Viatris Inc

This table is part of a November 2023 report that looks at what actions each company in scope of the Antimicrobial Resistance (AMR) Benchmark has taken with regards to each of the Opportunities set out in its 2021 AMR Benchmark Report Card. The full 2021 Report Card is also included in this PDF.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Viatris can set limits and quantify discharge levels to track compliance at all suppliers' sites and it can publicly disclose the results. Viatris can also publish information on how it manages environmental risk related to antibacterial manufacturing. To provide clear evidence of its progress it can publicly report compliance at all sites. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.	Viatris continues to report that all its own manufacturing sites are compliant with discharge limits in the receiving environment. Viatris also publicly discloses this information. In addition, Viatris publicly reports that it has adopted the AMR Industry Alliance's Antibiotic Manufacturing Standard to manage AMR risk from antibacterial manufacturing. The company publicly reports that 15 supplier sites have been audited against the AMR Industry Alliance guidelines through 2022.
Improve accessibility of pretomanid (Dovprela) and delamanid (Deltyba). Viatris filed delamanid (Deltyba) and pretomanid (Dovprela) for registration in seven and 23 access countries. It can expand the availability of these MDR-TB treatments by filing for registration in more access countries, in particular the countries with a high burden of MDR-TB identified by the WHO, where it has commercialisation rights. Accessibility can be improved through public/private partnerships, patient assistance programmes and donations.	Viatris has registered, or has filed for registration, delamanid (Deltyba®) and pretomanid (Dovprela) in six and 27 countries in scope of the Benchmark respectively, in comparison to seven and 23 countries recorded in 2021. Collaborating with MedAccess and the TB Alliance in 2022, Viatris announced an agreement to reduce the price of pretomanid by 34%. As a result, the maximum price of pretomanid charged by Viatris came down to USD 240 per six-month treatment course. As a result of the price reduction, it is projected that globally an additional 36,000 patients can be treated successfully, and 31,000 adverse events can be averted. Furthermore, Viatris reports that the shelf life of pretomanid has been extended from 36 months to 48 months, allowing for longer storage periods, reducing the frequency of resupply and allowing for optimised logistics and reduced waste. Pretomanid is newly included in the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML) for treatment of multidrug-resistant or rifampicin-resistant tuberculosis.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
Expand registration of generic antibacterial and antifungal medicines. Viatris can expand registration of its generic antibiotics and antifungals listed on the 2021 WHO EML, such as linezolid, polymyxin B, and amphotericin b, to more countries, including low-income countries.	Since 2021, Viatris has increased the number of filed registrations for amoxicillin, amoxicillin/clavulanic acid, isoniazid, linezolid, vancomycin and flucytosine in multiple countries within scope of the AMR Benchmark. Since 2021, these products – all listed on the WHO EML 2023 – are on average filed in two additional countries in scope. Among these, filed registrations for linezolid have increased the most, from two countries by 2021 to 13 countries by 2023.
Fully decouple incentives for sales agents from sales volumes. Viatris does not promote pretomanid (Dovprela) and flucytosine. Viatris can expand this practice to all antibacterial and antifungal medicines. Alternatively, it can fully decouple incentives for sales agents from sales volumes of all antibacterial and antifungal medicines.	Viatris reports that in many low- and middle-income countries (LMICs) it sells directly to distributors, and that in these countries, it does not deploy sales agents. The company did not disclose an update on sales incentives in countries where it deploys sales agents for antibacterial and antifungal medicines.
Adapt brochures and packaging. In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Viatris can adapt its brochures and packaging to consider local languages, literacy levels, paediatric use, environmental conditions and patient adherence to treatment.	For its generic medicines, Viatris reports it does not adapt brochures and packaging for its antibacterial and antifungal medicines. For pretomanid, Viatris reports inserting information leaflets in the regulatorily required languages and four additional languages (English, French, Spanish, and Russian), unless one of those four is the regulatory authority language.

Overall Performance

2020 2021

53% 67% ▲

Viatris Inc

Generic medicine manufacturer

Stock exchange: NASDAQ • Ticker: VTRS • HQ: Canonsburg, PA, US • Employees: 45,000

PERFORMANCE

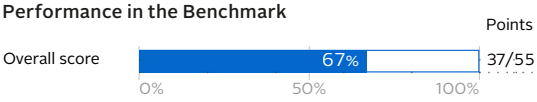
Viatris performs well overall in its evaluated Research Areas compared to the other generic medicine manufacturers in scope.

Responsible Manufacturing: Performs well. Reports environmental risk-management strategy for own sites and suppliers; co-leads in reporting compliance with limits at own sites.

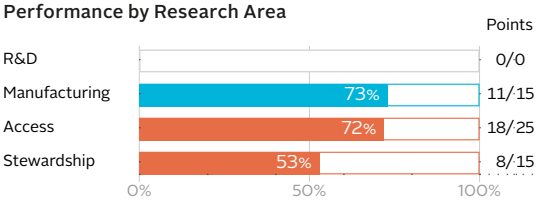
Appropriate Access: Performs strongly. Files some of its on- and off-patent products for registration in access countries. Reports several strategies to expand access and ensure continuous supply of its relevant products.

Stewardship: Middle-performing. It does not promote two products to healthcare professionals, however it does not decouple sales incentives from sales volumes for its other products. It reports comprehensive conflict of interest mitigation for its educational programmes. It does not adapt brochures or packaging for patients.

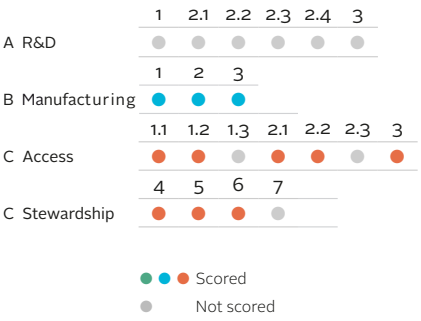
Performance in the Benchmark



Performance by Research Area



How Viatris was evaluated



OPPORTUNITIES FOR VIATRIS

Ensure compliance with antibacterial discharge limits at suppliers' sites by tracking and publicly disclosing progress and results specific to antibacterials for all sites. Viatris can set limits and quantify discharge levels to track compliance at all suppliers' sites and it can publicly disclose the results. Viatris can also publish information on how it manages environmental risk related to antibacterial manufacturing. To provide clear evidence of its progress it can publicly report compliance at all sites. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.

Improve accessibility of pretomanid (Dovprela) and delamanid (Deltyba®). Viatris filed delamanid (Deltyba®) and pretomanid (Dovprela) for registration in seven and 23 access countries. It can expand the availability of these MDR-TB treatments by filing for registration in more access countries, in particular the countries with a high burden of MDR-TB identified by the WHO, where it has commercialization rights. Accessibility can be improved through public/private partnerships, patient assistance programs and donations.

Expand registration of generic antibacterial and antifungal medicines. Viatris can expand registration of its generic antibiotics and antifungals listed on the 2021 WHO EML, such as linezolid, polymyxin B, and amphotericin b, to more countries, including low-income countries.

Fully decouple incentives for sales agents from sales volumes. Viatris does not promote pretomanid (Dovprela) and flucytosine. Viatris can expand this practice to all antibacterial and antifungal medicines. Alternatively, it can fully decouple incentives for sales agents from sales volumes of all antibacterial and antifungal medicines.

Adapt brochures and packaging. In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Viatris can adapts its brochures and packaging to consider local languages, literacy levels, paediatric use, environmental conditions and patient adherence to treatment.

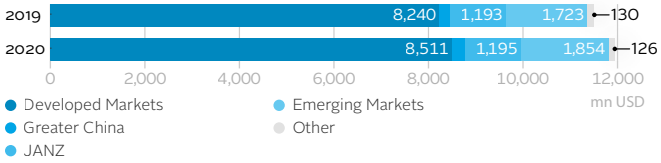
CHANGES SINCE 2020

Viatris was formed on November 16, 2020 through the combination of Mylan and Upjohn, a legacy division of Pfizer.

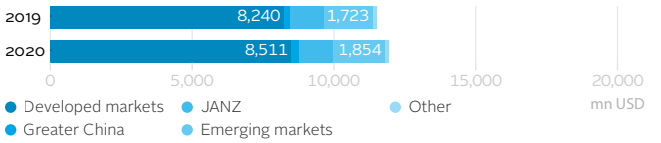
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, CNS and anesthesia, Dermatology, Diabetes and metabolism, Gastroenterology, Immunology, Infectious disease, Oncology, Respiratory and allergy, Women's healthcare.
Business segments: Developed Markets, Greater China, JANZ, Emerging markets
Product categories: Biosimilars, Generic medicines, Innovative medicines
M&A since 2020: Viatris was formed on November 16, 2020 through the combination of Mylan and Upjohn, a legacy division of Pfizer.

Revenue by business segment



Revenue by region



PORTFOLIO *for pathogens in scope*

Comparatively large portfolio: At least 87 products: 72 antibacterial medicines; 15 antifungal medicines
On-patent medicines: 2 (delamanid, pretomanid)
Off-patent/generic medicines: 9 of 85 were selected for analysis* (amoxicillin [A], amoxicillin/clavulanic acid [A], amphotericin b [F], flucytosine [F], isoniazid [T], linezolid [T], piperacillin/tazobactam [W], polymyxin B [R], vancomycin [W])
AWaRe medicines:** 24 Access group; 34 Watch group; 1 Reserve group
Anti-TB medicines:** 5

Products on the market

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

As a generic medicine manufacturer, Viatris is not evaluated in this Research Area.

B RESPONSIBLE MANUFACTURING Evaluated: antibacterials manufacturing (APIs and drug products)

B.1 Environmental risk-management for own sites and suppliers; tracks compliance with limits at own sites

Viatris reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits every five years. It reports setting discharge limits in the receiving environment for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. Discharge levels are quantified at all sites using a mass balance approach. All its sites, or 100%, are reported to be compliant with discharge limits. It reports that eight of its sites that manufacture antibacterials are ZLD and that recycled water was analysed for presence of antibacterials which was found to be zero.

Viatris requires third-party suppliers of antibacterials to follow the same standards, including limits based on PNECs. It engaged with EcoVadis to start an audit programme among its top 35 antibiotic suppliers to assess AMR risk. It also requests and reviews the discharge levels of its suppliers as part of these audits. It is unclear how many of the 35 suppliers are assessed so far and have quantified discharge levels.

There is limited information on the requirements Viatris makes of external private and public waste-treatment plants, in terms of strategy, audits and antibacterial discharge limits and levels.

B.2 Publicly discloses some information on environmental risk management and quantifying discharge levels at own sites

Viatris publishes some components of its environmental risk-management strategy. It is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Viatris publishes its commitment to setting these targets. It also publicly discloses that all of its own sites have quantified antibacterial discharge levels. It does not publish: (1) the results of environmental audits, whether conducted at its own sites, the sites of suppliers or external private and public waste-treatment plants; (2) a list of these suppliers and plants; or (3) the levels of antibacterial discharge from its own or suppliers' sites.

B.3 System in place to maintain production quality for own and suppliers' sites; no requests for official corrective action

Viatris reports that its own sites and suppliers have a system to maintain high-quality antibacterial production consistent with international GMP standards. This includes periodic risk-based audits and tracking of corrective and preventive actions. Viatris also requires its suppliers to audit their own suppliers. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Viatris' own sites or any subsidiaries that manufacture antibacterials.

* See Appendix VII for information about eligibility criteria for products.
** Listed on the 2019 WHO EML.

C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS

Evaluated: access activities relating to antibacterial & antifungal medicines & vaccines in 102 access countries***

Viatris is not eligible for indicators: C.1.3 and C.2.3. For more information, see Appendix VII.

C.1.1 Filed to register on-patent medicines in 15 access countries on average

Viatris performs above average, filing its two relevant on-patent medicines for registration in access countries. Its most widely filed relevant product is the anti-tuberculosis medicine pretomanid, filed in 23 access countries, including five LICs. Under its licensing agreement with Otsuka, Viatris filed delamanid for registration in seven access countries.

C.1.2 Filed to register off-patent/generic medicines in 7 access countries on average

Viatris has an average performance, filing seven of its nine sample off-patent/generic medicines for registration in seven access countries on average. Its most widely filed relevant product is vancomycin, filed in 15 access countries. Six of its sample products are filed in less than 10 access countries. Five of its sample products are filed for registration in at least one LIC.

C.2.1 Several strategies to expand access to on-patent medicines

Viatris performs above average, with access strategies reported for both its two relevant on-patent medicines. It aims to expand access to its on-patent medicines in access countries through public/private partnerships, donations, tenders and a named patient access program. Viatris partners with the GDF–Stop TB Partnership to provide pretomanid at a global access price of USD 364 per treatment course to 150 countries. Viatris provides evidence of patient reach and geographic reach for all its reported approaches. In 2019 and 2020, it provided 6,000 treatment courses of delamanid through a government tender in South Africa.

C.2.2 Some strategies to expand access to off-patent/generic medicines

Viatris has an average performance. It reports that it aims to expand access to its off-patent/generic medicines in access countries through equitable pricing and public/private partnerships. For example, Viatris partnered with stakeholders such as UNITAID, CHAI, and the Global Fund to provide flucytosine, prior to WHO-prequalification.

C.3 Several strategies to ensure continuous supply

Viatris performs above average, with strategies reported in all four areas assessed. Viatris ensures accurate demand planning and data sharing by having a 24-months horizon planning and daily, weekly, or monthly operational meetings and supply reviews. Viatris mitigates against shortage risks by keeping buffer stocks and conducting supplier audits. It registers several of its products at multiple production sites, including in China, South Africa, and Zambia, ensuring geographical diversification and dual sourcing. Viatris estimates 50% of its main products' APIs or finished forms to be dually sourced. To mitigate against sub-standard and falsified products, Viatris has a dedicated infrastructure to monitor product safety and manage related efforts. This includes, but is not restricted to, a product portfolio risk assessment process, analysis and market monitoring, a suspicious order monitoring program, and a product diversion program that includes anonymous reporting mechanisms and a supplier code of conduct. Viatris uses security features such as serialisation or 2D data matrix.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Comprehensive COI mitigation strategies in place for its educational programmes

Viatris performs strongly in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. To mitigate COI for one programme, it provides financial resources to an independent third party (Omnicuris), which collaborated with another independent organisation (ISCCM) to develop the programme. The remaining four programmes have all three COI mitigation strategies looked for by the Benchmark: (1) content is developed independently from its marketing department; (2) a pledge not to provide financial or material incentives; and (3) it does not use branded materials.

C.5 Engages in sales practices but does not engage in marketing practices to address appropriate use

Viatris performs above average in sales practices. It does not deploy any sales agents to promote pretomanid and flucytosine to healthcare professionals. However, for the remaining antibacterial and/or antifungal medicines it does not report whether it decouples incentives for sales agents from sales volumes to help prevent the inappropriate use of such medicines.

Viatris does not report to engage in marketing practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines as its marketing materials do not reflect emerging resistance trends or include treatment guidelines for healthcare professionals to raise awareness of AMR and address appropriate use.

C.6 Does not report adapting brochures and/or packaging to facilitate appropriate use by patients

Viatris does not report adapting brochures and/or packaging to facilitate the appropriate use of its antibacterial and/or antifungal medicines by patients.

C.7 AMR Surveillance

As a generic medicine manufacturer, Viatris is not assessed in this indicator but its activities in AMR surveillance are reported. The Benchmark notes that Viatris is active in two AMR surveillance programmes. It supports the national Data Development programme, which is a retrospective study of antimicrobial resistance in ICU patients in India and has been running since 2019. Viatris reports that it intends to share results in a peer-reviewed medical journal. Moreover, Viatris runs the multinational Pretomanid Resistance Surveillance Program, which is focused on resistance against pretomanid in eight countries until 2025. Once data collection has been completed, Viatris intends to share data with regulatory authorities and in a peer-reviewed journal article.

*** 102 low- and middle-income countries where better access to medicine is most needed.