Abbott Laboratories

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?
Request and review discharge levels of all suppliers and increase public disclosure on environmental risk management. Abbott can expand its environmental risk management requirements to all suppliers by fully implementing its supplier contract template which outlines specific provisions for AMR. Abbott currently requests and reviews discharge levels for only a subset of its suppliers. Abbott can also publicly disclose more information on how it manages environmental risk related to antibacterial manufacturing. It can publish information on its progress in implementing the strategy, the limits it sets, and the results of the audits of own and suppliers' sites including antibacterial discharge levels.	In 2021, Abbott introduced AMR provisions within the medicines business' template contract for its suppliers. These provisions require suppliers to implement liquid and solid waste management practices, adhere to antimicrobial discharge limits, and provide discharge level information upon request. Abbott publicly reports that the contract is being implemented with suppliers for its branded generic medicines business. In addition, support is provided to suppliers to cohere with the provisions. For example, since 2022, Abbott offers free wastewater analysis to all suppliers that exceed discharge limits based on mass balance quantifications. To identify high-risk suppliers for AMR, Abbott reports the use of a desktop assessment tool since 2023. This involves a questionnaire including questions on pharmaceuticals in the environment and AMR. It is unclear how many supplier sites out of the total are compliant with discharge limits. In the public domain, Abbott reports regularly quantifying antibiotic discharge levels against set discharge limits.
Expand registration and ensure availability of antibacterial and antifungal medicines. Abbott can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as gentamicin, itraconazole and tigecycline, to more countries, including low-income countries, with a high burden of disease. Further, it can expand equitable access in countries where medicines have been registered.	In India, Abbott has expanded registration for two Access antibiotics and two antifungals listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML). Similarly, in the Middle East, Turkey, Africa and Pakistan, Abbott has registered four Watch antibiotics listed on the same EML. Clarithromycin is the company's most widely filed antibiotic, with filings spanning 31 low-income countries and 55 lower-middle income countries, and market presence in the majority of them. Abbott highlights that registration expansion for in-licensed products can be constrained by contractual terms with licensors. Abbott did not report any developments pertaining to expanding access to its off-patent/generic antibacterials and antifungals.
Fully decouple incentives for sales agents from sales volumes. Abbott ran a pilot in India where it fully decoupled incentives for sales agents from sales volumes of an anti-infective for three months. It can expand this practice to more countries where it markets antibacterial and/or antifungal medicines and to more relevant products.	Abbott reports that its sales agents are incentivised for the sales of a basket of medicines that covers different therapeutic areas and includes antibacterial and antifungal medicines. Sales incentives are partially decoupled from sales volumes and, in India, are partially based on qualitative targets, including targets related to AMR risks. However, the specific percentage of variable pay or the level at which incentives are set is not disclosed.

2021 OPPORTUNITY What was the Opportunity shared in the AMR Benchmark?	2023 UPDATE What progress has been made on this Opportunity?
Comprehensively mitigate COI for educational programmes. Abbott organises medical education programmes for healthcare professionals on responsible use of antimicrobial medicines. It can ensure that branded materials are not used in any educational programmes, as is now the case for some.	Abbott continues to organise medical education programmes that focus on the responsible use of antimicrobial medicines for healthcare professionals, tailored to the needs of healthcare systems and in collaboration with appropriate partners across all regions where its medicines business operates. As of 2023, branded materials are no longer used in any educational programmes.

Overall Performance

2020 2021

53% 69%▲

Abbott Laboratories

Generic medicine manufacturer

Stock exchange: NYSE • Ticker: ABT • HQ: Chicago, IL, US • Employees: 109,000

PERFORMANCE

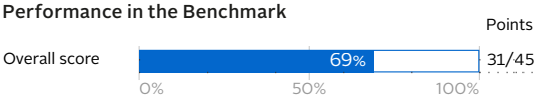
Abbott performs well overall in its evaluated Research Areas compared to the other generic medicine manufacturers in scope.

Responsible Manufacturing: Performs well. Reports comprehensive environmental risk-management strategy for own sites and suppliers; quantifies discharge levels at all own sites.

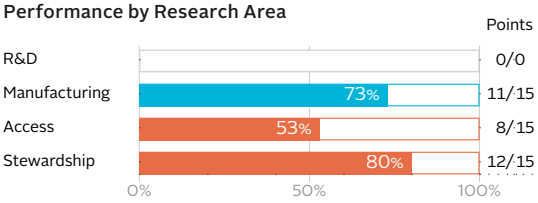
Appropriate Access: Middle-performing. Files some of its off-patent/ generic medicines for registration in access countries. Reports some strategies to expand access and ensure continuous supply of its relevant product.

Stewardship: Performs well. It ran a pilot where it fully decoupled incentives for sales agents from sales volumes for an anti-infective, however it does not decouple such incentives for its other products. It reports broad conflict of interest mitigation for its educational programmes. It adapts packaging for patients.

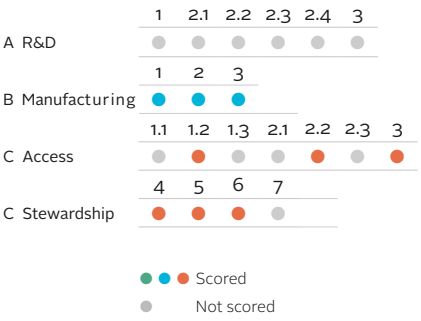
Performance in the Benchmark



Performance by Research Area



How Abbott was evaluated



OPPORTUNITIES FOR ABBOTT

Request and review discharge levels of all suppliers and increase public disclosure on environmental risk management. Abbott can expand its environmental risk management requirements to all suppliers by fully implementing its supplier contract templete which outlines specific provisions for AMR. Abbott currently requests and reviews discharge levels for only a subset of its suppliers. Abbott can also publicly disclose more information on how it manages environmental risk related to antibacterial manufacturing. It can publish information on its progress in implementing the strategy, the limits it sets, and the results of the audits of own and suppliers' sites including antibacterial discharge levels.

Expand registration and ensure availability of antibacterial and antifungal medicines. Abbott can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as gentamicin, itraconazole and tigecycline, to more countries, including low-income countries, with a high burden of disease. Further, it can expand equitable access in countries where medicines have been registered.

Fully decouple incentives for sales agents from sales volumes. Abbott ran a pilot in India where it fully decoupled incentives for sales agents from sales volumes of an anti-infective for three months. It can expand this practice to more countries where it markets antibacterial and/or antifungal medicines and to more relevant products.

Comprehensively mitigate COI for educational programmes. Abbott organises medical education programmes for healthcare professionals on responsible use of antimicrobial medicines. It can ensure that branded materials are not used in any educational programmes, as is now the case for some.

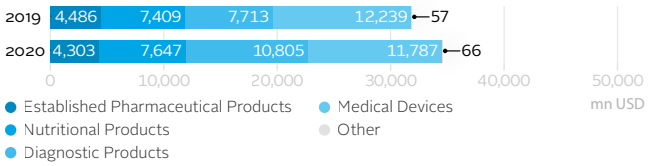
CHANGES SINCE 2020

- In 2021, Abbott introduced a new contract template for suppliers of APIs and drug products with clauses that specifically require implementation of AMR standards.
- In response to an opportunity from the 2020 AMR Benchmark, Abbott ran a new pilot in which it fully decoupled incentives for sales agents from sales volumes of an anti-infective in India for three months.
- Abbott is funder and member of the consortium VALUE-Dx. VALUE-Dx is the first Innovative Medicines Initiative project initiated by six *in vitro* diagnostic companies who work with 20 non-industry partners to combat AMR and improve patient outcomes.
- Since 2020, Abbott has adapted packaging of eight of its antibacterial medicines, including amoxicillin and azithromycin, to take account of adherence to treatment, literacy and paediatric use to facilitate the appropriate use of such medicines by patients.

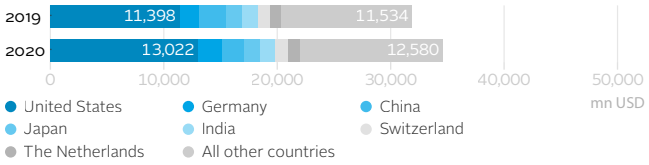
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, Diabetes care, Gastro intestinal/immunity health, Infectious disease (Diagnostic, Covid-19), Metabolic disorders, Pain/central nervous system, Respiratory, Women's health.
Business segments: Established pharmaceutical products, Nutritional products, Diagnostic products, Medical devices
Product categories: Diagnostics, Generic medicines, Medical devices, Vaccines
M&A since 2020: None in the antibacterial and/or antifungal sectors

Net sales by business segment



Net sales by region



PORTFOLIO *for pathogens in scope*

Comparatively large portfolio: At least 85 products: 75 antibacterial medicines; 3 antibacterial vaccines; 7 antifungal medicines
Off-patent/generic medicines: 10 of 85 were selected for analysis* (amoxicillin/clavulanic acid [A], amphotericin b [F], cefixime [W], clarithromycin [W], clofazimine [T], colistin [R], gentamicin [A], itraconazole [F], linezolid [T], tigecycline [R])
AWaRe medicines:** 16 Access group; 20 Watch group; 3 Reserve group
Anti-TB medicines: 10

Products on the market

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

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

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

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

Abbott reports a comprehensive strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits every three 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 the AMR Industry Alliance. Discharge levels are quantified using a mass balance approach, verified by chemical analysis if applicable. It reports tracking compliance with discharge limits of own sites.

Abbott requires third-party suppliers of antibacterials to follow the same standards, including limits based on PNECs. It reports conducting on-site audits every 3-5 years. It requests and reviews the discharge levels of its suppliers. A subset of its suppliers' sites report to have quantified discharge levels.

Abbott expects external private waste-treatment plants to comply with its general environmental standards. It audits these plants at least every five years (based on risk) which includes checking the suitability of technologies used for processing waste and protocols for preventing contamination. It also employs conservative measures for effluents sent to external private and public wastewater treatment plants.

B.2 Limited publicly available information on environmental risk management

Abbott publishes some components of its environmental risk-management strategy, without specific references to AMR. It does publish having a programme in place to assess and minimise the impact of discharges, from own and suppliers' sites manufacturing APIs, on the environment. Abbott does not publish: (1) the results of environmental audits, conducted at its own sites, the sites of suppliers and/or external private and public waste-treatment plants; (2) a list of these suppliers and plants; or (3) the limits and 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

Abbott reports 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. Abbott 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 Abbott's 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***

Abbott is not eligible for indicators: C1.1, C1.3, C.2.1 and C.2.3. For more information, see Appendix VII.

C.1.2 Filed to register 8 of 10 relevant off-patent/generic medicines in 8 access countries on average

Abbott has an average performance, filing eight of its ten relevant off-patent/generic medicines for registration in eight access countries on average. Its most widely filed relevant product is the antibiotic clarithromycin filed in 58 access countries. Seven of its relevant products are filed in less than ten access countries. One of its relevant products is filed for registration in at least one LIC.

C.2.2 Limited information on strategies to expand access to off-patent/generic medicines

Abbott has an average performance as it reports limited information on how it expands access to its ten relevant off-patent/generic medicines.

Abbott reports two simplified treatment regimens examples in Bolivia, India, and Peru. It estimates its simplified treatment regimen containing clarithromycin to reach 5,000 cumulative patients per year in Peru and Bolivia.

C.3 Several strategies to ensure continuous supply

Abbott has an average performance, with strategies reported in all four areas assessed. It ensures accurate demand planning and data sharing by having a monthly rolling forecast with a 24-months horizon. Abbott mitigates against shortage risks by keeping a buffer stock for critical APIs and finished products. It has a dual-sourcing strategy for its strategic APIs. Abbott reports one technology transfer initiative of its drug product unit operations to a third-party drug manufacturer. To mitigate against substandard and falsified products, Abbott uses packaging features, conducts employee's trainings, and tests potential falsified products in a dedicated laboratory.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

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

Abbott performs well in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. To mitigate COI for three programmes, it provides financial resources to independent third parties (APUA, Medscape, BSAC and the University of Dundee) to develop the programme. One programme has 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 to participants; and (3) it does not use branded materials. The remaining programme has two of three COI mitigation strategies looked for by the Benchmark: it is unclear whether branded materials are being used.

C.5 Engages in sales and marketing practices to address appropriate use

Abbott performs above average in sales practices. It ran a pilot in 2021 where it fully decoupled incentives for sales agents from sales volumes of an anti-infective in India for three months. However, outside of this pilot Abbott does not report whether it decouples incentives for sales agents from sales volumes to help prevent the inappropriate use of its antibacterial and/or antifungal medicines.

Abbott engages in marketing practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines. Its marketing materials reflect emerging resistance trends and/or include treatment guidelines for healthcare professionals: for clarithromycin.

C.6 Makes three types of brochure and/or packaging adaptations to facilitate appropriate use by patients

Abbott adapts packaging to facilitate the appropriate use of its antibacterial medicines by patients. Abbott performs strongly in this measure, taking account of adherence to treatment, literacy and paediatric use. It adapts the package size of clarithromycin in eight countries to a full treatment course of either a 7-, 10-, or 14-day treatment. Moreover, Abbott has dose marking on the packaging of cefixime in India to improve patient adherence to treatment. Further, it includes a QR code on the packaging of amoxicillin that directs patients to information on the appropriate use and the course of treatment to improve adherence to treatment. Additionally, Abbott adapts packaging for antibacterial medicines in India by including pictograms to support literacy challenges. Finally, it includes a QR code on the packaging of eight antibacterial paediatric suspensions that directs to a video explaining how to use them appropriately.

C.7 AMR Surveillance

As a generic medicine manufacturer, Abbott is not assessed in this indicator but its activities in AMR surveillance are reported. The Benchmark notes that Abbott is active in two AMR surveillance programmes. It runs the national ARISE programme, which is focused on regional sensitivity indices at a state level on hospital- and community-acquired infections in India since January 2019. Abbott only shares the data collected in this programme through a data platform in a restricted manner. Moreover, the CANWARD programme is a national programme managed by the Canadian Antimicrobial Resistance Alliance with support from Abbott, among others. Only the aggregated results are shared through an open-access data platform, as well as through peer-reviewed journal articles.

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