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.

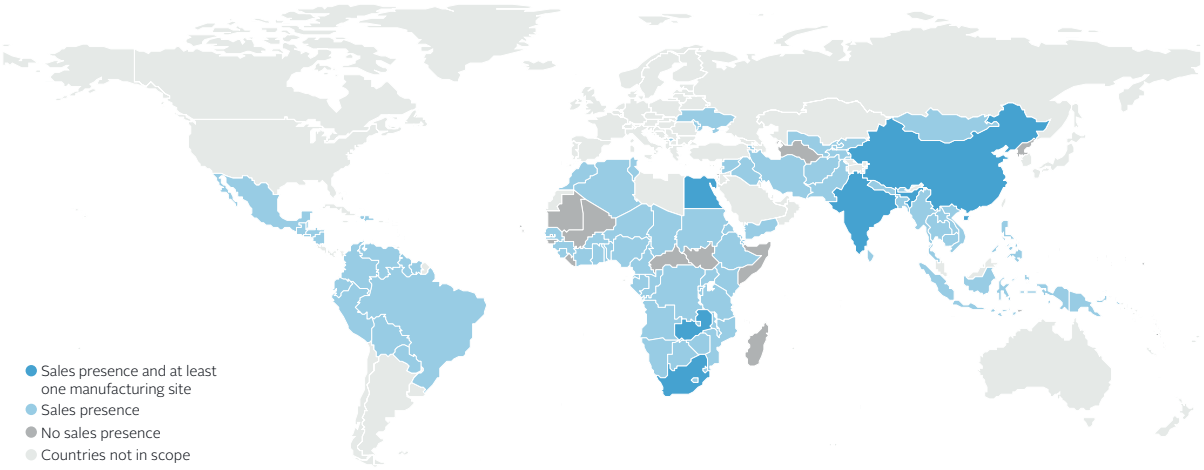
Expand engagement in voluntary licensing agreements
As a sublicensee in various licensing agreements, Viatris is following through on its commitments to register in-licensed products in LMICs in scope. Viatris can build on these efforts by continuing to register products such as dolutegravir (paediatric) 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.

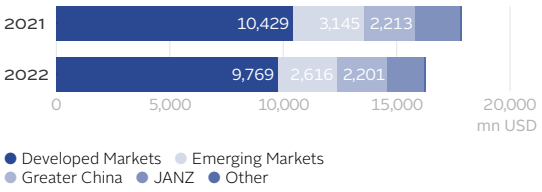
**Refers to countries in which sales are conducted through suppliers, pooled procurement and/or the company sales offices.

COMPANY PRESENCE & REVENUE

Sales and manufacturing presence in countries in scope



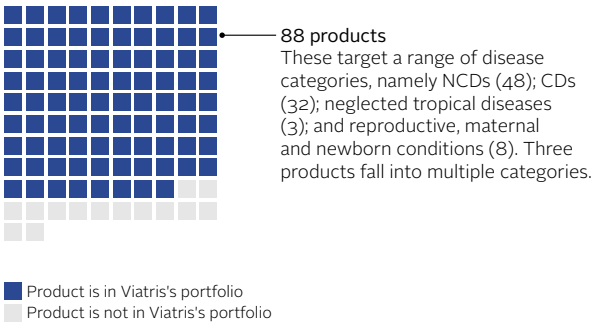
Revenue by business segment and region*



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.

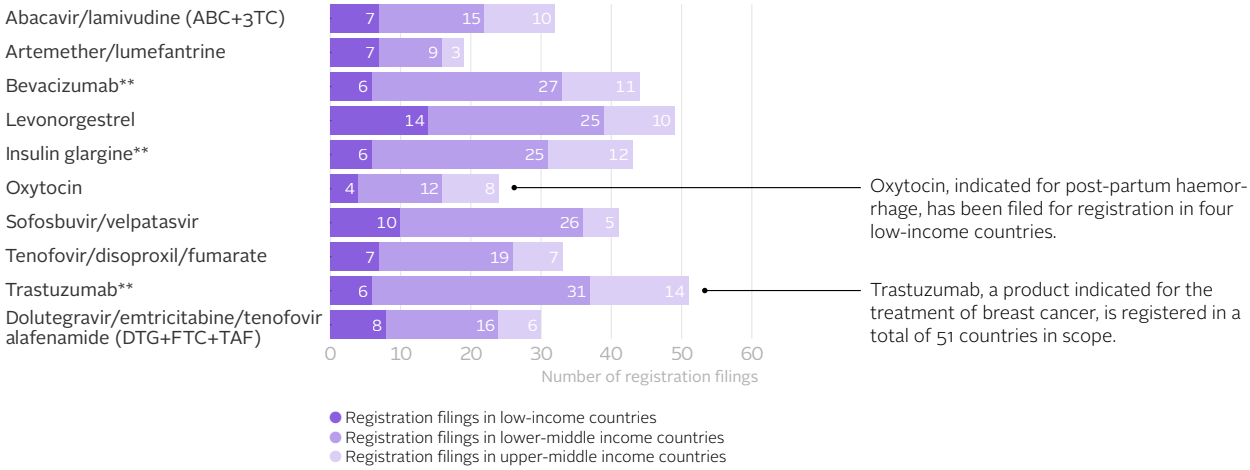
Ten off-patent medicines from Viatris's portfolio were selected for assessment. The company has filed at least one of these products for registration in 72 out of the 88 LMICs (82%) where it has pre-existing regulatory filings,** showing the company's extensive capacity to register its products across 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.

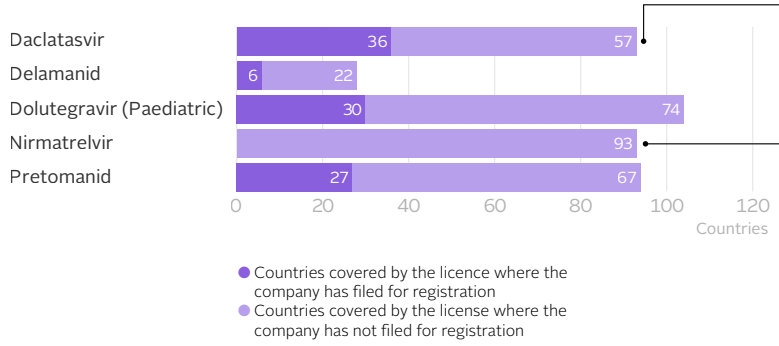
Additionally, Viatris is a sublicensee of a NEVL for paediatric dolutegravir. This NEVL was facilitated by the Medicines Patent Pool (MPP) and involves ViiV Healthcare, CHAI, and Unitaid.

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