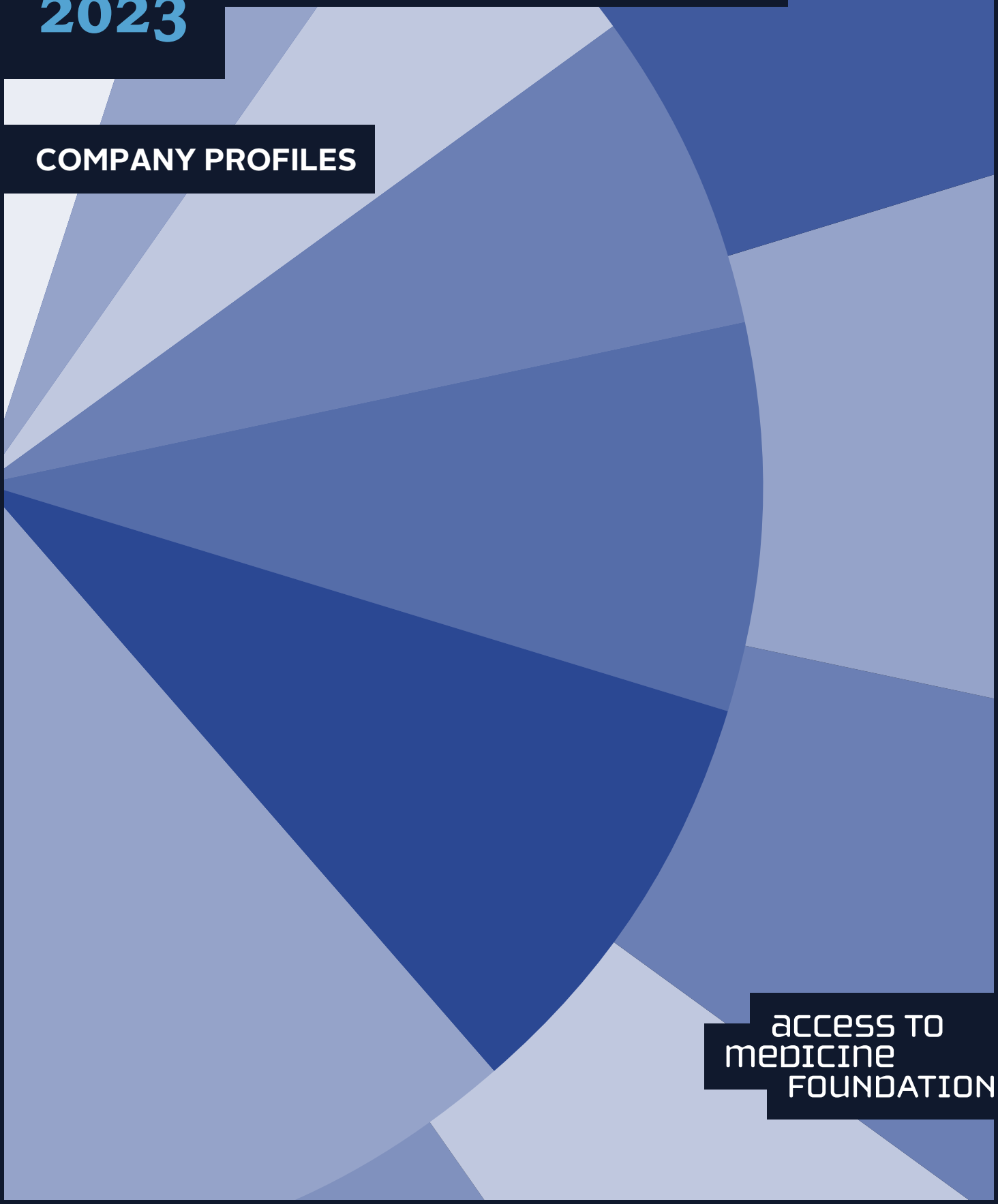
Generic & Biosimilar Medicines Programme 2023

COMPANY PROFILES



access to medicine FOUNDATION

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This acknowledgement is not intended to imply that the individuals and institutions referred to above endorse the framework for the Generic & Biosimilar Medicines Programme, analyses or results. Decisions regarding the final analysis were ultimately made by the Access to Medicine Foundation.

ACCESS TO MEDICINE FOUNDATION

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

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The untapped potential of the generics industry

For decades, the power and potential of the generics industry to expand access to medicine has been hugely underestimated. This goes beyond the transactional relationship of selling drugs at volume and competing on price. To truly move the dial toward health equity, companies must engage with the unmet medical need globally, and be proactive about making sure those needs are met. They can engage more fully, for example, by working with local manufacturers to improve supply; by taking steps to safeguard quality; by making their essential products available in more countries; and by addressing affordability for the poorest patients who often pay out-of-pocket.

The bottom line is that patients and practitioners still struggle every day to access essential medicines, especially in low- and middle-income countries (LMICs). In too many places, and in too many cases, generic and biosimilar medicines are unavailable or unaffordable to the people who need them.

This is why we felt the time was right to launch a dedicated Generic & Biosimilar Medicines Programme, which will build on the Access to Medicine Foundation's strong track record of stimulating pharmaceutical companies to move in the right direction on key access issues (e.g., via the Access to Medicine Index). Earlier this year we published a first-of-its-kind Analytical Framework, validated by experts in the field; and I am now pleased to share our inaugural analysis carried out using the framework, which puts the spotlight on five of the world's largest and most influential generic and biosimilar medicine manufacturers. Between them, they manufacture key products for HIV, cancer, diabetes and cardiovascular disease, and for women and girls' health – all of which are critical to improving health in LMICs.

Overall, there is a pressing need for greater accountability and disclosure, which would enable more informed decision-making and sharing of successful approaches. That said, our analysis has uncovered some real insights, including insights about the individual companies as well as broader cross-company findings. We have fresh data on product registration that reveals untapped opportunities in LMICs, and we zoom in on affordability, supply and local availability. We also look at adaptive R&D, revealing how some companies are utilising their R&D capabilities to develop fixed dose combinations and other adaptations that suit the needs of people living in LMICs – and identifying priorities for expanding these efforts.

Broadly, the companies have opportunities to look beyond the markets where they are already well-established and expand their reach to more countries. Some essential medicines are currently far from accessible in LMIC markets; this is something companies can tackle either via direct engagement in countries where they operate, or by working with local manufacturers and other partners in countries where they have limited networks. After all, as the COVID-19 pandemic has shown, boosting local availability is critical to limiting preventable deaths.

One final note: generic medicine manufacturers need to keep high standards in production, invest in quality control procedures, and maintain these high standards across all markets where they operate. In light of the recent issues and concerns regarding quality – albeit unrelated to these five specific companies – it is crucial for manufacturers, in general, to recognise that not investing in quality is going to affect both their bottom line and their reputation. While companies compete on price, quality must never be compromised. The measures companies report taking to safeguard quality are outlined in each of their Company Profiles.

This report showcases what is currently being done by major industry players to expand access to their essential medicines in LMICs, highlighting stand-out examples – but it also identifies the areas where companies can concentrate their efforts to drive change. We hope that, alongside the Analytical Framework, it will also serve both as a roadmap for other manufacturers of generic and biosimilar medicines who seek to step up their approach to access to medicine, and as a tool for investors, policymakers, practitioners and patients to engage the generics industry on how to move forward.

Jayasree K. Iyer
Chief Executive Officer
Access to Medicine Foundation

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About this report

This report is the first-ever independent assessment of what generic and biosimilar medicine manufacturers are doing to expand access to medicine in low- and middle-income countries (LMICs), profiling five major players: Cipla, Hikma, Sun Pharma, Teva, and Viatris. These companies have a vital role to play in manufacturing essential medicines at scale globally. It is the first research report from the Access to Medicine Foundation's Generic & Biosimilar Medicines Programme, with analysis carried out using the Analytical Framework published in February 2023.

Each Company Profile summarises the company's commitments, strategies, and activities to enhance the availability and affordability of its generic and biosimilar products in LMICs. It offers a detailed analysis of the company's actions in three assessed areas: Expanding Access, Supply & Quality, and Research & Development (where applicable). The companies vary in their operations, market reach, and portfolio of off-patent medicines, all of which can impact access. Each profile highlights specific opportunities for the company to further improve access, considering factors including its geographic footprint, product portfolio, and current access strategies.

The report also includes a broader industry analysis, drawing on data from across the five companies, culminating in four key findings. Within this analysis, positive examples and trends are identified, along with challenges and areas where urgent improvement is needed to expand access to essential medicines in LMICs.

SCOPE OF THE RESEARCH

Companies
Cipla, Hikma, Sun Pharma, Teva, and Viatris.

Products
102 off-patent essential health products.

- For certain topics, detailed data about a subset of 10 off-patent products per company has been collected and analysed.
- For the topic of voluntary licensing of on-patent products, analysis was carried out based on a selection of up to 5 in-licensed products per company.

Countries
Analysis has been carried out based on what companies are doing to expand access in 108 low- and middle-income countries (LMICs).

Diseases
Data analysed relates to 82 diseases, conditions and pathogens that disproportionately impact people living in LMICs.

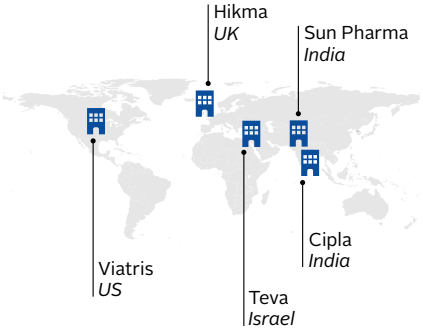
Executive Summary

In low-and middle-income countries (LMICs), generic and biosimilar medicines serve as vital lifelines. Manufacturers of these drugs are key actors in the global health landscape - stimulating price competition and offering more cost-effective alternatives to originator medicines. However, the mere availability of generic and biosimilar medicines in some markets does not ensure widespread access. Unfortunately, even when these medicines are available, they often remain beyond the reach of patients in LMICs, leaving a multitude of individuals susceptible to unnecessary suffering and premature loss of life.

This report assesses what five major generic and biosimilar medicine manufacturers - Cipla, Hikma, Sun Pharma, Teva, and Viatris - are doing to expand access to their essential products in LMICs. These companies were chosen for their size, influence and involvement in global health.

Collectively, the five companies have a wide portfolio of essential medicines. Of the 102 products within the scope of the Programme, which were identified during the development of the Analytical Framework as products that should be priorities for expanding access in LMICs, 90% are in the portfolio of at least one of the companies. In addition, the companies have a well-established presence in LMICs; in 89 out of the 108 countries in scope, at least one company has a sales presence. Given their strategic positioning in LMICs, these companies are well-positioned to effectively cater to these markets and ensure wider access to their products for more people in these countries.

The 5 companies assessed in this report
This report includes Company Profiles of five major generic and biosimilar medicine manufacturers. On the map, the countries where they have their headquarters are shown.



KEY FINDINGS

1 Companies have a collectively broad regulatory footprint in LMICs, yet many essential products are not widely registered

The five companies assessed in this report are among the major manufacturers of the world's supply of generic and biosimilar medicines, which means that their decisions about registration – in terms of which products they register, in which countries – can have a huge impact on whether an essential medicine ultimately becomes available to the people who need it. In addition, even if other manufacturers do already have versions of the same generic or biosimilar medicine on the market in an LMIC, there is still great value in the five assessed companies registering their product; healthy competition can ultimately contribute to greater affordability and availability for patients.

This analysis has found that the companies collectively have a wide existing regulatory reach in LMICs. In aggregate, they have previously registered products in 90 of the 108 countries in scope, demonstrating their ability to navigate complex regulatory environments in LMICs. However, data for the ten products per company selected for specific analysis – all off-patent essential medicines identified as particular priorities for access – showed that, in aggregate, companies have registered their assessed products in 77 countries in scope (compared to the 90 in which they have existing regulatory reach). Some products had also been registered in very few LMICs, despite the high need for them. Companies in scope demonstrably have the potential to register more of the essential products in their portfolios in more countries – and this key finding highlights the opportunities for them to do so.

2 Companies are using access strategies to expand access to their products in LMICs, yet efforts fall short for the poorest patients

To understand how companies reach the different segments of the population in LMICs, a subset of 50 products was analysed (ten per company). For 41 of these, companies provided evidence of an access strategy for at least one LMIC. The strategy most commonly used by companies to ensure access for patients accessing care via the public sector was to participate in tenders. For patients accessing care via the private sector, strategies were more limited. In particular, affordability was not adequately considered in pricing strategies for products, with only one of the 41 strategies including a pricing strategy that considers payers' ability to pay in both the public and private sector. This particularly affects low-income and vulnerable populations. Companies can participate in public sector tenders for more products from their portfolios, while also broadening the scope of their access strategies to include patients paying out-of-pocket.

3 Despite initiatives to strengthen manufacturing, further efforts needed to safeguard product availability

Ensuring an uninterrupted supply and availability of essential medicines remains a challenge for health systems in LMICs. Among the five companies, a handful of initiatives to bolster local manufacturing capacity in LMICs or facilitate knowledge transfer to local partners have been identified. Notably, two companies provided examples of engaging in technology transfers and local capacity development with third-party companies in four African countries. Companies can expand local manufacturing and facilitate technology transfers to ensure quality products. Additionally, they can establish regional distribution hubs and support local sourcing, while adopting company-wide approaches and participating in multistakeholder initiatives to enhance supply chain resilience.

4 Companies are engaging in adaptive R&D, tailoring products to the needs of people in LMICs

The assessment highlights nine examples of product adaptations with the potential to enhance accessibility, with companies developing products better suited for use in LMICs. These include products specifically adapted for children; products adapted so that they do not require refrigeration; and formulations that simplify dosing regimens. Generic and biosimilar medicine manufacturers can further amplify their impact by engaging in adaptive R&D projects that address identified R&D product gaps. There is also room for companies to strengthen their plans to ensure widespread and rapid access to adapted products in LMICs upon market launch. While all of the examples of late-stage adaptive R&D projects analysed in this report are supported by access plans, these plans are limited in scope. Making more comprehensive access plans would enable companies to ensure the swift and effective delivery of adapted medicines to the people who need them most.

TOWARDS INCLUSIVE ACCESS

Based on their geographic reach and product portfolios, generic and biosimilar medicine manufacturers utilise diverse approaches and strategies to make products more available and affordable to people living in LMICs. Despite challenges such as regulatory constraints and unstable supply chains, companies have clear opportunities to expand access to essential products in LMICs and play a more substantial role as global health actors. By extending product registration, fine-tuning access strategies, and adopting pricing strategies that factor in end-users' ability to pay, companies can enhance their impact. Strengthening supply chains, local manufacturing, and adaptive R&D efforts, such as adapting products for children or warm environments, also offer promising pathways to ensuring access.

Methodology

How the Company Profiles were developed

The Company Profiles in this report were created by analysing the actions of each company according to the areas and themes outlined in the Generic & Biosimilar Medicines Programme Analytical Framework, published by the Access to Medicine Foundation in February 2023. These profiles are based on publicly available information and data submitted by the companies. Public information encompasses the companies' published reports and third-party sources, while data submitted by companies includes both information collected specifically for this publication and data gathered for the 2021 Antimicrobial Resistance Benchmark (for Cipla, Sun Pharma, Teva, and Viatris).

The five companies were requested to provide data on the various assessment themes outlined in the Analytical Framework. While data was received from all five companies, some companies did not submit data for certain themes and/or areas of assessment. In such instances, publicly available information was used. Preliminary versions of the Company Profiles were shared with each company for their review, allowing them the opportunity to propose corrections for any data inaccuracies or omissions. However, the Access to Medicine Foundation retained authority over the incorporation and presentation of information to ensure consistency across profiles.

These profiles encompass the companies' actions and activities from 1 January 2020, to 30 April 2023, in accordance with the Analytical Framework and the scopes of the Programme.

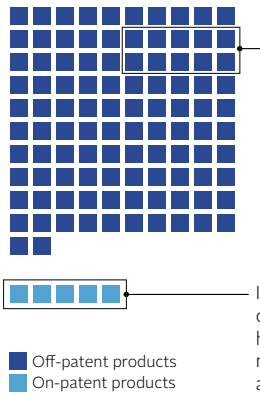
SCOPES OF THE PROGRAMME

This section provides a brief overview of key information about the product, disease and country scopes that have been used in this analysis. More details can be found in the 2023 Analytical Framework for the Generic & Biosimilar Medicines Programme, and in the appendices of this report.

Products in scope

Data analysed relates to 102 off-patent essential health products listed on the 22nd World Health Organization (WHO) Model List of Essential Medicines (EML).* The products included represent those with proven affordability and availability issues in LMICs.

FIGURE 1 **Products in scope**
Analysis was carried out based on a product scope of 102 essential off-patent medicines – see appendix V for method of selection. Each of the five companies in scope has many of these products in their portfolios.



Detailed data about a subset of 10 off-patent products per company was also collected – see appendix VI for method of selection. The specific products selected differ between companies. Companies' actions in relation to these 10 products were analysed in EA2 (product registration) and EA3 (expanding access and pricing strategies).

In addition, data was collected about a maximum of five on-patent products per company, for which the company had engaged in a licensing agreement as a licensee. Companies' actions in relation to these in-licensed products were analysed in EA4 (engaging in licensing activities).

Off-patent products
On-patent products

*The Programme's scope of 102 products includes three fixed dose combinations (FDCs) that are not explicitly listed on the 22nd WHO EML as specific products. However, the compounds included in the FCDs are listed on the EML either individually or as part of other FDCs (see appendix V).

Diseases, conditions and pathogens in scope

Data analysed relates to 82 diseases, conditions and pathogens that disproportionately impact people living in LMICs. This includes:

- 22 communicable diseases, including 12 priority pathogens
- 18 non-communicable diseases
- 20 neglected tropical diseases
- 10 maternal and neonatal health conditions, including reproductive health.

Countries in scope

This report is focused on the context and actions taking place in 108 low- and middle-income countries (LMICs) that are home to over 80% of the world's population. It uses the same inclusion criteria as the 2022 Access to Medicine Index.

HOW EACH RESEARCH AREA WAS ASSESSED

Companies have been assessed in three Research Areas. These are: Expanding Access; Supply & Quality; and Research & Development (R&D). Each Research Area includes specific themes under which companies' activities are assessed.

EXPANDING ACCESS

- Themes *EA1) Access-to-Medicine Strategy* and *EA5) Improving Product Availability* assess companies' strategies, initiatives, and examples of activities falling under these themes.
- *Themes EA2) Product Registration* and *EA3) Expanding Access & Pricing* assessed companies' activities in relation to ten off-patent products per company, which were individually selected for assessment. Additional information regarding this assessment can be located in Appendix VI.
- *Theme EA4) Engaging in Licensing Activities* assessed companies' activities in relation to up to five in-licensed products per company, which were individually selected for assessment. Additional information regarding this assessment can be located in Appendix VI and an overview of companies' engagement in additional licensing activities can be located in Appendix I.

SUPPLY & QUALITY

- Themes in this Area assessed companies' strategies, initiatives, and concrete examples to ensure a continuous supply and production of quality-assured products.
- *Theme SQ4) Manufacturing quality-assured products* assessed companies' compliance with good manufacturing practice (GMP) and efforts in ensuring quality-assured products globally. In addition to data submitted by companies, a search for publicly available regulatory warning letters and non-compliance reports was conducted.

RESEARCH & DEVELOPMENT

- Themes in this Area assessed companies' activities in adaptive R&D and Access Planning. The analysis was limited to companies with applicable adaptive R&D activities (Cipla, Hikma, Sun Pharma, and Viatris).
- *Theme RD1) Adaptive R&D* assessed up to five late-stage adaptive R&D projects per company, targeting in-scope diseases or conditions. These projects were submitted by companies for assessment and were included based on the criteria outlined in the programme's Analytical Framework.

KEY FINDING 1: PRODUCT REGISTRATION

Companies have a collectively broad regulatory reach in LMICs, yet many essential products are not widely registered

- Collectively, across their product portfolios, the five companies have registered at least one product in 90 of the 108 low and middle-income countries (LMICs) in scope, demonstrating a broad existing regulatory reach.
- However, an analysis of a subset of ten off-patent essential medicines per company* shows that registration practices vary significantly, with one company failing to file any of its ten assessed products in any low-income country.

Registering products with a country's national regulatory authority (NRA) is an essential first step in making quality-assured products available in that country's market. Registration alone does not guarantee that a product will be accessible to all patients, and factors including commercialisation, affordability, marketing and supply are also critical to ensuring equitable access. Nonetheless, registration is key, not just in terms of product availability, but also because registering a product plays a critical role in strengthening regulatory capacity of NRAs, market surveillance and quality control of products, in pharmacovigilance activities, and ultimately ensuring that patients have access to safe, effective and high-quality medicines.

Where have companies previously filed for registration?

Cipla, Hikma, Sun Pharma, Teva and Viatris collectively have a broad existing regulatory reach (see box). However, an analysis of a subset of products from each company reveals that they do not always register these products in countries where they have previously registered other products – for example, in countries where they have the proven capability to work with NRAs.

The companies' existing regulatory reach was assessed by analysing whether they had filed any products from their entire product portfolios within any of the 108 countries in scope. Collectively, the five companies have filed at least one product for registration in 90 of these countries. Among these companies, at least one product is registered in 25 out of the 27 low-income countries, 42 of the 55 lower-middle income countries, and 23 of the 26 upper-middle income countries in scope.

While this does not necessarily mean that the companies are all registering a wide range of the products in these countries, it does highlight the essential role generic and biosimilar medicine manufacturers already play in supplying medicines in LMICs. It also demonstrates the companies' ability to register products with these NRAs, and may therefore indicate where they have the capability to register more products, including those within scope of this analysis, which are essential medicines identified as priorities for access.*

How was companies' existing regulatory reach assessed?

The Generic & Biosimilar Medicines Programme assessed companies' registration efforts by analysing their previous registration filings, specifically looking at instances where each company registered at least one product within a country in scope. This assessment was based on the registration of products from companies' entire portfolios, including those beyond the 102 products in scope. If a company has previously registered any product in a particular country, it demonstrates their capability to register other products within that same country.

Where are products registered?

While various factors can influence companies' registration strategies, such as commercial potential and market competition, companies have the capability to improve access and reach populations in need. One approach is for companies to strategically leverage their existing regulatory reach by registering more of their products in countries where they have previously registered other products. To determine if companies were already adopting this approach, registration filings for a subset of off-patent essential medicines – ten products from each of the companies' portfolios – were analysed. Overall, the companies have registered these products in 77 countries in scope, despite having previous regulatory activity in 90 countries. Among the 77 countries, this includes registrations in 38 of the 55 lower-middle income countries, 19 of the 27 low-income countries, and 20 of the 26 upper-middle income countries in scope.

Furthermore, companies do not need to limit themselves to countries where they have existing regulatory reach, but can look at extending their footprint to more LMICs. By registering their products in markets where they do not have an existing or established presence, companies can promote better access to essential medicines for a broader population.

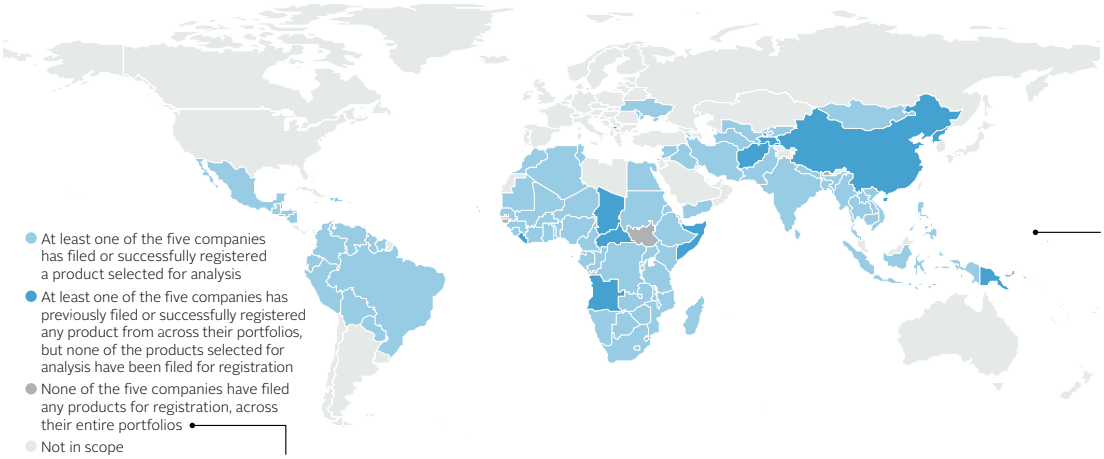
Registration data was also collected for a sample of in-licensed products manufactured under licensing agreements with innovator companies, which can facilitate access to innovative medicines in LMICs. Data about eight licensed compounds** reveals that, while all of the licenses would allow the sub-licensee to register their generic or biosimilar version of the product in at least 90 countries, the number

*Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines from each company's portfolio were selected for specific analysis.

**Licenses cover the compounds needed to manufacture specific products.

FIGURE 2 **Where have the companies filed their products for registration?**

This map highlights the 77 countries (out of the 108 countries in scope) in which companies have filed at least one of the ten off-patent medicines per company that were selected for analysis in this report based on identified access gaps in LMICs.* Overall, it also shows the 90 countries in which at least one company has filed at least one product for registration, out of all the products in their entire portfolios.



Despite the five companies assessed having filed products for registration in many LMICs, there are 18 countries in scope in which none of the companies had previous registrations. These include countries that participate in the Collaborative Registration Procedure (CRP) for stringent regulatory authority (SRA)-approved products or WHO prequalified products, such as Bhutan, Cabo Verde and São Tome and Principe.

Some Pacific Islands Countries (PICs), specifically Tonga, Tuvalu, Kiribati, Federated States of Micronesia, Samoa, Solomon Islands and Vanuatu also received no previous registrations. However, registration in some PICs might not be possible, and the islands have regulatory systems and procurement mechanisms with varying capacities.

of registrations per product spans a wide range. For example, there were minimal to no registrations for COVID-19 therapeutics, while registrations for HIV treatments covered approximately 40% of the countries within the licences' scope.

Majority of companies include low-income countries in their registration strategies

Among the 27 low-income countries in scope, the five companies collectively demonstrate their capability to register their products in 25 countries. Narrowing down from the companies' entire portfolios to look specifically at the ten products per company selected for analysis,* companies have filed for registration or successfully registered these products in a collective total of 19 low-income countries. This can be considered a positive achievement as some of these countries have limited regulatory capacity or are perceived as having lower commercial potential.

Despite the overall promising picture, there is a disparity between companies' registration efforts in low-income countries for the subset of products selected for assessment; one company has not registered any of these products in any low-income countries, while another has registered products in 16 low-income countries.

Mechanisms to facilitate registration are used, but not extensively

Three out of the five companies assessed are engaged in mechanisms to facilitate registration. However, these mechanisms are still underutilised, despite their potential to facilitate timely access to products. These companies have made use of mechanisms including the WHO Collaborative Registration Procedure (CRP) for WHO prequalified products, as well as regional joint assessments including ZaZiBoNa and ECOWAS.** When countries utilise these facilitated mechanisms, this aids in improving their regulatory preparedness and capacity. It also accelerates the registration of quality-assured products in their markets, while easing some of the challenges faced by companies in registering their products in LMICs – thereby incentivising them to register their products.

What needs to happen next?

Companies can broaden the registration of essential products through two key steps: firstly, by registering more of their products in the LMICs where they already have existing regulatory reach; and secondly, by expanding their reach to additional countries. As part of their registration strategies, they can prioritise products already registered by SRAs or prequalified by WHO, using mechanisms such as CRP or regional joint assessments that can facilitate and accelerate registration. They can also prioritise registration in countries with a high burden of disease, focusing on medicines with access gaps in LMICs, including cancer, cardiovascular diseases, HIV, diabetes and mental health conditions. This effort can include in-licensed products supplied through voluntary licensing agreements. Some companies have registered several of their assessed products in low-income countries, and they can now expand these efforts to ensure all products in their portfolio are registered in low-income countries.

*Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines from each company's portfolio were selected for analysis.

**The ZaZiBoNa process is a work-sharing initiative between NRAs in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Democratic Republic of Congo, Tanzania, Malawi and Mozambique. ECOWAS is the Economic Community of West African States.

KEY FINDING 2: ACCESS STRATEGIES

Companies are using access strategies to expand access to their products in LMICs, yet efforts fall short for the poorest patients

- Of the 50 products analysed in this report, 41 are covered by an access strategy in at least one of the low- and middle-income countries (LMICs) in scope.
- However, among the 41 examples of access strategies, this analysis identified only four that include elements to improve affordability and availability, and only one that includes elements of considering payers' ability to pay in both the public and private sector.
- Companies can strengthen their access strategies by considering alternative strategies to complement their current approaches, such as intra-country pricing or engaging with local organisations to ensure access for vulnerable patient population groups.

Generic and biosimilar medicine manufacturers expand access to medicine globally. As an integral part of the sector's business model, they provide large quantities of medicines, and sell them at lower prices and smaller profit margins than originator companies. These companies primarily focus on producing and distributing generic or biosimilar versions of off-patent drugs – a category that includes most of the essential medicines. Some of these companies are also involved in manufacturing in-licensed products (i.e. on-patent medicines) via licensing agreements with originator companies, meaning that newer medicines can reach more people, in more countries, at more affordable prices.

However, while the low cost/high volume approach can inherently help expand access globally major challenges exist with both affordability and availability of essential medicines in LMICs. For example, even if a generic medicine (whether off-patent or in-licensed) is priced lower than the originator, it still may be unaffordable to large numbers of the patients who need it, especially those who rely on the private market and pay out-of-pocket. Another barrier to access is availability; for example, a company may target the most lucrative markets and not make its product available in many LMICs, in which case health systems and patients in those countries cannot take advantage of more affordable generic options.

What is an access strategy?
The range of mechanisms that a company can implement to provide access to its products for a specific group of patients within a country. Access strategies with the biggest potential impact in terms of equitable access are those that aim to promote affordable access to medicine for all segments of the population by considering the payer's ability to pay, and those that take the needs and characteristics of healthcare systems into account.

How were companies' access strategies assessed?
To understand how companies tailor their access strategies to reach people in LMICs, a sample of ten products from each of the five companies' portfolios were selected for specific analysis. For each of the ten products, one example of a country-specific access strategy for that product was analysed.

Lack of comprehensive access strategies targeting vulnerable patients

Generic and biosimilar medicine manufacturers can take deliberate steps to improve access to their products in LMICs – engaging in "access strategies" that promote affordability and availability (see box). All five companies in scope of this analysis – Cipla, Hikma, Sun Pharma, Teva and Viatris – are implementing strategies to expand the reach of their products in LMICs, with examples of access strategies identified for 41 of the 50 products analysed in this assessment.

Yet, there is limited evidence that companies are considering affordability for different payers when setting prices for their products. Payers can include public and private entities, organisations and patients paying out-of-pocket. Among the 41 access strategies, only 14 targeted both the public and private sectors and included comprehensive approaches for wider patient reach. Among the remaining 27 strategies, two were donation programmes and 25 exclusively targeted either the public or private sector, but lacked specific elements for improving access for vulnerable populations, including low-income patients and paediatric populations.

Out of the 25 strategies, nine target the public sector, with the government offering partial or total reimbursement for the products. By engaging in public sector contracts, such as tenders, companies can widen medicine access to a large number of patients. However, public payers may not always have enough funds to procure sufficient units of the medicine, leading to out-of-pocket payments. In such cases, companies must ensure that their access strategies consider private sector patients and their ability to pay.

Tenders are the main strategies used to promote access in the public sector

Among the 41 examples of access strategies submitted by companies, the access strategy most commonly used to promote access in the public sector is to engage in tenders, whether that involves a single procurer (e.g. a public health service) or multiple procurers (i.e. via pooled procurement).

FIGURE 3 **The majority of the products in scope are covered by an access strategy**

A sample of maximum of ten products, deemed essentials for public health, were analysed for each company. For each of the ten products, companies were requested to provide one example of a country-specific access strategy covering that product, including a minimum of three low-income countries and three lower-middle income countries. Further examples could come from upper-middle income countries.

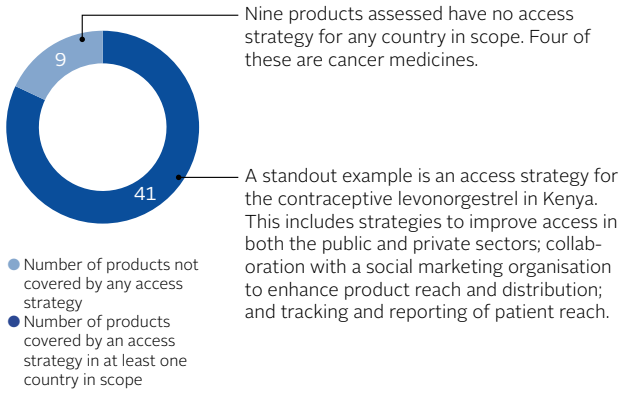
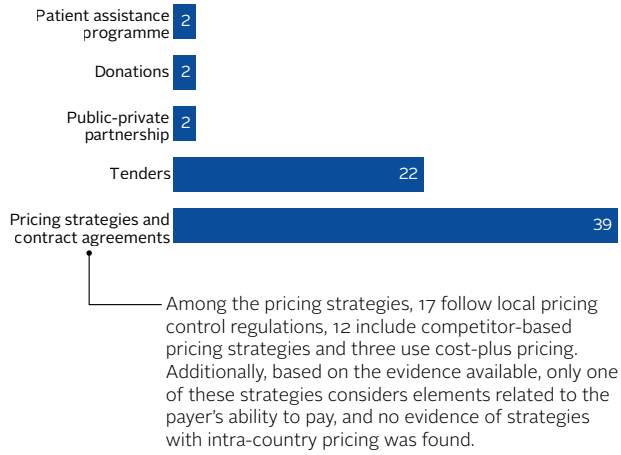


FIGURE 4 **What types of access strategies are companies implementing?**

Companies utilise a variety of strategies to provide access, including tenders, pricing strategies, donations and patient assistance programmes. Of the 41 products, 14 have comprehensive access strategies, which include more than one component from the graph.



These mechanisms allow governments and other tender issuers (e.g., public hospitals) to secure cost savings by inviting competitive bidding from manufacturers. They can also be a way for companies to improve access to their products in LMICs. Yet, their ability to enhance affordability might be restricted if negotiation is limited or market competition is lacking. Moreover, at times, manufacturing and distributing expenses for companies might exceed public sector payments, posing challenges to the viability of the business case.

Four companies reported using public sector tenders in countries in scope to expand access to the products selected for analysis. Additionally, two companies engage in supranational procurement to mitigate commercial risks and expand access to products. The access strategy examples shared by Viatris for four of its assessed products included participation in supranational procurement to expand access to the product – with examples submitted for Malawi, Namibia, Uganda and Zambia. Additionally, Cipla reports supplying abacavir/lamivudine, an antiretroviral procured through the Global Fund to Fight AIDS, Tuberculosis and Malaria in at least one LMIC (Benin).

Competitor-based pricing and local price controls shape private sector pricing

Collectively, the companies submitted 24 examples that included strategies focused on pricing in the private sector – specifically competitor-based pricing and/or local pricing control mechanisms.

For 17 of these 24 products, the country-specific examples of access strategies indicated that the product was only available through the private sector. For instance, in the examples provided for four antihypertensive medicines (telmisartan in Zambia, valsartan in Sudan, metoprolol in Nepal, and lisinopril in Nigeria), the companies supplied these products solely in the private sector. In these countries, only a small percentage of the population (around 3%) is covered by private insurance, meaning most pay out-of-pocket, while public sector coverage remains inadequate due to governments' challenges in procuring essential products.[1,2,3,4]

Ultimately, a company's use of competitor-based pricing and pricing mechanisms in ensuring equitable access might not significantly enhance affordability unless the company factors in the payers' capacity to pay. The analysis reveals companies aiming to tackle affordability challenges for lower-income groups through the private sector, for example Viatris is implementing a patient assistance programme in India, offering financial support to low-income patients who pay out-of-pocket for the cancer drug bevacizumab. However, overall examples are limited.

What needs to happen next?

While companies are often incentivised to gain a competitive advantage to secure tenders in the public market or to supply in the private market, relying solely on competitor-based models falls short in terms of securing equitable access. Companies can continue to expand their access strategies to include more products in their portfolios and consider payers' ability to pay in their pricing approaches. Engaging with the public sector is vital, encompassing strategies such as intra-country differential pricing for broader patient coverage, and participating in specific public sector programmes, such as those tackling NCDs. Equally essential is reaching vulnerable populations, especially the 43% of people in the poorest countries facing catastrophic healthcare expenses due to out-of-pocket costs. Lastly, companies can engage directly with the private sector, such as wholesalers, as well as social marketing organisations, private insurers, and NGOs to ensure medicines are accessible and affordable for those that need them.

KEY FINDING 3: PRODUCT AVAILABILITY

Despite initiatives to strengthen manufacturing, further efforts needed to safeguard product availability

- ▶ Companies report limited strategies to improve the availability of their products.
- ▶ Among the strategies employed, leveraging local and regional manufacturing presence in low- and middle- income countries (LMICs) shows potential to ensure availability.

In LMICs, the supply of essential medicines encounters various challenges. There is a growing understanding of the need to strengthen local availability, which is increasingly urgent due to geopolitical uncertainties and challenges in global health. Upstream, dependence on few suppliers of critical components can lead to supply interruptions. Downstream, inadequate and expensive local distribution channels make it difficult for people to access essential medicines, and disproportionately impact countries heavily reliant on imports, such as those in sub-Saharan Africa. Addressing these obstacles requires a multistakeholder approach, with companies playing a crucial role. Establishing and expanding manufacturing sites in LMICs where gaps exist, and strengthening third-party local manufacturing capabilities are two ways in which companies can help safeguard product availability.

Embracing local manufacturing for improved product availability

One effective strategy for promoting product availability is establishing local manufacturing presence. When companies' manufacturing sites are located within or near LMICs, product availability can be more easily assured. Hikma, for example, has leveraged its active pharmaceutical ingredient production for oncology products to supply these in the Middle East and North Africa, including Algeria and Egypt. This approach has helped address demand surges, ensuring a steady supply. Moreover, companies such as Sun Pharma and Cipla have well-established presence in African markets, covering countries such as Kenya, Nigeria and South Africa. Cipla is planning on leveraging its manufacturing presence in South Africa to manufacture an HIV prevention drug as part of a licensing agreement, providing the potential for increased availability. While Cipla has committed to strengthening its manufacturing presence in African countries, it recently decided to divest its stake in Quality Chemical Industries Limited (QCIL) in Uganda, which supplies medicines such as antiretrovirals in the region. This latest development raises uncertainty as to what extent the company will retain manufacturing capabilities for such products in the continent.

Investments in packaging and distribution facilities, along with the strategic use of regional manufacturing and distribution hubs, can help ensure local availability of medicines. Viatris, for instance, has invested in packaging and distribution facilities in sub-Saharan Africa, making medicines targeting diseases like HIV and malaria more available. Viatris has also established hubs in regions like Latin America to supply multiple LMICs. Regional hubs not only have the potential to facilitate access to products for neighbouring countries but offer advantages such as optimised distribution channels.

Additionally, some companies, including Cipla, Hikma and Sun Pharma, report that they implement local sourcing strategies, whereby they source components from local suppliers, including packaging materials. Such strategies have the potential of enhancing control over product availability at the end stage of production while introducing resilience to the supply chain.

Overall, some companies' efforts show a general, but limited, move towards investing in strengthening their own manufacturing capacity, particularly in Africa. Examples of companies engaging in initiatives with local partners to build manufacturing capacity or transfer technical skills remain scarce, with only two companies reporting such activities.

What needs to happen next?

Companies can contribute to improving the local availability of their products through several strategies. They can extend their manufacturing presence within LMICs, decreasing reliance on imported finished goods. This includes expanding current manufacturing facilities, constructing new ones, and/or establishing regional distribution hubs. Companies can also enhance the capabilities of local third-party manufacturers through technology transfers, for instance as part of contract manufacturing or licensing agreements. Investments in local manufacturing can be integrated into company-wide approaches to increase access in LMICs, alongside activities in areas such as expanding registration and pricing strategies.

In tandem with companies' actions, local authorities can also help incentivise local manufacturing and increase the availability of locally manufactured medicines. This involves prioritising procurement from locally based companies, collaborating with regional pharmaceutical associations to stimulate localised production, and implementing policies that encourage technology transfers.

Emphasis on multistakeholder strategies can lead to more resilient supply chains, ensuring people in LMICs have uninterrupted availability of essential medicines.

KEY FINDING 4: RESEARCH & DEVELOPMENT

Companies are engaging in adaptive R&D, tailoring products to the needs of people in LMICs

- Strong examples of adaptive research and development (R&D) projects can be identified, with companies developing products better suited for use in low- and middle-income countries (LMICs), including those specifically developed for paediatric populations.
- However, access plans for adaptive R&D projects lack depth, predominantly focusing on registration plans, with limited geographical reach.

Although the traditional business model of generic and biosimilar manufacturers has not focused on new product development, historically several companies have demonstrated R&D capabilities to adapt existing products to address unmet healthcare care needs in LMICs, e.g, new fixed-dose combinations (FDCs) for HIV.

Furthermore, the presence and extensive experience of these companies in LMIC markets offers significant potential for developing and expanding access to these adapted products in LMICs. To ensure the rollout of these medicines rapidly and broadly upon market launch, it is imperative that companies develop comprehensive and wide-reaching access plans in the R&D phase of product development.

What is adaptive R&D?
The process of adapting existing medicines via R&D – for example, to create products better suited to the needs of patients and health systems in LMICs. This can include developing new formulations, developing new fixed-dose combinations of existing chemical or biological entities, repurposing an existing product for additional indications, or developing a version of the medicine for a new target age group, e.g., children.

The majority of companies in scope are engaging in adaptive R&D

Four companies reported engaging in adaptive R&D activities and were assessed in this area. In total, companies submitted nine examples of adaptive projects that met the criteria for inclusion in this analysis. These projects involved adapting formulations to improve storage conditions or administration and tailoring products for paediatric populations.

Currently, specific R&D gaps exist for products needed globally to address unmet healthcare needs, particularly concerning diseases most prevalent in LMICs. Therefore, adapting existing products through R&D has the potential to address these gaps and cater to the needs of people living in LMICs, including specific age-groups like children. If a priority R&D gap exists, it signifies a lack of effective or suitable medicines to treat a disease or condition. For instance, there might already be a tablet available on the market, but there is a need to develop a formulation suitable for use in children, such as a flavoured syrup, a dispersible tablet or an alternative smaller dose. Gaps are identified by organisations such as Policy Cures Research, the World Health Organization (WHO), the Global Accelerator for Paediatric formulations (GAP-f) and the Rome Action Plan on Paediatric HIV and Tuberculosis.

Six of the nine projects include adaptations that are addressing priority R&D gaps identified specifically by Policy Cures Research G-FINDER report, which publishes data on R&D investments for diseases of global health importance

FIGURE 5 **Examples of adaptive R&D projects**

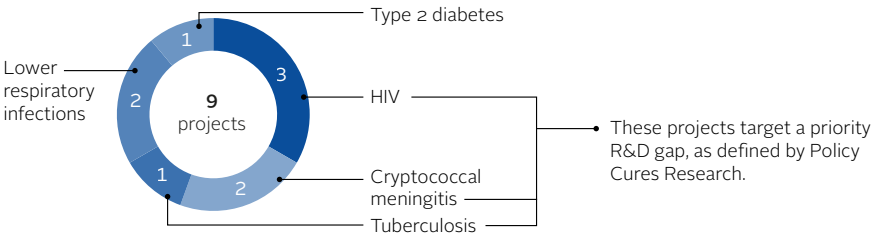
Cipla's heat-stable 4-in-1 fixed-dose combination (FDC) combines four different antiretroviral drugs that can be used in children with HIV. The strawberry-flavoured granules do not contain alcohol or inappropriate solvents and can be sprinkled on food, making it easier for children to take their medication. This FDC was approved by the South African Health Products Regulatory Authority in June 2022 and is currently awaiting US FDA approval.

Viatris is developing a sustained-release formulation of flucytosine. The project is currently in Phase I of development and is intended to treat cryptococcal meningitis, one of the leading causes of death in patients with advanced HIV disease. This adaptation reduces dosage frequency, simplifying treatment regimens for patients.

Hikma has developed single-dose dry powder sachets of the antibiotics cefalexin and cefaclor, used to treat lower respiratory infections amongst other indications. The single unit dosage form means that, unlike the existing multi-dose dry powder formulations, refrigeration upon reconstitution is not required – an advantage in many low-resource settings. These products were approved by the Algerian regulatory authority in 2022 and 2023, respectively.

Sun Pharma is developing an extended-release FDC of three medicines: dapagliflozin, glimepiride and metformin, indicated for type 2 diabetes. This project is currently in phase III of clinical development. Reducing the number of tablets a patient takes, simplifies dosage regimens and promotes adherence.

FIGURE 6 **Diseases targeted by adaptive R&D projects in scope**



that disproportionately affect people living in LMICs. Generic and biosimilar medicine manufacturers can continue extending their proven R&D capabilities to further engage in adaptive R&D by focusing on these important gaps.

R&D projects have access plans, but these plans are not yet comprehensive

Planning for access during the R&D phase is essential to ensure widespread availability, accessibility and affordability of medicines once a product has been launched. This includes considering access barriers in LMICs. In the past decade, the Access to Medicine Index noted increased access planning among R&D-based pharmaceutical companies. Now, in this assessment of generic and biosimilar medicine manufacturers, the Access to Medicine Foundation examines whether and how this group of companies are engaging in access planning for their late-stage adaptive R&D projects, so that their products reach the people who need them once launched.

All eight late-stage (i.e., Phase II and beyond) adaptive R&D projects in scope are supported by access plans, and there is room for those plans to be strengthened.

Currently, most of the companies' access plans include intentions to file their product for registration in at least one LMIC. However, half of the access plans submitted by companies do not specify the LMICs in which they intend to register, and the more detailed plans only cover one to two countries.

Furthermore, while product registration is a necessary first step to ensuring product availability, it is equally important for companies to address other access barriers by including additional elements within their access plans to ensure affordability and supply. Few of the plans submitted by companies incorporate considerations such as supply and demand planning, applications for WHO prequalification (PQ), and the development of equitable pricing strategies.

Out of the eight projects, two were developed in collaboration with access-oriented organisations, such as the Drugs for Neglected Diseases Initiative (DND*i*). These partnerships can play a crucial role in both developing products adapted to the needs of people in LMICs and ensuring the implementation of access planning that prioritises equitable and affordable access during the drug development process. Generally, access plans developed with access-oriented organisations were found to be more comprehensive than those developed in-house by companies and were the only access plans assessed that included WHO PQ or equitable pricing plans during the product development phase.

Generic and biosimilar medicine manufacturers have shown that they have the capability to engage in adaptive R&D, effectively targeting both priority R&D gaps, as well as the specific needs of patients living in LMICs. Adaptive R&D, by its nature, strives to tailor innovations to suit the needs of patients, including those living in LMIC contexts and climates. However, without access planning to ensure the widespread availability, accessibility and affordability of these essential medicines once they do reach the market, those who require them most may not gain access to the product – despite it being tailored to their needs.

What needs to happen next?

Companies can utilise their expertise and proven capabilities in adaptive R&D to further engage in developing products that specifically cater to the needs of people living in LMICs.

In doing so, they can strategically target existing product gaps. This analysis shows that companies in scope are already actively engaging in R&D projects to address several of these priority gaps. However, there are still many remaining R&D gaps related to diseases prevalent in LMICs and/or formulations suitable for specific patient populations (e.g., children and pregnant people) who currently lack suitable treatment options.

One effective approach to achieving this is by establishing partnerships with product development partners. For example, WHO's GAP-f has identified strategic business relationships with generic manufacturers as an opportunity to enable accelerated product development of paediatric formulations of priority drugs.[5]

Additionally, planning for access during R&D is crucial to ensure widespread and rapid availability of these adapted products in LMICs when they are launched on the market. Companies can further enhance their efforts by creating more comprehensive access plans that include provisions for timely access in LMICs post-launch, such as registration planning, equitable pricing plans, WHO PQ and supply and demand plans. Companies can also expand the scope of their access plans to encompass a broader range of LMICs to ensure widespread availability.

Company Profiles

This section of the report includes Company Profiles for:

- Cipla Ltd
- Hikma Pharmaceuticals Plc
- Sun Pharmaceutical Industries Ltd
- Teva Pharmaceutical Industries Ltd
- Viatris Inc

Cipla Ltd

HQ: Mumbai, India • Ticker: CIPLA • Stock exchange: NSE • Nr. of employees: 26,615

COMPANY SUMMARY

Cipla has a broad portfolio of off-patent medicines covering a diversity of therapeutic areas, and manufactures products at 47 sites across the world. The company's access efforts encompass its corporate social responsibility activities and its "Cipla Global Access" business, through which it collaborates with international organisations and procurement agencies to supply essential medicines to low- and middle-income countries (LMICs). Cipla registers its products across a variety of LMICs, including low-income countries. Cipla expands access to its products by engaging in competitive tenders by governments and hospitals, while adhering to local pricing policies and competitor-based pricing strategies in the private sector. Cipla has signed licensing agreements that allow the company to market generic products in LMICs to treat diseases such as HIV and COVID-19. Cipla implements forecasting mechanisms and promotes supplier diversity, among other strategies, to ensure continuous product supply and mitigate shortages. Cipla reports one example of an adaptive R&D project, consisting of a paediatric fixed-dose combination of four antiretrovirals, which can simplify dosage and improve treatment adherence.

Main therapeutic areas
Cardiovascular diseases; infectious diseases; metabolic disorders; oncology; respiratory diseases; dermatology; gastrointestinal; urology; central nervous system.

Business segments
New Ventures; Pharmaceuticals.

Product categories
Active pharmaceutical ingredients (APIs); biosimilars; consumer health products; generic medicines.

Sales presence*
Cipla reports sales in 26 countries in scope.

OPPORTUNITIES FOR CIPLA

Expand efforts to ensure product availability in sub-Saharan Africa.
Cipla has made a commitment to improve product availability by strengthening its local manufacturing presence, incorporating this commitment into its business strategy for the SAGA region.** Cipla can deliver on this commitment by expanding in-house manufacturing and by engaging in the transfer of skills to local manufacturers to develop and strengthen capacity for manufacturing products targeting high burden diseases in the region.

Continue to engage in adaptive R&D to develop products that address R&D priority gaps.
Cipla has partnered with the Drugs for Neglected Diseases initiative (DND*i*) to produce a 4-in-1 fixed-dose combination for the treatment of HIV in children. The company can continue to leverage its R&D expertise to adapt products targeting diseases with high burden in LMICs, where treatment options are ineffective or lacking, such as paediatric formulations.

Expand registration and affordability of essential cancer products.
Cipla can expand access to essential cancer products in its portfolio by pursuing broader registration filings in LMICs, particularly in high-burden and low-income countries. For cisplatin and carboplatin, indicated for various cancers including cervical cancer, Cipla can file for registration in LMICs with high cervical cancer burdens where it has previously registered other products in its portfolio including Botswana, Suriname, and Zimbabwe. Moreover, in the countries where these cancer treatments are already registered, Cipla can prioritise implementing access strategies, using approaches that include elements to address affordability, supply, and local barriers to access. Cipla can apply such strategies to expand access to cisplatin in Nepal, which is a country where Cipla has registered the product; cervical cancer is prevalent; and the majority of patients pay out-of-pocket.

Expand engagement in voluntary licensing agreements.
As a sublicensee in various licensing agreements, Cipla is following through on its commitments to register in-licensed products in LMICs in scope. Cipla can build on these efforts by continuing to register products like dolutegravir in more countries, especially to reach children and young women living with HIV. Having recently signed a non-exclusive licence for cabotegravir long-acting, used for HIV pre-exposure prophylaxis (PrEP), Cipla can ensure broad registration in countries with high HIV burden, once possible. The company can also explore engaging in additional voluntary licensing agreements across other therapeutic areas, including non-communicable diseases, when relevant.

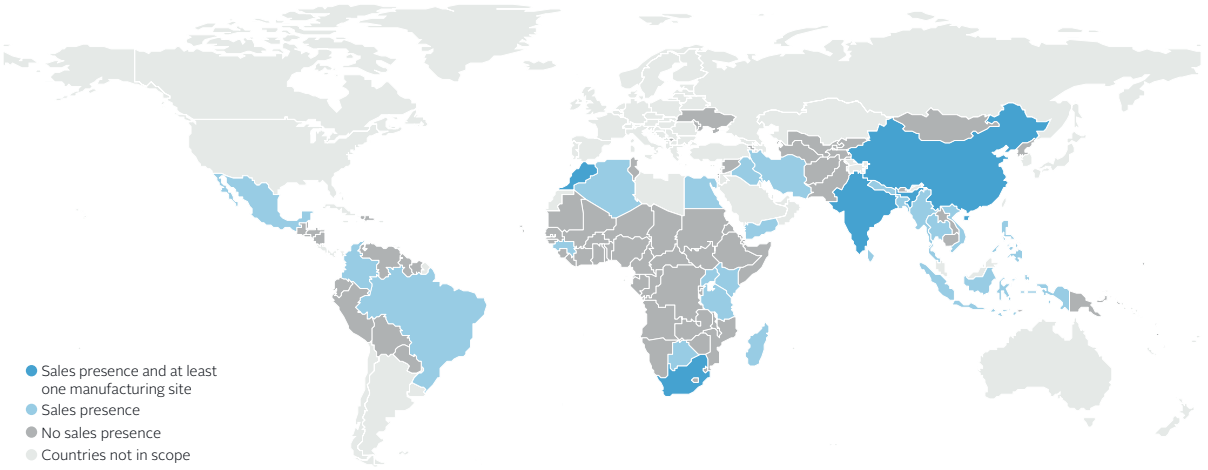
*Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

**South Africa, sub-Saharan Africa, and the countries covered by the Cipla Global Access business.

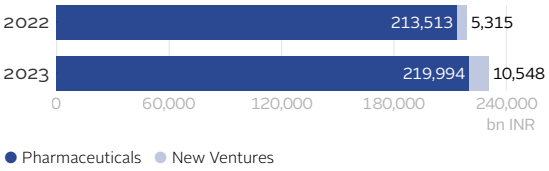
Cipla exclusively submitted data for the evaluation of themes EA2, EA3, EA4, RD1 and RD2. All other information was initially sourced from publicly available data and subsequently fact checked by the company.

COMPANY PRESENCE & REVENUE

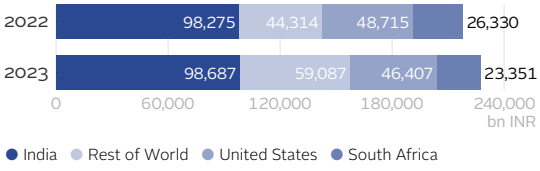
Sales and manufacturing presence in countries in scope



Revenue by business segment*



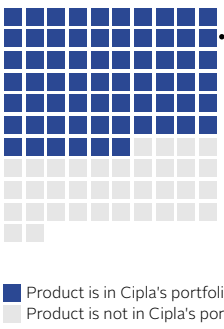
Revenue by region*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Cipla has 66 products within its portfolio. Cipla's portfolio has a strong focus on non-communicable diseases (NCDs), as well as communicable diseases (CDs) including bacterial infections, HIV and hepatitis B and C.



66 products
These target a range of disease categories, namely NCDs (40), CDs (21), neglected tropical diseases (3) and reproductive, maternal and newborn conditions (4). Two products fall into multiple categories.

Products selected for assessment

Of the in-scope products that Cipla has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Carboplatin	Cancer
Cisplatin	Cancer
Rituximab	Cancer
Telmisartan	Hypertensive heart disease
Formoterol/budesonide	Asthma
	Chronic obstructive pulmonary disease (COPD)
Salbutamol	Asthma
	COPD
Metformin	Diabetes mellitus
Nitrofurantoin	Bacterial infection
Abacavir/lamivudine (ABC+3TC)	HIV
Sofosbuvir	Hepatitis C

*Financial year (FY) 2022 covers April 2021 - March 2022. FY 2023 covers April 2022 – March 2023.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Cipla commits to ensuring access to its medicines globally and reports working towards improving their availability and affordability, but does not present evidence of an overarching access-to-medicine strategy. The company's Corporate Social Responsibility (CSR) division carries out its activities through the Cipla Foundation, the company's philanthropy arm, and focuses on five key areas: health, education, environmental sustainability, disaster response activities and skillset development. Additionally, through its "Cipla Global Access" (CGA) business, the company expands access to products, including those targeting HIV, tuberculosis, and malaria, by working with international and donor organisations to supply essential medicines in LMICs. CGA also collaborates with procurement agencies to identify reliable suppliers and ensure efficient delivery of medicines. While the board approves and monitors the company's CSR activities, Cipla does not report where the highest responsibility lies for ensuring access to medicine in LMICs. Moreover, the company identifies availability and affordability of its medicines as a high-priority topic in its recent materiality assessment, providing evidence of supplying medicines for affordable prices. For example, since 2001 it offers a one-dollar-a-day treatment for HIV patients in Africa. Although access considerations guide some of the company's activities, it does not disclose measurable and time-bound objectives for its access-to-medicine commitments, nor specific strategies to ensure sustainable access and expand patient reach.

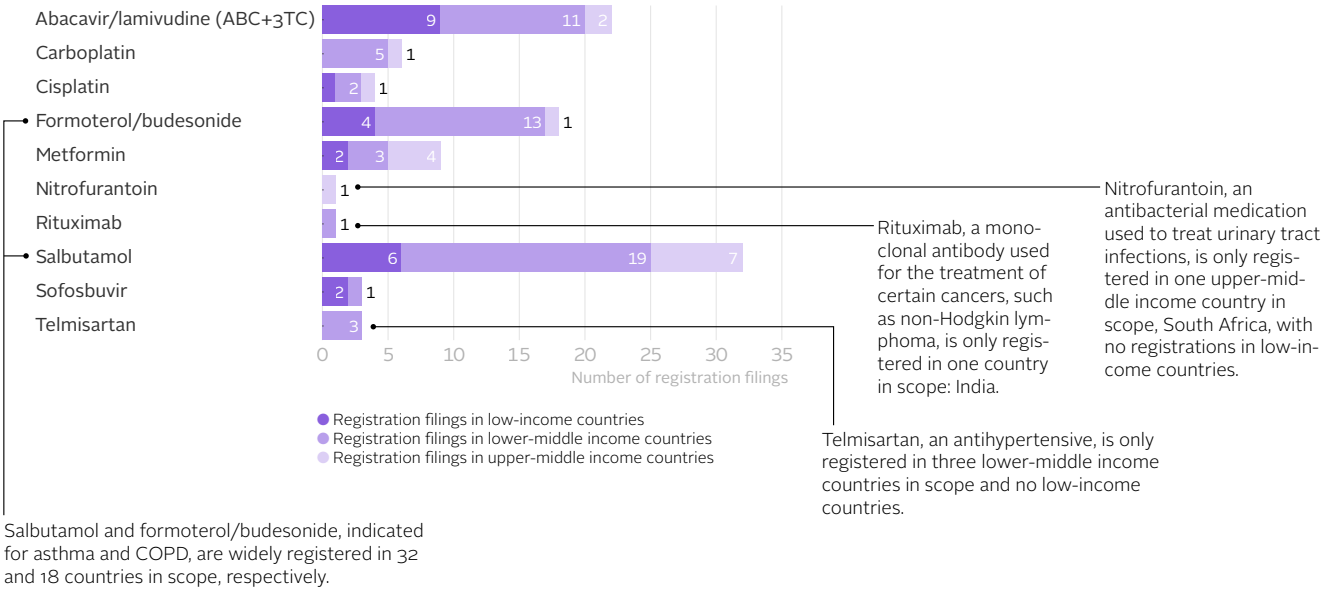
EA2. PRODUCT REGISTRATION

Cipla has filed to register or successfully registered at least one product within its entire portfolio in 61 LMICs in scope. This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in LMICs in scope.

Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines were selected for assessment. Cipla has filed at least one of these products for registration in a total of 48 out of the 61 LMICs (79%) where it has pre-existing regulatory filings,* showing the company's capacity to register across a wide geographic area. These ten products have all been registered in at least one country in scope, with one product registered in a total of 32 countries. For low-income countries, the company registers the ten products selected for assessment in 14 out of the 15 low-income countries where it has pre-existing regulatory filings.* This is significant as in general regulatory filings in these countries are low, and significant gaps in access to essential medicines remain.** However, carboplatin, rituximab, telmisartan and nitrofurantoin were not registered in any low-income countries. The company engages in mechanisms designed to facilitate the registration of quality-assured products in LMICs. Several of the company's products have been registered in the AFRO*** region and Ukraine through the World Health Organization (WHO) Collaborative Registration Procedure (CRP) for WHO Prequalified products, including products to treat HIV, hepatitis C, malaria, soil-transmitted helminthiasis, maternal haemorrhage, and tuberculosis. Examples of such products are fixed-dose antiretroviral combinations abacavir/lamivudine and dolutegravir/lamivudine/tenofovir disoproxil fumarate to treat HIV, along with an emergency contraceptive method, levonorgestrel. Moreover, five of the company's products (outside the product scope of this analysis) have been recommended for approval by ZaZiBoNa.†

In April 2021, the company's subsidiary Cipla Quality Chemical Industries Limited (CiplaQCIL), based in Uganda, was approved to manufacture and distribute medicines to the Economic Community of West African States and ZaZiBoNa regions in Africa. In March 2023, the company announced it would be divesting its stake in CiplaQCIL. The impact of this divestment is unknown, however, Cipla reports that they have reached mutual agreements with CiplaQCIL for transition and technology support, ensuring business continuity for the near and medium term.

FIGURE 1 **Registration filings of ten products selected for assessment across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall outside the scope of the Generic & Biosimilar Medicines Programme.

**Based on data analysed in the 2022 Access to Medicine Index and the 2021 Antimicrobial Resistance Benchmark.

***AFRO region includes countries including but not limited to: Botswana, Democratic Republic of the Congo, Ghana, Malawi, Mozambique, Namibia, Nigeria, Tanzania, Uganda, Zambia and Zimbabwe

†ZaZiBoNa process is a work-sharing initiative amongst national regulatory authorities (NRAs) in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Democratic Republic of Congo, Tanzania, Malawi and Mozambique.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

Seven out of the ten products selected for assessment are covered by an access strategy in the public and/or private market. Cipla submitted examples of access strategies for its products in a range of country income classifications, with examples provided from three upper-middle income countries, one lower-middle income country and three low-income countries. For the country examples provided, the company primarily participates in government tenders to facilitate access to its products within the public sector. In the private sector, Cipla adheres to local pricing policies and employs competitor-based pricing strategies to determine the pricing of its products. However, the company only provides evidence of the number of patients reached for one product, and it does not provide evidence of forecasting patient reach for any of the ten products.

For one of the products, sofosbuvir, indicated for hepatitis C, the company participates in tenders to supply the product in the public sector in several countries; this includes Rwanda, which was selected as a specific country example. In Rwanda, the product is fully funded by the government, meaning that individual patients do not have to pay for their treatment.

For three of the ten products assessed (metformin, nitrofurantoin and salbutamol), Cipla reports implementing access strategies in both the public and private sectors within South Africa. In the public sector, the company supplies the three products via government tenders which are awarded based on the lowest pricing, and the entire cost is government funded. In the private sector, the company implements competitor-based pricing strategies. The resulting price is then submitted to the Department of Health, which approves the final price (the single exit price) at which the company sells the products. The product's price is covered by private insurance, either fully or partially, depending on the plans to which the patient is subscribed. Patients not part of a private scheme will pay out-of-pocket for their medicines, and it is unclear if the product is affordable for these patients. Furthermore, the success of these tender strategies remains uncertain due to the lack of evidence regarding the number of patients reached by such initiatives.

Cipla supplies abacavir/lamivudine (ABC + 3TC) in 20 countries, in which its access strategies are primarily focused on the public sector. Of these, Benin, a low-income country, has been selected as an example for this analysis. In Benin, the company supplies the product via participating in tenders issued by the government or by international agencies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). By engaging in supranational procurement, Cipla aims to expand access to affordable, quality-assured products while reducing commercial risks. The company supplies products below agency-set ceiling prices, with tender allocation based on factors including competitive pricing, delivery timeline and minimum procurement quantities. Cipla submitted patient reach data for abacavir/lamivudine (ABC+3TC), using the volume of tablets supplied as a metric for number of patients reached. In the period from April 2019 to July 2023, the company provided a total of 1.6 million tablets in Benin. Across the 20 countries it supplies, the company supplied 180 million tablets between January 2020 and April 2023.

For two of the ten products assessed, formoterol/budesonide and telmisartan, the examples of access strategies submitted – in Zambia and Madagascar, respectively – only cover patients in the private sector. In these countries, the price of each product is set based on the competitor landscape, and patients have to pay out of pocket. Furthermore, the company did not provide evidence of patient reach, therefore it is unclear if the company has ensured access to the two products in the countries where it operates.

FIGURE 2 **How many products are covered by an access strategy?**

For each of the ten products selected for assessment, Cipla was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure. Where details on country-specific access strategies were not shared, the company was not assessed.

International Nonproprietary Name (INN)	Country	Public market access/pricing strategies	Private market access/pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability*
Abacavir/lamivudine (ABC+3TC)	Benin (LIC)	●		●		
Carboplatin	No country-specific access strategy					
Cisplatin	No country-specific access strategy					
Formoterol/budesonide	Madagascar (LIC)		●			
Metformin	South Africa (UMIC)	●	●			
Nitrofurantoin	South Africa (UMIC)	●	●			
Rituximab	No country-specific access strategy					
Salbutamol	South Africa (UMIC)	●	●			
Sofosbuvir	Rwanda (LIC)	●				
Telmisartan	Zambia (LMIC)		●			

For three assessed products, carboplatin, cisplatin, rituximab, Cipla did not provide evidence of expanding access within LMICs in scope.

*For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

Five in-licensed products were selected for assessment: dolutegravir (adult) and lopinavir/ritonavir (paediatric), indicated for HIV; dulaglutide, indicated for type 2 diabetes; and molnupiravir and remdesivir, indicated for COVID-19.

Cipla was granted a non-exclusive voluntary licensing agreement (NEVL) for dolutegravir (adult) facilitated through the Medicines Patent Pool (MPP). The company has registered this product in 22 countries in scope, including Mozambique, Zambia and Zimbabwe, three of the ten countries with the highest disease burden for HIV. The company supplied approximately 25 million tablets in countries in scope and has supplied over one billion doses of the fixed dose combination (FDC) tenofovir, lamivudine, and dolutegravir globally.

The company has an exclusive licensing agreement with Eli Lilly to market and distribute Trulicity® (dulaglutide), a treatment for type 2 diabetes, in India.* Eli Lilly is responsible for manufacturing the product and is the primary marketing authorisation holder, with Cipla being the second. It was reported that 142,800 units of Trulicity® were sold from June 2022 to June 2023.

Examples of Cipla's licensing agreements

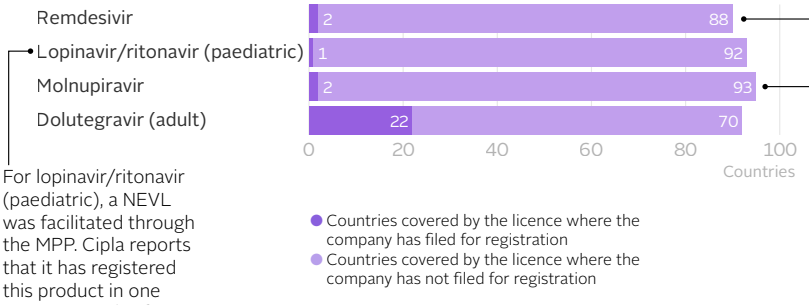
In March 2023, Cipla entered into a NEVL with ViiV Healthcare, facilitated by the MPP, for cabotegravir (CAB) long acting (LA) for HIV pre-exposure prophylaxis (PrEP) which will be manufactured in India and South Africa. An extended-release formulation of CAB, the first long-acting injectable for HIV PrEP, was approved in 2021. This extended dosing regimen, administered through a single injection every two months, offers a convenient alternative to daily oral medication, by reducing dosing frequency and improving treatment adherence and administration challenges in LMICs. The agreement allows three generic manufacturers to develop, manufacture, and supply generic versions in 87 countries in scope, prior to patent expiry of the original drug in 2031.

Cipla and ViiV Healthcare also signed an MPP licence for dolutegravir (paediatric), the terms of which also allows licensees to combine dolutegravir with other antiretrovirals to develop fixed dose combinations.

In December 2022, Cipla received approval from the Global Fund for abacavir, lamivudine and dolutegravir FDC for use in children.

FIGURE 3 **Registration filings of Cipla's in-licensed products****

This figure shows the number of LMICs in scope where Cipla has filed for registration or registered four in-licensed products out of the five selected for assessment, compared to the total number of countries covered by the licensing agreement.*



For lopinavir/ritonavir (paediatric), a NEVL was facilitated through the MPP. Cipla reports that it has registered this product in one country, South Africa.

Cipla was granted NEVLs for two COVID-19 products, molnupiravir and remdesivir. Several factors including clinical guidelines and widespread rollout of COVID-19 vaccinations reduced demand for these products and as a result both products were only registered in Thailand and Indonesia. However, the company retains the right to register and supply these products, should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Cipla's manufacturing network consists of 47 sites globally, with several sites located in LMICs in scope, including China, India, Morocco and South Africa. As part of its three-year (2020-2023) business strategy within its SAGA*** region, covering countries across the African continent, Cipla aims to improve product availability by strengthening its local manufacturing presence through expansions and optimisations of its existing sites and by developing new sites. As part of this strategy, it also states that it aims to maintain its focus in sub-Saharan Africa by growing and launching new products, including cardiovascular and respiratory therapies. For 2023-2024, the company reports that it aims to strengthen its private market position in the region and is planning new product launches targeting cardiovascular diseases and diabetes.

Cipla reports market growth in certain African countries. For instance, in South Africa, the growth appears to be driven by products in the private market, including those targeting neurological and respiratory diseases. Cipla has also reported a strong presence in Kenya, where it markets a branded fixed-dose antidiabetic medication, and it has entered the market in Ghana, following recent regulatory approvals.

In 2014, Cipla acquired a stake in Quality Chemical Industries Limited (QCIL) in Uganda, which has served as a hub to supply antiretrovirals (ARVs), antimalarials and hepatitis B products in the country and the region. However, in March 2023 it was announced that Cipla will divest its stake in QCIL, with the site ceasing to be a subsidiary of the company. Cipla and QCIL have established transition agreements for short and medium-term business continuity. The extent of Cipla's continued manufacturing and supply presence in the region remains uncertain. Furthermore, Cipla commissioned a new manufacturing site during 2021 - 2022 in Qidong, China to manufacture respiratory products for emerging markets.† The company recently reported growth in countries including Nepal and Sri Lanka.

Cipla does not disclose being involved in technology transfers or partnerships to develop or enhance local manufacturing in countries in scope.

*Cipla's Trulicity® licence with Eli Lilly was excluded from this analysis as Cipla is not the primary market authorisation holder and therefore not responsible for registering the product.

**Products may be available through other mechanisms without having been filed for registration by the company.

***South Africa, sub-Saharan Africa and Cipla Global Access.

†Cipla's definition of emerging markets covers the Latin American, North African, Middle Eastern, South Asian (excluding India) and the Pacific regions.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Cipla reports having an internal system for forecasting and demand planning. This includes both a 12-month rolling forecast process, and a long-term demand planning process that looks five years ahead to assess future need, to evaluate, and to build capabilities to meet demand. The company holds monthly planning meetings with its sales and supply chain teams to review the latest demand and supply updates and to take corrective actions. Cipla also reports it has integrated both its Production Planning and Detailed Scheduling system and its Integrated Business Planning system, helping the company improve its capacity utilisation.

While Cipla company reports communicating with critical vendors to ensure a continuous supply of its products, the company did not provide information about data sharing initiatives with external stakeholders such as government agencies and wholesalers to align supply and demand.

SQ2. DELIVERY PERFORMANCE

Cipla reports having a vendor engagement programme to support its vendors by assisting them in improving their performance, such as their On Time in Full (OTIF) scores. The programme seeks to reduce the risk of vendor disqualification and resultant supply chain disruption. The company reports that it uses OTIF to monitor internal delivery performance. During the fiscal year (FY) 2022-2023, it achieved 90% compliance for 21 vendors (as compared to a target of 85% for 20 vendors). In addition, it supported 18 vendors in improving their OTIF scores. For FY 2023-2024, it has set a compliance target of 85%. However, the company does not report how it meets its supply commitments to national and international procurement agencies. Cipla reports implementing tools for improving its supply chain responsiveness, such as a digital platform providing users with updates on purchase order statuses, and a mobile application providing access to supply chain Key Performance Indicators.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Cipla has implemented multiple strategies to promote a continuous supply of its products and mitigate the risk of shortages and stockouts.

The company reports maintaining sufficient buffer stock and inventory of critical components. Cipla reports using stock norms ranging from two to 12 months in India, with some exceptions made for certain components. It also audits its stocks on a regular basis and secures quantities of active pharmaceutical ingredients (APIs) in advance. To mitigate shortages, the company applies a rolling 12-month open purchase order pipeline for key components. It also reports monitoring the risk of shortages and stockouts on a monthly basis and planning corrective or preventive actions accordingly. However, the company does not disclose the specific countries in which it holds stocks for regional supply, or where it has taken steps to decentralise stocks of critical components.

Cipla reports having diversified its sources for critical APIs, intermediates and key starting materials to reduce single source dependency. In line with this, the company has taken steps to de-risk its upstream supply by implementing an alternative vendor development strategy, which also aims to reduce costs and promote local manufacturing. It also reports implementing vendor reviews as a way to address logistical challenges and ensure uninterrupted raw material supply. In addition, for 2022-2023, the company reports having spent 62% of its total procurement budget on sourcing locally to the country of operation, including in India, South Africa and Uganda.

Cipla produces APIs both for its own use and for supplying customers in over 50 countries. It reports having supplied over 110 distinct APIs to third parties during 2022-2023, which include ingredients for gastrointestinal, central nervous system and respiratory therapies. It also states it will continue focusing on critical and high-demand APIs to ensure uninterrupted supplies to key customers. The company has transitioned its supply chain management strategy from a pull to a push strategy to manufacturing products in advance to reduce lead times and maintain sufficient stocks.

Cipla's additional approaches to prevent shortages and stockouts include placing advance orders with vendors and transporters, entering rate contracts with sea liners and booking cargo slots in advance.

FIGURE 4 **What steps is Cipla taking to mitigate stockouts and shortages?**
This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	●
Disclosure of the frequency of stock auditing	
Holding regional stocks and/or making efforts to decentralise stocks of critical components	●
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	●
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	●
Other initiatives to fulfil emergency orders and/or surges in demand	●

Cipla has implemented an alternative vendor development strategy, which aims to de-risk its upstream supply, reduce costs and promote local manufacturing.

Cipla states that they hold regional stocks in LMICs, however, it does not disclose specific strategies to expand or decentralise its stocks.

Cipla reports engaging in local sourcing in India, South Africa and Uganda.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Cipla reports that its 47 manufacturing facilities are current Good Manufacturing Practices (cGMP) compliant, in alignment with international regulatory authorities. It also reports that its sites have been inspected by Stringent Regulatory Authorities (SRAs) including MHRA (UK), EMA (EU), FDA (US), TGA (Australia) and by National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) such as EDA (Egypt), and CDSCO (India). However, there is no publicly available information on which of the 47 manufacturing sites have approval from at least one SRA and/or NRA operating at ML3/4.* The company does participate in the WHO Prequalification programme and is subject to inspections by WHO.

Cipla has implemented various initiatives to standardise quality management across its manufacturing sites. For instance, the company has rolled out the Quality Metric Program (QMP), a compliance monitoring tool, in additional regions in Africa and emerging markets. QMP, is a governance programme used to track quality critical key performance indicators through the company's Quality Management System (QMS). Furthermore, Cipla has implemented several digitisation and automation projects to reduce variability and ensure consistency in quality control processes. For example, the company implemented a laboratory information management system and a software platform, 'TrackWise', at its sites in India and overseas to digitise and automate its QMS data. This platform aims to streamline operations and improve risk management, including management of Corrective Action and Preventive Action (CAPA) processes. This module of the QMS has already been implemented in several countries in scope, including South Africa and Uganda.

Cipla evaluates its vendors, suppliers, and contract manufacturing organisations on quality parameters to ensure compliance with cGMP requirements. The company has a supplier code of conduct to follow and performs annual supplier audits and event-based supplier engagement on compliance and QMS. To address gaps in cGMP practices, regulatory compliance, and audit readiness, the company has a vendor engagement programme and a 'Supplier Scorecard', which is a performance monitoring tool that evaluates supplier transactions on quality, delivery and cost parameters and approximately 1,100 suppliers have been assessed.

Cipla received a warning letter from the FDA (US) on 25 February 2020, regarding significant GMP violations for finished pharmaceuticals at its Goa site in India.** Cipla reported the site was reinspected in August 2022 and is working with the FDA to address the observations from the inspection.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Cipla implements strategies to ensure the quality and safety of its marketed products. The company discloses the number of annual recalls it receives and conducts a Health Hazard Evaluation for each recalled batch to assess the impact on public health. Additionally, it reports that it responds to regulatory audit observations within defined timelines. The company reported that if a falsified medicine is confirmed, it will promptly notify authorisation holders, customers, regulatory bodies and relevant authorities. However, the company does not disclose whether it has a policy to mitigate the circulation of substandard and falsified medicines.

In an effort to mitigate falsified and substandard medicines, the company has introduced an automated track and trace system with unique product serialisation for the EU, and primary packaging serialisation for US-bound products. Cipla reports automated tracking and tracing systems outside the EU and US.The company reports that for its products marketed in India, it provides details of the primary manufacturer plant and discloses third party sourced product components on the packaging.

FIGURE 5 **Depth and breadth of quality-assurance strategies**
This table shows the types of strategies Cipla implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	●
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)*	
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficient manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including to which authorities and/or organisations the company reports encounters of substandard or falsified medicines	
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	●
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	●

The company also reports that its sites have been inspected by multiple SRAs and by NRAs operating at ML3*. However, outside of the company's API sites, there is no publicly available information on which of the company's 47 manufacturing sites have approval from at least one SRA and/or NRA operating at ML3/4.*

Cipla reports that its automated track and trace systems are implemented to other countries outside the EU and US.

*As benchmarked against WHO Global Benchmarking Tool (GBT).

**Cipla Limited, FEI 3004081307, at L138; L!39 - 146; L147/A; L147/1 - 147/3; S103 - 105; S107 - 112; M61 - 63, Verna, Goa.

RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

During the period of analysis, Cipla had one adaptive R&D project in its pipeline, meaning the company was adapting a product to ensure it was better suited for LMIC settings. Cipla developed a granule-filled capsule containing a 4-in-1 paediatric fixed-dose combination (FDC) of ARVs (abacavir, lamivudine, lopinavir, ritonavir) for the treatment of HIV. The FDC is heat-stable and does not contain alcohol or inappropriate solvents. The HIV drug was developed in partnership with Drugs for Neglected Diseases initiative (DND*i*), Unitaid, Stellenbosch University, and Tygerberg Hospital and was approved by South African Health Product Regulatory Authority (SAHPRA) in June 2022. This product is currently awaiting approval from other regulatory bodies, such as the US FDA. It can be sprinkled on food without leaving an aftertaste, due to its granular texture and strawberry flavour. Additionally, by developing a new FDC, a complicated dosage regimen is simplified, which helps with treatment adherence. The development of this product has the potential to ease administration and improve outcomes in children living with HIV.

RD2. ACCESS PLANNING

The company does not disclose having an overarching policy or structured framework in place for systematically developing access plans during R&D for its adapted products.

However, for the one adaptive R&D project example in scope, Cipla has a comprehensive access plan in place. The product, Quadrimune, was developed in collaboration with product development partner DND*i*, who ensure that plans for equitable and affordable access are put in place during the drug development process. The product was approved in South Africa and dispatched to the Democratic Republic of Congo (DRC), as per temporary authorisation received for the DRC during the period of analysis. However, the company did not disclose further details on plans for registration in countries in scope.

To address affordability, the access plan includes transparent and publicly available details on pricing plans for South Africa. Cipla has committed to offering Quadrimune at ex-factory prices of USD 15 for 120 capsules for young children and infants. Ultimately, this commitment will price the drug USD 1 per day (USD 360 per year) for children weighing 10 to 13.9 kg. For younger children and infants, this price drops to USD 0.50 per day.

FIGURE 6 **Example of a late-stage adaptive R&D project in Cipla's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
4 in 1 combination of ARVs (abacavir/ lamivudine/lopinavir/ritonavir)	HIV/AIDS	Approved	Drugs for Neglected Diseases initiative (DND*i*), Stellenbosch University, Tygerberg Hospital, Unitaid and others	New paediatric fixed dose combination with strawberry flavour and granules, which ease administration and improve adherence	Equitable pricing plan; Partnership with an accesss-oriented organisation; Approved in South Africa and temporarily authorised in the Democratic Republic of the Congo

Hikma Pharmaceuticals Plc

HQ: London, United Kingdom • Ticker: HIK • Stock exchange: LSE • Nr. of employees: 8,800

COMPANY SUMMARY

Hikma has access to medicine commitments integrated within its business strategy. To expand access to its off-patent and in-licensed products, the company leverages its strong presence and local manufacturing capacity in the Middle East and North Africa (MENA) region. By actively participating in government tenders, the company secures the supply of medicines to the public sector in the countries in which it operates. As a sublicensee, the company has helped lower the price of cancer products, showcasing its ability to utilise its local presence and distribution capabilities to improve product availability and promptly respond to shifts in demand. To ensure a continuous supply of quality-assured products, Hikma implements multiple strategies, including data sharing initiatives and efforts to improve the management of its own supply chain. The company maintains robust quality assurance systems at its own sites and manages quality risks at third-party sites. Hikma reports two examples of adaptive R&D projects, both of which are for antibiotics targeting respiratory infections. The company has also developed formulations with enhanced stability and storage requirements, suitable for use in low- and middle- income countries (LMICs).

Main therapeutic areas
Antidiabetics; anti-infectives; cardiovascular; central nervous system; gastrointestinal; oncology; respiratory.

Business segments
Branded; Generics; Injectables; Other.

Product categories
Active pharmaceutical ingredients (APIs); biosimilars; generic medicines.

Sales presence*
Hikma reports sales in nine countries in scope.

OPPORTUNITIES FOR HIKMA

Expand registration of essential cancer products.
Hikma has registered fluorouracil, a chemotherapy treatment for various cancers, in one country in scope: Egypt, a lower-middle income country. The company has registered gemcitabine, another treatment targeting multiple cancers, in two countries in scope: Algeria, a lower-middle income country, and Sudan, a low-income country. Hikma can consider expanding the registration of these cancer products to other LMICs, particularly those with a high disease burden or those where the company has previously filed other products for registration, such as Morocco and Tunisia.

Strengthen access strategies for oxytocin to ensure availability and affordability for low-income and vulnerable patients
Hikma implements a private sector pricing strategy for oxytocin in Iraq that follows local pricing policies. Oxytocin is crucial for preventing postpartum haemorrhage, a leading cause of maternal mortality in the country. In Iraq, private health insurance is uncommon, and most patients rely on paying out-of-pocket. To expand equitable access and adequate supply for pregnant patients paying out-of-pocket, Hikma can employ access strategies that include elements to address affordability and local barriers to access. Hikma can also engage with public procurement authorities to expand access to oxytocin in the public sector.

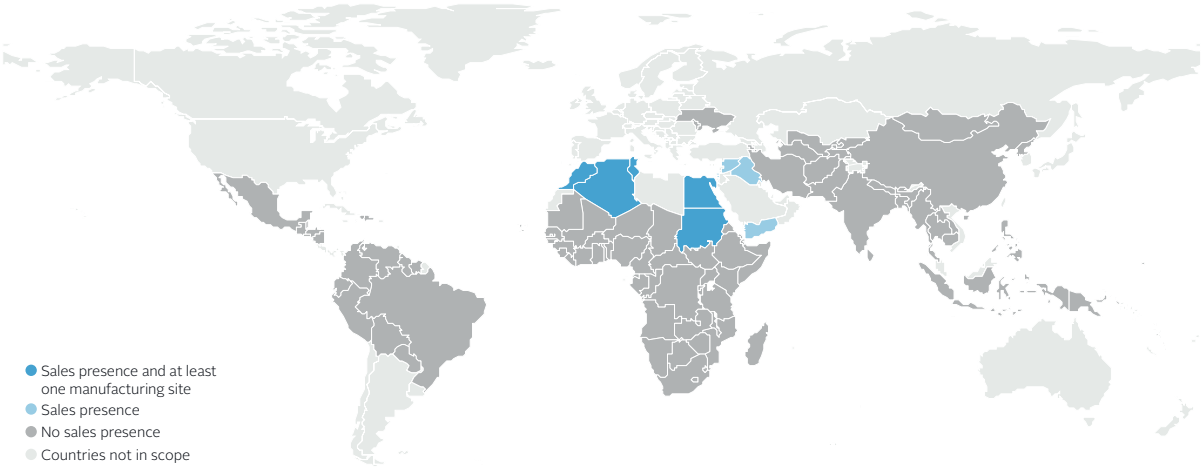
Engage further in adaptive R&D to develop products that address the needs of people in LMICs.
Hikma has demonstrated its capability to develop adaptive R&D projects with favourable storage conditions for people living in LMICs, by developing single-dose sachets of the antibiotics cefaclor and cefalexin - indicated for lower respiratory infections, among other infections. The company can continue leveraging its R&D expertise to adapt products targeting diseases with high burdens in LMICs, where treatment options are ineffective or lacking, such as paediatric formulations.

Expand reach to more LMICs in Africa
Hikma seeks to expand the availability of its generic medicines through harnessing its manufacturing footprint and established local presence across the Middle East and North Africa (MENA) region. Hikma can build on this foundation to expand its operations and reach more LMICs, within the MENA region and beyond, especially in more countries across Africa. The company can leverage its expertise in both direct sales, and distribution and licensing partnerships to address unmet needs in more countries. This is in line with Hikma's corporate strategy, as the company underscored the importance of expanding its reach into new markets in its Sustainability Report 2022.

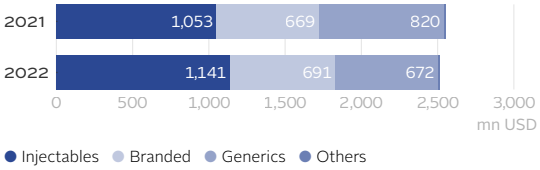
*Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

COMPANY PRESENCE & REVENUE

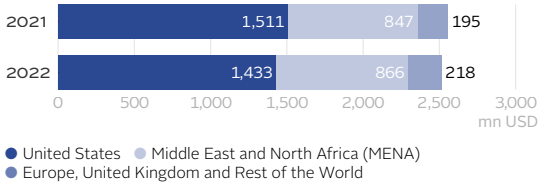
Sales and manufacturing presence in countries in scope



Revenue by business segment*



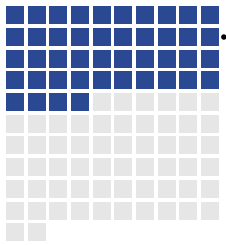
Revenue by region*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Hikma has 44 products within its portfolio. Hikma's portfolio has a strong focus on non-communicable diseases (NCDs), particularly cancer, with 14 products. Additionally, the company focuses on certain communicable diseases (CDs), including bacterial infections, for which it has ten antibiotics in scope.



44 products
These target NCDs (29); CDs (13); neglected tropical diseases (1); and reproductive, maternal and newborn conditions (2). One product falls into multiple categories.

Product is in Hikma's portfolio
Product is not in Hikma's portfolio

Products selected for assessment

Of the in-scope products that Hikma has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Amikacin	Bacterial infection
Bisoprolol	Hypertensive heart disease
	Ischaemic heart disease
Fluorouracil	Cancer
Gemcitabine	Cancer
Metformin	Diabetes mellitus
Metronidazole	Bacterial and parasitic infection
Oxytocin	Maternal haemorrhage
Risperidone	Schizophrenia
	Bipolar affective disorder
Salbutamol	Asthma
	Chronic obstructive pulmonary disease (COPD)
Valsartan	Hypertensive heart disease

*Financial year (FY) 2021 covers January - December 2021. FY 2022 covers January - December 2022.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Hikma integrates its access-to-medicine commitments within its business model and corporate strategy, demonstrating how access is a crucial part of its business operations and long-term growth. The company states a commitment towards improving access to medicine across its geographies, which is supported by its sustainability focus area of "advancing health and wellbeing" and its corporate social responsibility (CSR) activities. These commitments and CSR activities encompass its product donations, market adaptations to address product shortages, collaborations with global health organisations and its initiatives to support education and community outreach. To ensure accountability for its access-to-medicine commitments and activities at the senior level, the company has established an Access to Medicine Committee, which is chaired by two members of its executive committee, one of whom is also a member of the board. The company does not disclose measurable and time-bound objectives for its access commitments, nor does it outline specific goals to extend its patient reach, other than expanding its product donations and growing sales and product volumes across its markets.

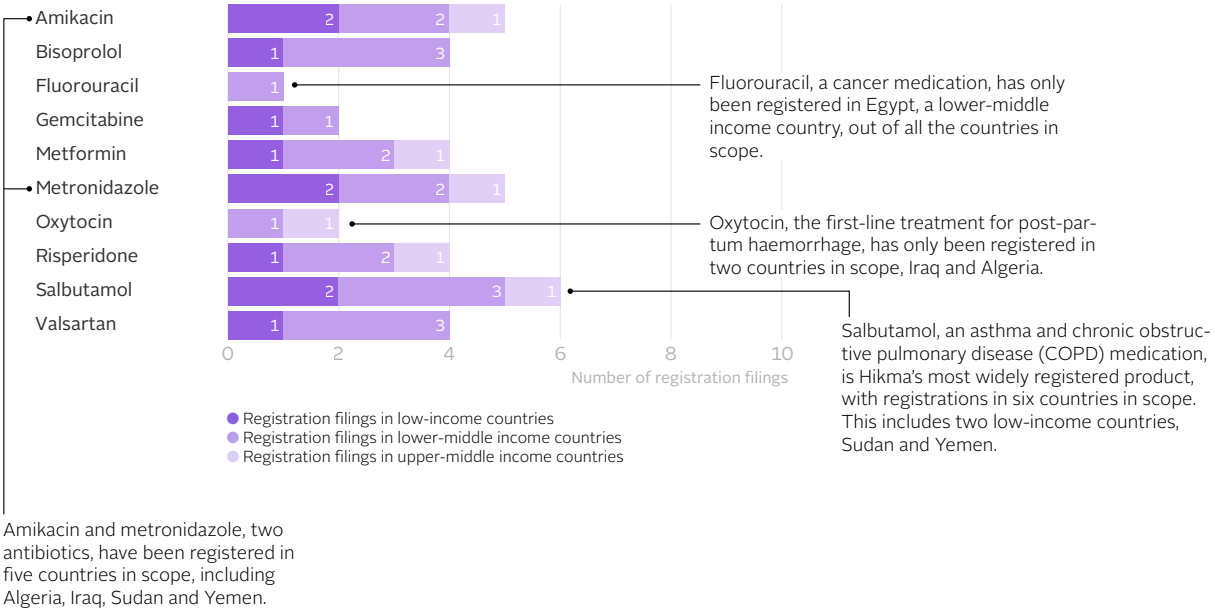
EA2. PRODUCT REGISTRATION

Hikma has filed to register or successfully registered at least one product within its entire portfolio in nine LMICs in scope, specifically, Algeria, Egypt, Iraq, Morocco, Palestine, Sudan, Syria, Tunisia, and Yemen. This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in LMICs in scope.

Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines were selected for assessment. Hikma has filed at least one of these products for registration in a total of seven out of the nine (78%) LMICs in scope where it has pre-existing regulatory filings*. Moreover, all ten products have been filed in at least one country in scope, with some registered in up to seven countries. The company demonstrates good practice by making efforts to file its products for registration in low-income countries. For example, eight of the ten products are filed for registration in at least one low-income country, with three products registered in two low-income countries (Sudan and Yemen) where the company operates. This is significant, as low commercial potential and limited regulatory capacity in low-income countries pose challenges to registering products and can prevent patients from receiving timely access to effective and quality-assured medicines **.

Hikma does not actively engage in mechanisms to facilitate registration, such as the World Health Organization (WHO) Collaborative Registration Procedure or regional joint assessments. In countries where Hikma has local manufacturing capabilities, including Algeria, Egypt, Morocco, Sudan and Tunisia, it engages with governing bodies to bring products to market.

FIGURE 1 **Registration filings of ten products selected for assessment across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall out side the scope of the Generic & Biosimilar Medicines Programme.

**Based on data analysed in the 2022 Access to Medicine Index and the 2021 Antimicrobial Resistance Benchmark.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

Hikma demonstrates its commitment to expanding access to the ten products selected for assessment, all of which are covered by at least one access strategy either in the public or private market. Hikma submitted examples of access strategies for one upper-middle, three lower-middle, and one low-income country. Nine products are further complemented by initiatives to build capacity in LMICs, such as educational activities for healthcare professionals and disease awareness programmes. The company provides evidence of the number of patients reached, reported as the number of units sold, for all ten products. It also reports forecasting patient reach to help anticipate future demand.

Of the ten products, the company makes at least one available in the public sector in four out of the nine countries in scope in which it operates, mainly by participating in tenders. During the period of analysis, Hikma was awarded or actively participated in tenders for seven of the ten products. These tenders were awarded based on multiple criteria, such as price, quality, and delivery time, and can be an effective tool for governments to obtain discounts. This includes medicines indicated for CDs, as well as medicines for NCDs including cancer, cardiovascular diseases, asthma and lower respiratory tract infections. Successful tender bids indicate that the company offered favourable terms compared to other suppliers, and that it satisfied requirements set by the public payer, including competitive pricing.

The company supplies its products in the public and/or private markets, while tailoring its approach depending on the country's context. The company supplies gemcitabine and metformin in Sudan, risperidone in Algeria and salbutamol in Morocco through public market tenders. Within these countries, some patients are covered by the national insurance scheme, where the public authority reimburses the products. In Egypt, the company sells three products, namely fluorouracil, bisoprolol and amikacin, in both the public and private markets. The company follows national regulations in Egypt, which involve pricing control measures for pharmaceutical products, which impact the maximum price manufacturers can set for their medicines sold in the private market. To reach different segments of the population, the company sets different prices for the public and private markets, with lower prices offered in public tenders. While such measures can contribute to affordability, it remains unclear whether and how Hikma implements efforts to ensure that those at the bottom of the income pyramid, particular those in the private market without health insurance, can afford its medicines.

For metronidazole, oxytocin and valsartan, the company provides examples of access strategies that exclusively target the private markets in Iraq (for metronidazole and oxytocin) and Sudan (for valsartan). In both countries, the price of generic medicine is regulated within the private market, where the company follows the local price control mechanisms. Moreover, to outperform competitors and offer more affordable prices, the company utilises competitive strategies to price some of the products.

Examples of Hikma's access and pricing strategies

In Sudan,* a low-income country, Hikma supplies gemcitabine, a cancer treatment, in the public sector via government tenders. The tender assessment considers price and lead time as key factors, and the product is fully funded by the government. Additionally, in 2022, the company partnered with the Sadagaat Charity Organization, a non-profit organisation supporting vulnerable populations, to conduct an educational programme in Khartoum, Sudan. The programme seeks to raise awareness about early diagnosis and prevention of breast cancer, targeting 15,000 underserved women and offering free examinations to approximately 5,000 women.

In Egypt, a lower-middle income country, the company supplies fluorouracil, a cancer treatment, and amikacin, an anti-infective, in the public sector via government tenders. For both products, it engages in initiatives to build healthcare capacity locally. For fluorouracil, it implements an annual breast cancer screening programme and, in some cases, follow-up testing to evaluate the medication response. Additionally, for amikacin, the company provides educational materials and access to testing and diagnostics, if not available at hospitals, seeking to ensure the appropriate use of antimicrobials.

FIGURE 2 **How many products are covered by an access strategy?**

For each of the ten products selected for assessment, Hikma was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure.

International Nonproprietary Name (INN)	Country	Public market access/pricing strategies	Private market access/pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability**
Amikacin	Egypt (LMIC)	●	●	●	●	
Bisoprolol	Egypt (LMIC)	●	●	●	●	
Fluorouracil	Egypt (LMIC)	●	●	●	●	
Gemcitabine	Sudan (LIC)*	●		●	●	
Metformin	Sudan (LIC)*	●		●	●	
Metronidazole	Iraq (UMIC)		●	●	●	
Oxytocin	Iraq (UMIC)		●	●	●	
Risperidone	Algeria (LMIC)	●		●	●	
Salbutamol	Morocco (LMIC)	●		●	●	
Valsartan	Sudan (LIC)*		●	●	●	

Hikma provided evidence of implementing initiatives aimed at strengthening healthcare systems in LMICs in scope. While such strategies can improve patient outcomes and help ensure continuity of care, there is currently no evidence suggesting they can improve affordability or availability of the products.

*The supply of this and other products in Sudan may be interrupted due to the ongoing conflict. However, the company's efforts during the period of analysis are captured in the assessment.

**For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

Four in-licensed products were selected for assessment: rituximab, indicated for leukaemia and non-Hodgkin's lymphoma; trastuzumab, indicated for breast and stomach cancer; and molnupiravir and nirmatrelvir, indicated for COVID-19.

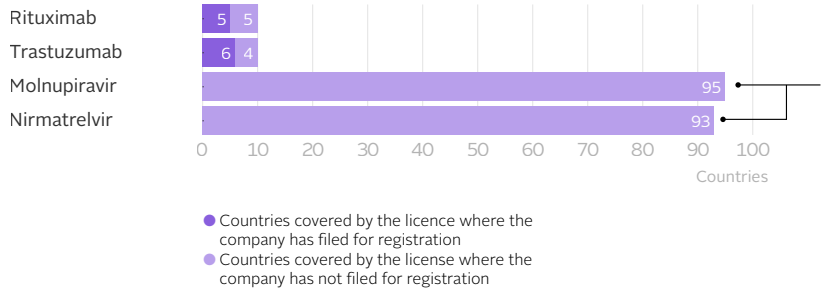
Hikma is currently engaged in two exclusive licensing agreements for trastuzumab and rituximab with Celltrion Healthcare Co., Ltd., who have received WHO prequalification (PQ) for both products. As part of these agreements, Celltrion is responsible for manufacturing the product, while Hikma is responsible for commercialisation across the MENA region.

The company reports that it has helped reduce the price of trastuzumab and rituximab by introducing the first biosimilar versions – the former in Iraq and Morocco, and the latter in Algeria. For both products, the company reports the number of patients reached.

Furthermore, Hikma has set objectives to increase the number of patients receiving trastuzmab in Algeria and rituximab in Iraq and Egypt. While licensing agreements increase availability and potentially reduce the price through biosimilar competition, it is unclear whether Hikma takes the payers' ability to pay into account across different segments of the population when setting the price for these products.

FIGURE 3 **Registration filings of Hikma's in-licensed products***

This figure shows the number of LMICs in scope where Hikma has filed for registration or registered its four in-licensed products selected for assessment, compared to the total number of countries covered by the licensing agreement.



Hikma has entered non-exclusive voluntary licenses for two COVID-19 antivirals – molnupiravir and nirmatrelvir – through the Medicines Patent Pool (MPP). These agreements were made after the COVID-19 vaccines were rolled out, which reduced the demand for these products. Consequently, the company has not filed these products for registration in any LMICs within scope. However, the company retains the right to register and supply these products, should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Hikma's manufacturing network comprises 32 sites globally, with a total of 16 located in Algeria, Egypt, Morocco, Tunisia and Sudan. Overall, the company has 23 sites in the MENA region, which may make it easier for the company to respond to demand fluctuations, prioritise certain products in specific markets, and understand local market needs.

The company implements efforts to scale up and develop its manufacturing presence and capacity in some of the LMICs in scope. For instance, in 2021, Hikma began operating its newly developed oral oncology plant, in Algeria, to supply oncology products within the country. In addition, the company is in the process of constructing two new injectable manufacturing sites in Algeria and Morocco, which will be leveraged to increase the supply of and access to injectable medicines within these two markets. In 2022, Hikma invested USD 72 million in its manufacturing sites across the MENA region to enhance manufacturing capacity, partly covering its injectable sites in Algeria and Morocco; however, the proportion of the investment going towards its sites in LMICs is not reported. In the same year, in response to increased demand, the company scaled up its manufacturing capacity in Algeria by increasing production of the anti-infective amoxicillin/clavulanic acid by adding additional filling lines.

Furthermore, the company reports engaging in technology transfers as part of its toll and contract manufacturing activities in LMICs in scope. This includes engaging in technology transfers to local pharmaceutical manufacturers in Egypt and Tunisia. However, the details and activities of these transfers remain unclear, as the company reports that its extensive market presence across the MENA region reduces the need for them.

*Products may be available through other mechanisms without having been filed for registration by the company.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Hikma reports that it has established an internal system for forecasting and demand planning that allows it to effectively manage inventory and identify potential supply constraints. The company undertakes sales and operations planning on a monthly basis, and it evaluates projections for both demand and supply. The company implements forecasting 24 months ahead, on a rolling basis, and creates five-year business plans. Hikma also collaborates with national authorities and procurement agencies to ensure its effective participation in tenders and to respond to specific product needs. For example, by sharing its supply plans and capacity, Hikma contributes to both preventing and fulfilling shortages, thereby ensuring an adequate supply of its products.

Examples of Hikma's data sharing initiatives

In Algeria, Hikma works with the Ministry of Pharmaceutical Industry to prevent product shortages by providing monthly reports with its production plans and current stocks of finished goods and APIs. Additionally, in Egypt, the company collaborates with stakeholders such as the Egyptian Drug Authority, the Unified Procurement Authority and health insurance companies to improve forecasting and demand planning. Through these collaborations, Hikma can promptly address shortages of oncology products in Egypt by scaling up its manufacturing capabilities as needed.

SQ2. DELIVERY PERFORMANCE

Hikma has implemented a system to monitor and track delivery performance within its MENA markets. This includes regular tracking of metrics such as On Time in Full (OTIF), Line-Item Fill Rate (LIFR) and Fill Rate on a quarterly basis. The company has dedicated teams to manage its supply chains at both the regional and site level.

In the event of delivery delays, Hikma's supply chain team maintains regular communication with its internal commercial team and follow-up meetings are held to review products' shipping status and agree on action plans, until the issue is resolved. The company has established a structured process to communicate information on supply constraints and potential delivery delays to external stakeholders, including local buyers', through its in-country key account managers. They work together, as needed, to develop a mitigation plan.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Hikma has implemented multiple strategies to promote a continuous supply of its products and mitigate the risk of stockouts and shortages.

The company reports maintaining a safety stock of raw materials, packaging materials and finished goods, and applies a policy of a minimum stock level of finished goods with its wholesalers and agents. To reduce the risk of stockouts, the company employs specific stocking strategies as needed. In 2020, the company conducted a reassessment of its stock levels and, as a result, increased its inventory levels. In addition, the company reports setting inventory targets per site and undertaking audit stocks on a monthly basis. Hikma reports specific steps to decentralise critical component stocks in the LMICs where it operates. For instance, it establishes stock levels and targets for each manufacturing site on a quarterly basis to meet demand.

The company reports taking steps to promote supplier diversity. In 2016, it implemented an enterprise risk management programme to establish alternative sources of active pharmaceutical ingredients (APIs) and improve supply reliability and continuity. Hikma also reports it is actively evaluating opportunities to qualify alternative sources of raw materials and packaging materials. As part of this effort, the company recently extended its assessment to include excipients and glass. Additionally, the company reports that the majority of its secondary packaging materials are sourced locally, which enables better control over product availability.

While the company is primarily involved in the production of finished dosage forms, it also has capabilities to manufacture APIs. One notable example is the company's manufacturing plant in Jordan, which specialises in APIs for oncology medicines. This capability enables the company to vertically integrate its supply chain and to manufacture and supply cancer products throughout the MENA region. The company also utilises manufacturing sites within its network to scale up production and maintain continuity of supply of high-demand products. For instance, it reports having restructured distribution models to adapt to supply needs in countries such as Sudan and Yemen. Furthermore, it has worked to secure capacity with freight forwarders and shipping companies to ensure a reliable supply chain.

Examples of Hikma's strategies to mitigate shortages

In Egypt, Hikma has implemented strategies to ensure a consistent supply of essential medicines. During the COVID-19 pandemic, the company quickly responded to market demands by significantly increasing its production of azithromycin, an anti-infective drug. In 2022, the company reports that it maintained an uninterrupted supply of capecitabine, a cancer medication, despite a tenfold increase in demand due to national import constraints. By leveraging its local presence, the company implemented effective measures to ensure a steady supply and meet patients' needs.

FIGURE 4 **What steps is Hikma taking to mitigate stockouts and shortages?**

This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	●
Disclosure of the frequency of stock auditing	●
Holding regional stocks and/or making efforts to decentralise stocks of critical components	●
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	●
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	●
Other initiatives to fulfil emergency orders and/or surges in demand	●

By identifying at-risk API sources, Hikma implements specific stocking strategies to minimise the risk of shortages.

Hikma leverages its API manufacturing capability in Jordan to manufacture and supply cancer products in the MENA region. It also reports having a Standard Operating Procedure (SOP) for scaling up and transferring technology for API processes across Hikma's API plants, should a surge in demand arise.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Hikma reports complying with a range of industry and government regulations to ensure the manufacturing of quality-assured products at its sites. This includes current good manufacturing practices (cGMPs) and current good distribution/storage practices set by various regulatory agencies such as the FDA (US), EMA (Europe), and MENA health authorities.

Of the company's 32 manufacturing sites, 15 are inspected by stringent regulatory authorities (SRAs) including US, UK or EU regulators. Of these 15, six are located in the MENA region, but in countries out of scope of this analysis. The remaining sites operate under national/local equivalent authorities. The company has not submitted any products to the WHO PQ programme, which exempts the company from manufacturing site inspections by the WHO. No warning letters from the FDA or non-compliance reports from the EMA were issued at Hikma's sites in countries in scope during the period of analysis.

The company utilises its engineering expertise from its FDA-inspected facilities, for example in Portugal, to standardise quality across other sites, including at its injectable sites in Algeria and Morocco, which are currently under construction. Hikma uses a variety of compliance monitoring and automated quality control systems to ensure quality assurance. The company has a Quality Council, which reports to the Executive Committee, which oversees and shares best practices. To ensure consistent cGMP, the company implements global quality systems across its sites, and the Global Quality team conducts frequent internal audits and implements corrective actions for deviations.

Suppliers and sub-licensors are audited and required to adhere to both company and regulatory standards through Quality Agreements. Before onboarding new API suppliers, a quality audit is conducted as a part of Hikma's supplier qualification system, and scheduled audits are also conducted for key suppliers. Suppliers and third parties must comply with the company's Supplier Code of Conduct, with non-compliance potentially leading to termination, depending on the severity of the breach.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Hikma implements strategies to maintain the quality and safety of its products. The company's Pharmacovigilance Policy includes strategies to mitigate the circulation of substandard and falsified medicines in LMICs. The policy includes taking immediate action and reporting any quality concerns and/or falsified medicines encounters to the appropriate authorities in accordance with applicable laws and regulations. Hikma also has a recall procedure in place, and in the event of recall, the company informs and works with the relevant regulatory authority to ensure appropriate actions are taken, in a timely and efficient manner.

The company complies with all applicable laws and regulatory requirements pertaining to falsified medicines, including any requirements for serialisation and track and trace. This includes printing a barcode on each package, that contains a product identifier, "Global Trade Item Number® (GTIN®)", as per the current requirements of the markets in scope. Moreover, Hikma is actively working on a project to serialise its finished products, ensuring product tracking in the case of recalls and mitigating the risks of falsified medicines.

In addition to complying with the product labelling instructions established by local regulatory authorities, the company indicates both the source of the finished product on the label and the distributor's details, if separate from the company. Hikma's internal Enterprise Resource Planning (ERP) system traces all produced lots and provides details of the origin, manufacturing sites, and packaging sites for each lot.

FIGURE 5 **Depth and breadth of quality-assurance strategies**

This table shows the types of strategies Hikma implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	●
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)*	●
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficent manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including information about which authorities and/or organisations the company reports encounters of substandard or falsified medicines	●
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	●
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	●

To manage third-party risks, the company introduced "RiskRate" in 2021, an automated system that assesses 96% of its suppliers, with high-risk suppliers facing enhanced due diligence measures.

Hikma's Pharmacovigilance Policy (PV) captures how the company mitigates the circulation of substandard and falsified medicines.

Hikma's "Global Trade Item Number® (GTIN®)" allows for the prompt detection of potential encounters of substandard and falsified medicines.

*As benchmarked against WHO Global Benchmarking Tool (GBT)

RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

Hikma has adaptive R&D projects in its pipeline to develop products that are better suited for LMIC settings. During the period of analysis, the company provided two examples of adaptive R&D projects for off-patent medicines in scope: cefalexin and cefaclor. Both products are antibiotics that can be used to treat lower respiratory tract infections, amongst other indications. The company has adapted existing formulations of cefalexin and cefaclor to manufacture single-dose sachets. Cefalexin single-dose sachets received marketing authorisation approval by the National Agency for Pharmaceutical Products in Algeria in August 2022, followed by cefaclor in February 2023. The product adaptation means the antibiotic powder can be reconstituted at the time of administration. As a result, they do not require refrigeration (a requirement for the pre-existing suspension formulation). Eliminating the need for refrigeration allows more storage flexibility – an advantage in many low-resource settings. Additionally, the single dose unit can be reconstituted when needed, helping to reduce waste.

RD2. ACCESS PLANNING

The company does not disclose having an overarching policy or structured framework in place for systematically developing access plans during R&D for their adapted products.

However, for both examples of adaptive R&D provided, the company showed evidence of access planning, specifically plans to register the products in at least one country in scope. The company registered both products in Algeria within the period of analysis. Whilst registration is a necessary first step to ensure availability in country, there is no evidence that the company's access plans for adaptive R&D projects consider other components conducive to access, such as affordability and supply. Additionally, to increase availability beyond Algeria, the company can plan to register the products in more countries in the MENA region.

FIGURE 6 **Examples of adaptive R&D projects in Hikma's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
Cefaclor	Lower respiratory infections	Market approval	N/A	Dry powder sachets	Registration plans in countries in scope; product approved in Algeria
Cefalexin	Lower respiratory infections	Market approval	N/A	Dry powder sachets	Registration plans in countries in scope; product approved in Algeria

Sun Pharmaceutical Industries Ltd

HQ: Mumbai, India • Ticker: SUNPHARMA • Stock exchange: NSE • Nr. of employees: 41,000+

COMPANY SUMMARY

Sun Pharma enables access and product availability through its manufacturing network, spanning 43 sites worldwide, and its presence across many low- and middle-income countries (LMICs). The company has successfully filed or registered products in 63 countries in scope, with the ten products selected for this assessment having been prioritised by Sun Pharma for registration in lower-middle and upper-middle income countries. Sun Pharma expands access to its products by engaging in competitive tenders by governments and hospitals to ensure availability in the public sector, while adhering to local pricing policies and competitor-based pricing strategies in the private sector. However, only six of the ten assessed products are covered by an access strategy, and the company submitted no examples of access strategies covering any low-income countries. The company has signed licensing agreements that allow the company to market generic versions of treatments for HIV and COVID-19, but no specific information is provided regarding the countries where Sun Pharma has registered these products. Sun Pharma uses several strategies to reduce the risk of product shortages, including demand forecasting and buffer stock maintenance. Sun Pharma reports one adaptive late-stage R&D project for a fixed dose combination of extended-release tablets treating type 2 diabetes.

Main therapeutic areas
Anti-infectives; cardiology; dermatology; diabetology; gastroenterology; gynaecology; nephrology; neurology; oncology; ophthalmology; orthopaedic; psychiatry; respiratory; urology.

Business segments*
Active pharmaceutical ingredients (APIs); Emerging Markets; Indian Branded Generics; US Business; Rest of the World; Others.

Product categories
APIs; branded generics; consumer health; innovative specialty medicines; generics.

Sales presence**
Sun Pharma reports sales in 49 countries in scope.

OPPORTUNITIES FOR SUN PHARMA

Engage further in adaptive R&D and strengthen access planning for products in the pipeline.
Sun Pharma's extended release fixed-dose combination of dapagliflozin/glimepriride/metformin, indicated for people with type 2 diabetes, demonstrates the company's capability to adapt products and simplify dosage regimens. Sun Pharma can further apply this expertise to adapt other products. For example, for the antiretroviral products in its pipeline, it can adapt products to be more suitable for population groups, such as children. It can also develop its access plans for its R&D projects to ensure they consider barriers to access, such as affordability and supply.

Expand access to essential cancer products, such as doxorubicin
In line with the company's sustainability 'focus area' of product accessibility and responsible pricing, Sun Pharma can use access strategies to increase the affordability and supply of essential cancer medicines in its portfolio. For doxorubicin, indicated for the treatment of different types of cancer, including non-Hodgkin lymphoma, the company can use access strategies that include elements to address affordability issues for patients paying out of pocket. Sun Pharma can apply such strategies in Myanmar, the country with the highest out-of-pocket healthcare spending in South-East Asia, where the company has registered the product.

Leverage manufacturing presence to address access-to-medicine gaps.
Sun Pharma can leverage its large manufacturing network and expand operations in countries where access gaps are prevalent. Drawing upon its experience using its South African manufacturing site to supply essential HIV treatments to neighbouring countries, Sun Pharma can expand the reach of its medicines to further countries in Africa, particularly low-income countries, by leveraging its manufacturing capabilities in South Africa and Nigeria.

Expand registration of in-licensed products as a sublicensee.
Sun Pharma is a sublicensee for a dolutegravir licensing agreement facilitated by the Medicines Patent Pool for the paediatric formulation (10mg scored, dispersible). Yet, the company has not registered this product in any country in scope. The company can file for registration in countries within the scope of the licence,*** prioritising countries with high disease burdens – particularly those where the company has previously successfully registered another project.

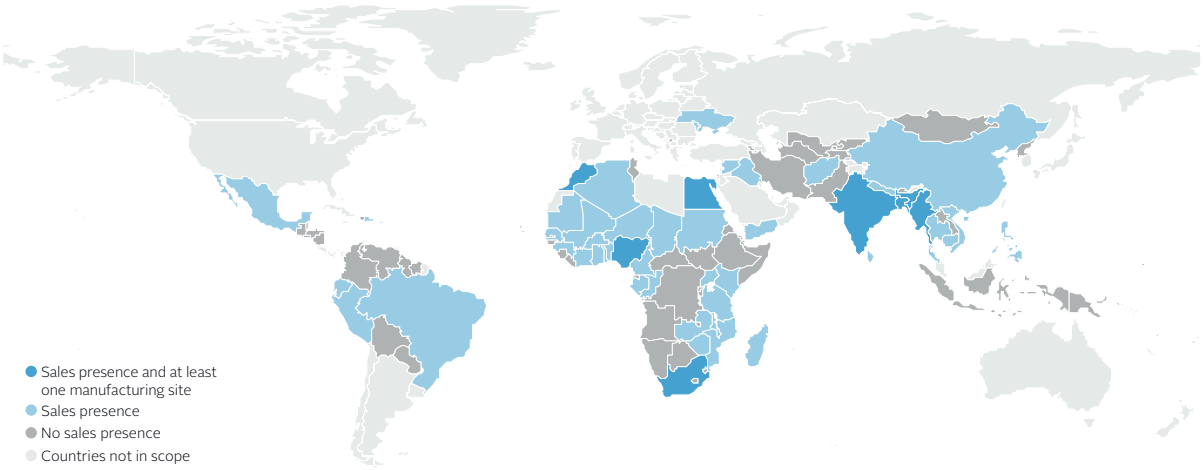
*Sun Pharma also reports the following segments: Global Specialty and Global Consumer Healthcare business.

**Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices. As Sun Pharma did not verify its company presence, this data was sourced from the public domain and previous submissions for the 2021 AMR Benchmark.

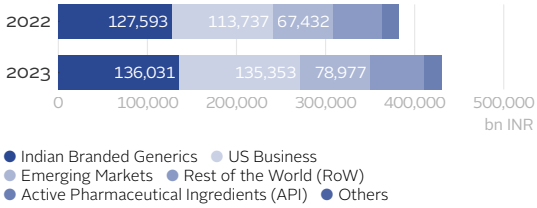
***The licence for dolutegravir paediatric formulation covers 102 countries within the scope of this Programme.

COMPANY PRESENCE & REVENUE

Sales and manufacturing presence in countries in scope

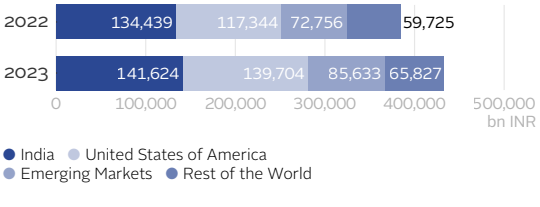


Revenue by business segment*



Indian Branded Generics · US Business · Emerging Markets · Rest of the World (RoW) · Active Pharmaceutical Ingredients (API) · Others

Revenue by region*

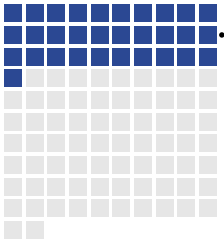


India · United States of America · Emerging Markets · Rest of the World

PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Sun Pharma has at least 31 products within its portfolio.***



31+ products
These target a range of disease categories, namely cancer, bacterial infections, mental health disorders, asthma, chronic obstructive pulmonary disease (COPD), and cardiovascular disease.

Product is in Sun Pharma's portfolio
Product is not in Sun Pharma's portfolio***

Products selected for assessment

Of the in-scope products that Sun Pharma has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Abacavir/lamivudine (ABC+3TC)	HIV
Atorvastatin	Ischaemic heart disease
Carbamazepine	Epilepsy
	Bipolar affective disorder
Doxorubicin	Cancer
Fluoxetine	Unipolar depressive disorders
	Anxiety disorders
Gemcitabine	Cancer
Gliclazide	Diabetes mellitus
Metoprolol	Hypertensive heart disease
	Ischaemic heart disease
Sumatriptan	Migraine
Tranexamic acid	Maternal haemorrhage

*Financial year (FY) 2022 covers April 2021 – March 2022. FY 2023 covers April 2022 – March 2023. The company reports the revenues from its Global Consumer Healthcare and Global Speciality businesses as part of the listed business segments.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

***Sun Pharma verified that the ten products selected for assessment are included in its portfolio. However, the company did not confirm which of the 102 products in scope are in its wider portfolio. Thus, the analysis relies on data from Sun Pharma's India catalogue and India Product list accessed on 14 June 2023.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Sun Pharma reports a general commitment to expanding access, but does not present evidence of an overarching access-to-medicine strategy. The company places emphasis on product accessibility and responsible pricing as crucial aspects of its sustainability focus, as highlighted in its Environment, Social, and Governance (ESG) strategy. Additionally, Sun Pharma has stated its commitment to provide uninterrupted access to quality-assured medicines. However, there is limited information available about the scope of this commitment, such as the countries and products covered.

Under Sun Pharma's ESG strategy, the corporate social responsibility (CSR) division reports directly to the board of directors. However, it is unclear whether the CSR committee or the board holds ultimate responsibility for access to medicine. Furthermore, the company does not disclose measurable and time-bound objectives for its access-to-medicine commitments, nor does it outline specific strategies for achieving sustainable access and expanding patient reach. Establishing such objectives and strategies is critical for guiding Sun Pharma's access-to-medicine efforts and demonstrating the importance of access in the company's long-term growth.

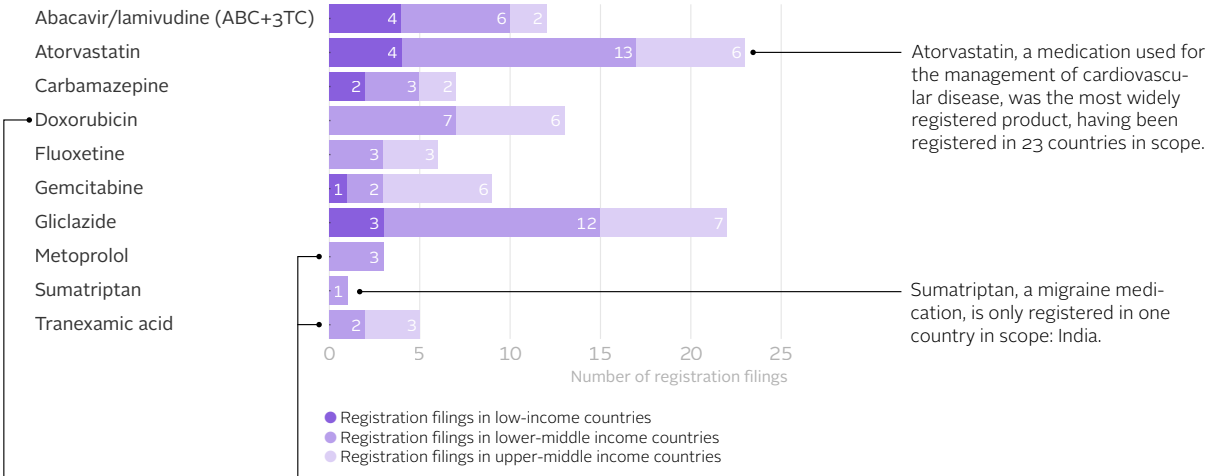
EA2. PRODUCT REGISTRATION

Sun Pharma has filed to register or successfully registered at least one product within its entire portfolio in 63 LMICs in scope. This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in LMICs in scope.

Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines were selected for assessment. Sun Pharma has filed at least one of these products in a total of 42 out of the 63 LMICs (67%) where it has pre-existing regulatory filings.* This shows the company's capacity to register across a wide geographic area. These ten products have all been registered in at least one country in scope, with one product registered in a total of 23 countries. Out of the ten products, only five are registered in at least one low-income country, where significant gaps in access to essential medicines are prevalent.**

For a variety of its products, the company engages in mechanisms designed to facilitate wider registration in LMICs. Several of the company's products have been registered through the World Health Organization (WHO) Collaborative Registration Procedure (CRP) for WHO Prequalified products in multiple countries in the AFRO region*** and the Philippines. These products include HIV medicines abacavir/lamivudine and dolutegravir/lamivudine/tenofovir disoproxil fumarate. Additionally, a few of the company's products (outside the product scope of this analysis) have been recommended for approval by ZaZiBoNa.†

FIGURE 1 **Registration filings of ten products selected for assessment across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall outside the scope of the Generic & Biosimilar Medicines Programme.

**Based on data analysed in the 2022 Access to Medicine Index and the 2021 Antimicrobial Resistance Benchmark.

***AFRO region includes countries including but not limited to: Botswana, Democratic Republic of the Congo, Ghana, Malawi, Mozambique, Namibia, Nigeria, Tanzania, Uganda, Zambia and Zimbabwe

†The ZaZiBoNa process is a work-sharing initiative amongst national regulatory authorities in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Democratic Republic of Congo, Tanzania, Malawi and Mozambique.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

In the country-specific examples provided by Sun Pharma, six out of the ten products selected for assessment are covered by an access strategy in the public and/or private market. Across the assessed products, Sun Pharma reported access strategies in lower- and upper-middle income countries, with no examples of access strategies for low-income countries. Based on the examples of in-country access strategies submitted for analysis, the company primarily participates in government and hospital tenders, which can facilitate access to its products within the public sector. However, the company only provides evidence of patient reach for two of the ten products, and it does not provide evidence of forecasting patient reach for any of the ten products.

In the private sector, Sun Pharma adheres to local pricing policies and employs competitor-based pricing strategies to determine the pricing of its products. Examples of access strategies submitted for atorvastatin, gliclazide, and metoprolol show that the company sets prices for its products based on local pricing policies, including the respective external reference pricing system implemented in each country.

For carbamazepine, fluoxetine and gemcitabine, Sun Pharma reports implementing access strategies in both the public and private sectors of LMICs in scope.

In Morocco, the company engages in government and hospital tenders to supply carbamazepine within the public sector. It also supplies the product in the Moroccan private sector, where it sets prices using competitor-based pricing. The company reports evidence of cumulative patient reach in five countries, including Morocco, where it supplies the product carbamazepine. Collectively, Sun Pharma estimates that approximately 523,000 patients were provided access to carbamazepine in five countries in scope between April 2020 and April 2023.

Sun Pharma adopts a similar strategy for fluoxetine and gemcitabine, participating in public sector tenders in countries in scope, while also supplying the private market – setting prices based on the competitor landscape. For fluoxetine, the company participates in public sector tenders in several countries in scope; this includes Kenya, which was selected as a specific country example. However, it emphasises that participation in tenders is not the primary strategy it employs to expand access. In the Kenyan private market, Sun Pharma employs competitor-based pricing strategies to supply the products. While the company provides evidence of the cumulative number of patients reached in five countries in scope where it supplies fluoxetine, including Kenya, it remains unclear whether the pricing strategies employed by the company ensure access to affordable prices for all patients across the income pyramid.

For gemcitabine, Sun Pharma reports engaging in public sector tenders in Thailand, as well as supplying the private market. However, the company does not provide any estimates regarding the number of patients reached through these efforts. It remains unclear whether Sun Pharma considers affordability when setting prices for the private sector, especially for individuals that pay out of pocket. Although the company reports implementing a patient support programme for gemcitabine in Thailand, there is a lack of available information regarding the programme's details and its effectiveness in ensuring access for patients within the country.

For three assessed products, abacavir/lamivudine, doxorubicin, and tranexamic acid, Sun Pharma did not report access strategies, indicating the company may not be taking steps to ensure the availability and affordability of these products in countries in scope. Additionally, while evidence was provided for improving the availability and affordability of sumatriptan, it was not specific to any country within the programme's scope.

FIGURE 2 **How many products are covered by an access strategy?**
For each of the ten products selected for assessment, Sun Pharma was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure. Where details on country-specific access strategies were not shared, the company was not assessed.

International Nonproprietary Name (INN)	Country	Public market access/pricing strategies	Private market access/pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability**
Abacavir/lamivudine (ABC+3TC)	No country-specific access strategy					
Atorvastatin	Bangladesh (LMIC)		●			
Carbamazepine	Morocco (LMIC)	●	●	●*		
Doxorubicin	No country-specific access strategy					
Fluoxetine	Kenya (LMIC)	●	●	●*		
Gemcitabine	Thailand (UMIC)	●	●			●
Gliclazide	Sri Lanka (LMIC)		●			
Metoprolol	Nepal (LMIC)		●			
Sumatriptan	No country-specific access strategy					
Tranexamic acid	No country-specific access strategy					

For these products, Sun Pharma provides evidence of implementing initiatives aimed at improving access to diagnostics and education materials in countries in scope. While such strategies can play a critical role in improving patient outcomes and ensuring continuity of care, there is currently no evidence suggesting they can improve affordability.

*Sun Pharma provided aggregated patient reach for carbamazepine and fluoxetine, and as such, the country-specific patient reach estimates are unknown.

**For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

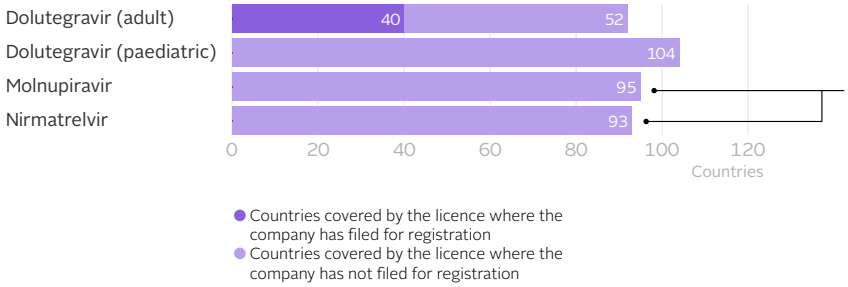
EA4. ENGAGING IN LICENSING ACTIVITIES

For Sun Pharma, five in-licensed products were selected for assessment: dolutegravir (paediatric) and dolutegravir (adult), indicated for the treatment of HIV; carbetocin, indicated for maternal haemorrhage; and molnupiravir and nirmatrelvir, indicated for COVID-19.

Sun Pharma was granted a non-exclusive voluntary licensing agreement (NEVL) for dolutegravir (paediatric) and dolutegravir (adult) facilitated through the Medicines Patent Pool (MPP). For the paediatric dose and formulation, the company did not report where this product was registered and as a result, the impact of this NEVL in countries in scope is unknown. For the adult dose and formulation of dolutegravir, the company reports that it is a global supplier with 40 registrations in LMICs;* however the company provided neither details on the specific countries where the product is registered, nor details of the impact of this licence on improving the affordability of this product.

Sun Pharma is currently engaged in one exclusive licensing agreement with Ferring Pharmaceuticals to distribute carbetocin, indicated for prevention of post-partum haemorrhage. This formulation is stable at room temperature and therefore offers advantages for use in LMICs over the current first-line treatment oxytocin (which requires refrigeration). Sun Pharma has only been granted co-marketing rights for heat-stable carbetocin in India, exclusively within the private market. The product was approved and launched in India in June 2021, and it was co-marketed with the originator company Ferring Pharmaceuticals. The company did not report further details on the licensing agreement, including whether the agreement has increased the number of patients receiving heat-stable carbetocin in India.

FIGURE 3 **Registration filings of Sun Pharma's in-licensed products****
This figure shows the number of LMICs in scope where Sun Pharma has filed for registration or registered four in-licensed products out of the five selected for assessment, compared to the total number of countries covered by the licensing agreement.***



Sun Pharma was granted two NEVLs for COVID-19 antivirals – molnupiravir and nirmatrelvir. The nirmatrelvir agreement was facilitated through the Medicines Patent Pool (MPP). These agreements were made after the COVID-19 vaccines were rolled out, which reduced the demand for these products. Consequently, the company has not filed these products for registration in any LMICs within scope. However, the company did report that molnupiravir is currently under review with WHO for prequalification (PQ) and the company retains the right to register and supply these products, should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Sun Pharma's manufacturing network comprises 43 manufacturing sites globally, including 29 finished dosage manufacturing sites and 14 API manufacturing facilities. The company reports that its large manufacturing network, with facilities in multiple countries, provides increased flexibility that enables it to effectively service the markets in which it operates, thereby leading to improved product availability. The company reports that it operates several finished dosage manufacturing sites located in LMICs in scope, including in Bangladesh, Egypt, Nigeria and South Africa.

Through the company's manufacturing presence in South Africa, Sun Pharma reports supplying antiretrovirals (ARVs) to neighbouring countries in southern Africa. It also reports supporting the HIV/AIDS Treatment Programme of the Ministry of Health of Morocco by making ARVs available in this country. Sun Pharma supplies medicines such as antibiotics and antihypertensives in South Africa and Nigeria.

Sun Pharma has stated that it undertakes technology transfers between its own manufacturing sites specifically pertaining to the transfer of product processes and analytical methods from one site to another within the same region in India. However, the details regarding these technology transfers and their impact on improving product availability within the region are currently unknown. Sun Pharma does not disclose being involved in technology transfers with external stakeholders and/or partnerships to develop or enhance local manufacturing in countries in scope.

*Sun Pharma did not disclose which specific 40 LMICs these are. The correspondence of the countries with the Programme's geographic scope therefore cannot be verified.

**Products may be available through other mechanisms without having been filed for registration by the company.

***The company did not provide registration data for the carbetocin licensing agreement.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Sun Pharma reports implementing demand forecasting in order to plan for short-, mid- and long-term requirements and to schedule production, using a forecasting system that operates up to 12 months in advance. It also reports that its demand planning teams work closely with sales teams to ensure adequate planning aligned with sales forecasts. In the financial year 2021-2022, Sun Pharma reported that it had maintained regular communication with the Indian government since the beginning of the COVID-19 pandemic providing updates on information such as sales, stock status and raw material status of key medicines.

However, there is no publicly available information indicating whether Sun Pharma engages in data sharing activities with external stakeholders from other countries, or beyond the context of COVID-19, to align supply and demand of its products.

SQ2. DELIVERY PERFORMANCE

Sun Pharma reports having systems in place to monitor and review internal delivery performance. However, it has not reported any information about what these systems consist of and/or how they are employed. The company states that it proactively communicates with stakeholders in case of delivery delays. However, no further details were provided regarding its communication strategies or other measures taken in such situations.

Furthermore, Sun Pharma does not report details about how successfully it fulfils its supply commitments to national and international procurement agencies. Additionally, the company does not publicly report its processes to ensure the consistent and timely delivery of quality-assured products to LMICs.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Sun Pharma has implemented some strategies to promote a continuous supply of products and mitigate the risk of shortages and stockouts.

The company reports maintaining a buffer stock of critical components such as raw materials, excipients, APIs and finished products. It has also stated that supply chain continuity, along with a focus on inventory optimisation, is a top priority for the financial year 2023. However, no information was provided regarding strategies to optimise inventories or conduct audits of the company's stock. Additionally, it is not clear in which LMICs in scope the company holds stocks or if it has taken any steps to decentralise stocks of critical components.

To reduce supply risks, Sun Pharma reports sourcing critical items from multiple suppliers and states that it evaluates alternative suppliers for critical or non-substitutable raw materials. In 2021-2022, Sun Pharma reported sourcing 61% of its direct procurement from local suppliers with the aim of strengthening its supply chain, improving operational flexibility and reducing costs.

Furthermore, the company has established a Strategic Procurement Committee to identify potential supply risks and implement mitigation measures. The company also reports coordinating with various stakeholders, including clearing and forwarding agents, who are responsible for ensuring that the company's products are cleared through customs. Ultimately, coordination with various stakeholders helps to ensure the overall availability of products.

Sun Pharma produces APIs, both to fulfil its product requirement and supply other manufacturers. This approach has the potential to reduce the company's dependence on third-party suppliers and ensure a reliable supply of APIs. With a portfolio comprising around 380 APIs manufactured across 14 sites (nine of them located in India) and supplied to over 60 countries, Sun Pharma has significant API capabilities. However, the company did not provide specific details on its approach to scaling up API production in response to surges in demand in LMICs, thereby preventing stockouts and shortages.

FIGURE 4 **What steps is Sun Pharma taking to mitigate stockouts and shortages?**
This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	
Disclosure of the frequency of stock auditing	
Holding regional stocks and/or making efforts to decentralise stocks of critical components	
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	●
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	
Other initiatives to fulfil emergency orders and/or surges in demand	●

Sun Pharma has manufacturing sites in LMICs in scope, suggesting the company likely maintains regional stocks. However, it does not disclose specific strategies to expand or decentralise its stocks.

Sun Pharma reports its percentage of procurement sourced from local suppliers. However, it does not provide a definition of local suppliers nor the location of its local sourcing approach.

Sun Pharma reports using multiple upstream suppliers for critical items. However, it does not report a specific strategy to qualify alternative suppliers.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Sun Pharma reports that its own and third-party manufacturing sites maintain a quality management system consistent with international good manufacturing practice (GMP). This includes tracking of corrective and preventive actions (CAPA), mitigating adverse drug events, field alert reporting, and a recall process.

The company does not publicly disclose the number of manufacturing sites that have received approval from at least one stringent regulatory authority (SRA) or NRAs operating at maturity levels 3 or 4.* However, it states that an undisclosed number of its manufacturing facilities are certified by international regulatory bodies, including the FDA (US); EMA (Europe); MHRA (UK); TGA (Australia); SAHPRA (South Africa); BfArM (Germany); ANVISA (Brazil); MFDS (South Korea) and PMDA (Japan). The company is engaged in the WHO prequalification programme, whereby relevant manufacturing sites are assessed in line with WHO GMP.

The company reports that it conducts audits of all its manufacturing sites, contract facilities and vendors, and assesses third-party suppliers and new vendors for compliance with its Supplier Code of Conduct and regulatory requirements. The company states that its vendor performance is tracked regularly, for which it uses a scorecard mechanism.

During the period of analysis, the company received official requests for corrective action from SRAs related to non-conformities with cGMP. In December 2022, the FDA (US) issued a warning letter concerning significant GMP violations for finished pharmaceuticals at the company's Halol** site in India and placed the Halol site on Import Alert 66-40, with 14 products exempted from import alert, subject to certain conditions. In April 2023, a consent decree correspondence/non-compliance letter was issued by the FDA (US), and the company must implement corrective actions at its Mohali*** site before releasing further final product batches into the United States. In 2022, Health Canada also issued non-compliant ratings to Sun Pharma's Halol** , Mohali***, and Paonta Sahib† sites. The company reports that it is taking the required corrective steps.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Sun Pharma reports that it has a policy to address complaints concerning potentially substandard products, including a system for recalling products from the market and alerting appropriate authorities within the required timelines by providing a recall return card and a destruction certificate. However, the company did not provide further details of the policy.

The company takes steps to tackle the risk of substandard and falsified medicines. For instance the company uses 'Track and Trace' technology, which works to ensure the authenticity of its products. However, it is unknown whether this system is applied in LMICs.

Sun Pharma's product packaging contains important information such as the safe use of products, the sourcing of ingredients, and guidance on appropriate storage conditions. The company reports that for every product, the necessary storage conditions are outlined, and the sourcing plant address is provided.

FIGURE 5 **Depth and breadth of quality-assurance strategies**
This table shows the types of strategies Sun Pharma implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)*	
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficient manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including to which authorities and/or organisations the company reports encounters of substandard or falsified medicines	
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	●

The company reports efforts to harmonise compliance processes as part of its quality practices, but it does not provide concrete evidence on whether it implements specific strategies to limit variability in manufacturing processes between sites.

While the company reports implementing a 'Track and Trace' technology, it is unknown whether this system is applied in LMICs.

*As benchmarked against WHO Global Benchmarking Tool (GBT).

**Halol Baroda Highway Halol, Gujarat India, 389350.

***Unit 1 Plot A-41, Sez Industrial Area, Phase Viii A, Mohali, Punjab, 160071 India.

†Paonta Sahib District Sirmour-Village Ganguwala, Himachal Pradesh India 173025.

RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

Sun Pharma has one adaptive R&D project in its pipeline to develop a product that is better suited for LMIC settings. During the period of analysis, the company provided an example of a late-stage (phase II and beyond) adaptive R&D project. This project, currently in Phase III of clinical development, is a fixed dose combination (FDC) of extended release dapagliflozin, glimepiride and metformin for the treatment of type 2 diabetes mellitus. Extended-release FDC tablets simplify dosage regimens and reduce dosage frequency, thus improving adherence and patient outcomes. This is advantageous for both patients and health systems, especially in resource-limited settings.

RD2. ACCESS PLANNING

The company does not disclose having an overarching policy or structured framework in place for systematically developing access plans during R&D for its adapted products.

For the one example of adaptive R&D submitted, the company provided evidence of an access plan. This access plan consists only of filing the product for registration in one country in scope, specifically India. Whilst registration is a necessary first step to ensure availability in a country, there is no evidence that the company's access plan for this product considers other components conducive to access, such as affordability and supply.

FIGURE 6 **Example of an adaptive R&D project in Sun Pharma's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
Dapagliflozin/glimepiride/metformin extended release FDC	Diabetes mellitus	Phase III	N/A	Extended release fixed-dose combination	Registration plans in India

Teva Pharmaceutical Industries Ltd

HQ: Tel Aviv, Israel • Ticker: TEVA • Stock exchange: NYSE / TASE • Nr. of employees: 37,000+

COMPANY SUMMARY

Teva demonstrates its commitment to access to medicine by integrating measurable and time-bound objectives into its business model and corporate strategy. These objectives are publicly reported and tied to the company's sustainability-linked financing framework, fostering accountability. While Teva's business model mostly focuses on high-income countries, the company's products are sold in approximately 40% of LMICs in scope, with the ten products selected for this assessment having been prioritised by Teva for registration in upper-middle income countries. To provide access to its assessed products, Teva employs various strategies, primarily in private markets across regions including sub-Saharan Africa. Teva reports using tender approaches in public markets. The company did not report strategies to increase access in public markets for the ten assessed products. The company has not been a sublicensee of voluntary licensing agreements within countries in scope. It leverages its manufacturing network to supply products globally, including in 39 LMICs where it has a sales presence. To ensure reliable product delivery and minimise shortages, Teva implements various strategies to ensure continuous supply of its products and to uphold quality standards, while making efforts to combat substandard and falsified medicines. Teva has not been assessed in R&D since it is not engaged in any adaptive R&D projects under the scope of this programme.

Main therapeutic areas
Anti-infectives; cardiovascular; central nervous system and pain; diabetes; gastrointestinal; immunology; mental health; oncology; respiratory.

Business segments
Europe; International Markets; North America.

Product categories
Active pharmaceutical ingredients (APIs); biosimilars; generic medicines; innovative medicines.

Sales presence*
Teva reports sales in 39 countries in scope.

OPPORTUNITIES FOR TEVA

Explore engagement in mechanisms to facilitate registration
Teva can explore engaging in mechanisms to facilitate the registration of eligible products, such as the WHO Collaborative Registration Procedure, regional Joint Assessments such as the ASEAN Joint Assessment, the African Regional Joint Assessment initiatives, the CARICOM Joint Assessment, ZaZiBoNa Collaborative Procedure, and Swissmedic MAGHP Procedure. For instance, for the ZaZiBoNa Collaborative Procedure, Teva could consider the inclusion of carboplatin, as well as analgesics, antibiotics, antineoplastic, and blood thinning agents.

Prioritise registration of essential medicines in more lower-middle and low-income countries
Across its entire portfolio, Teva has registered products in 44 countries in scope. For the subset of ten off-patent products selected for assessment, the company has filed for registration in ten upper-middle income countries and six lower-middle income countries. In line with its access target of increasing the number of registrations by 150% in LMICs** by the end of 2025, Teva can expand registration filings across a broader spectrum of countries. For example, it can file cisplatin, an essential medicine indicated for multiple cancers, for registration in lower-middle and low-income countries.

Improve access strategies for essential medicines to ensure affordability for low-income and vulnerable people.
Teva implements an access strategy for lisinopril in Nigeria, specifically targeting the private sector. This medicine treats hypertension, the most common cardiovascular disease in the country. In Nigeria, less than 10% of the population is covered by any health insurance, leading patients to heavily rely on out-of-pocket payments to access health care, which poses significant affordability issues. To expand equitable access and adequate supply for private sector patients, Teva can further strengthen its existing private market access strategy to better address ability to pay and local barriers to access. This approach could help low-income and uninsured patients gain access to essential medicines such as lisinopril.

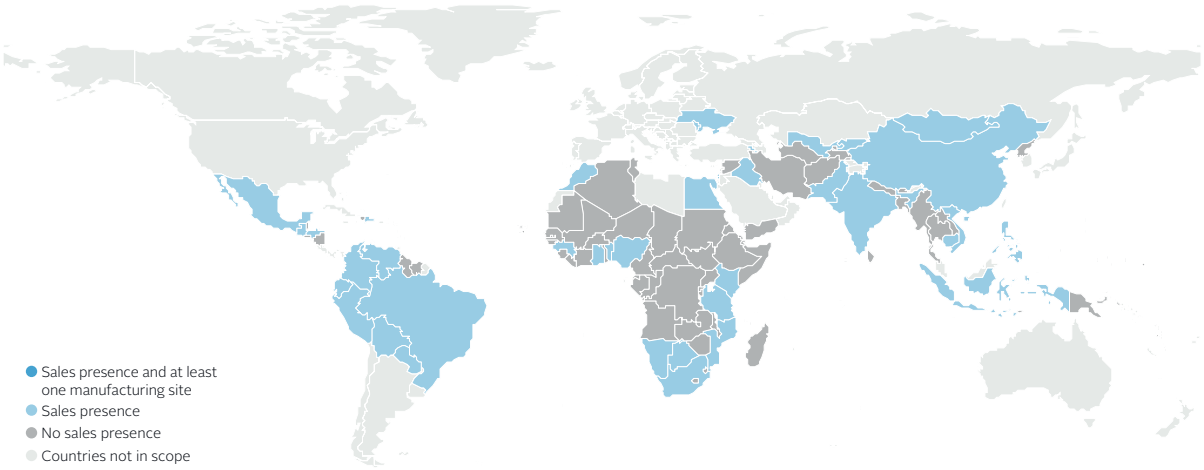
Expand access approaches to incorporate long-term sustainability
Teva has set targets to expand affordable access to medicines to underserved and vulnerable populations in LMICs** through donations and access programmes. Its partnership with Global HOPE to donate cancer medicines in sub-Saharan Africa serves as a strong starting point. Teva can consider expanding and strengthening its access programmes towards sustainable approaches and across more therapeutic areas. By working with local partners such as distributors and local organisations, the company can put in place sustainable access models that increase the availability and affordability of its essential products.

*Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

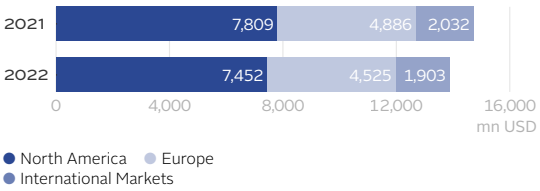
**Teva's definition of LMICs encompasses 127 countries following the 2020 World Bank classification as outlined within its sustainability-linked financing framework. This scope does not precisely match the Programme's country scope of 108 LMICs.

COMPANY PRESENCE & REVENUE

Sales and manufacturing presence in countries in scope



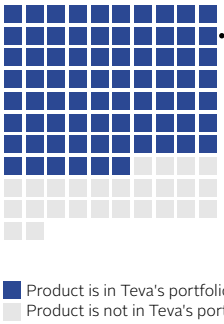
Revenue by business segment*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Teva has 76 products within its portfolio. Teva's portfolio has a strong focus on non-communicable diseases (NCDs), particularly respiratory diseases and cancer, with 18 products for cancer, and 13 products for cardiovascular disease. Additionally, the company focuses on certain communicable diseases (CDs), including bacterial infections, for which it has ten antibiotics in scope.



76 products
These target a range of disease categories, namely NCDs (50); CDs (21); neglected tropical diseases (2); and reproductive, maternal and newborn conditions (6). Three products fall into multiple categories.

Products selected for assessment

Of the in-scope products that Teva has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Azithromycin	Bacterial infection
Budesonide	Asthma
	Chronic obstructive pulmonary disease (COPD)
Capecitabine	Cancer
Carbamazepine	Epilepsy
	Bipolar affective disorder
Carboplatin	Cancer
Cisplatin	Cancer
Fluoxetine	Unipolar depressive disorders
	Anxiety disorders
Lisinopril	Hypertensive heart disease
Risperidone	Schizophrenia
	Bipolar affective disorder
Sumatriptan	Migraine

*Teva reports revenue by region in the same regions that represent the business segments. Financial year (FY) 2021 covers January - December 2021. FY 2022 covers January - December 2022.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Teva integrates its access-to-medicine strategy within its business model and corporate strategy, indicating the company's commitment to addressing access to medicine in LMICs. This strategy is further supported by the company's Environmental, Social and Governance (ESG) strategy.

Teva conducted a materiality assessment in 2022 to inform its strategy, which includes commitments to quantify savings for health systems, implement initiatives such as access programmes for vulnerable populations and patients at the last mile in LMICs,* and establish donation and social business programmes. Teva sets measurable and time-bound objectives as part of its access strategy, which are publicly reported. These objectives and the reporting are tied to its sustainability-linked financing framework and sustainability-linked bonds, enhancing transparency and accountability for its access commitments. Among the objectives are targets to increase the cumulative number of new regulatory submissions by 150% in LMICs across six therapeutic areas** by 2025 (using a 2017-2020 baseline) and to increase product volume by 150% for certain access programmes in LMICs across the same therapeutic areas by 2025 (using a 2020 baseline). As per Teva's 2022 ESG Progress Report, it has accomplished 28% of this target, translating to 21 submissions. Teva announced a new strategy in 2023, which involves reallocating resources from generics to innovative medicines, focusing on high-value products. The impact on the product portfolio and access strategies is as yet unknown. The responsibility for Teva's ESG and access-to-medicine strategy lies with executive management, and oversight is provided by the Compliance Committee of the Board of Directors. The ESG steering committee governs the implementation of the strategy, ensuring accountability at the senior level, with the ultimate responsibility resting with the board of directors.

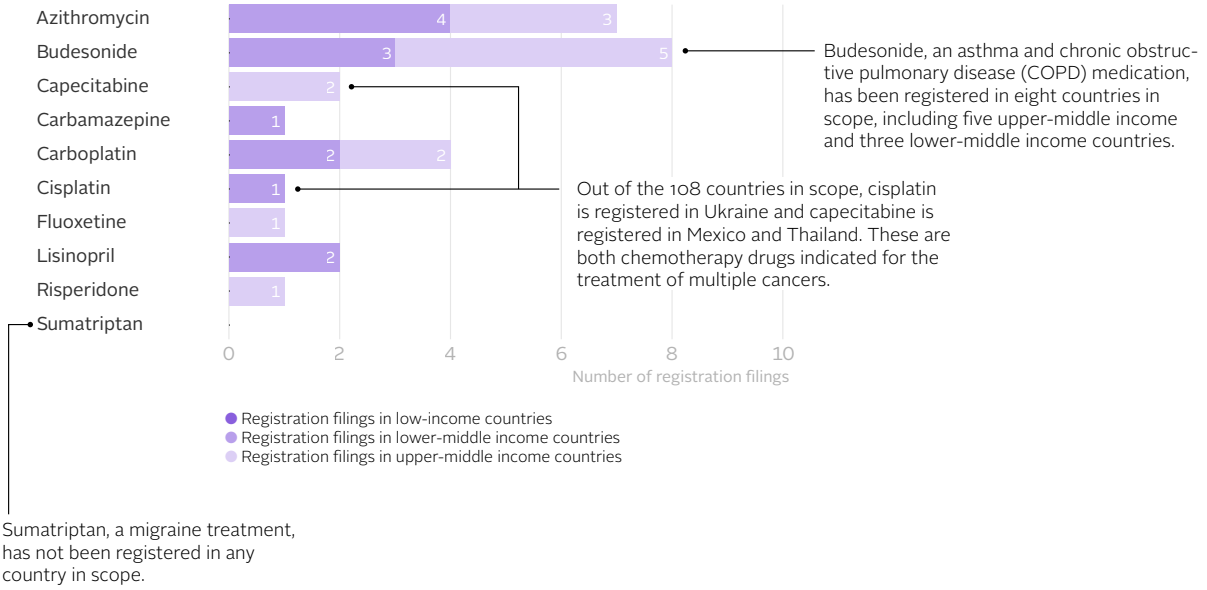
EA2. PRODUCT REGISTRATION

Teva has filed to register or successfully registered at least one product within its entire portfolio in 44 LMICs in scope. This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in LMICs in scope.

Of the products within the scope of the Generic & Biosimilar Medicines Programme, ten off-patent medicines were selected for assessment. Teva has filed at least one of these products for registration in a total of 16 of the 44 LMICs where it has pre-existing regulatory filings.*** Teva's registration efforts for these ten products have primarily focused on upper and lower-middle income countries. The company has not filed any of these products in low-income countries.

Teva does not actively engage in mechanisms to facilitate registration, such as the World Health Organization (WHO) Collaborative Registration Procedure or regional joint assessments.

FIGURE 1 **Registration filings of ten products selected for assessment across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Teva's definition of LMICs encompasses 127 countries following the 2020 World Bank classification as outlined within its sustainability-linked financing framework. This scope does not precisely match the Programme's country scope of 108 LMICs.

**The six therapeutic areas are: cardiovascular diseases; oncology; respiratory diseases; diabetes; mental health; and pain/palliative care. This scope does not exactly coincide with the Programme's disease scope.

***Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall outside the scope of the Generic & Biosimilar Medicines Programme.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

For eight out of the ten products included in this assessment, Teva submitted an example of a strategy to expand access to that product in a specific country in scope. This included examples of access strategies in three upper-middle, four lower-middle, and one low-income country.

For six of these products, the examples consist of pricing strategies, with the majority exclusively focused on the private sector. For two of these products, Teva enables access through product donations. Additionally, the company provides evidence of the number of patients reached for all eight products, with evidence of forecasting patient reach provided for the two of them (carboplatin and cisplatin).

Among the six products with pricing strategies, Teva provides evidence of implementing different types of strategies for each of the six country-specific examples provided. These include a competitor pricing strategy, a transfer pricing model, and pricing strategies that follow local pricing policies in those specific countries. While Teva adheres to local control pricing policies imposed by governments, which aim to limit product prices, this may not be sufficient to make the prices affordable for all relevant payers.

For the other four products which follow local pricing policies, namely, azithromycin, carbamazepine, budesonide and capecitabine, Teva reports setting the price by referring to the pricing policies set by the local governments. Within the private market in South Africa, an upper-middle income country, Teva supplies budesonide, a treatment indicated for asthma and chronic obstructive pulmonary disease (COPD), at a price aligned with the government reference price, ensuring patients can access the treatment without making co-payments. In Thailand, an upper-middle income country, Teva supplies capecitabine within the private market, adhering to government pricing regulations that set the ceiling price. Teva has provided evidence of product volumes sold within private markets for the six assessed products.

For two products, cisplatin and carboplatin, Teva implements product donation programmes In Ghana, a lower-middle income country, the company collaborates with Direct Relief and Breast Cancer International to supply cisplatin through its breast cancer donation programme. Teva reports that approximately 400 women across two hospitals received treatment between January 2020 and March 2023. In Malawi, a low-income country, the company implements its Global HOPE Donation programme* in collaboration with Texas Children's Hospital and Direct Relief to provide carboplatin for children with cancer and blood disorders.

FIGURE 2 **How many products are covered by an access strategy?**

For each of the ten products selected for assessment, Teva was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure. Where details on country-specific access strategies were not shared, the company was not assessed.

International Nonproprietary Name (INN)	Country	Public market access/ pricing strategies	Private market access/ pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability**
Azithromycin	Uzbekistan (LMIC)		●	●		
Budesonide	South Africa (UMIC)		●	●		
Capecitabine	Thailand (UMIC)		●	●		
Carbamazepine	Ukraine (LMIC)		●	●		
Carboplatin	Malawi (LIC)			●	●	●
Cisplatin	Ghana (LMIC)			●	●	●
Fluoxetine	No country-specific access strategy reported					
Lisinopril	Nigeria (LMIC)		●	●		
Risperidone	Peru (UMIC)		●	●		
Sumatriptan	No country-specific access strategy reported					

For capecitabine and budesonide, Teva reports participating in tenders to supply the public sector. However, it is unknown whether the company secured and/or were awarded the tender in Thailand and South Africa.

For cisplatin and carboplatin, donation programmes were the only strategy employed by Teva to ensure access.

*The Global Hope Donation programme is active in other countries in scope, which are not covered under this assessment: Botswana, Ghana, Rwanda Tanzania, and Uganda.

**For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

During the period of analysis, Teva did not report engaging in any non-exclusive voluntary licensing agreements or exclusive licensing agreements within the geographic scope of the Programme.

EA5. IMPROVING PRODUCT AVAILABILITY

Teva's manufacturing network consists of 53 manufacturing sites and 25 R&D centres spread across 27 countries. While the specific LMICs where these sites are located are not disclosed by the company, Teva does report that the majority of its production capacity is located in Europe, India, Israel, Latin America and North America.* Out of the 53 sites, 16 specifically focus on active pharmaceutical ingredient (API) manufacturing. Teva recently announced a new strategy in 2023, indicating its intention to adapt its manufacturing footprint and reduce its number of sites to reach a range of 40 to 44 by 2027. It is uncertain whether the planned closures involve sites in LMICs in scope.

Teva utilises its manufacturing network to ensure product availability in the different markets in which it is present, therefore its operation of local manufacturing sites in LMICs in scope is limited. Teva aims to maximise its global manufacturing capabilities to meet the supply needs of different countries and regions. For instance, the company's sites in the Latin American and Asia-Pacific regions serve different LMIC markets. Teva also reports striving to simplify its network by creating clusters and specialised sites focusing on specific manufacturing technologies and products. This approach can help enhance efficiency in terms of lead times and cost optimisation.

Teva does not disclose being involved in technology transfers and/or partnerships to develop or enhance local manufacturing in countries in scope.

*Teva. United States Securities and Exchange Commission. Form 10-K. Annual Report for the Fiscal Year Ended 31 December 2022.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Teva reports that is has established an internal system for forecasting and demand planning, both for its regular supply activities and for new product launches. This system includes a 24-month forecast which is shared with the company's manufacturing sites during its annual operational plan and adjusted accordingly on a monthly basis.

The company reports that in certain circumstances it collaborates with government agencies and authorities, disclosing information regarding stocks in order to fulfil local needs.

SQ2. DELIVERY PERFORMANCE

Teva uses a global logistics system to track the delivery of its finished goods, and plans to extend the coverage to APIs and raw materials. Teva reports measuring On Time in Full (OTIF) for every delivery and aggregating performance results to a monthly Key Performance Indicator, which is assessed globally. Additionally, the company reports having established last-mile tracking systems for product distribution within countries where delivery takes place, however, it is unknown whether this is also applied in LMICs. The company did not provide any specific examples of how it communicates with procurement agencies or the steps it takes to address issues that may impact product delivery.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Teva has implemented multiple strategies to promote a continuous supply of its products and mitigate the risk of shortages and stockouts.

The company reports that it maintains buffer stocks of APIs, critical components and finished goods, alongside having a finished good stock policy in place. The company reports conducting weekly and monthly regional audits to identify and mitigate out-of-stock risks. Additionally, Teva reports having developed a special software for optimising global stocks. The company does not disclose holding regional stocks of finished goods in countries in scope, or taking steps to decentralise stocks of critical components, as it states leveraging its global network to meet supply needs in different locations.

The company reports implementing a dual sourcing policy in some instances, based on the risk profile and portfolio importance. Additionally, Teva states using a mix of global and local suppliers to promptly meet demand but does not report the proportion of locally sourced materials. The company also reports taking steps to maintain the availability of APIs and meet surges in demand. Teva operates a separate API business that produces over 350 APIs for both vertical integration and sale to third parties, while also outsourcing additional APIs from suppliers across Europe, Asia and the Americas. The company has an API department with dedicated teams that engage in prioritisation and risk mitigation. During the COVID-19 pandemic, Teva leveraged its API production and overall manufacturing capabilities to meet surges in demand. However, no specific examples of these steps were publicly disclosed. The company has also established a Critical Action Committee (CAC) to address emergencies related to drug or API shortages, in all countries where the company operates. There were no concrete examples provided to demonstrate how CAC has addressed shortages specifically in LMICs in scope.

To further meet product demand, Teva reports developing a global platform that facilitates fulfilling product demand in case of emergency needs, allowing the company to move available stocks to other locations.

FIGURE 3 **What steps is Teva taking to mitigate stockouts and shortages?**
This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	●
Disclosure of the frequency of stock auditing	●
Holding regional stocks and/or making efforts to decentralise stocks of critical components	
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	●
Other initiatives to fulfil emergency orders and/or surges in demand	●

Teva reports implementing a dual sourcing policy in some instances.

Teva implements a global platform that allowed it to move 5,000 units of vincristine, a cancer treatment (not in scope of this Programme) from one market to another to address shortages.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Teva reports that all its manufacturing sites comply with the required regulatory standards, including current good manufacturing practices (cGMPs) and other standards set by organisations such as the International Council for Harmonization. These standards are enforced by regulatory authorities such as the FDA (US), EMA (Europe), MHRA (UK), PMDA (Japan), and NMPA (China). The company reports that most of its sites have stringent regulatory authority (SRA) approval from the EMA or FDA. Its remaining sites, located across Latin America, have been approved by national regulatory authorities (NRAs). Teva has not submitted any products to the WHO prequalification (PQ) programme, which exempts the company from site inspections by the WHO. No warning letters from the USFDA or non-compliance reports from the EMA were issued at Teva's sites in countries in scope during the period of analysis.

The company reports that it prioritises maintaining quality across all 53 of its manufacturing sites. To achieve this, Teva has implemented a quality management system (QMS) that enables continuous monitoring throughout the manufacturing process. Through this system, the company addresses any quality concerns and takes corrective and preventive measures when necessary. To ensure any quality related issues are addressed, the company monitors the execution of corrective actions on a monthly basis. The Senior Vice President of Global Quality and the Chief Quality Officer are ultimately responsible for quality compliance and for establishing, implementing and continuously improving Teva's QMS.

Teva utilises multiple methods to evaluate its third-party suppliers on GMP and compliance. This includes a certification programme used to assess third party suppliers on GMP, which considers suppliers' audit outcomes amongst other criteria. Additionally, Teva requires its suppliers to adhere to its Code of Conduct, which includes a requirement for suppliers to inform the company immediately of any significant inspection or regulatory issue with national or international authorities.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Teva implements strategies to maintain the quality and safety of its products. The company reports having strategies in place to combat falsified, substandard and/or unsafe medicines. The company's Anti-counterfeiting Policy aims to protect customers' safety and the integrity of the supply chain and applies to all aspects of the company's supply chain, including third-party manufacturers.* Teva Global Corporate Security focuses on product security and is responsible for enforcing these policies and managing supply chain security. When a falsified medicine is detected, the company alerts the appropriate health or regulatory authorities, along with any immediate trading partners that could have received the product. Additionally, the company engages in several partnerships to help address the risk of substandard and falsified medicines. Teva has established processes for managing crisis events, such as product recalls. These processes are applied globally, and in compliance with local laws and regulations. The company also works with local health authorities to address potential product recalls and take appropriate action to protect consumers.

The company works to keep its supply chain secure through implementing technologies and systems to mitigate the circulation of substandard and falsified medicines. For example, the company has implemented mechanisms to improve the traceability of its global shipments, including 'Real Time Tracking' to track its shipped products to increase supply chain visibility worldwide. This system enables the company to respond to any temperature and/or route deviations and ensures that customers maintain visibility of any deviations that may occur. However, no information is publicly available on whether the company makes efforts to disclose the source of finished products, including specifying the primary manufacturing plant, and disclosing product components and materials that are third-party sourced.

FIGURE 4 **Depth and breadth of quality-assurance strategies**

This table shows the types of strategies Teva implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	●
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)**	
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficent manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including to which authorities and/or organisations the company reports encounters of substandard or falsified medicines	●
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	●
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	

Teva has set the goal to maintain 100% annual evaluations of identified high-risk third-party partners through its Third-Party Due Diligence tool, which screens for possible compliance risks using a database of publicly available information on compliance.

Teva reports the majority of its sites are approved by SRAs, while others have the approval of NRAs. However, it does not disclose any further details.

The company has an Anti-Counterfeiting Policy to mitigate the circulation of substandard and falsified products.

*Falsified medicines are included in the company's Anti-Counterfeiting Policy. Teva states that the terms "falsified" and "counterfeit" are used interchangeably when addressing this issue. The definition of falsified medicines used in this report can be found in the Appendix.

**As benchmarked against WHO Global Benchmarking Tool (GBT).

Viatris Inc

HQ: Canonsburg, United States • Ticker: VTRS • Stock exchange: NASDAQ • Nr. of employees: 38,000

COMPANY SUMMARY

Viatris expands access to its products through its broad off-patent medicine portfolio, geographic footprint spanning over 70% of countries in scope, and global supply network. Some of the company's access commitments are supported by measurable and time-bound objectives, including its goal to reach 30 million HIV/AIDS patients with antiretroviral therapies by 2025. Viatris files products widely for registration and has filed or registered the ten assessed products in a high number of low-income countries. Viatris expands access to its products through supranational procurement, government tenders and public partnerships. It also employs free pricing and competitor-based pricing strategies for its products sold in the private sector. Moreover, it presents evidence of tailoring some of its pricing strategies to payers' ability to pay. As a sublicensee for treatments targeting infectious diseases, Viatris facilitates products' availability through registration and supranational mechanisms. It ensures a secure supply of quality-assured products, leveraging its regional presence to address shortages and implementing strategies to tackle substandard and falsified medicines. Additionally, Viatris engages in adaptive R&D, reporting five examples of projects targeting HIV, tuberculosis and meningitis. These adaptations aim to extend products' shelf-lives and ease administration.

Main therapeutic areas
Cardiovascular; central nervous system; dermatology; diabetes; gastrointestinal; immunology; infectious disease; oncology; ophthalmology; respiratory; women's healthcare.

Business segments
Developed Markets; Emerging Markets; Greater China; Japan, Australia and New Zealand (JANZ).

Product categories*
Branded off-patent medicines; consumer health; generic medicines; innovative medicines.

Sales presence**
Viatris reports sales in 85 countries in scope.

OPPORTUNITIES FOR VIATRIS

Expand access strategies to more products and countries.
Viatris implements strategies for some medicines in its portfolio, such as bevacizumab, a monoclonal antibody used to treat certain types of cancer. In India, the company considers local barriers to access and some payers' ability to pay, to improve affordability in the private sector. Viatris's strategy for this product includes initiatives such as a patient assistance programme, which is used to expand access to low-income patients facing affordability barriers. Viatris can now scale up its efforts by establishing comprehensive access strategies for more products in its portfolio, across therapeutic areas. The company can utilise such strategies in more LMICs, especially low-income countries.

Expand registration of oxytocin in high-burden countries.
Viatris has registered oxytocin, an essential treatment for maternal haemorrhage, in 24 countries in scope: eight upper-middle income, 12 lower-middle income, and four low-income countries. Viatris can file for registration in other LMICs, particularly those where it has previously filed other products for registration, such as Nigeria and Tanzania. These are both among the ten countries with the highest burden of disease globally for maternal haemorrhage.

Strengthen the quality and geographic scope of R&D access plans.
Viatris has access plans in place for all of its late-stage adaptive R&D projects assessed. These plans focus primarily on registering in countries in scope, and/or supply and demand planning. Viatris can consider broadening its access plans to include further components to improve accessibility, such as equitable pricing plans. Furthermore, to ensure widespread access in LMICs, the company can ensure that its access plans have a broad geographic reach.

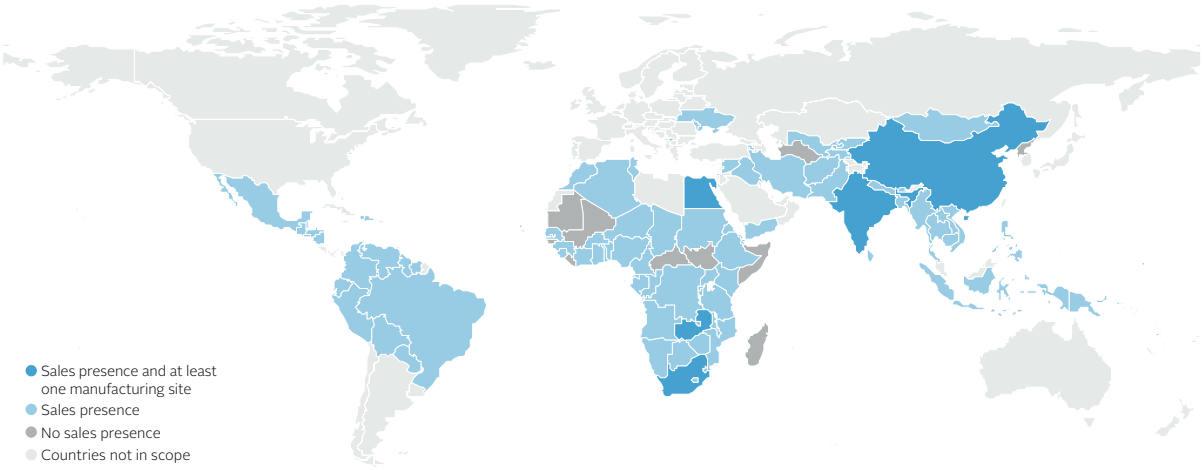
Expand engagement in voluntary licensing agreements
As a sublicensee in various licensing agreements, Viatris is following through on its commitments to register in-licensed products in LMICs in scope. Viatris can build on these efforts by continuing to register products such as dolutegravir (paediatric) in additional countries within the licence's scope, especially to reach children and young women living with HIV. Having recently signed a non-exclusive licence for cabotegravir long-acting, used for HIV pre-exposure prophylaxis (PrEP), Viatris can ensure broad registration in countries with high HIV burden, once possible. The company can also explore engaging in additional voluntary licensing agreements across other therapeutic areas, including non-communicable diseases, when relevant.

*In November 2022, Viatris announced it completed the transaction with Biocon Biologics Limited for the transfer of its biosimilars portfolio. Viatris is expected to provide commercialisation and certain transition services for two years. Viatris has also announced its intention to divest its API business by the end of 2023.

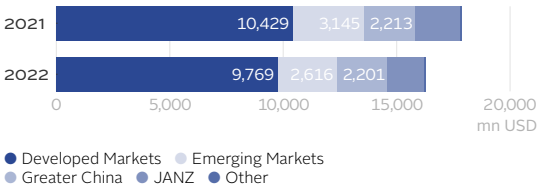
**Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

COMPANY PRESENCE & REVENUE

Sales and manufacturing presence in countries in scope



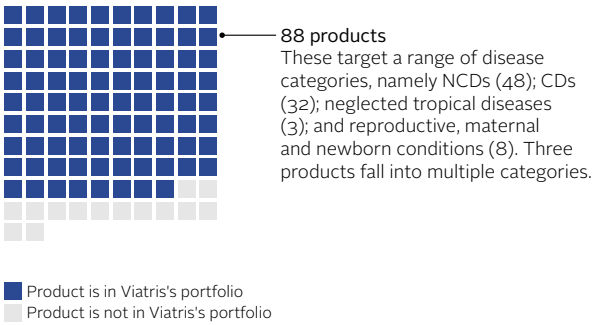
Revenue by business segment and region*



PORTFOLIO & PRODUCTS ANALYSED

Products in scope from the company's portfolio

Out of the 102 products in scope of this analysis,** Viatris has 88 products within its portfolio, targeting a range of disease categories. These target non-communicable diseases (NCDs) (48); communicable diseases (CDs) (32); neglected tropical diseases (3); and reproductive, maternal and newborn conditions (8) with 3 products falling into multiple categories. Viatris's portfolio showcases a strong focus on NCDs. Additionally, the company focuses on maternal and newborn conditions and certain CDs, including bacterial infections, HIV and hepatitis C.



Products selected for assessment

Of the in-scope products that Viatris has in its portfolio, ten off-patent medicines were selected for analysis for the themes EA2 (product registration) and EA3 (expanding access and pricing strategies).

Product	Indication
Abacavir/lamivudine (ABC+3TC)	HIV
Artemether/lumefantrine	Malaria
Bevacizumab	Cancer
Levonorgestrel	Contraceptive method
Insulin glargine	Diabetes mellitus
Oxytocin	Maternal haemorrhage
Sofosbuvir/velpatasvir	Hepatitis C
Tenofovir disoproxil fumarate	Hepatitis B
	HIV
Trastuzumab	Cancer
Dolutegravir/emtricitabine/tenofovir alafenamide (DTG+FTC+TAF)	HIV

*Viatris reports revenue by region in the same regions that represent the business segments. Financial year (FY) 2021 covers January - December 2021. FY 2022 covers January - December 2022.

**The Generic & Biosimilar Medicines Programme's product scope includes 102 off-patent medicines, most of which are listed on the 22nd World Health Organization's Model List of Essential Medicines. Essential medicines are those that satisfy the priority health care needs of a population.

EXPANDING ACCESS

EA1. ACCESS-TO-MEDICINE STRATEGY

Viatris consolidates its access-to-medicine strategy within its business model and corporate strategy, reporting that access is central to the company's mission. The company reports implementing its access strategy across all its operations and therapeutic areas.

To support its access efforts, Viatris has developed the Global Healthcare Gateway™, an operating platform that enables external organisations to partner with the company. Through this platform, these organisations can leverage Viatris's infrastructure and expertise to expand access to their healthcare products and services. In doing so, the company is supporting its corporate social responsibility (CSR) activities and sustainability commitments. Moreover, some of Viatris's access commitments are supported by measurable and time-bound objectives, with the company publicly disclosing its progress for these objectives. For example, by the end of 2025, the company aims to provide antiretroviral therapy to 30 million patients, including two million children, living with HIV/AIDS in the countries where it operates. Additionally, within the same timeframe, Viatris strives to extend healthcare professional education and NCD outreach initiatives to reach 100 million patients in LMICs. The executive management team, including the Chief Executive Officer (CEO) and President, oversee the company's mission and access strategy and report progress to the board of directors, ensuring accountability at the highest level.

The company also reports that it aims to ensure sustainable access to its products by leveraging its resources to support sustainable markets and continuously seeking opportunities to expand product registrations within the coming years.

EA2. PRODUCT REGISTRATION

Viatris has demonstrated its ability to file or successfully register its products in 88 LMICs in scope, as evidenced by the company's registration filings across its entire portfolio in these countries, including a high proportion of low-income countries, where significant gaps in access to essential medicines are prevalent.* This demonstrates the company's ability to register products with national regulatory authorities (NRAs) in the majority of the LMICs in scope.

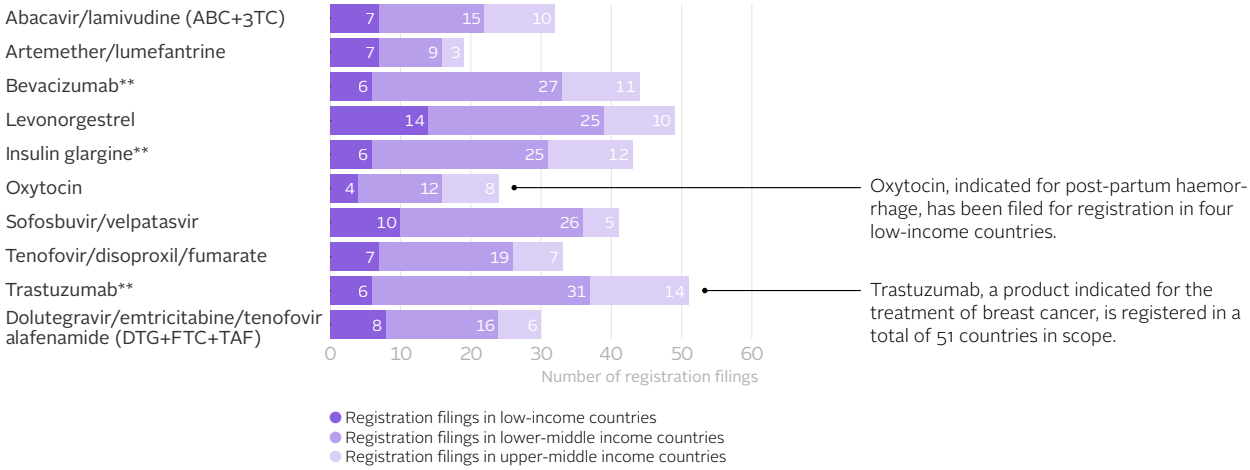
Ten off-patent medicines from Viatris's portfolio were selected for assessment. The company has filed at least one of these products for registration in 72 out of the 88 LMICs (82%) where it has pre-existing regulatory filings,** showing the company's extensive capacity to register its products across a wide geographic area. Viatris demonstrates good practice by filing all of the ten products assessed in low-income countries.

Furthermore, for each of these products, the company provides evidence of the number of regulatory filings, ranging from 19 to 51 countries within scope. Of its biosimilar products*** under assessment, Viatris has filed bevacizumab in 44 countries in scope, insulin glargine in 43 and trastuzumab in 51. This demonstrates that the company has made proactive efforts to bring biosimilars to market in LMICs, considering the additional regulatory requirements and technical expertise involved in registering biosimilars.

Viatris actively participates in mechanisms to facilitate registration, such as the Collaborative Registration Procedure (CRP) for the World Health Organization (WHO) prequalified (PQ) products and ZaZiBoNa.† Mylan Laboratories Limited, a subsidiary of Viatris, has received over 60 approved registrations for WHO PQ.

Example of Viatris's engagement in regional joint assessments
Viatris participates in ZaZiBoNa, a regional joint assessment. As part of this collaboration, five products have been recommended for approval, including essential antiretrovirals (ARVs) such as dolutegravir/emtricitabine/tenofovir alafenamide, darunavir/ritonavir, dolutegravir, and lopinavir/ritonavir in a paediatric formulation, as well as isoniazid, which is used to treat tuberculosis. If approved, these products could help improve access to quality-assured medicines in the region.

FIGURE 1 **Registration filings of ten products across income categories**
This figure shows the number of registrations for the ten off-patent products included in this assessment, categorised by whether the filing is in a low-, lower-middle or upper-middle income country.



*Based on data analysed in the 2022 Access to Medicine Index and the 2021 Antimicrobial Resistance Benchmark.

**Refers to all the countries in scope where the company has previously filed for or successfully registered any of its products. This includes products that fall outside the scope of the Generic & Biosimilar Medicines Programme.

***Viatris is currently in the process of transferring its biosimilars portfolio to Biocon Biologics Limited. As part of the agreement Viatris will retain the responsibility for commercialisation and certain transition services for a period of two years.

†ZaZiBoNa process is a work-sharing initiative amongst NRAs in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Democratic Republic of Congo, Tanzania, Malawi and Mozambique.

EXPANDING ACCESS

EA3. EXPANDING ACCESS AND PRICING STRATEGIES

In the country-specific examples provided by Viatris, all products are covered by an access strategy in the public and/or private market, thus demonstrating the company's commitment to expanding access to the ten products selected for assessment. Two strategies are complemented by additional initiatives to improve affordability and availability, including a patient assistance programme and a partnership with a local organisation, encompassing initiatives to strengthen local production (see example box, right). The company provides evidence of patients reached for nine of the ten products and evidence of forecasting patient reach for six of the ten products.

The company makes four of its generic medicines selected for assessment available in four of the in-country examples provided (Malawi, Namibia, Uganda and Zambia), by participating in tenders issued by supranational procurement organisations. Engaging in supranational procurement allows Viatris to expand access to affordable and quality-assured products while mitigating commercial risks. These tenders were awarded based on price, lead time, supply capacity, and by having required registrations, among other considerations.

In Malawi, Viatris supplies abacavir/lamivudine, an ARV, in the public and private markets. The company engages in agreements with four procurement organisations, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and the US President's Emergency Plan for AIDS Relief (PEPFAR), which distribute the product within the country. In Uganda, Viatris supplies artemether/lumefantrine, a malaria treatment, through the Global Fund, which distributes the product within the public and private markets. The company provides evidence of patient reach, reporting that more than 120,000 patients in Malawi and more than three million patients in Uganda received the products between January 2020 and March 2023.

For two products selected for assessment, Viatris provided two in-country examples of collaborations with local stakeholders to increase the affordability of the products. Firstly, for trastuzumab, a breast cancer treatment, the company collaborated with local authorities in the Philippines, to address the unmet need for breast cancer therapies, resulting in the product being procured through a public tender. Products procured under this scheme are available to certain patients at no out-of-pocket cost at 18 public institutions. Secondly, in Kenya, the company supplies levonorgestrel, a contraceptive, to both public and private institutions, including a social marketing organisation, via participation in competitive bidding mechanisms. Between January 2020 and April 2023, the company estimates to have reached 900,000 women in Kenya and further plans to provide access to 1.3 million women within the next three years.* Viatris's success in securing these tenders and participating in bidding mechanisms indicate how it provided favourable terms, including competitive pricing, to the payers involved.

Examples of Viatris's access strategies across countries

In India, a lower-middle income country, the company supplied bevacizumab, a cancer product, during the period of analysis, through national pooled procurement in the private market. The price is set considering various factors, including volume and market competition. Additionally, Viatris implements a patient assistance programme, "Ashray", that provides financial support to low-income payers and those not covered by private or public insurance. By considering payers' ability to pay and engaging in access strategies, the company engages in efforts to improve the affordability of the product in India and reach patients across the income pyramid. Between January 2020 and February 2023, the company reached approximately 500 patients through the programme.

In Thailand, an upper-middle income country, the company supplies sofosbuvir/velpatasvir, a hepatitis C treatment, via the national procurement programme through the Government Pharmaceutical Organization (GPO), determining the product price based on the maximum procurement price, price negotiations with the government and local NGOs, and the competitive landscape. The company also supplies this product through private hospitals and clinics. Additionally, Viatris supplies active pharmaceutical ingredients (APIs) to the GPO to facilitate local production of the product. The company estimates to have reached more than 30,000 patients since 2020, further estimating that more than 40,000 patients will require the medication moving forward.

FIGURE 2 **How many products are covered by an access strategy?**

For each of the ten products selected for assessment, Viatris was requested to provide one example of a country-specific access strategy covering that product. The company was asked to include examples from a minimum of three low-income countries (LICs) and three lower-middle income countries (LMICs). Further examples could come from upper-middle income countries (UMICs). The types of access strategies the company utilises for each product are outlined in this figure.

International Nonproprietary Name (INN)	Country	Public market access/ pricing strategies	Private market access/ pricing strategies	Evidence of patient reach	Evidence of forecasting patient reach	Additional initiatives to improve affordability and availability**
Abacavir/Lamivudine (ABC+3TC)	Malawi (LIC)	●	●	●		
Artemether/Lumefantrine	Uganda (LIC)	●	●	●		
Bevacizumab	India (LMIC)		●	●	●	●
Dolutegravir/emtricitabine/tenofovir alafenamide (DTG+FTC+TAF)	Zambia (LIC)	●		●		
Insulin Glargine	Guatemala (UMIC)		●	●	●	
Levonorgestrel	Kenya (LMIC)	●	●	●	●	●
Oxytocin	Burkina Faso (LIC)		●	●	●	
Sofosbuvir/Velpatasvir	Thailand (UMIC)	●	●	●	●	●
Tenofovir disoproxil fumarate	Namibia (UMIC)	●				
Trastuzumab	Philippines (LMIC)	●	●	●	●	

Viatris was the first manufacturer to offer biosimilar insulin glargine at a discounted price to a distributor, improving affordability compared to the branded originator. However, it remains uncertain how these discounts can effectively enhance product affordability for all patients in need, across the income pyramid.

*In November 2022, Viatris declared its intention to divest its stake in businesses that no longer align with its future strategy by the end of 2023. This divestment includes certain contraceptives, but is unclear whether it will involve the sale of levonorgestrel.

**For example: donations, public-private partnerships, or patient assistance programmes.

EXPANDING ACCESS

EA4. ENGAGING IN LICENSING ACTIVITIES

Five in-licensed products were selected for assessment: delamanid and pretomanid, indicated for tuberculosis (TB), daclatasvir, indicated for hepatitis C, dolutegravir (paediatric), indicated for HIV, and nirmatrelvir, indicated for COVID-19.

Viatris was granted a non-exclusive voluntary licensing agreement (NEVL) by the TB Alliance for pretomanid,* a multi-drug-resistant TB (MDR-TB) medicine, to commercialise this product in LMICs. Under this agreement, the company has filed the product for registration in 27 countries in scope. Since 2021, the product has been registered in six additional LMICs, including Zambia, which has a high burden of MDR-TB.** Furthermore, pretomanid is WHO PQ, allowing the product to be supplied through the Stop TB Partnership's Global Drug Facility. Through this provider, the company has supplied more than 36 countries with a high burden of MDR-TB in the last three years. In 2022, Viatris partnered with MedAccess and TB Alliance to lower the price of pretomanid by 34%, with a volume guarantee by MedAccess allowing Viatris to set a ceiling price for a six-month treatment course.

The company was granted an exclusive licensing agreement by Otsuka for delamanid, also indicated for the treatment of MDR-TB. Through this agreement, the company has filed for registration in six countries in scope, among them India and South Africa, which are two of the 30 countries with a high burden of MDR-TB. In India, the company estimates having reached approximately 10,000 patients in 2022, while in South Africa, the estimated reach exceeds 2,500 patients.

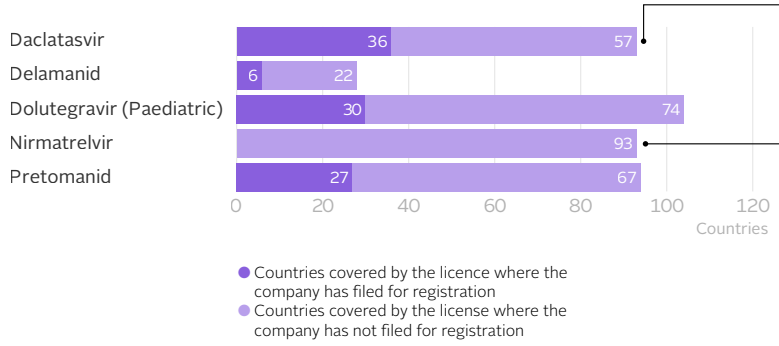
Additionally, Viatris is a sublicensee of a NEVL for paediatric dolutegravir. This NEVL was facilitated by the Medicines Patent Pool (MPP) and involves ViiV Healthcare, CHAI, and Unitaid.

Examples of Viatris's licensing agreements

In March 2023, Viatris entered into a NEVL with Viiv Healthcare, facilitated by the MPP for cabotegravir (CAB) long acting (LA) for HIV pre-exposure prophylaxis (PrEP) which will be manufactured in India. An extended-release formulation of CAB, which in 2021 became the first long-acting injectable option approved for HIV PrEP. This extended dosing regimen, administered through a single injection every two months, offers a convenient alternative to daily oral medication, improving treatment adherence and addressing administration challenges in LMICs. The agreement allows generic manufacturers to develop, manufacture, and supply generic versions in 87 countries in scope, prior to patent expiry of the original drug in 2031. Through Viatris' participation as a sublicensee for dolutegravir (paediatric), the company has received a tentative approval from the USFDA for its generic fixed-dose combination (FDC) of abacavir, lamivudine and dolutegravir for use in children.

FIGURE 3 **Registration filings of Viatris's in-licensed products*****

This figure shows the number of LMICs in scope where Viatris has filed for registration or registered its five in-licensed products selected for assessment, compared to the total number of countries covered by the licensing agreement.



Viatris is a sublicensee of a NEVL with Bristol Myers Squibb, facilitated by the MPP, for daclatasvir, indicated for hepatitis C. Through this agreement Viatris has increased the product's availability by filing for registration in 36 countries in scope and supplying it via pooled procurement mechanisms and public procurement.

Viatris is a sublicensee of a NEVL with Pfizer, facilitated by the MPP, for nirmatrelvir, a COVID-19 antiviral. This agreement was made after the COVID-19 vaccines were rolled out, and as a result, reduced the demand for this product. Consequently, the company has not registered the product in any LMIC within the scope. However, Viatris retain the right to register and supply the product should the need arise.

EA5. IMPROVING PRODUCT AVAILABILITY

Viatris's manufacturing network comprises approximately 40 manufacturing sites worldwide, including 19 sites in LMICs in scope, such as China, Egypt, India, South Africa and Zambia†. The company reports using its global network, consisting of local, regional and global sites, to improve product availability and respond to patient needs. Viatris positions its manufacturing sites strategically to facilitate access across LMICs, reporting that its regional manufacturing and packaging sites enable benefits of centralisation, resulting in increased regional supply.

Viatris has implemented initiatives to strengthen local capacity in LMICs, such as investing in new packaging and distribution facilities. In Zambia, for example, it established a facility dedicated to packaging and distribution of medicines manufactured in India, such as ARVs and antimalarials. Through this facility, the company reports working towards increasing local capacity through technology transfers and trainings in quality-assured production. The company also partners with local companies in Mozambique and Kenya for packaging and distributing ARVs, reporting that the collaboration contributes to the development of local capacity.

Additionally, Viatris participates in global health partnerships. In June 2020, it became a member of the Cancer Access Partnership (CAP), established by the Clinton Health Access Initiative (CHAI) and the American Cancer Society. CAP aims to increase affordability and availability of 26 key cancer treatments in selected LMICs across Asia and Africa. The partnership generates healthcare savings for governments and requires members like Viatris to fulfil specific volume and supply commitments to remain part of the partnership.

*Pretomanid (Pa) is used in combination with bedaquiline (B), linezolid (L), and sometimes moxifloxacin (M) to form BPaL and BPaLM.

**Based on data analysed in the 2021 Antimicrobial Resistance Benchmark.

***Products may be available through other mechanisms without having been filed for registration by the company.

†Due to Viatris's announced upcoming API divestiture, the number of manufacturing sites may decrease.

SUPPLY & QUALITY

SQ1. DEMAND PLANNING AND DATA SHARING

Viatris reports that its internal Rapid Response Advanced Planning system plays a crucial role in forecasting and demand planning. This system enables the company to plan its supply chain forecast demand in the different markets in which it operates. With a 24-month forecast, Viatris aims to ensure it has sufficient stock to meet any fluctuations in demand. In 2021, the company's supply chain team collaborated with its commercial teams to gain a better understanding of customer needs, with an aim of improving forecast accuracy, facilitating better production planning, and reducing the risk of excess stock.

In certain cases, Viatris reports working with external stakeholders to secure supply of in-demand products. This includes partnerships with governments and health authorities, such as those in India. In the event of supply disruptions caused by external events, the company alerts its commercial and regulatory teams operating in local markets. These teams then communicate the issues and neccesary actions to local customers and health authorities. Furthermore, the company reports collaborating with drug shortage task forces organised by national health authorities to provide information regarding the supply chain and to develop solutions to minimise shortages.

SQ2. DELIVERY PERFORMANCE

Viatris has established a system to measure and track delivery performance, which includes the use of On Time in Full (OTIF) as a customer service level metric, measured according to customer agreements. When supply delays occur, the company reports assessing all relevant safety stock levels and implementing manufacturing and packaging prioritisation to balance supply across its network. Additionally, Viatris prioritises filling local market stocks with key products, to ensure orders from critical customers, such as hospitals are fulfilled. The company also reports offering alternative products or pack sizes to customers, moving stock from other network locations, and transferring orders from ocean to air to reduce transportation time to market.

SQ3. STOCKOUTS AND SHORTAGES MITIGATION

Viatris employs multiple strategies to ensure a continuous supply of its products and mitigate the risk of stockouts and shortages. This includes maintaining safety stocks in-country and regionally, monitoring inventory levels of raw materials, and auditing stocking locations following good distribution practice (GDP). To promote a reliable supply chain, Viatris leverages its in-country and regional presence. It reports holding stocks in local markets of nine countries in scope, including four upper middle-income and five lower middle-income countries. The company also has regional hubs in the Middle East and Latin America that supply countries in these regions.

Viatris mitigates supply chain risks through dual sourcing of key APIs and finished products. It also conducts a third-party due diligence programme, specifically focusing on high-risk suppliers, to ensure compliance and create action plans for identified risks. Moreover, the company has a cross-departmental committee responsible for Sourcing and Quality, which considers the proximity of component and material suppliers to its manufacturing locations when formulating its sourcing strategy. To further mitigate risks and increase flexibility in meeting demand, Viatris leverages its regional and global network, collaborating with over 650 third parties. For instance, the company operates 15 manufacturing sites across seven different states in India, which helps mitigate the potential disruption risks within the country.

Viatris reports that approximately half of its APIs are sourced from China and India, while the remaining half are procured from North America, Europe, and countries within its Emerging Markets segment. This segment covers over 165 countries, including LMICs in scope. The specific LMICs from which APIs are sourced are not disclosed. The company has produced APIs for a wide range of therapeutics, including ARVs and cardiovascular medicines, both for its use in-house and to supply customers in over 100 countries. However, it announced in November 2022 its intention to divest its API business by the end of 2023. Despite this decision, the company intends to retain "some selective development API capabilities".

FIGURE 4 **What steps is Viatris taking to mitigate stockouts and shortages?**
This table shows the approaches the company reports taking to ensure the uninterrupted supply of its products.

Approaches to mitigate stockouts and shortages	
Strategies to maintain sufficient stock for critical components, including buffer and safety stocks	●
Conducting regular audits of its stock	●
Disclosure of the frequency of stock auditing	
Holding regional stocks and/or making efforts to decentralise stocks of critical components	●
Strategies to promote third-party supplier diversity, such as establishing alternative sources of APIs, excipients and packaging materials	●
Implementation of sourcing strategies, such as procuring from local suppliers in LMICs	●
Evidence of a policy or approach for scaling up the production of APIs to quickly adapt to meet surges in demand, when applicable	
Other initiatives to fulfil emergency orders and/or surges in demand	●

Viatris holds stocks in local markets of nine countries in scope. It also uses regional hubs to supply additional countries in regions such as Latin America.

Viatris has engaged in partnerships with local organisations to respond to surges demand. During the COVID-19 pandemic, it worked with Indian authorities to ensure sufficient product stock.

SUPPLY & QUALITY

SQ4. MANUFACTURING QUALITY ASSURED PRODUCTS

Viatris has approximately 40 manufacturing sites that are all subject to the same Viatris Global Quality Management System (QMS). These sites maintain the necessary licenses and good manufacturing practice (GMP) certificates required for the markets it supplies. The company reports that the majority of sites have approval from a stringent regulatory authority (SRA). The remaining sites supply local markets only and are therefore approved by local authorities.

The company provides evidence of standardising quality across all manufacturing sites to ensure product quality and safety. For example, it is standard protocol to implement the same QMS across all sites. All manufacturing and operations strive to continuously meet the regulatory requirements and international standards for all markets where it has a presence. Moreover, to ensure consistency and quality assurance across its network, the company implements Global Quality IT systems.

Viatris maintains a Global Operations Audit programme that plays a key role in oversight and surveillance of quality across all its sites. This programme seeks to ensure compliance with cGMP and conducts internal audits on a one-year cycle for manufacturing sites, and on a two- to three-year cycle for other facilities such as distribution centres, considering factors such as historical regulatory inspection performance. In response to audit observations, internal sites have 15 business days to respond and establish corrective and preventative actions within set timelines. Quality oversight is provided by a quality council at each site, reporting to senior quality leadership, which ensures global quality oversight.

Viatris assesses its third-party suppliers through a screening process and expects all suppliers to adhere to its Supplier Code of Conduct. All suppliers undergo audits that seek to ensure ongoing compliance with regulatory requirements and to evaluate maintenance of regulatory reporting requirements. On 20 August 2020, one of the Mylan sites in India was issued a warning letter for significant deviations from cGMP for APIs.* However, Viatris addressed the deviations and received a closeout letter on 16 February, 2023, indicating the issues had been resolved.

SQ5. SAFEGUARDING QUALITY & SAFETY OF MARKETED PRODUCTS

Viatris implements quality and product safety management systems designed to detect and manage any potential product recalls. The company's internal global standard operating procedure (SOP) outlines the protocol for the notification regulatory authorities should critical quality events arise. Outside the global SOP, each site must maintain a written procedure for how to govern recalls based on each regulatory authority's requirements.

The Product Security team performs annual risk assessments, investigates suspicious products, and collaborates with health authorities and law enforcement as needed.

The company has invested in packaging and information technology to detect and prevent the distribution of falsified products. To ensure a uniform approach, the company implemented global policies on validation, operations, packaging, serialisation, and product security which are applied across manufacturing sites in alignment with government regulations. A serialisation system is used to place a 2D data matrix on products, allowing for track and trace capabilities and endpoint authorisation to prevent falsified or substandard products from reaching customers. In addition, Viatris implemented a Center of Excellence for Global Serialization dedicated to improving the quality of the serialisation processes and to expand these efforts to additional countries. This is demonstrated through the company's Rest of World Verification and Traceability Initiative, developed to support countries to reduce the risk of falsified medicines in national supply chains.

Example of voluntary recall during period of analysis

The company provides evidence of its ability to handle a product recall in a timely and efficient manner. In September 2022, a market complaint was reported regarding commingled medications. The company promptly informed the health authority in South Africa and submitted a recall proposal for the affected batch. Subsequently, a voluntary recall was initiated within the same month.

FIGURE 5 **Depth and breadth of quality-assurance strategies**

This table shows the types of strategies Viatris implements to maintain the production of quality-assured products and to safeguard the quality and safety of products already in the market.

Quality-assurance strategies		
Manufacturing quality-assured products	Strategies to standardise quality management systems and compliance monitoring tools across all manufacturing sites	●
	Strategies to assesses third party suppliers on GMP compliance	●
	Disclosure of the number of manufacturing sites with approval from a stringent regulatory authority (SRA) or national regulatory authority (NRA) operating at maturity level 3 or 4 (ML3 or ML4)**	
Safeguarding quality & safety of marketed products	System for recalling products promptly and effectively and alerting the appropriate authorities in a timely and efficent manner	●
	A clear policy to mitigate the circulation of substandard and falsified medicines, including to which authorities and/or organisations the company reports encounters of substandard or falsified medicines	●
	Evidence of concrete strategies to mitigate the risk of substandard and falsified medicines	●
	Efforts to disclose the source of finished products, including specifying the primary manufacturing plant and disclosure of product components and materials that are third-party sourced	

As part of the external audit process with third parties, auditees are required to respond to observations cited to Viatris's Global Operations Audit team within 30 days.

Majority of sites have SRA approval and a few sites that supply local markets are approved solely by local authorities. The company's Cairo, Egypt site is approved by the Egyptian Drug Authority which operates at a ML3. However, Viatris does not disclose any further details.

VTI is a multi-stakeholder partnership that supports countries to reduce the risk of falsified medicines in national supply chains. The first two markets under the VTI programme will be Malawi and Nepal.

*Mylan Laboratories Limited, Unit 7, FEI 3003227156, at Plot No. 14, 99, & 100, Phase-II, IDA, Pashamylaram, Patancheru (M), Sangareddy District, India, from February 24 to 28, 2020.

**As benchmarked against WHO Global Benchmarking Tool (GBT).

RESEARCH & DEVELOPMENT

RD1. ADAPTIVE R&D

Viatris has adaptive R&D projects in its pipeline to develop products that are better suited for LMIC settings. During the period of analysis, the company provided five examples of adaptive R&D projects, including one project which was submitted confidentially, and one in Phase I of clinical development. The Phase I project is a partnership with Drugs for Neglected Disease Initiative (DND*i*) to develop a sustained-release formulation of flucytosine (5FC), an oral compound used to treat cryptococcal meningitis for paediatric patients with advanced HIV. Paediatric product developments are important as this population group is often overlooked in clinical research and suitable treatment options are sparse. Currently, standard formulations of this WHO-recommended drug are delivered in four divided doses per day and given through nasogastric intubation. This Phase I project aims to ease self-administration and patient adherence to this drug, by reducing the dosing frequency and adapting the product's formulation. Furthermore, the company is researching shelf-life extensions to products for multiple diseases in scope.The projects aim to increase the current recommended shelf life of TLD (tenofovir disoproxil fumarate, lamivudine, dolutegravir), used for the treatment of HIV, and pretomanid, for tuberculosis, from 36 to 48 months. Additionally, Viatris is researching the extension of the shelf life of flucytosine, used to treat meningitis, from 24 to 36 months. Increasing shelf-life can provide additional flexibility for health systems in LMICs.

RD2. ACCESS PLANNING

The company does not disclose having an overarching policy or structured framework in place for systematically developing access plans during R&D for their adapted products.

However, for the examples of adaptive R&D provided, the company showed evidence of access planning. For example, for adaptive R&D projects of communicable disease impacting LMICs, the company integrates access planning into its business model. This includes planning to register the eventual products and their adaptations as widely as possible through SRAs. When applicable, the company plans for WHO prequalification, to speed up access through international procurement. Furthermore, Viatris states that it develops demand and supply plans based on work with organisations such as pooled procurement and market shaping organisations. Additionally, Viatris partners with access-oriented organisations, such as DND*i*, that make it a prerequisite for companies to engage in access planning during R&D, thus ensuring timely and equitable access in LMICs after product launch.

FIGURE 6 **Examples of adaptive R&D projects in Viatris's pipeline**

International Nonproprietary Name (INN)	Disease in scope	Development stage	Partner(s)	Description of the adaptation	Evidence of an access plan
Sustained-release flucytosine (5FC) for patients with advanced HIV disease	Meningitis	Phase I	Drugs for Neglected Diseases initiative (DND*i*) and European and Developing Countries Clinical Trials Partnership (EDCTP)	Adaptation to simplify inpatient and outpatient treatment of cryptococcal infections.	N/A (too early in development)
Shelf-life extension TLD	HIV/AIDS	Not disclosed	N/A	Shelf-life extension from 3 to 4 years	Registration plans in countries in scope; supply and demand planning
Shelf-life extension flucytosine	Meningitis	Not disclosed	N/A	Shelf-life extension from 2 to 3 years	Registration plans in countries in scope; supply and demand planning
Shelf-life extension pretomanid	Tuberculosis	Not disclosed	N/A	Shelf-life extension from 3 to 4 years	Registration plans in countries in scope; supply and demand planning

APPENDICES

APPENDIX I. OVERVIEW OF NON-EXCLUSIVE VOLUNTARY LICENSING AGREEMENTS OF COMPANIES IN SCOPE

This table outlines a comprehensive list of non-exclusive licensing agreements for which companies in scope are sublicensees for within the period of analysis.

TABLE 1 **All non-exclusive voluntary licences engaged in by companies in scope**

Licenced product/compound	Disease	Sublicensee(s)	Licensor	Intermediary
Nirmatrelvir	COVID-19	Cipla, Hikma, Mylan (Viatris), Sun Pharma	Pfizer	Medicines Patent Pool
Baricitinib	COVID-19	Cipla, Sun Pharma	Eli Lilly	Not applicable
Remdesivir	COVID-19	Cipla, Mylan (Viatris)	Gilead	Not applicable
Molnupiravir	COVID-19	Cipla, Mylan (Viatris), Sun Pharma	Merck & Co, Inc	Not applicable
		Hikma		Medicines Patent Pool
Atazanavir	HIV	Cipla, Mylan (Viatris)	Bristol Myers Squibb	Medicines Patent Pool
Cabotegravir long-acting (LA)	HIV	Cipla, Mylan (Viatris)	ViiV Healthcare	Medicines Patent Pool
Dolutegravir (Adult)	HIV	Cipla, Mylan (Viatris), Sun Pharma	ViiV Healthcare	Medicines Patent Pool
Dolutegravir (Adult) for AZ, BY, KZ, and MY	HIV	Mylan (Viatris), Sun Pharma	ViiV Healthcare	Medicines Patent Pool
Dolutegravir (paediatric)	HIV	Cipla, Mylan (Viatris), Sun Pharma	ViiV Healthcare	Medicines Patent Pool
Lopinavir/Ritonavir	HIV	Sun Pharma	AbbVie	Medicines Patent Pool
Lopinavir/Ritonavir Paediatric	HIV	Cipla	AbbVie	Medicines Patent Pool
Tenofovir Alafenamide	HIV	Cipla, Mylan (Viatris), Sun Pharma	Gilead	Not applicable
Bictegravir	HIV	Mylan (Viatris), Sun Pharma	Gilead	Medicines Patent Pool
Elvitegravir	HIV	Mylan (Viatris)	Gilead	Not applicable
Cobicistat	HIV	Mylan (Viatris)	Gilead	Not applicable
Raltegravir	HIV	Mylan (Viatris)	MSD	Not applicable
Doravirine	HIV	Mylan (Viatris)	MSD	Not applicable
Pretomanid	TB	Mylan (Viatris)	TB alliance	Not applicable
Daclatasvir	Viral Hepatitis C	Cipla, Mylan (Viatris)	Bristol Myers Squibb	Medicines Patent Pool
Glecaprevir/Pibrentasvir	Viral Hepatitis C	Mylan (Viatris)	AbbVie	Medicines Patent Pool
Sofosbuvir	Viral Hepatitis C	Cipla, Mylan (Viatris), Sun Pharma	Gilead	Not applicable
Ledipasvir	Viral Hepatitis C	Cipla, Mylan (Viatris), Sun Pharma	Gilead	Not applicable
Velpatasvir	Viral Hepatitis C	Cipla, Mylan (Viatris), Sun Pharma	Gilead	Not applicable
Voxilaprevir	Viral Hepatitis C	Cipla, Mylan (Viatris), Sun Pharma	Gilead	Not applicable

APPENDIX II. DISEASES IN SCOPE OF THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

The disease scope for the Generic & Biosimilar Medicines Programme includes 82 diseases, conditions and pathogens as defined in the 2022 Access to Medicine Index and the Programme's 2023 Analytical Framework. Coronaviral diseases are only considered for in-licensed products and cancer is counted as one non-communicable disease within the disease list, encompassing 19 specific sub-types of cancer.

TABLE 2 **Disease scope**

Diseases, conditions and pathogens in scope of the Generic & Biosimilar Medicines Programme.

	Rationale for inclusion				
Communicable Diseases	Top 10 DALY burden in countries in scope	≥95% disease burden in countries in scope	WHO-identified NTD or MNH condition	R&D priority*	Stakeholder consensus**
Arenaviral haemorrhagic fevers (Lassa fever)				●	
Bunyaviral diseases				●	
Coronaviral diseases*				●	
Enteric diseases	●	●		●	
Diphtheria		●			
Emergent non-polio enteroviruses				●	
Filoviral diseases		●		●	
Henipaviral diseases				●	
HIV/AIDS	●	●		●	
Leptospirosis				●	
Lower respiratory infections	●			●	
Malaria	●	●		●	
Measles	●	●			
Meningitis	●	●		●	
Pertussis	●	●			
Rheumatic fever				●	
Sexually transmitted infections (STIs)†	●	●		●	
Tetanus		●			
Tuberculosis	●			●	
Viral hepatitis (B and C)	●	●		●	
Yellow fever		●			
Zika				●	
Non-Communicable Diseases					
Alzheimer's disease					●
Anxiety disorders	●				
Asthma	●				
Bipolar disorder					●
Cancer‡				●	●
Chronic obstructive pulmonary disease (COPD)	●				
Diabetes mellitus	●				
Endometriosis					●
Epilepsy					●
Hypertensive heart disease	●				●
Ischaemic heart disease	●				
Kidney diseases	●				
Migraine	●				
Schizophrenia					●
Thalassemia		●			●
Sickle cell disease		●			
Stroke	●				
Unipolar depressive disorders	●				

	Rationale for inclusion				
Neglected Tropical Diseases	Top ten DALY burden in countries in scope	≥95% disease burden in countries in scope	WHO-identified NTD or MNH condition	R&D priority*	Stakeholder consensus**
Buruli ulcer			●	●	
Chagas disease			●	●	
Dengue and Chikungunya		●	●	●	
Dracunculiasis		●	●		
Echinococcosis			●		
Food-borne trematodiases		●	●		
Human African Trypanosomiasis		●	●	●	
Leishmaniasis		●	●	●	
Leprosy		●	●	●	
Lymphatic filariasis		●	●	●	
Mycetoma, chromoblastomycosis and other deep mycoses			●	●	
Onchocerciasis		●	●	●	
Rabies		●	●		
Scabies and other ectoparasites		●	●	●	
Schistosomiasis		●	●	●	
Snakebite envenoming		●	●	●	
Soil-transmitted helminthiasis		●	●	●	
Taeniasis/cysticercosis			●	●	
Trachoma		●	●	●	
Yaws		●	●		
Reproductive, Maternal and Newborn Health Conditions					
Birth asphyxia and birth trauma		●	●		
Contraceptive methods			●	●	
Hypertensive disorders of pregnancy		●	●	●	
Abortion and miscarriage		●	●		
Maternal haemorrhage		●	●	●	
Maternal sepsis		●	●		
Neonatal sepsis and infections		●	●		
Obstructed labour		●	●		
Other neonatal conditions		●	●		
Preterm birth complications		●	●		

* Only in scope for in-licensed products.
† Excludes HIV/AIDS.
‡ Includes 19 cancer types: bladder; brain, nervous system; breast; cervical; colorectal; gallbladder; head and neck; Kaposi sarcoma; leukaemia; liver; lung; non-Hodgkin lymphoma; oesophageal; ovarian; prostate; stomach; thyroid; uterine; osteosarcoma.

Priority pathogens

Acinetobacter baumannii (carbapenem-resistant)
Campylobacter spp. (fluoroquinolone-resistant)
Enterobacteriaceae (carbapenem-resistant, 3rd generation cephalosporin-resistant)
Enterococcus faecium (vancomycin-resistant)
Haemophilus influenzae (ampicillin-resistant)
Helicobacter pylori (clarithromycin-resistant)
Neisseria gonorrhoeae (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)
Pseudomonas aeruginosa (carbapenem-resistant)
Salmonella spp. (fluoroquinolone-resistant)
Shigella spp. (fluoroquinolone-resistant)
Staphylococcus aureus (methicillin-resistant, vancomycin-intermediate and vancomycin-resistant)
Streptococcus pneumoniae (penicillin-non-susceptible)

APPENDIX III. COUNTRIES IN SCOPE OF THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

The geographic scope for the Generic & Biosimilar Medicines Programme consists of 108 countries as included in the 2022 Access to Medicine Index and 2023 Analytical Framework.

TABLE 3 **Geographic scope**

Countries in scope of the Generic & Biosimilar Medicines Programme.

East Asia & Pacific	
Cambodia	LMIC
China	UMIC
Indonesia	LMIC
Kiribati	LMIC
Korea, Dem. People's Rep.	LIC
Lao PDR	LMIC
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LMIC
Papua New Guinea	LMIC
Philippines	LMIC
Samoa	LMIC
Solomon Islands	LMIC
Thailand	UMIC
Timor-Leste	LMIC
Tonga	UMIC
Tuvalu	UMIC
Vanuatu	LMIC
Vietnam	LMIC
Europe & Central	
Armenia	UMIC
Kosovo	UMIC
Kyrgyz Republic	LMIC
Moldova	UMIC
Tajikistan	LMIC
Turkmenistan	UMIC
Ukraine	LMIC
Uzbekistan	LMIC
Latin America & Caribbean	
Belize	LMIC
Bolivia	LMIC
Brazil	UMIC
Colombia	UMIC
Dominican Republic	UMIC
Ecuador	UMIC
El Salvador	LMIC
Guatemala	UMIC
Guyana	UMIC
Haiti	LMIC
Honduras	LMIC
Mexico	UMIC
Nicaragua	LMIC
Paraguay	UMIC
Peru	UMIC
Suriname	UMIC
Venezuela	UMIC
Middle East & North Africa	
Algeria	LMIC
Djibouti	LMIC
Egypt, Arab Rep.	LMIC
Iran	LMIC
Iraq	UMIC
Morocco	LMIC
Palestine, State of/ West Bank Gaza	LMIC
Syrian Arab Republic	LIC
Tunisia	LMIC
Yemen, Rep.	LIC
South Asia	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
India	LMIC
Maldives	UMIC
Nepal	LMIC
Pakistan	LMIC
Sri Lanka	LMIC
Sub-Saharan Africa	
Angola	LMIC
Benin	LMIC
Botswana	UMIC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cameroon	LMIC
Central African Republic	LIC
Chad	LIC
Comoros	LMIC
Congo, Dem. Rep.	LIC
Congo, Rep	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	UMIC
Eritrea	LIC
Ethiopia	LIC
Gabon	UMIC
Gambia	LIC
Ghana	LMIC
Guinea	LIC
Guinea-Bissau	LIC
Kenya	LMIC
Lesotho	LMIC
Liberia	LIC
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
Mozambique	LIC
Namibia	UMIC
Niger	LIC
Nigeria	LMIC
Rwanda	LIC
São Tomé and Principe	LMIC
Senegal	LMIC
Sierra Leone	LIC
Somalia	LIC
South Africa	UMIC
South Sudan	LIC
Sudan	LIC
Swaziland/Eswatini	LMIC
Tanzania	LMIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LMIC

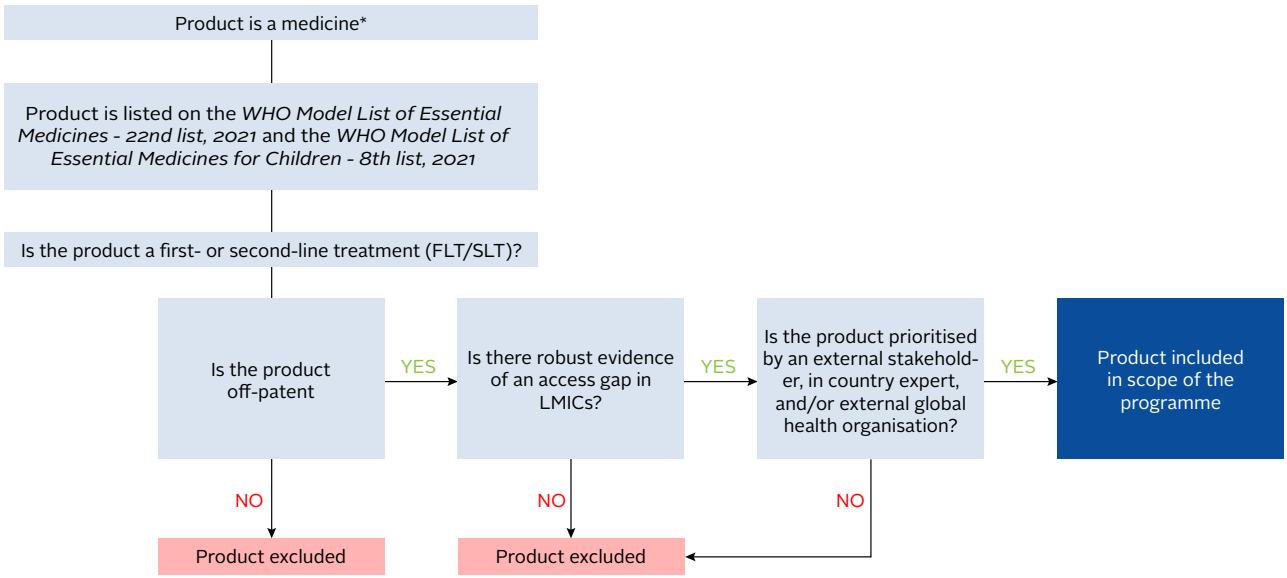
LIC Low-income country
LMIC Lower-middle income country
UMIC Upper-middle income country*
World Bank income classifications (FY2022)

*UMICs were included based on their UNDP Human Development Index group and inequality-adjusted Human Development Index.

APPENDIX IV. PRODUCT PRIORITISATION PROCESS AND PRODUCT SCOPE FOR THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

The product prioritisation process for the Generic & Biosimilar Medicines Programme outlines and identifies the inclusion and exclusion criteria for the product scope of the programme, as described in the 2023 Analytical Framework.

TABLE 4 **Product prioritisation process**



*Excludes vaccines and diagnostics but includes contraceptive devices.

APPENDIX V. PRODUCTS IN SCOPE OF THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

The product scope for the Generic & Biosimilar Medicines Programme includes 102 off-patent essential health products. Products were identified through the Programme's product prioritisation process and are listed following the World Health Organization's (WHO) List 88 of recommended International Nonproprietary Names (INN)[6]. Most of the products included in the scope of the programme are part of the 22nd WHO Model List of Essential Medicines (EML), with the exception of three fixed dose combination products, which were included due to prioritisation by global health stakeholders. The product scope will be updated for future iterations of the analysis, considering updates to the WHO EML and shifting priorities within the global health community.

TABLE 5 **Product scope**

Products in scope of the Generic & Biosimilar Medicines Programme.

International Nonproprietary Name (INN)	Disease
bevacizumab	Cervical, ovarian, colorectal and liver cancer
capecitabine	Breast, colorectal and stomach cancer
carboplatin	Cervical, breast, ovarian, head and neck, lung, osteosarcoma, prostate, brain, nervous system and bladder cancer
cisplatin	Cervical, head and neck, brain and nervous system, lung, osteosarcoma, ovarian and stomach cancer
cyclophosphamide	Leukaemia, breast, brain and nervous system and non-hodgkin lymphoma
docetaxel	Breast, prostate and stomach cancer
doxorubicin	Leukaemia, kaposi sarcoma, breast and non-hodgkin lymphoma cancer
etoposide	Leukaemia, lung, osteosarcoma and ovarian cancer
fluorouracil	Breast, colorectal and stomach cancer
gemcitabine	Ovarian, lung and breast cancer
hydroxyurea (hydroxycarbamide)	Leukaemia and sickle cell disease
methotrexate	Leukaemia, osteosarcoma and breast cancer
oxaliplatin	Colorectal and stomach cancer
paclitaxel	Cervical, ovarian, breast, kaposi sarcoma and lung cancer
rituximab	Leukaemia and non-hodgkin lymphoma cancer
tamoxifen	Breast cancer
trastuzumab	Breast and stomach cancer
amlodipine	Hypertensive heart disease
amlodipine/lisinopril	Hypertensive heart disease
enalapril	Hypertensive heart disease
hydrochlorothiazide	Hypertensive heart disease
lisinopril	Hypertensive heart disease
lisinopril/hydrochlorothiazide	Hypertensive heart disease
telmisartan	Hypertensive heart disease
telmisartan/amlodipine	Hypertensive heart disease
telmisartan/ hydrochlorothiazide	Hypertensive heart disease
valsartan	Hypertensive heart disease
bisoprolol	Hypertensive heart disease and ischaemic heart disease
metoprolol	Hypertensive heart disease and ischaemic heart disease
atorvastatin	Ischaemic heart disease
warfarin	Stroke
fluoxetine	Unipolar depressive disorders, anxiety disorders
sertraline	Unipolar depressive disorders, anxiety disorders
diazepam	Anxiety disorders, epilepsy
fluphenazine	Schizophrenia
paliperidone	Schizophrenia
haloperidol	Schizophrenia, bipolar affective disorder
risperidone	Schizophrenia, bipolar affective disorder
lamotrigine	Epilepsy
sodium valproate	Epilepsy, bipolar affective disorder
carbamazepine	Epilepsy, bipolar affective disorder
sumatriptan	Migraine
beclometasone	Asthma, chronic obstructive pulmonary disease
budesonide	Asthma, chronic obstructive pulmonary disease
formoterol/budesonide	Asthma, chronic obstructive pulmonary disease
ipratropium bromide	Asthma, chronic obstructive pulmonary disease
salbutamol	Asthma, chronic obstructive pulmonary disease
tiotropium	Asthma, chronic obstructive pulmonary disease
gliclazide	Diabetes mellitus
insulin injection (soluble)	Diabetes mellitus
intermediate-acting insulin	Diabetes mellitus
long-acting insulin analogues	Diabetes mellitus
metformin	Diabetes mellitus
misoprostol	Maternal haemorrhage
oxytocin	Maternal haemorrhage
tranexamic acid	Maternal haemorrhage
calcium gluconate	Hypertensive disorders of pregnancy
hydralazine	Hypertensive disorders of pregnancy
magnesium sulfate	Hypertensive disorders of pregnancy
methyldopa	Hypertensive disorders of pregnancy
dexamethasone	Preterm birth complications
ethinylestradiol/levonorgestrel	Contraceptive methods
etonogestrel (implant)	Contraceptive methods
levonorgestrel	Contraceptive methods
tenofovir disoproxil fumarate	Hepatitis B
daclatasvir	Hepatitis C
daclatasvir/sofosbuvir	Hepatitis C

International Nonproprietary Name (INN)	Disease
ribavirin	Hepatitis C
sofosbuvir	Hepatitis C
sofosbuvir/velpatasvir	Hepatitis C
abacavir/lamivudine (ABC+3TC)	HIV/AIDs
abacavir/dolutegravir/lamivudine (ABC+DTG+3TC)*	HIV/AIDs
darunavir/ritonavir (DRV/r)*	HIV/AIDs
dolutegravir (DTG)/lamivudine (3TC) (or emtricitabine (FTC))/tenofovir alafenamide (TAF) (DTG+XTC**+TAF)*	HIV/AIDs
dolutegravir (DTG)/lamivudine (3TC) (or emtricitabine (FTC))/tenofovir disoproxil fumarate (DTG+XTC**+TDF)	HIV/AIDs
artemether/lumefantrine	Malaria
azithromycin***	Trachoma, yaws, enteric diseases and sexually transmitted infections (STIs)
ivermectin	Lymphatic filariasis, onchocerciasis (river blindness), scabies and other ectoparasitoses, soil transmitted helminthiasis
amphotericin B	Leishmaniasis, antifungal infections
praziquantel	Schistosomiasis, taeniasis/cysticercosis
amikacin	Bacterial infection
ampicillin	Bacterial infection
benzathine-benzylpenicillin	Bacterial infection
benzylpenicillin	Bacterial infection
cefalexin	Bacterial infection
cefazolin	Bacterial infection
chloramphenicol	Bacterial infection
clindamycin	Bacterial infection
cloxacillin	Bacterial infection
doxycycline	Bacterial infection
gentamicin	Bacterial infection
nitrofurantoin	Bacterial infection
phenoxymethylpenicillin	Bacterial infection
procaine-benzylpenicillin	Bacterial infection
spectinomycin	Bacterial infection
sulfamethoxazole/ trimethoprim	Bacterial infection
trimethoprim	Bacterial infection
metronidazole	Bacterial infection and parasitic infection
isoniazid	Tuberculosis
linezolid	Tuberculosis
rifampicin	Tuberculosis
sulfamethoxazole/trimethoprim/isoniazid/pyridoxine hydrochloride	Used for prevention of HIV-related opportunistic infections such as tuberculosis

*Products not included in 22nd WHO EML but deemed of high access priority according to stakeholder consultations.

**XTC stands for either emtricitabine (FTC) or lamivudine (3TC).

***Antibiotic not listed in the Access category as per the WHO AWaRe classification (2021), but indicated for the treatment of certain Neglected Tropical Diseases in scope: Trachoma & Yaws.

APPENDIX VI. METHOD OF PRODUCT SPECIFIC ANALYSIS FOR THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

For the first evaluation of companies under this framework, the Foundation carried out an in-depth analysis of a subset of ten off-patent products per company, selected from the Programme's product scope (see Appendix V). This product-specific analysis covered the company's actions in registration (theme EA2. product registration) and access and pricing strategies (theme EA3. expanding access and pricing strategies). The company-specific product selection included medicines in each company's portfolio and was representative of the different therapeutic areas in which the company is active. If applicable, the selection included therapies targeting a diversity of diseases in scope, covering non-communicable diseases, communicable diseases, neglected tropical diseases, and maternal health products. The Foundation made a preliminary product selection for each company, and companies were provided with the opportunity of adapting this selection in consultation with the Foundation.

Moreover, in-licensed products were included for an analysis of companies' activities and efforts to expand access in their role as licensees, as part of the theme EA4. engaging in licensing activities. These are products for which the generic or biosimilar medicine manufacturer has entered into a licence via the Medicines Patent Pool and/or directly with the originator company. Companies were provided with the opportunity of submitting data for a maximum of five licensing agreements in which the company participated in during the period of analysis.

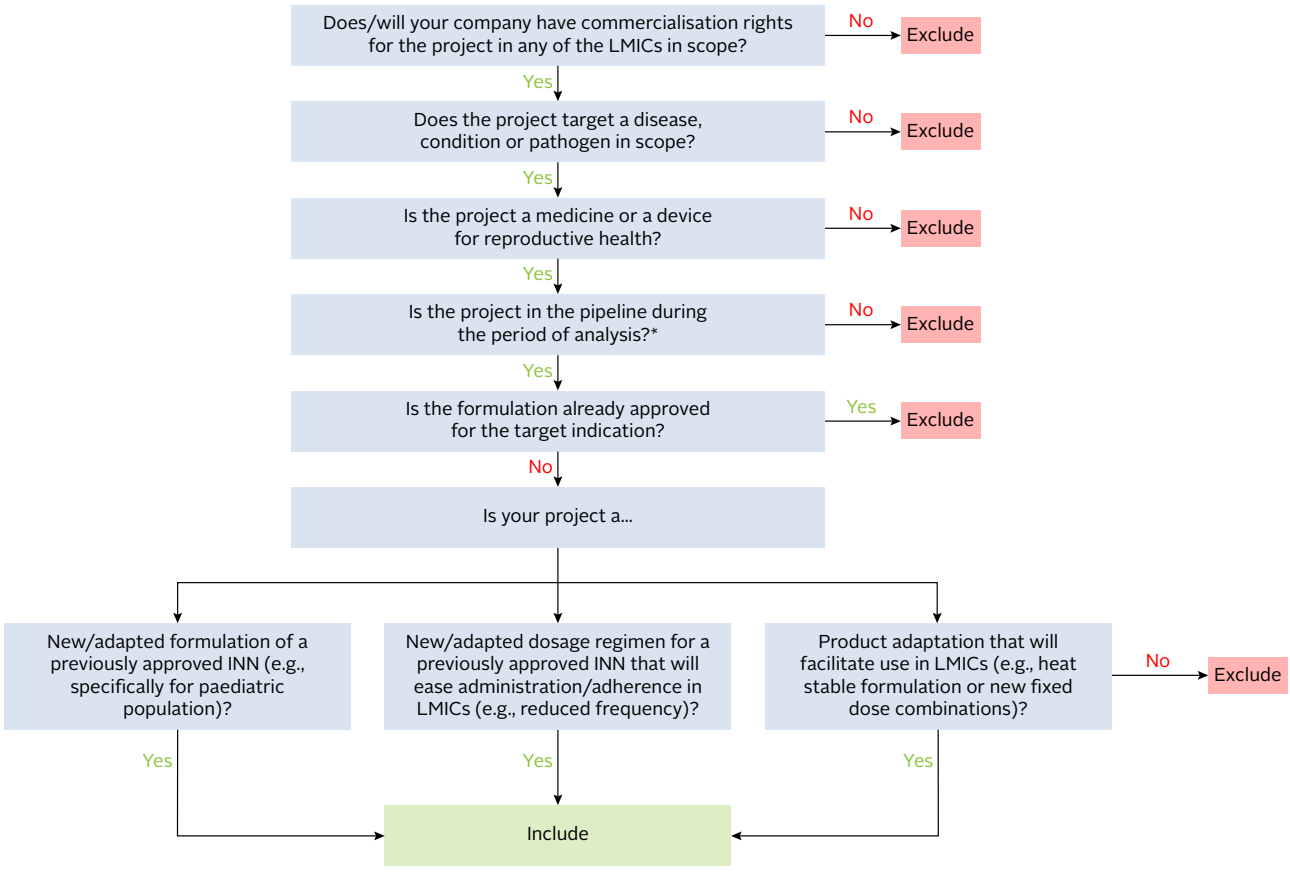
APPENDIX VII. ELIGIBILITY OF R&D PROJECTS FOR INCLUSION IN THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

To determine the eligibility of the R&D projects, the following inclusion criteria apply, and as further outlined in the figure below:

1. The company must have commercialisation rights in at least one country in scope of the programme;
2. The project must target a disease, condition or pathogen listed within the disease scope of the programme;
3. The project should fall within the product types in scope of the programme;
4. The project must be in the pipeline during the period of analysis;
5. Projects should be adaptations for existing products (for example: new/adapted formulations; new/adapted dosage regimens; or adaptations to facilitate use in LMICs, such as heat stable/fixed dose combinations).

Note: the Generic & Biosimilar Medicines Programme considered projects that met the criteria outlined above. When applicable, examples of late-stage adaptive R&D projects that target priority product gaps identified by WHO and/or Policy Cures Research (as defined in APPENDIX VIII) were highlighted.

TABLE 6 **R&D inclusion and exclusion criteria**



*The period of analysis is 1 January 2020 - 30 April 2023.

APPENDIX VIII. R&D PRIORITY PRODUCT GAPS FOR THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

The Generic & Biosimilar Medicines Programme considers R&D priorities as those identified and listed by the WHO and/or Policy Cures Research, an independent research group. The following lists were used to determine priority product gaps:

- WHO Priority Pathogen List[7];
- WHO R&D Blueprint[8];
- Policy Cures Research G-FINDER emerging infectious diseases[9];
- Policy Cures Research G-FINDER sexual & reproductive health[10];
- Policy Cures Research G-FINDER neglected diseases[11].

TABLE 7 **Priority gaps for R&D**

Gap identified
Restricted gap*

Group	Disease	Specific disease target	R&D Priority Lists: Medicines	Devices (for reproductive health only)	G-FINDER Neglected Diseases	G-FINDER Sexual & Reproductive Health	G-FINDER Emerging Infectious Diseases	WHO R&D Blueprint	WHO Priority Pathogens List
R&D priorities: R&D analysis	Arenaviral haemorrhagic fevers (Lassa fever)						●	●	
	Bunyaviral diseases	Crimean-Congo haemorrhagic fever					●	●	
		Rift Valley fever					●	●	
		Severe fever with thrombocytopenia syndrome (SFTS)					●		
		Other bunyaviral diseases					●		
	Buruli ulcer				●				
	Cancer	HPV-related cervical cancer (1)				●			
	Chagas disease				●				
	Contraceptive methods (2)					●			
	Coronaviral diseases	Middle East respiratory syndrome coronavirus (MERS-CoV)					●	●	
		Severe acute respiratory syndrome (SARS)					●	●	
		Coronavirus disease 2019 (COVID-19)					●		
		Other highly pathogenic coronaviral diseases					●		
	Dengue and Chikungunya	Chikungunya					●		
		Dengue			●				
	Enteric infections	Cholera (3)			●				
		Cryptosporidiosis (3)			●				
		Shigellosis (3)			●				
		Typhoid and paratyphoid fever (*S. typhi, S. paratyphi* A)			●				
		Non-typhoidal S. enterica (NTS)			●				
	Emergent non-polio enteroviruses (including EV71, D68)						●		
	Filoviral diseases	Ebola					●	●	
		Marburg					●	●	
		Other filoviral diseases					●		
	Henipaviral diseases	Nipah					●	●	
		Other henipaviral diseases					●	●	
	HIV/AIDS (4)				●				
	Human African trypanosomiasis				●				
	Hypertensive disorders of pregnancy	Pre-eclampsia (5)				●			
	Leishmaniasis				●				
	Leprosy				●				
	Lymphatic filariasis				●				
	Malaria	*P. falciparum*			●				
		P. vivax			●				
	Maternal haemorrhage	Postpartum haemorrhage (6)				●			
		Cryptococcal meningitis			●				
	Mycetoma, chromoblastomycosis and other deep mycoses	Mycetoma			●				

*A restricted gap is defined as the situation in which a gap for a therapeutic area exists, but the gap is restricted to certain circumstances. For example, a restricted gap may solely refer to certain subtypes of a disease or for a specific population. R&D projects that target indications with restricted gaps are only considered as 'priority R&D' if they address these specific gaps.

Gap identified
Restricted gap

Group	Disease	Specific disease target	R&D Priority Lists: Medicines	Devices (for reproductive health only)	G-FINDER Neglected Diseases	G-FINDER Sexual & Reproductive Health	G-FINDER Emerging Infectious Diseases	WHO R&D Blueprint	WHO Priority Pathogens List
R&D priorities: R&D analysis	Onchocerciasis				●				
	Scabies				●				
	Schistosomiasis				●				
	Sexually transmitted infections (STIs)	Gonorrhoea (7)				●			
		HSV-2				●			
		HTLV-1				●			
		Syphilis (8)				●			
		Other STIs (9)				●			
	Soil transmitted helminthiasis	Hookworm diseases			●				
		Strongyloidiasis			●				
		Trichuriasis			●				
		Ascariasis			●				
	Snakebite envenoming (10)				●				
	Taeniasis/cysticercosis				●				
	Tuberculosis (13)				●				
	Viral hepatitis (B and C)	Hepatitis B (11)			●				
		Hepatitis C (12)			●				
	Zika						●	●	
	Other prioritised antibacterial-resistant infections (13)	*Acinetobacter baumannii* (carbapenem-resistant)							●
		Campylobacter (fluoroquinolone-resistant)							●
		Enterobacteriaceae (carbapenem-resistant, 3rd generation cephalosporin-resistant)							●
		Enterococcus faecium (vancomycin-resistant)							●
		Haemophilus influenzae (ampicillin-resistant)							●
		Helicobacter pylori (clarithromycin-resistant)							●
		Neisseria gonorrhoeae (3rd generation cephalosporin-resistant, fluoroquinolone-resistant)							●
		Pseudomonas aeruginosa (carbapenem-resistant)							●
		Salmonella spp. (fluoroquinolone-resistant)			●				●
		Shigella spp. (fluoroquinolone-resistant)			●				●
		Staphylococcus aureus (methicillin-resistant, vancomycin intermediate and resistant)							●
		Streptococcus pneumoniae (penicillin-non-susceptible)							●

General notes:
• In addition to the above diseases and specific targets, the priority lists also include products targeting multiple included diseases.
• In some cases of duplicates (an R&D gap has been identified on more than one list) one list may define specific restriction for this gap. The Programme will consider projects targeting either the general gap or restricted gap equally.
• Where WHO priority pathogens are linked to specific diseases without reference to a specific form of antibacterial resistance, these gaps are defined separately for both the disease and for the antibacterial-resistant priority pathogen.
• Priority R&D product gaps may be updated as new iterations of priority lists are updated. Any changes that would result in the exclusion of a priority R&D project will be discussed internally, with any resulting changes communicated to companies.

(1) HPV-related cancer priority R&D restrictions are in place for medicines (ONLY includes medicines to clear or prevent HPV infection; anti-neoplastic drugs for cervical cancer are EXCLUDED). Includes devices that either clear HPV infection or treat cervical lesion.
(2) Contraceptive methods are restricted to on-demand (requiring action at the time of intercourse or pericoitally for efficacy [e.g., emergency contraception]), short-acting (working for <1 year but do not require action at the time of intercourse [e.g., injectable hormones]), long-acting reversible (working for ≥1 year [e.g., implants; IUDs]) and permanent (irreversible) methods.
(3) Restrictions for cholera, cryptosporidiosis and shigellosis are in place for medicines (ONLY includes pharmacological interventions that target the pathogen. Supportive therapies [e.g., zinc treatment, oral rehydration therapy, or other fluid and nutritional supplements] are EXCLUDED).
(4) HIV/AIDS priority R&D restrictions for medicines only includes LMIC-specific label expansions of new medicines (e.g., changes in manufacturing, recommended patient population and/or formulation for medicines after they have been approved) and formulations for LMIC use (e.g., paediatric or slow-release formulations; fixed-dose combinations; low-dose drug formulations for prophylaxis; long-acting injectables for treatment or prophylaxis).
(5) ONLY includes R&D for medicines to prevent and/or treat pre-eclampsia and/or eclampsia that offer improvements over existing products and therapies. This includes R&D for novel or existing (re-purposed) drugs, as well as research into magnesium sulphate dosing regimens.
(6) R&D for postpartum haemorrhage devices ONLY includes devices to treat PPH by targeting the underlying pathophysiology (e.g., uterine atony).
(7) Medicines for gonorrhoea MUST prevent or treat antimicrobial-resistant gonorrhoea.
(8) Medicines for syphilis MUST prevent or treat late latent, tertiary, maternal or congenital syphilis.
(9) Other STIs are defined as STIs that disproportionately affect populations in LMICs, including but not limited to trichomoniasis, chancroid, Mycoplasma genitalium, lymphogranuloma venereum and granuloma inguinale (donovanosis).
(10) Snakebite envenoming priority R&D is restricted for medicines (ONLY includes medicines being developed specifically for LMIC needs [e.g., antivenoms incorporating small-molecule inhibitors, heat-stable venom-agnostic oral medicines to slow neurotoxicity and antivenom immunoglobulins based on the venom of snakes from LMICs]).
(11) Medicines for hepatitis B ONLY include LMIC-specific label expansions of new medicines and formulations for LMIC use (e.g., curative therapies; medicines for preventing mother-to-child transmission of HBV; long-acting treatment formulations). Medicines that are biologics must at a minimum provide coverage across HBV genotypes prevalent in LMICs (A, B, C, D, E, F, H and/or I).
(12) Medicines for hepatitis C ONLY include LMIC-specific label expansions of new medicines and formulations for LMIC use (e.g., fixed-dose combinations).
(13) While M. tuberculosis has been listed as a priority pathogen by WHO, this pathogen is assessed separately as tuberculosis.

APPENDIX IX. DEFINITIONS FOR THE GENERIC & BIOSIMILAR MEDICINES PROGRAMME

Terms defined below are tailored to the objectives and methodology of the Generic & Biosimilar Medicines Programme (the Programme) and should be understood within the context of this report.

Access plans

Plans to ensure that access needs in low- and middle-income countries are taken into consideration during the R&D stage. Access plans can be developed in-house or in collaboration. They can include commitments and strategies, as well as more concrete access provisions, such as specific measures developed in partnership with other organisations that can enforce accountability. Potential components of an access plan include registration commitments, equitable pricing strategies, sufficient supply commitments, and applying for World Health Organization prequalification. Access plans facilitate availability, affordability and supply for patients in countries within the scope of the Programme.

Access strategy (product specific)

The range of mechanisms a company can implement to provide access to its product for a specific group of patients within a country. An access strategy can be composed of different elements, including pricing strategies and additional initiatives to improve the affordability and availability of the product. Access strategies with the biggest potential impact in terms of equitable access are those that aim to promote affordable access to medicine for all income groups of the population by considering the ability to pay of the payer, and by taking healthcare systems' needs and characteristics into account.

Access-to-medicine strategy

A strategy specifically intended to improve access to medicine, that includes all the typical elements of a strategy (for example, a clear rationale, targets, objectives and expected outcomes). In low-and middle-income countries where the company operates, the strategy may apply to a defined set of diseases, products or therapeutic areas, or ideally to the whole pipeline and portfolio.

Active pharmaceutical ingredient (API)

The active pharmaceutical component of a medicine that causes its intended effects. Some medicines, such as combination therapies, have multiple active ingredients that target multiple disease pathways and/or symptoms. The inactive ingredients of a medicine are referred to as excipients.

Adaptive R&D

R&D adaptations of existing/registered medicines, or other health products in scope that may address an unmet need in countries in scope of the Programme. This can include adding new indications, new target patient populations (e.g., infants/children, pregnant and lactating people), environmental conditions (e.g., heat-resistant formulations) or new formulations (e.g., oral formulations).

Affordability

This refers the payer's ability to pay for a product (whether or not they are the end user) – see 'payers' for definition. Affordability is one of the key dimensions for access to medicine. The Programme takes this into account when assessing pricing strategies for relevant products. A product's affordability depends on different factors, including socioeconomic, demographic and healthcare system characteristics, which should be considered by pharmaceutical companies when setting the price of the products.

Biosimilar medicine

A biological product that is highly similar – in terms of its efficacy, clinical benefits and safety – to an already licensed biological medicine, referred to as the 'reference product'. Biosimilar medicines are not referred to as generic medicines, due to the natural variability, as well as the greater complexity in the development and manufacturing processes which prevents biosimilar medicines from being replicated exactly.

Bottom/base of the (income) pyramid (BOP)

This refers to the poorest two-thirds of the economic human pyramid, a group of more than four billion people living in abject poverty.[12]

Branded generic

A generic medicine which is branded and marketed under a specific trade name. An unbranded generic is a generic medicine which is sold and marketed under the International Nonpropriety Name (INN).

Competitor-based pricing strategy

A pricing strategy used by companies whereby they base the prices of their medicines on the prices that competitor companies set for their medicines.

Disability-adjusted life year (DALY)

A measure of disease burden that combines disease-associated mortality and morbidity. It is the sum of the number of years of life lost (YLLs) and years lived with disability (YLDs). DALYs allow the comparison of disease burden across different populations and health conditions across time. One DALY equals one lost year of healthy life.

Equitable pricing strategy

A targeted pricing strategy which aims to improve access to medicine for those in need by considering the relevant payer's ability to pay, and by taking healthcare systems' needs and characteristics into account.

Essential medicine
Medicines that satisfy the priority healthcare needs of the population. They are selected by the World Health Organization with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness. They are intended to be available in functioning health systems at all times, in appropriate dosage forms, of assured quality and at prices individuals and health systems can afford.[13]

Exclusive licensing agreement
Licensing agreements where the licensor (usually the patent-holder) grants the licensee (usually the generic or biosimilar medicine manufacturer) the rights to manufacture, commercialise and/or distribute a patented medicine in certain countries. This is granted on an exclusive basis, and according to the terms of the licence.

Existing regulatory reach
A company's existing regulatory reach refers to the subset of countries within the 108 countries in scope of the Programme, where the company has previously successfully registered any of the products in its entire product portfolio. This includes products that fall outside the Programme's scope. This parameter was used in the analysis to assess whether or not the company could further expand its registration efforts to countries where it has previously registered any of its products, for each company's ten assessed products.

External reference pricing
Also known as international reference pricing, refers to the practice of using the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark or reference price. Note that jurisdictions refer to countries, regions or other organised purchasing authorities.[14]

Falsified medicines
Medicines or other health products that deliberately/ fraudulently misrepresent their identify, composition or source.[15]

Free pricing
Prices are set by the manufacturer with no direct price control regulation applied. Indirect price control regulation may be in place, e.g., on reimbursement.[16]

Generic medicine
A pharmaceutical product developed and manufactured to be identical to the originator medicine which has already been authorised. Generic medicines offer the same therapeutic and clinical benefits as the originator medicine and contain the same active pharmaceutical ingredient, dose, strength, and route of administration. Generic medicines are manufactured in compliance with the same stringent rules and regulations regarding quality, safety and efficacy as the originator medicine.

Good distribution practice (GDP)
This describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.[17]

Good manufacturing practice (GMP)
A system employed to ensure that products are consistently produced and controlled according to appropriate quality standards. Within pharmaceutical production this serves to minimise risks such as unexpected contamination, incorrect labelling or incorrect dosing of the active ingredient. GMP covers all aspects of pharmaceutical production (e.g., starting materials, premises, equipment, training and personal hygiene of staff) and includes processes that provide documented proof that correct procedures are consistently followed at each step of the manufacturing process. GMP guidelines are established and overseen by regulatory agencies in individual countries or regions, as well as the World Health Organization.

International Nonproprietary Name (INN)
A name given to pharmaceutical products and active pharmaceutical ingredients for identification purposes. All INNs are unique and are globally utilised.

Local manufacturing
Local manufacturing in low- and middle-income countries (LMICs) refers to the production of active pharmaceutical ingredients, finished products or the manufacturing of any other pharmaceutical product components within an LMIC. This includes companies' actions to strengthen local manufacturing by collaborating or partnering with third-party manufacturers located in LMICs to transfer manufacturing knowledge, tools and/or technology. It can also refer to a company's in-house manufacturing in an LMIC.

National regulatory authority (NRA)
A national regulatory agency responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as vaccines and medical devices including test kits) are evaluated properly and meet international standards of quality, safety and efficacy.[18]

Non-exclusive voluntary licences
Licences which enable - on a non-exclusive basis, and according to the terms of the licence agreed - the manufacture and supply of generic versions of patented medicines by other manufacturers.

Off-patent medicine
A medicine whose granted patent protection has expired, meaning it is no longer protected by exclusive marketing rights. Patent protection typically lasts for 20 years and is specific to each country.

On-patent/patented medicine
A medicine which has received exclusivity rights, allowing the patent holder to prevent or stop others from making, using, selling or importing the medicine within the country that granted the patent.

Out-of-pocket payment
Payments made by people at the time of getting any type of service provided by any type of healthcare provider. They include cost-sharing (the part not covered by a third party like an insurer) and informal payments, but they exclude insurance premiums. Out-of-pocket payments exclude any reimbursement by a third party, such as the government, a health insurance fund or a private insurance company.[19] In the Programme's context, out-of-pocket payments relate to payments made for medicines or other health products in scope.

Patient assistance programmes
Programmes initiated by pharmaceutical companies which provide financial assistance or free-of-charge medicines for a defined patient population with limited ability to pay.

Patient reach
The number of people benefitting from access to a company's product(s), which can be demonstrated through, for example, annual sales volume divided by volume per patient or the estimated number of patients reached by a particular access strategy, initiative, or partnership.

Payers
Entities, including individuals, private health insurers, governments, and international organisations, which are responsible for funding and facilitating medical services. The entities vary based on the healthcare system's financial structure.

Period of analysis
For the first iteration of Company Profiles, the time period for which data was analysed covered the company's activities (which must have been ongoing) between January 2020 and April 2023.

Pooled procurement
A process through which a buyer pulls together demand to increase the total quantity of a specific product to include in a tender, in order to benefit from better procurement conditions and economies of scale.

Priority R&D
R&D that addresses product gaps resulting from a lack of effective or suitable products to treat, prevent or detect certain diseases, conditions and pathogens in countries within scope of the Programme. These product gaps are defined as being those listed in a series of six priority lists developed by the World Health Organization and Policy Cures Research, an independent R&D-focused policy group.

Product development partners
Non-profit organisations that facilitate financial risk-sharing across the public and private sectors by pooling and sharing resources, both tangible and intangible, for the development of medicines, vaccines and other health tools.

Public-private partnership (PPP)
A partnership between one or more public organisation(s) and a private sector company or companies for providing a public asset or service, in which the private party bears significant risk and management responsibility, and remuneration is linked to performance. The Programme also considers a partnership between a non-profit organisation and the private sector to be a PPP.

Social marketing organisation
An organisation that aims to benefit society by applying commercial marketing techniques to improve public health. In the context of the Programme, pharmaceutical companies can collaborate with these organisations to improve the affordability and supply of medicines in low-and middle-income countries.

Stringent regulatory authority (SRA)
A national drug regulation authority that is considered by the World Health Organization to implement stringent requirements in regard to quality, safety, and efficacy throughout the regulatory review of drugs and vaccines for marketing authorisation.

Substandard medicines
Also called 'out of specification', these are authorised medicines or other health products that fail to meet either their quality standards or specifications, or both.[15]

Supranational procurement
Procurement mechanisms which extend beyond national boundaries or governments. This can include international and/or regional pooled procurement mechanisms, which typically enable price reductions as a result of aggregated order volumes.

Swissmedic Marketing Authorisation for Global Health Products (MAGHP)
A procedure developed by Swissmedic, the Swiss Agency for Therapeutic Products, to improve and accelerate access to health interventions and therapeutic products in low- and middle-income countries. MAGHP focuses on the sub-Saharan region of Africa and on medicines for diseases that disproportionately affect this region, although other countries or regions may also be considered.

Technology transfer
A pharmaceutical company transfers knowledge, tools and/or technology necessary for producing a specific product (e.g., medicine, vaccine) to a manufacturer. Technology transfer can improve the supply and availability of products, while also building manufacturing capacity that can be applied to other manufacturing processes.

Vulnerable populations
People at greater risk of facing barriers to accessing medicines due to social, economic and/or health considerations.

The World Health Organization (WHO) Collaborative Registration Procedure (CRP)
A procedure launched by the WHO that aims to expedite registration of prequalified finished pharmaceutical products. It accelerates registration through improved information sharing between the WHO prequalification system and national regulatory authorities. By leveraging assessment and inspection outputs already produced by WHO prequalification, and thereby eliminating duplicative regulatory work, it speeds up in-country registration of quality-assured products and contributes to their wider availability.[20]

The World Health Organization (WHO) prequalification (PQ)
A service provided by the WHO to assess the quality, safety and efficacy of those products that address global public health priorities. If the products meet international standards, they are listed on the WHO website as eligible for procurement, giving purchasing agencies a range of quality-assured diagnostics, medicines and vaccines from which to choose. Many low-income countries also use WHO's lists of prequalified products to guide their selection of medicines, vaccines and technologies for national procurement.[21] Its long-term goal is to increase the availability of quality-assured medicines by assisting manufacturers to comply with WHO standards and supporting regulatory authorities to implement them.[22]

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