Aurobindo Pharma Ltd

Generic medicine manufacturer
Stock exchange: NSE • Ticker: AUROPHARMA • HQ: Hyderabad, India • Employees: 17,855

PERFORMANCE

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

Responsible Manufacturing: Middle-performing. Reports an environmental risk-management strategy for own sites, including initiation of risk assessments based on discharge limits. Limited information available on how the strategy applies for suppliers.

Appropriate Access: Middle-performing. Files for registration for over half of relevant off-patent products in access countries. Supplies forgotten antibiotics to several access countries.

Stewardship: Performs low. 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: Gastroenterology; Infectious diseases; Neurology
Business segments: Pharmaceuticals (including APIs and formulations)
Product categories: Generic medicines; Vaccines

Manufacturing & supply: Aurobindo reports having 18 manufacturing sites that produce antibacterial APIs and/or drug products. It supplies its antibacterial medicines, antifungal and antibacterial APIs and/or drug products across more than 150 countries.

M&A since 2018: In September 2018, Aurobindo announced that it would acquire the dermatology and oral-solids businesses from Novartis’ generic division, Sandoz, for USD 900 million. Earlier that year, Aurobindo signed a definitive agreement in July to acquire Apotex’s businesses in Belgium, Czech Republic, the Netherlands, Poland and Spain for more than USD 80 million.

PORTFOLIO for diseases in scope

Mid-sized portfolio: At least 43 products (30 unique INNs): 37 antibacterial medicines; 1 antibacterial vaccine; 5 antifungal medicines

Essential medicines: 68% (29) of products are on the 2019 WHO EML
AWaRe medicines*: 12 Access group; 5 Watch group; 1 Reserve group

Anti-TB medicines*: 5 (incl. 1 Watch group, 2 Reserve group)

Performance in the Benchmark

Overall score: 31% (11/35)

Performance by Research Area

- R&D: N/A
- Manufacturing: 53% (8/15)
- Access: 30% (3/10)
- Stewardship: 0% (0/10)

How Aurobindo was evaluated

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

Products on the market

- 37 Antibacterial (AB) vaccine
- 35 Antibacterial (AB) medicine
- 18 Antifungal (AF) medicine
- 1 AB+AF combination

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

* Listed on the 2019 WHO EML (Section 6).
OPPORTUNITIES FOR AUROBINDO

Expand registration and ensure adequate supply of antibacterial medicines in more access countries. Aurobindo 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 colistin, phenoxymethylpenicillin and sulfamethoxazole/trimethoprim) in more access countries. Implement and monitor its environmental risk-management strategy, including discharge limits, at its own manufacturing sites, at third-party suppliers and at external private waste-treatment plants. Aurobindo currently has an environmental risk-management strategy and auditing processes for its own manufacturing sites and has started implementing discharge limits. The company can ensure such limits cover all antibacterials manufactured at its own sites and, along with the strategy, extend fully to the sites of third-party suppliers and external private waste-treatment plants. It can also ensure any relevant auditing and discharge-monitoring processes are in place. 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, Aurobindo can decouple sales incentives from sales volumes and/or avoid deploying sales agents, as appropriate.

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT
As a generic medicine manufacturer (GMM), Aurobindo is not evaluated in this Research Area.

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

B.1 Environmental risk-management strategy for own sites
Aurobindo reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, which includes audits. It reports being in the process of implementing adaptations to this strategy that take AMR into account. This includes setting antibacterial discharge limits based on PNECs to limit AMR (or more stringent PNECs), as published by the AMR Industry Alliance. It will use these limits in a future risk assessment of its sites with respect to AMR. For a subset of its antibacterials (beta-lactams and cephalosporins), Aurobindo already employs a deactivation procedure to ensure that antibacterial levels in wastewaters are below these limits.

B.2 Publicly discloses some information on environmental risk management
Aurobindo publishes some components of its environmental risk-management strategy. Further, it is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Aurobindo 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 antibacterial discharge from its own sites.

B.3 Has system to maintain production quality for own and suppliers’ sites; regulator requested official corrective action
Aurobindo reports having a system to maintain high-quality antibacterial production, consistent with international GMP standards, including protocols to track corrective and preventive actions. In February 2019, an FDA drug quality inspection identified non-conformities with cGMP at three of the company’s antibacterial API sites, resulting in an official request for corrective action. The company reports requiring suppliers to abide by regulatory and company quality standards. This includes submitting suppliers to a qualification process and periodic audits.

CHANGES SINCE 2018

- Joined the AMR Industry Alliance and began data collection on antibacterial discharge from its sites for comparison with the predicted no-effect concentrations (PNECs) published by the Alliance.
- Received market authorization for its antifungal product terbinafine in March 2019 in Tanzania.
C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS
Evaluated: access activities relating to antibacterial & antifungal medicines & vaccines in 102 access countries**

C.1.1 Registering on-patent products
Aurobindo 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 5.3 access countries on average
Aurobindo is a middle-performing company when it comes to filing relevant off-patent products for registration. It has filed 67% of its relevant products (6/9 antibacterial and antifungal medicines) for registration in access countries. Its most widely filed product in this analysis is the antibacterial cefepime, used for conditions including pneumonia and urinary tract infections. Aurobindo has filed its version of this product in 30 access countries. Cefepime is followed by the antifungal terbinafine and antibacterial clarithromycin, filed by Aurobindo for registration in eight and five access countries, respectively.

C.2.1 Pricing strategies for on-patent products
Aurobindo 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. Aurobindo does report that it participates in tendering in the EU and that its product prices are based on market-driven competitive prices.

C.3 Limited information on measures to ensure continuous supply of relevant products
Aurobindo discloses limited information on how it takes steps to ensure the continuous supply of antibacterial or antifungal medicines or vaccines to access countries. It does report supplying the forgotten antibiotics† cefepime, cefpodoxime, phenoxymethylpenicillin and sulfamethoxazole/trimethoprim to several access countries.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP
Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Educational stewardship activities
Aurobindo is not eligible for this indicator as it reports no involvement in AMR-related educational programmes aimed at healthcare professionals (HCPs). After the period of analysis, the company stated that it has been involved in several educational programmes for HCPs.

C.5 Reports no marketing or sales practices that aim to address appropriate use
Aurobindo 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
Aurobindo 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, Aurobindo is not eligible for this indicator as GMMs have a limited role in AMR surveillance activities.

---

** 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.
*** See Appendix VII.
† A set of older off-patent antibacterials that are not always marketed or available, due to economic reasons, lack of awareness and lack of demand but are still considered effective as a treatment for bacterial infections. See Appendix VII for citation.