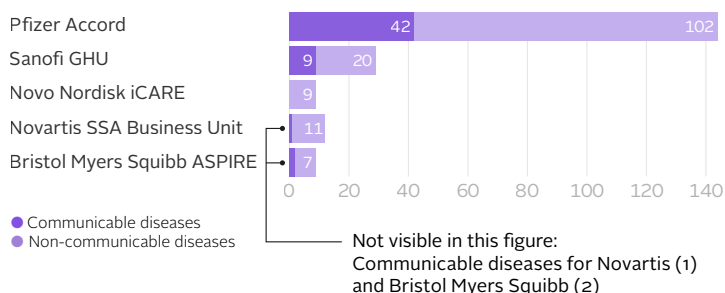
- Four of the models also include products indicated for diabetes, including human and analogue insulins.
- Three of the five models include products indicated for cardiovascular diseases.

Given that low-income countries have, historically, been overlooked when it comes to being supplied with NCD products, this coverage within the companies' business models is encouraging. Especially since NCDs disproportionately affect people in LMICs, where 80% of those affected live (5.7 billion) and more than three-quarters (31.4 million) of global deaths related to NCDs occur.^{2,3} Globally, cardiovascular diseases account for the majority of NCD deaths, followed by cancers, chronic respiratory diseases and diabetes, conditions that several of the products in these models' portfolios target.

Notably, Pfizer's Accord also includes contraceptives from the company's portfolio. This is the first time such products have been made available via a model like this and can be particularly impactful for sexual and reproductive health and rights in LMICs; 164 million women globally wish to delay or prevent pregnancy but are not using any form of contraception. Sub-Saharan Africa exemplifies this gap, with

FIGURE 2 Products covered by inclusive business models

This figure shows the number of communicable and non-communicable diseases in scope of the Index for each inclusive business model.



the usage of modern contraceptives being the lowest in the world at 56%.⁴

The remaining 27% of products in these models' portfolios are indicated for communicable diseases that still pose a high burden of disease in LMICs. Products included are mainly for malaria, neglected tropical diseases and tuberculosis, as well as antibacterials indicated for multiple infections.

Delivery still limited, with little information on how many patients are being reached

The wide-reaching product and country coverage across these five models is encouraging, but the 2024 Index finds that the outcomes of these models are somewhat mixed, with overall delivery lagging. While the more recently launched models are still in earlier stages, for the older, more established models, implementation is currently limited. Moreover, Sanofi is the only company, so far, to clearly report on how many patients are specifically being reached with the products delivered via its model.

Examples of implementation, and patient reach reporting, of the five companies' inclusive business models are ordered based on chronological order of establishment:

- ▶ **Novartis** implements intra-country pricing through its second brand strategy, which is one of the elements that is central to its Sub-Saharan African (SSA) Business Unit. This has been made available to most countries covered by the Index analysis, including lower-middle-income countries covered by the Unit, such as Ghana, Kenya and Nigeria. Notably, the Index identified that Novartis also launched a second brand through its SSA Business Unit for its product sacubitril/valsartan (Entresto®), indicated for chronic heart failure, in one low-income country. Novartis does not publish specific patient reach outcomes for the SSA Business Unit.
- ▶ **Novo Nordisk** launched the iCARE model to provide access to its human insulins in various LMICs, including a number of low-income countries. During the period of analysis for the 2024 Index, the company had active partnership agreements with subnational or national governments in 17 countries covered by the Index analysis, including Ethiopia, Ghana, Kenya, Mali, Nigeria, Senegal, Sudan and Uganda. Since initiating these partnerships, affordability plans have already been initiated in seven of these 17 countries. For example, Novo Nordisk reported delivering isophane human insulin (Insulatard®) and biphasic human insulin (Mixtard®) to Ethiopia and Sudan, respectively, through these partnerships, utilising both intra- and inter-country pricing strategies. As of 2023, Novo Nordisk does report reaching 433,000 patients through iCARE, but it is not clear whether this solely represents access to diabetes products, or includes patients reached through other initiatives, such as patient empowerment and education.
- ▶ **Sanofi's** Global Health Unit (GHU) reached patients with NCD care in 31 countries, 23 countries for tuberculosis care and 19 countries for malaria care as of 2023.^{***} The first insulin products from its second brand – analogue insulin, insulin glargine Impact SoloStar®, and anticoagulant enoxaparin sodium Impact® – were delivered to Djibouti in late 2023, with Tanzania expected to receive insulin glargine next. During the period of analysis, five products assessed by the Index were supplied to several countries through the GHU, including insulin glargine in seven lower-middle-income and ten low-income countries, and enoxaparin in six lower-middle-income and 12 low-income countries, including Gambia, Niger and Togo. Sanofi is the only company to clearly report how many patients are being reached with products delivered through its model. The company does this regularly, with 2023 figures showing that 261,977 patients were reached with NCD treatments via its GHU.^{***}
- ▶ **Pfizer**, through its Accord for a Healthier World, has signed agreements with eight countries, including Ghana, Malawi, Rwanda and Senegal to enable access to its medicines and vaccines on a not-for-profit basis.[†] In September 2022, Rwanda was the first country to receive a shipment of Pfizer Accord medicines and vaccines for infectious and inflammatory diseases, as well as certain cancers through the Accord. Pfizer does not publish specific patient reach outcomes for the Accord.
- ▶ **Bristol Myers Squibb** reported that its ASPIRE model was active in 19 countries and supported over 80 LMICs through its Direct Import and Direct-to-Institution managed access pathways, with implementation at various stages in each country. For example, in one low-income country, the company collaborates with local partners to supply two oncology products directly to healthcare facilities under a newly launched pathway that aims to increase access and cost efficiencies. In 2023, Bristol Myers Squibb reported that ASPIRE contributed to the company's overall patient reach of 104,000 across LMICs, but it is not clear whether this represents access to company products or other non-product-related initiatives like capacity building.

Long way to go to sustainably impact the lives of patients

Aside from the overall lack in clear and consistent reporting from companies on the patient reach outcomes of their respective models, patient reach figures that have been reported still fall short of meeting a realistic percentage of the healthcare needs of neglected populations across LMICs. Given the rising burden of NCDs in these countries, for example, many patients are still being left behind in receiving the vital healthcare products that these models have been designed to provide access to.

In addition, the 2024 Index finds that reporting on the specific needs for further advancement of partnerships is lacking

***After the period of analysis, in October 2024, Sanofi reported that over 40 LMICs had been supplied with NCD treatments, 10 through the Impact® brand. As of October 2024, the company also reported

reaching 586,024 patients with NCD treatments via its Global Health Unit.

†Agreements with two additional countries were signed after the period of analysis.

across the board. Overall details regarding which products have been registered and made available, as well as any memoranda of understanding established with national governments for product delivery, remain insufficiently documented. Moving forward, it is vital that companies consistently and transparently report this information and the level of progress, especially the number of patients reached.

Although current progress on the implementation of these five models is limited, the small steps that have already been taken can be meaningful if companies and their partners can accelerate access and deliver on the wide-reaching commitments to reach more patients across LMICs.

What next?

As more companies engage in inclusive business models with wide-ranging product and country coverage, it is important that they drive progress to deliver and expand on their commitments. Central to this will be continuing to evolve models in a way that is informed by local needs and countries' priorities to ensure these models effectively address the access challenges they have been designed to overcome.

By seeking greater synergies for collaboration across industries and with governments, particularly in low-income countries, for example, companies can amplify their impact and more successfully leverage shared expertise and resources.

It is also critical that progress (or lack thereof) is transparently reported, particularly data on patients reached, to ensure no one is left behind. Not only does this promote accountability in delivering on commitments, it also supports partnerships with other key stakeholders (e.g., local governments) who are working on existing initiatives to promote access to care. This will also help map out tangible, sustainable and replicable solutions to bridging chronic access issues in low-income countries, which can be explored by other companies.

READ MORE IN THE 2024 INDEX ON THE TOPICS COVERED IN THIS KEY FINDING

- Product Delivery Technical Area analysis p. xx
- Best Practice on inclusive business models p. xx
- Company Report Card Opportunities related to inclusive business models
 - Bayer's newly launched Global Health Unit (not included in the five) p. xx
 - Bristol Myers Squibb's ASPIRE p. xx
 - Novo Nordisk's iCare p. xx
 - Novartis's SSA Business Unit p. xx
 - Pfizer's Accord p. xx
 - Sanofi's Global Health Unit p. xx

1. Unctad. (2021). The Least Developed Countries Report 2021 – The least developed countries in the post-COVID world: Learning from 50 years of experience.

2. Institute For Health Metrics and Evaluation. Global Burden of Disease (GBD) Results. Published 2021. Accessed May 6, 2024. <https://www.healthdata.org/data-tools-practices/interactive-visuals/gbd-results>

3. World Health Organization. (2023, September 16). Noncommunicable diseases. <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>

4. United Nations Department of Economic and Social Affairs PD. World Family Planning 2022 Meeting the Changing Needs for Family Planning: Contraceptive Use by Age and Method.; 2022. Accessed May 6, 2024. https://www.un.org/development/desa/pd/sites/www.un.org/development/desa/pd/files/files/documents/2023/Feb/undesa_pd_2022_world-family-planning.pdf