Sun Pharmaceutical Industries Ltd

Generic medicine manufacturer
Stock exchange: NSE • Ticker: SUNPHARMA • HQ: Mumbai, India • Employees: 17,501

**PERFORMANCE**

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

**Responsible Manufacturing:** Performs less well. Reports general environmental risk-management strategy for own sites without the specific aim to limit AMR.

**Appropriate Access:** Performs low. No information is disclosed on where products are registered. No information is reported on its strategies for pricing and ensuring continuous supply.

**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:** Cardiology; Dermatology; Gastroenterology; Infectious diseases; Oncology

**Business segments:** Formulations; OTC; APIs

**Product categories:** Generic medicines; Innovative medicines

**Manufacturing & supply:** No information available

**M&A since 2018:** In November 2018, Sun Pharma announced the acquisition of Pola Pharma in Japan.

**PORTFOLIO for diseases in scope**

**Mid-sized portfolio:** At least 90 products (53 unique INNs): 79 antibacterial medicines; 11 antifungal medicines

**Essential medicines:** 37% (33) products are on the 2019 WHO EML

**AWaRe medicines**
- **Access group:** 14
- **Watch group:** 7
- **Reserve group:** 1

**Anti-TB medicines:** 4 (incl. 1 Watch group)

All companies were assessed based on data available in the public domain, including information the companies have made publicly available. This was supplemented by data submitted directly to the Benchmark by the companies. Sun Pharma declined to submit data to the 2020 AMR Benchmark.
OPPORTUNITIES FOR SUN PHARMA

Step up engagement on AMR and increase disclosure of AMR strategies and activities. Sun Pharma is one of the generic medicine manufacturers (GMMs) with the largest portfolio of antibacterial and/or antifungal medicines, including 33 products on the 2019 WHO EML. Sun Pharma can disclose more information (publicly and/or through the Benchmark) about its strategies to improve access and stewardship to the medicines within its portfolio, including their availability in access countries and its steps to mitigate the risk of inappropriate use.

Develop an AMR-specific environmental risk-management strategy. Sun Pharma reports a commitment to manufacture its products in an environmentally responsible manner and a management system to ensure environmental regulations are met. Yet, it is unclear whether AMR is specifically taken into account. The company can develop a strategy that takes AMR into account, including discharge limits based on PNECs to limit AMR (or more stringent) at the company’s own manufacturing sites, the sites of third-party suppliers and external private waste-treatment plants. The AMR Industry Alliance has developed a Common Antibiotic Manufacturing Framework and list of discharge limits that could serve as a starting point for such endeavour.

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, Sun Pharma can decouple sales incentives from sales volumes and/or avoid deploying sales agents, as appropriate.

PERFORMANCE BY RESEARCH AREA

A  RESEARCH & DEVELOPMENT

As a GMM, Sun Pharma is not evaluated in this Research Area.

B  RESPONSIBLE MANUFACTURING

Evaluated: antibacterials manufacturing (APIs and drug products)

B.1  General environmental risk-management strategy for own sites

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 wastewater and solid waste from antibacterial manufacturing at its own sites, third-party suppliers of antibacterial APIs and/or drug products or external private waste-treatment plants.

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 antimicrobial resistance. 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 sites; limited information on corrective and preventive action tracking

Sun Pharma reports having a system to maintain high-quality antibacterial production, consistent with international antibacterial production, consistent with international GMP standards, including internal audits to assure compliance. However, there is limited information on how corrective actions are implemented and tracked and on how the company ensures that its suppliers uphold quality standards comparable to its own. 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.**

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

Sun Pharma 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  No information on registration filings for relevant off-patent products†

Sun Pharma reports no evidence of filing its relevant off-patent products for registration in access countries. However, there is evidence of sales in at least one access country.

C.2.1  Pricing strategies for on-patent products

Sun Pharma 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. There is no available evidence that Sun Pharma considers affordability or socioeconomic factors when setting prices for off-patent antibacterial or antifungal medicines or vaccines.

C.3  Limited information on measures to ensure continuous supply of relevant products

Sun Pharma discloses limited information on how it takes steps to ensure the continuous supply of antibacterial or antifungal medicines or vaccines to access countries. It publicly reports that it has 40 sites (manufacturing APIs and finished dose products) located in 15 countries, with trained personnel and quality systems and procedures in place. Site locations span access countries on all continents.

CHANGES SINCE 2018

• Acquired Pola Pharma in Japan, which was announced in November 2018.

** Including only wholly-owned direct subsidiaries of the company. More information in Appendix I.

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

† See Appendix VII.
C  APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP
Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4  Educational stewardship activities
Sun Pharma is not eligible for this indicator as there is no information regarding its involvement in AMR-related educational programmes aimed at healthcare professionals (HCPs).

C.5  No information on marketing or sales practices that aim to address appropriate use
There is no information regarding Sun Pharma's engagement 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  No information on brochure and/or packaging adaptations to facilitate appropriate use
There is no information regarding Sun Pharma's adaptations in 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, Sun Pharma is not eligible for this indicator as GMMs have a limited role in AMR surveillance activities.