

**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

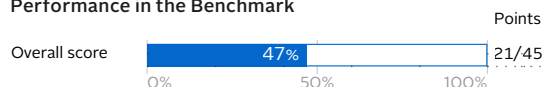
Sun Pharma performs average overall in its evaluated Research Areas when compared to the other generic medicine manufacturers in scope.

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

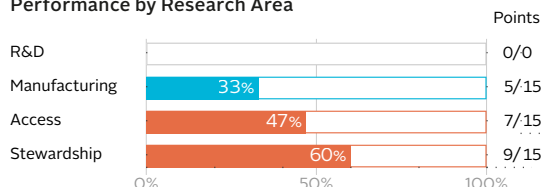
**Appropriate Access:** Middle-performing. Files its off-patent products in access countries. Discloses some strategies to expand access and ensure continuous supply of its off-patent products.

**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.

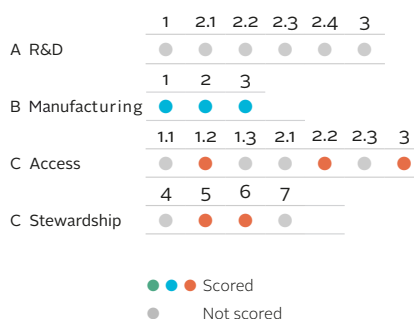
### Performance in the Benchmark



### 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**

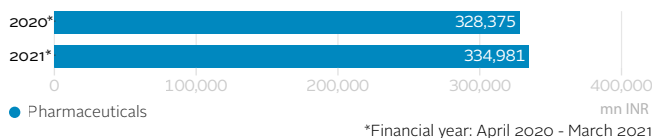
**Therapeutic areas:** Anti-infectives, Cardiology, Dental, Dermatology, Diabetology, Gastroenterology, Gynaecology, Nephrology, Neurology, Nutritionals, Oncology, Ophthalmology, Orthopaedic, Psychiatry, Respiratory, Urology

**Business segments:** Pharmaceuticals

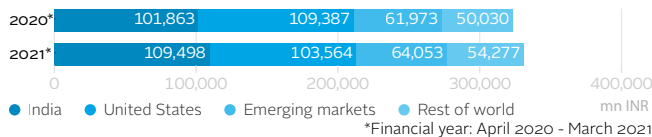
**Product categories:** Consumer health products, Generic medicines, Innovative medicines

**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.