

Aurobindo Pharma Ltd

Generic medicine manufacturer

Stock exchange: NSE • Ticker: AUROPHARMA • HQ: Hyderabad, India • Employees: 23,000

PERFORMANCE

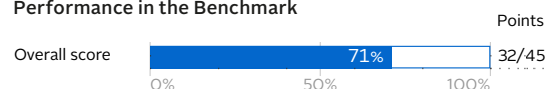
Aurobindo is the leader among the generic medicines manufacturers in scope and performs well in its evaluated Research Areas.

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

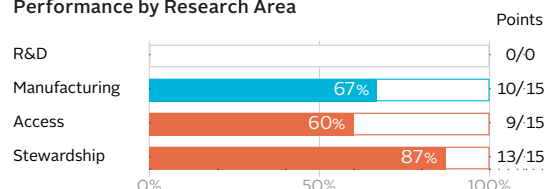
Appropriate Access: Middle-performing. Files its off-patent/generic medicines for registration in access countries. Reports some strategies to expand access and ensure continuous supply of its relevant product.

Stewardship: Performs strongly. It does not promote antibacterial and/or antifungal medicines to healthcare professionals. It reports comprehensive conflict of interest mitigation for its educational programme. It adapts brochures for patients.

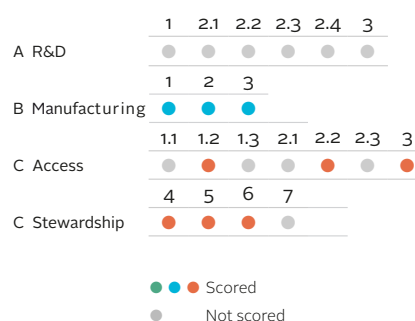
Performance in the Benchmark



Performance by Research Area



How Aurobindo was evaluated



OPPORTUNITIES FOR AUROBINDO

Increase public disclosure on environmental risk management. Aurobindo publishes information on some of the components of its general environmental risk-management strategy. It can publish more information on how it manages environmental risk related to antibiotic discharge in to environment to curb AMR. While Aurobindo reports that all its own sites are compliant with set limits, it can provide clear evidence by publicly disclosing its progress in implementing the strategy and by publishing the audit results of own and suppliers' sites, including antibacterial discharge levels if applicable.

Expand access and ensure adequate supply of antibacterial and antifungal medicines in more access countries. Aurobindo has a Day-1 generic policy by which it introduces a generic product as soon as the patent on a brand expires for the EU and USA. It can expand access to its generic antibiotics and antifungals listed on the 2021 WHO EML to more products and countries, allowing for generic options to be made available in access countries as soon as the originator's patent expires. **Expand adaptations to brochures and packaging to consider more patient needs.** In order to support the appropriate use of its antibacterial and/or antifungal medicines by patients, Aurobindo adapts brochures to take account of local languages. It can further adapt its brochures and packaging to consider literacy levels, paediatric use, environmental conditions and patient adherence to treatment.

CHANGES SINCE 2020

- Since 2020, Aurobindo has extended the environmental risk management strategy requirements of its own sites to its suppliers.
- Since 2020, Aurobindo reports that all its own sites that manufacture antibacterials are compliant with discharge limits.
- Aurobindo reports that it fully decouples incentives for sales agents from sales volumes in emerging markets to help prevent the inappropriate use of its antibacterial medicine. It sells antibacterial and antifungal medicines only through tenders in Europe and the US.

SALES AND OPERATIONS

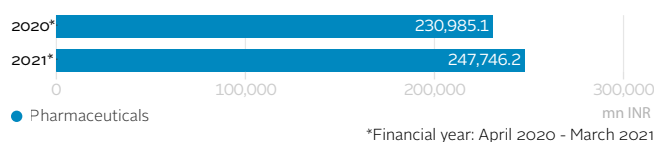
Therapeutic areas: Anti-allergies, Antibiotics, Anti-diabetics, Anti-retroviral, Cardio-vascular (CVS), Central nervous system (CNS), gastroenterology.

Business segments: Pharmaceuticals (including APIs and formulations)

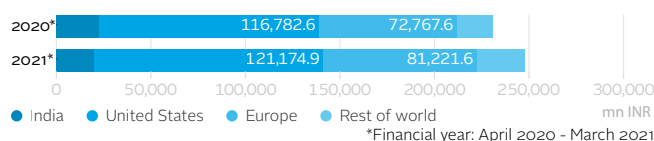
Product categories: Generic medicines, Biosimilars

M&A since 2020: In February 2020, Aurobindo finalised acquisition of certain Profectus BioSciences Inc assets, including preventative and therapeutic R&D assets to develop vaccine for infectious diseases, for USD 11.29 mn and created a new subsidiary called Auro Vaccines LLC.

Total income by business segment



Total income by region



PORTFOLIO for pathogens in scope

Mid-sized portfolio: At least 39 products: 32 antibacterial medicines; 2 antibacterial vaccines; 5 antifungal medicines

Off-patent/generic medicines: 6 of 39 were selected for analysis* (amoxicillin [A], amoxicillin/clavulanic acid [A], cefuroxime [W], ciprofloxacin [W], fluconazole [F], terbinafine [F])

AWaRe medicines:** 11 Access group; 18 Watch group; 2 Reserve group

Anti-TB medicines:** 1

Products on the market



PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

As a generic medicine manufacturer, Aurobindo 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

Aurobindo reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits at least every five years. It reports setting discharge limits for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. It also reports quantifying discharge levels at all sites using a mass balance approach, supported by chemical analysis for beta-lactams and cephalosporins. All its 15 sites, of which 4 are ZLD, are reported to be compliant with discharge limits.

Aurobindo requires third-party suppliers of antibacterials to follow the same standards, including audits every five years. It reports procuring around 1% of its antibacterial API volume from 2 supplier sites, which are both ZLD sites. No antibacterial drug products are procured from suppliers.

Aurobindo requires external private and public waste-treatment plants to follow local

regulatory standards. It reports auditing the private plants on a yearly basis which includes checking the suitability of technologies used for processing waste and protocols for preventing contamination.

B.2 Publicly discloses some information on environmental risk management

Aurobindo publishes some components of its environmental risk-management strategy. This includes disclosure of the ongoing implementation of necessary processes to deactivate API residues in wastewater. Since 2019, it is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Aurobindo publishes that mass balance estimations of antibiotics are conducted. The corresponding results or the discharge levels themselves are not published. Aurobindo also 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.

B.3 System in place to maintain production quality for own and suppliers' sites; regulator requested official corrective action

Aurobindo 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. There is limited information on whether Aurobindo requires its suppliers to audit their own suppliers. In September 2019, an FDA drug quality inspection identified non-conformities with cGMP at one of the company's sites that manufactures antibacterials (Polepally, Mahaboob Nagar, India), resulting in official requests for corrective action. Aurobindo reports that the issue of non-conformities with cGMP have since been resolved with no impact on business continuity, but the regulatory status remains as is because of delays to FDA inspections due to the COVID-19 pandemic.

* 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***

Aurobindo is not eligible for indicators: C.1.1, C.1.3, C.2.1 and C.2.3. For more information, see Appendix VII.

C.1.2 Filed to register off-patent/generic medicines in 19 access countries on average

Aurobindo performs above average, filing all its six relevant off-patent/generic medicines for registration in 19 access countries on average. Its most widely filed relevant product is amoxicillin/clavulanic acid filed in 35 access countries. Two of its relevant products are filed in less than 10 access countries. Five of its relevant products are filed for registration in at least one LIC.

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

Aurobindo has an average performance. It aims to expand access to its off-patent/generic medicines in access countries through affordable prices, tenders and direct sales to its dis-

tributors. Between April 2020 and March 2021, Aurobindo estimates to have reached 600,000 patients in Vietnam with its amoxicillin/clavulanic acid generic version.

C.3 Some strategies to ensure continuous supply

Aurobindo 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. Aurobindo has a direct-selling model where demand is directly generated by its customers or driven by tenders. Aurobindo mitigates against shortage risks by keeping a buffer stock for its key starting material, APIs and finished products. It reports manufacturing more than 99% of its API in-house. Aurobindo's manufacturing facilities are located in India. It supplies APIs to low- and middle-income countries and aims to improve their capacity to produce finished med-

icines. To mitigate against substandard and falsified products, it uses security features such as tamper-proof stickers, hot-glue sealing techniques, self-destructing packing materials and serialisation.

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 programme

Aurobindo performs strongly in conflict of interest (COI) mitigation for the one AMR-related educational programme for HCPs assessed by the Benchmark. The 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) a policy of not using branded materials.

C.5 Does not promote its antibacterial and/or antifungal medicines

Aurobindo performs strongly in sales practices. It does not deploy any sales agents to promote its antibacterial and/or antifungal medicines to healthcare professionals. Since Aurobindo does not develop or use marketing materials for antibacterial and/or antifungal medicines to pro-

mote such medicines to healthcare professionals, the company is not eligible to be assessed on marketing materials.

C.6 Makes one type of brochure and/or packaging adaptation to facilitate appropriate use by patients

Aurobindo adapts brochures to facilitate the appropriate use of amoxicillin/clavulanic acid by patients. It is middle-performing in this measure, taking account of language. Aurobindo has translated package inserts for amoxicillin/clavulanic acid in Vietnamese.

C.7 AMR Surveillance

As a generic medicine manufacturer, Aurobindo is not assessed in this indicator nor does it report any involvement in AMR surveillance activities.

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