

Cipla 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>Expand environmental risk-management strategy to include suppliers and ensure compliance with limits. Cipla tracks compliance with discharge limits it set for its own manufacturing sites. It can quantify discharge levels at all suppliers' sites and track compliance with limits, and publicly disclose the results. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.</p>	<p>Cipla has conducted a workshop with suppliers on how to quantify discharge levels with mass balance calculations. To support its suppliers, Cipla reports it will conduct training and awareness sessions on a regular basis. Currently, it is unclear how many of the supplier sites have quantified discharge levels and are compliant with discharge limits. Cipla highlights that due to the absence of any regulations, ensuring supplier adherence to discharge limits poses challenges.</p> <p>In regard to its own manufacturing sites, Cipla reports that all ten of its sites are now compliant with discharge limits in the receiving environment – up from two sites in 2021. The company reports that Zero Liquid Discharge (ZLD) systems are applied at its manufacturing sites in Bommasandra, Goa, Indore, Kurkumbh, Sikkim and Virgonagar. In addition, Cipla eliminates the risk of AMR by not reusing recycled water from ZLD sites in horticulture and gardening.</p>
<p>Expand registration antibacterial medicines to more access countries and ensure adequate supply. Cipla can expand registration of its antibiotics and anti-fungals listed on the 2021 WHO EML, such as itraconazole and levofloxacin to more countries, including low-income countries and ensure adequate supply. To ensure adequate supply, Cipla can promote capacity building and technology transfer initiatives in access countries, to improve access to its medicines.</p>	<p>Cipla reports it has marketed ceftazidime/avibactam in India. In 2022, this antibiotic – also featured on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML) as a Reserve antibiotic – lost its exclusivity status and became a generic drug in India. In South Africa, Cipla has registered fosfomycin and nitrofurantoin, both listed on the 2023 WHO EML as Reserve and Access antibiotics respectively.</p> <p>While no specific initiatives are reported, Cipla states its intentions toward expanding access to plazomicin (Zemdri®) and ceftriaxone/sulbactam (Elores™) in low- and middle-income countries (LMICs).</p> <p>However, due to a lack of evidence-based indications for use or recommendations in high-quality international guidelines, WHO actively advises against the clinical use of ceftriaxone/sulbactam.</p> <p>The company does not report any updates on how it ensures an adequate supply of antibacterial medicines in LMICs.</p>
<p>Fully decouple incentives for sales agents from sales volumes. Cipla links part of its sales agents' incentives to sales volumes. It can fully decouple incentives for sales agents from sales volumes of antibacterial and antifungal medicines again.</p>	<p>Cipla did not report any developments specific to this Opportunity.</p>

Overall Performance

2020	2021
70%	60%▼

Cipla Ltd

Generic medicine manufacturer

Stock exchange: NSE • Ticker: CIPLA • HQ: Mumbai, India • Employees: 25,672

PERFORMANCE

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

Responsible Manufacturing: Performs well. Reports environmental risk-management strategy for own sites; initial risk assessment of suppliers ongoing.

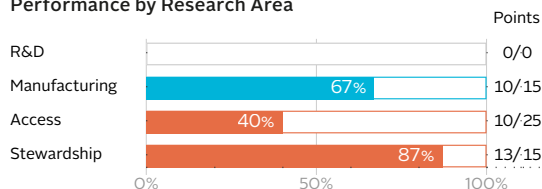
Appropriate Access: Middle-performing. Filed its on-patent medicine in India. Files some of its off-patent/generic medicines for registration in access countries. Reports some strategies to ensure continuous supply of its relevant product.

Stewardship: Performs strongly. It decouples incentives for sales agents from sales volumes for >99%. It reports comprehensive conflict of interest mitigation for its educational programmes. It adapts brochures and packaging for patients.

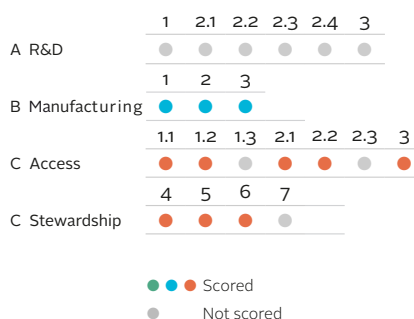
Performance in the Benchmark



Performance by Research Area



How Cipla was evaluated



OPPORTUNITIES FOR CIPLA

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Expand registration antibacterial medicines to more access countries and ensure adequate supply. Cipla can expand registration of its antibiotics and antifungals listed on the 2021 WHO EML, such as itraconazole and levofloxacin to more countries, including low-income countries and ensure adequate supply. To ensure adequate supply, Cipla can promote capacity building and technology transfer initiatives in access countries, to improve access to its medicines.

Fully decouple incentives for sales agents from sales volumes. Cipla links part of its sales agents' incentives to sales volumes. It can fully decouple incentives for sales agents from sales volumes of antibacterial and antifungal medicines again.

CHANGES SINCE 2020

- As part of the 3-year strategy (2020-2023), Cipla will submit and launch plazomicin in India and other countries, as well as explore multiple opportunities to out-license the product.
- Since 2020, Cipla is in the process of assessing all its suppliers related to the risk of AMR, including requesting data from suppliers on discharge levels.
- Since 2020, Cipla is no longer a member of the AMR Industry Alliance.
- In June 2020, Cipla withdrew its EMA application for a marketing authorization of plazomicin (Zemdri®), to treat complicated urinary tract infection, due to lack of financial viability.

SALES AND OPERATIONS

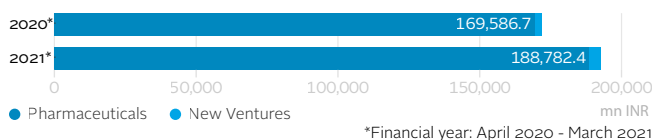
Therapeutic areas: Cardiovascular diseases, Central nervous system, Dermatology, Diagnostics, Gastrointestinal, Infectious diseases, Metabolic disorders, Oncology, Ophthalmology, Orthopaedics, Respiratory diseases, Urology, Women’s Health.

Business segments: Pharmaceuticals, New ventures

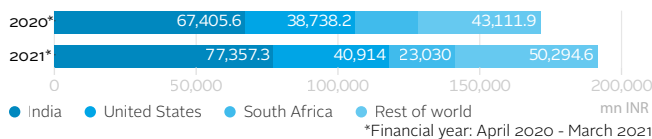
Product categories: Biosimilars, Consumer health products, Generic medicines, Innovative medicines, Respiratory devices.

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

Revenue by business segment



Revenue by region



PORTFOLIO for pathogens in scope

Mid-sized portfolio: At least 59 products: 46 antibacterial medicines; 13 antifungal medicines

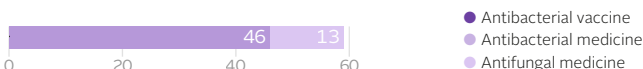
On-patent medicine: 1 (plazomicin)

Off-patent/generic medicines: 9 of 58 were selected for analysis* (amoxicillin [A], amoxicillin/clavulanic acid [A], ciprofloxacin [W], colistin [R], fluconazole [F], Fosfomycin [R], itraconazole [F], levofloxacin [W], linezolid [T])

AWaRe medicines:** 5 Access group; 15 Watch group; 8 Reserve group

Anti-TB medicines:** 3

Products on the market



PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

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

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

B.1 Environmental risk-management including limits for own sites; tracks compliance with limits at own sites

Cipla reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits. It reports setting discharge limits in the receiving environment for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. Discharge levels are quantified using a mass balance approach, verified by chemical analysis if applicable. It reports three of 10 sites have quantified discharge levels and two, or 20%, of those are compliant with discharge limits. It also reports that the levels of 70% of all antibacterials are quantified and 100% is expected by March 2022.

Cipla will require third-party suppliers of antibacterials to follow similar standards, including limits based on PNECs, after it completes the ongoing initial assessments of all its 57 suppliers. It requests and reviews discharge levels of its suppliers as part of the assessments. It reports

34 of 57 supplier sites, or 60%, are fully assessed but it is unclear how many of the 34 have quantified discharge levels. Complete assessment of all suppliers is expected by March 2022.

There is limited information on the requirements Cipla makes of external private and public waste-treatment plants, in terms of environmental strategy and antibacterial discharge limits. Cipla reports that it requests flow rates from common effluent treatment plants to accurately determine dilution factors and mass balance calculations.

B.2 Publicly discloses some information on environmental risk management and AMR risk identification of own sites

Cipla publishes some components of its environmental risk-management strategy. It publishes that the risk of AMR at all own sites is assessed and priority sites are implementing responsible practices related to AMR. It also publishes that risk assessments of its supplier sites are ongoing. Cipla 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; 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 and suppliers’ sites; no requests for official corrective action

Cipla 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. Cipla also requires its suppliers to audit their own suppliers. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Cipla’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***

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

C.1.1 Registration filings for relevant on-patent medicines

Cipla's performance is low as it filed its newly acquired on-patent medicine, the reserve antibiotic plazomicin (Zemdri®) used to treat complicated urinary tract infections, in one access country (India).

C.1.2 Filed to register off-patent/generic medicines in 4 access countries on average

Cipla has an average performance, filing eight of its nine relevant off-patent/generic medicines for registration in six access countries on average. Its most widely filed relevant product is the antifungal fluconazole, filed in 21 access countries. Six of its relevant products are filed in less than 10 access countries. Three of its relevant products are filed for registration in at least one

LIC.

C.2.1 Expanding access to on-patent medicines

Cipla's performance is low as its on-patent medicine, plazomicin, (Zemdri®) is not yet marketed in access countries.

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

Cipla has an average performance. It reports several examples to demonstrate the number of people who benefitted from its eligible medicines in India and South Africa during the COVID-pandemic peak. For example, Cipla's colistin is available in 500 Indian hospitals and was used to treat 20,000 Indian patients per month. In South Africa, Cipla estimates to have provided access to azithromycin to 280,000 patients. In 2020 and 2021, Cipla participated in a tender to distribute more than 1 mn tablets of

Q-TIB, a fixed dose combination used in tuberculosis prevention for people living with HIV, in seven access countries including Haiti, Rwanda and Uganda.

C.3 Some strategies to ensure continuous supply

Cipla has an average performance with strategies reported in three of four areas assessed. It ensures accurate demand planning and data sharing by having a 12-month rolling forecast and conducting long-term demand planning (up to five years). Cipla mitigates against shortage risks by keeping safety stocks and securing sufficient APIs stocks. Cipla does not report capacity building and technology transfer initiatives. To mitigate against substandard and falsified products, Cipla uses an automated Track&Trace system and product or primary packaging 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 programmes

Cipla performs strongly in the analysis of its top five AMR-related educational programmes for healthcare professionals in conflict of interest (COI) mitigation. All five programmes have all three COI mitigation strategies looked for by the Benchmark: (1) content is developed independently from its marketing department; (2) participants are not provided financial or material incentives; and (3) a policy of not using branded materials.

C.5 Engages in sales and marketing practices to address appropriate use

Cipla performs above average in sales practices. It reports that it partly decouples incentives for sales agents from sales volumes of its antibacterial and/or antifungal medicines. Its percentage of variable pay linked to sales volumes is <1% and sales targets are set at the national level.

Cipla engages in marketing practices that

aim to address the appropriate use of its antibacterial and/or antifungal medicines. Its marketing materials reflect emerging resistance trends and/or include treatment guidelines for healthcare professionals: for colistin and itraconazole.

C.6 Makes two types of brochure and/or packaging adaptations to facilitate appropriate use by patients

Cipla adapts brochures and packaging to facilitate the appropriate use of itraconazole, amrolofine, oxiconazole and fosfomycin trometamol by patients. Cipla performs well in this measure, taking account of language and adherence to treatment. It provides packages and leaflets for these products with QR codes that direct patients to information on antifungal resistance in eight to ten regional languages in India. This information aims to improve adherence to treatment.

C.7 AMR Surveillance

As a generic medicine manufacturer, Cipla is not assessed in this indicator but its activities in AMR surveillance are reported. The Benchmark notes that Cipla funds a surveillance programme in the US focused on resistance to plazomicin and has been running since 2018. The programme is an FDA postmarketing requirement and data collection is not complete, therefore data is not yet shared publicly. However, Cipla reports that aggregated results are shared and presented at international infectious disease conferences.

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