

Sun Pharmaceutical Industries Ltd

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?
<p>Develop an AMR-specific environmental risk-management strategy and increase public disclosure.</p> <p>Sun Pharma reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. It reports having one owned manufacturing site, which employs Zero Liquid Discharge (ZLD) treatment processes. The company can develop an AMR strategy for its own site and suppliers, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Sun Pharma can publish information on how it manages environmental risk related to antibacterial manufacturing. The company publishes limited information about this.</p>	<p>Sun Pharma reports a correction to the information contained in the 2021 Benchmark regarding its number of antibiotic manufacturing sites. Sun Pharma reports that antibiotics are manufactured at four active pharmaceutical ingredient (API) manufacturing sites and eight formulation sites. All 12 sites are reported to be Zero Liquid Discharge (ZLD) sites, implying that no liquid is discharged into the environment from these facilities. However, it remains unclear whether recycled water is reused for gardening and horticulture. Sun Pharma has initiated a process to measure antibiotic levels in wastewater to verify discharge limit compliance. The company did not demonstrate any progress on increasing public disclosure concerning its environmental risk management.</p> <p>In 2022, Sun Pharma faced penalties from the Punjab Pollution Control Board due to discharge of untreated wastewater from its Toansa site into the environment. In a separate case, the National Green Tribunal asked Sun Pharma to pay compensation for releasing untreated wastewater from its Madhuranthagam's site, despite being labelled as a ZLD site. In both instances, it's unclear whether wastewater containing antibiotics was discharged.</p>
<p>Expand availability and ensure continuous supply of antibacterial and antifungal medicines to more access countries.</p> <p>Sun Pharma can ensure equitable access and adequate supply of its antibiotics and antifungals listed on the 2021 WHO EML (e.g. the antifungal itraconazole and the reserve antibiotic tigecycline) in more access countries. For example, Sun Pharma can ensure accurate demand planning and data sharing, build on capacity or mitigate against shortages by working with several API suppliers.</p>	<p>Sun Pharma reports it has increased access to anti-infectives in nine African countries with varying product counts, including Benin (6), Gabon (5), Togo (5), Burkina Faso (4), Mali (2), Niger (2), Chad (2), Mauritania (1). The company also reports it has registered or filed for registration at least one product in 64 low- and middle-income countries (LMICs). Yet, it is unclear whether these products include antibacterial and antifungal medicines listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML), along with the strategies employed to ensure availability and affordability in the mentioned African countries.</p> <p>To ensure accurate demand planning, Sun Pharma reports forecasting 6-12 months in advance and closely monitoring buffer stocks.</p>
<p>Apply responsible sales practices for antibacterial and antifungal medicines.</p> <p>Sun Pharma can apply responsible sales practices for antibacterial and antifungal medicines by not deploying sales agents. Alternatively, it can fully decouple incentives for sales agents from sales volumes of such medicines.</p>	<p>Sun Pharma did not report any progress on this Opportunity.</p>

Overall Performance

2020 2021

11% 47%▲

Sun Pharmaceutical Industries Ltd

Generic medicine manufacturer

Stock exchange: NSE • Ticker: SUNPHARMA • HQ: Mumbai, India • Employees: 36,000

PERFORMANCE

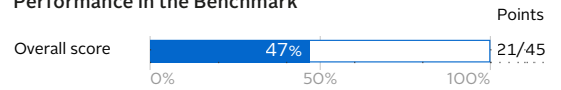
Sun Pharma performs average overall in its evaluated Research Areas when compared to the other generic medicine manufacturers in scope.

Responsible Manufacturing: Performs low. Reports a general environmental risk-management strategy but without a specific aim to limit AMR.

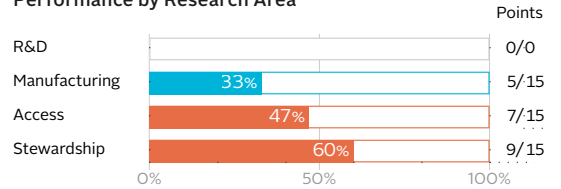
Appropriate Access: Middle-performing. Files its off-patent products in access countries. Discloses some strategies to expand access and ensure continuous supply of its off-patent products.

Stewardship: Middle-performing. It does not report decoupling incentives for sales agents from sales volumes. It reports comprehensive conflict of interest mitigation for its educational programme. It adapts brochures and/or packaging for patients.

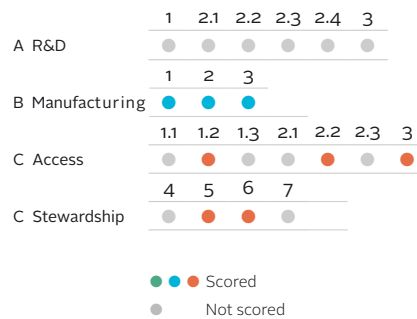
Performance in the Benchmark



Performance by Research Area



How Sun Pharma was evaluated



OPPORTUNITIES FOR SUN PHARMA

Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Sun Pharma reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. It reports having one owned manufacturing site, which employs Zero Liquid Discharge (ZLD) treatment processes. The company can develop an AMR strategy for its own site and suppliers, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Sun Pharma can publish information on how it manages environmental risk related to antibacterial manufacturing. The company publishes limited information about this.

Expand availability and ensure continuous supply of antibacterial and antifungal medicines to more access countries. Sun Pharma can ensure equitable access and adequate supply of its antibiotics and antifungals listed on the 2021 WHO EML (e.g. the antifungal itraconazole and the reserve antibiotic tigecycline) in more access countries. For example, Sun Pharma can ensure accurate demand planning and data sharing, build on capacity or mitigate against shortages by working with several API suppliers.

Apply responsible sales practices for antibacterial and antifungal medicines. Sun Pharma can apply responsible sales practices for antibacterial and antifungal medicines by not deploying sales agents. Alternatively, it can fully decouple incentives for sales agents from sales volumes of such medicines.

CHANGES SINCE 2020

No changes are reported for Sun Pharma.

SALES AND OPERATIONS

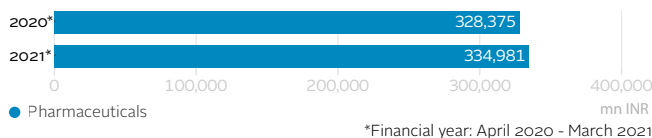
Therapeutic areas: Anti-infectives, Cardiology, Dental, Dermatology, Diabetology, Gastroenterology, Gynaecology, Nephrology, Neurology, Nutritionals, Oncology, Ophthalmology, Orthopaedic, Psychiatry, Respiratory, Urology

Business segments: Pharmaceuticals

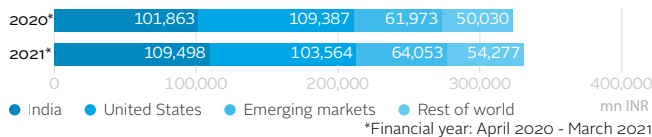
Product categories: Consumer health products, Generic medicines, Innovative medicines

M&A since 2020: None in the antibacterial and/or antifungal sectors

Total income by business segment



Total income by region



PORTFOLIO for pathogens in scope

Mid-sized portfolio: At least 52 products: 44 antibacterial medicines; 8 antifungal medicines

Off-patent/generic medicines: 8 of 52 were selected for analysis* (amoxicillin [A], amoxicillin/clavulanic acid [A], ciprofloxacin [W], colistin [R], itraconazole [F], levofloxacin [W], nystatin [F], tigecycline [R])

AWaRe medicines:** 9 Access group; 19 Watch group; 3 Reserve group

Products on the market



PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

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

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

B.1 No AMR-specific environmental risk management strategy; ZLD at own site

Sun Pharma reports a commitment to manufacture its products in an environmentally responsible manner, supported by a management system that includes periodic audits. It is unclear how the strategy takes AMR into account or aims to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its own site, third-party suppliers of antibacterials or external private and public waste-treatment plants. Sun Pharma does report that its sole site that manufactures antibacterials is ZLD implying that no liquid waste is discharged into the environment from this site. It also reports that any antibacterial residue from ZLD is sent for incineration.

B.2 Limited publicly available information on environmental risk management

Sun Pharma publishes limited information on its approach to environmental risk-management, without specific references to AMR. It publishes that any manufacturing site that manufactures antibiotics is qualified as ZLD. It does not publish: (1) the results of environmental audits, whether conducted at its own site, the sites of suppliers 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 sites; no requests for official corrective action

Sun Pharma publicly discloses that its own site has a system, including audits, to maintain high-quality antibacterial production, consistent with international GMP standards. It reports auditing its suppliers on quality standards as well. There is limited information on how corrective actions are implemented and tracked. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Sun Pharma'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***

Sun Pharma 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 8 access countries on average

Sun Pharma has an average performance, filing all its 8 relevant off-patent/generic medicines for registration in 8 access countries on average. Its most widely filed relevant product is the antibiotic amoxicillin/clavulanic acid filed in 22 access countries. Four 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

Sun Pharma has an average performance. It reports providing access to its antibiotics and antifungals to 45 access countries, of which

low-income countries such as Chad, Nepal and Syria. In 2020, Sun Pharma estimates to have provided access to its amoxicillin/clavulanic acid to 890,000 patients in 19 access countries, including Cameroon, Myanmar, and Peru.

C.3 Some strategies to ensure continuous supply

Sun Pharma has an average performance with strategies reported in three of four areas assessed. It reports complying with good manufacturing practices when producing API and drug products. Sun Pharma works towards product accessibility by ensuring regular supply of its products and having a robust distribution network in India, where it supplied its medicines to more than 500,000 pharmacies in urban and rural areas in 2020. Sun Pharma does not report capacity building and technology transfer initia-

tives. It mitigates against falsified and substandard medicines by reporting any suspicion of counterfeit to the appropriate regulatory authorities. It uses a 'Track and Trace' technology to prevent the sale of counterfeit medicines and to ensure the authenticity of its products. Sun Pharma has a dedicated task force in place to train field forces to identify counterfeits.

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

Sun Pharma performs strongly in conflict of interest (COI) mitigation for the five AMR-related educational programme for HCPs assessed by the Benchmark. To mitigate COI for all five programmes, it provides financial resources to independent third parties (DocMode, KOL International Academy, Mediquest and Mindsync) to develop the programmes.

C.5 Does not report sales or marketing practices that aim to address appropriate use

Sun Pharma performs low in sales practices. It 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.

Sun Pharma 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 Makes two types of brochure and/or packaging adaptations to facilitate appropriate use by patients

Sun Pharma adapts brochures and/or packaging to facilitate the appropriate use of amoxicillin/clavulanic acid by patients. Sun Pharma performs well in this measure, taking account of language and adherence to treatment. It has created a QR code which directs to information on how to take the product appropriately translated in ten regional languages in India. It also adapts packaging to include information on AMR and how to take the product appropriately.

C.7 AMR Surveillance

As a generic medicine manufacturer, Sun Pharma 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.