Abbott Laboratories

PERFORMANCE

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

Responsible Manufacturing: Performs strongly. Reports comprehensive environmental risk management strategy, including ongoing risk assessments using discharge limits at own sites; suppliers are covered but degree of implementation is lower.

Appropriate Access: Performs well. Files for registration for all relevant off-patent products in access countries. Reports some information on the basis of confidentiality on its strategies for pricing and ensuring continuous supply.

Stewardship: Performs less well. It has educational programmes with broad conflict of interest (COI) mitigation. It has no marketing or sales practices that aim to address appropriate use and it does not adapt its brochures or packaging.

SALES AND OPERATIONS

Therapeutic areas: Cardiovascular diseases; Gastroenterology; Metabolic disorders; Women’s health; Pain and movement disorders

Business segments: Pharmaceutical Products; Diagnostic Products; Nutritional Products; Cardiovascular; Neuromodulation Products

Product categories: Diagnostics; Generic medicines; Medical devices; Nutritionals; Vaccines

Manufacturing & supply: No information available

M&A since 2018: None in the antibacterial and/or antifungal sectors

PORTFOLIO for diseases in scope

Mid-sized portfolio: At least 85 products (51 unique INNs): 79 antibacterial medicines; 2 antibiotic vaccines; 4 antifungal medicines

Essential medicines: 41% (35) of products are on the 2019 WHO EML

AWaRe medicines*: 12 Access group; 10 Watch group; 1 Reserve Group

Anti-TB medicines*: 7 (incl. 2 Watch group, 2 Reserve group)

Performance in the Benchmark

Overall score 53%

How Abbott was evaluated

A R&D 1 2.1 2.2 2.3 2.4 3 4

B RM 1 2 3

C AA 1.1 1.2 2.1 2.2 3

C STW

Scored

Not scored

Each indicator is worth a max score of 5. Indicators are not applicable to every company. See Appendix for full overview.

Revenues by product (2018)

<table>
<thead>
<tr>
<th>Category</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibacterial (AB)</td>
<td>2</td>
</tr>
<tr>
<td>AB+AF combination</td>
<td>4</td>
</tr>
</tbody>
</table>

The number of products is based on data from public sources, IQVIA, and data submitted by the company. It may not account for Abbott’s entire portfolio.
OPPORTUNITIES FOR ABBOTT

Expand registration and ensure adequate supply of antibacterial medicines to access countries. Abbott can file for registration and ensure adequate supply of antibacterial medicines on the 2019 WHO EML within its current portfolio (e.g., the forgotten antibiotics sulfamethoxazole/trimethoprim, chloramphenicol, and colistin) in more access countries.

Expand its environmental risk-management strategy to suppliers and waste-treatment plants. Abbott currently has a comprehensive environmental risk-management strategy, including auditing processes and discharge limits for the majority of antibacterials manufactured at its own sites. The company can ensure that such limits cover all antibacterials manufactured at its own sites and, along with the strategy, are implemented at the sites of third-party suppliers and external private waste-treatment plants, including any relevant discharge-monitoring processes.

Decouple sales incentives from sales volumes and/or avoid deploying sales agents. In order to mitigate the risk of inappropriate use of its antibacterial and/or antifungal medicines, Abbott can decouple sales incentives from sales volumes and/or avoid deploying sales agents, as appropriate.

Adapt brochures and packaging. In order to support the appropriate use of its antibacterial and/or antifungal medicines by all patients, Abbott can make brochure and/or packaging adaptations that take account of language, literacy, paediatric use, adherence to treatment and the environment.

CHANGES SINCE 2018

This section lists notable changes in companies’ activities since the 2018 Benchmark. Since Abbott was not in scope for evaluation in 2018, no changes are reported.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

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

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

B.1 Comprehensive environmental risk-management; less information on discharge limits for own sites and suppliers

Abbott reports a comprehensive strategy to minimise the environmental impact of wastewater and solid waste from antibacterial manufacturing at its sites. This includes audits typically every three years. The company reports setting discharge limits for the majority of antibacterials manufactured at its sites based on PNECs to limit AMR (or more stringent PNECs), as published by the AMR Industry Alliance. For the antibacterials for which effluent analytical methods or PNECs are not published, it reports requiring sites to work towards developing them. Abbott reports using a combination of mass balance estimation and analytical testing to assess whether discharge levels meet these limits.

Abbott expects third-party suppliers of antibacterial APIs and drug products to follow the company’s supplier guidelines, including minimisation of water and waste impacts. The company has developed audit programmes specifically for suppliers of APIs, including antibacterial APIs, and surveys high-risk suppliers on their waste management practices. It expects external private waste treatment plants to comply with its environmental standards and guidelines. The company reports auditing these plants at least every five years but does not report whether it requires the wastewater plants to set antibacterial discharge limits.

B.2 Publicly discloses some information on environmental risk management

Abbott publishes some components of its environmental risk-management strategy. It does not publish: (1) the results of environmental audits, whether conducted at its own sites, the sites of suppliers or external private waste-treatment plants; (2) a list of these suppliers and waste-treatment plants; or (3) the levels of nor limits for antibacterial discharge from its own sites.

B.3 Has system to maintain production quality for own and suppliers’ sites; no requests for official corrective action

Abbott reports having a system to maintain high-quality antibacterial production, consistent with international GMP standards. This includes periodic internal audits and protocols in place for handling corrective and preventive actions. The company reports requiring suppliers to abide by regulatory and company quality standards. This includes submitting suppliers to a qualification process, after which a quality agreement is established and periodic re-evaluations are conducted to assess compliance. 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.**

** Including only wholly-owned direct subsidiaries of the company. More information in Appendix I.
C.1.1 Registering on-patent products
Abbott was not eligible for this indicator, as it does not have on-patent antibacterial or antifungal medicines or vaccines in its portfolio.

C.1.2 Filed to register relevant off-patent products* in 8.6 access countries on average
Abbott is a leading company among generic medicine manufacturers when it comes to filing its relevant off-patent products for registration. It reports filing all of its relevant products (11/11 antibacterial and antifungal medicines) for registration in several access countries. Its most widely filed product in this analysis is the antibacterial medicine clarithromycin, used to treat conditions such as pneumonia, and skin and ear infections. Abbott has filed its version of this product in 60 access countries. Further details were provided on the basis of confidentiality.

C.2.1 Pricing strategies for on-patent products
Abbott was not eligible for this indicator, as it does not have on-patent antibacterial or antifungal medicines or vaccines in its portfolio.

C.2.2 Pricing strategies for off-patent products
Companies were not scored for this indicator as the available data was insufficient for a comparative analysis. Abbott does report some pricing strategies, but further details were provided on the basis of confidentiality.

C.2.3 File to register relevant off-patent products
Abbott is a middle-performing company, compared to other generic medicine manufacturers evaluated, when it comes to taking steps to ensure the continuous supply of its antibacterial or antifungal medicines or vaccines. It has forecasting processes in place to share API and drug supply requirements with suppliers. Shortage mitigation is addressed by targeting at least two sources and by keeping buffer stocks of critical ingredients. To secure the supply of critical ingredients, Abbott states that it is working toward agile relationships with its suppliers, to enable global sourcing and more insight into local opportunities. Abbott keeps a buffer stock of critical ingredients and targets from at least two sources when in need of critical ingredients. To reduce the introduction of falsified medicines into the supply chain, Abbott employs several strategies, such as making use of security features; using an advanced program to detect and delete illicit internet sales; and working with law enforcement to disrupt criminal organisations.

C.3 Some strategies to ensure the continuous supply of relevant products
Abbott is a middle-performing company, compared to other generic medicine manufacturers evaluated, when it comes to taking steps to ensure the continuous supply of its antibacterial or antifungal medicines or vaccines. It has forecasting processes in place to share API and drug supply requirements with suppliers. Shortage mitigation is addressed by targeting at least two sources and by keeping buffer stocks of critical ingredients. To secure the supply of critical ingredients, Abbott states that it is working toward agile relationships with its suppliers, to enable global sourcing and more insight into local opportunities. Abbott keeps a buffer stock of critical ingredients and targets from at least two sources when in need of critical ingredients. To reduce the introduction of falsified medicines into the supply chain, Abbott employs several strategies, such as making use of security features; using an advanced program to detect and delete illicit internet sales; and working with law enforcement to disrupt criminal organisations.

C.4 Broad strategy to mitigate COI for most educational programmes
The Benchmark analysed four AMR-related educational programmes for healthcare professionals (HCPs) from Abbott. Abbott reports broad COI mitigation strategies for three of four programmes. Further details were provided on the basis of confidentiality. However, for the remaining programme, it is unclear how the company mitigates COI. After the period of analysis, the company reported that it has policies in place to mitigate COI for all its educational events, which ensure independence of presentations by HCPs and prohibit compensating attendees for time spent at an Abbott-organized educational meeting.

C.5 Reports no marketing or sales practices that aim to address appropriate use
Abbott does not report engaging in practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines, either regarding its marketing materials or its sales practices.

C.6 Does not adapt brochures and/or packaging to facilitate appropriate use
Abbott does not provide evidence of adapting its brochures and/or packaging to facilitate appropriate use of its antibacterial and/or antifungal medicines by patients beyond regulatory requirements.

C.7 Antimicrobial surveillance
As a GMM, Abbott is not eligible for this indicator as GMMs have a limited role in AMR surveillance activities. The Benchmark notes that Abbott is active in CANWARD, a long-term AMR surveillance programme. This is a national programme that is managed by the Canadian Antimicrobial Resistance Alliance with support from Abbott, among others. Its results are shared through an open-access database on its website and in peer-reviewed open-access journal articles.

Diagnostics, animal health & agriculture
Activities in this area are not scored by the Benchmark. This information is provided given the importance of diagnostics, animal health and agriculture on the topic of AMR.

Abbott has its own diagnostic division and offers products including: (1) Alere™ PBP2a SA Culture Colony Test for the rapid detection of Methicillin-resistant S. aureus (MRSA) directly from bacterial isolates in 5 minutes; (2) Afinion™ CRP test for the quantitative determination of C-reactive protein to differentiate bacterial from viral respiratory tract infections; (3) ID NOW™ Influenza A & B test to diagnose the flu caused by a viral infection. Abbott also provides healthcare professionals with diagnostic information through their Test Target Treat™ website.

*** 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.
† See Appendix VII.