

Alkem Laboratories 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. Alkem reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. The company can develop an AMR strategy for its own manufacturing sites, the sites of suppliers and external private waste-treatment plants, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Moreover, Alkem can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.</p> | <p>For the first time, Alkem has publicly reported the implementation of Zero Liquid Discharge (ZLD) systems across 64% of its manufacturing sites. The company also publicly reports the city-level locations of its manufacturing sites, with 18 located in India and two in the United States. However, it remains unspecified which sites manufacture antibacterials and/or antifungals. In addition, Alkem does not report an AMR-specific environmental risk-management strategy.</p> |
| <p>Expand registration and ensure availability of antibacterial and antifungal medicines. Alkem can expand registration and ensure equitable access of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefotaxime and tigecycline, to more countries, including low-income countries, with a high burden of disease. It can improve transparency on where its medicines are registered and made available.</p> | <p>Alkem did not report any developments specific to this Opportunity.</p> |
| <p>Apply responsible sales practices for antibacterial and antifungal medicines. Alkem 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 medicine.</p> | <p>Alkem did not report any developments specific to this Opportunity.</p> |

Overall Performance

2020 2021

14% 20%

Alkem Laboratories Ltd

Generic medicine manufacturer
 Stock exchange: NSE • Ticker: ALKEM • HQ: Mumbai, India • Employees: 14,331

PERFORMANCE

Alkem performs low 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.

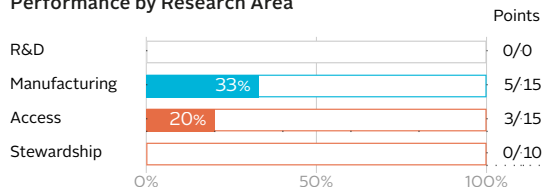
Appropriate Access: Performs low. Discloses no information on registration filings, expanding access or ensuring continuous supply for its off-patent/generic medicines.

Stewardship: Performs low. It does not report decoupling incentives for sales agents from sales volumes. It does not adapt brochures or packaging for patients.

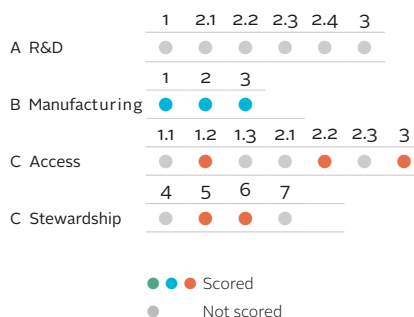
Performance in the Benchmark



Performance by Research Area



How Alkem was evaluated



OPPORTUNITIES FOR ALKEM

Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Alkem reports a commitment to manufacture its products in an environmentally responsible manner without specifying whether AMR is taken into account. The company can develop an AMR strategy for its own manufacturing sites, the sites of suppliers and external private waste-treatment plants, based on the guidelines of the AMR Industry Alliance. This includes setting limits and quantifying discharge levels to track compliance. Moreover, Alkem can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.

Expand registration and ensure availability of antibacterial and antifungal medicines. Alkem can expand registration and ensure equitable access of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefotaxime and tigecycline, to more countries, including low-income countries, with a high burden of disease. It can improve transparency on where its medicines are registered and made available.

Apply responsible sales practices for antibacterial and antifungal medicines. Alkem 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 Alkem.

* All companies were assessed based on data submitted to the Benchmark in the current and previous periods of analysis, as well as information the companies have made publicly available, or that are

accessible through other sources. For the 2021 Benchmark, Alkem declined to submit data to the Antimicrobial Resistance Benchmark.

SALES AND OPERATIONS

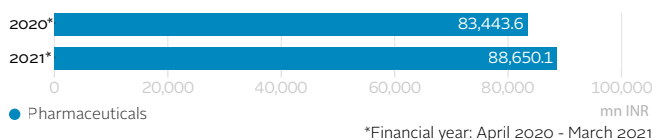
Therapeutic areas: Anti-diabetes, Anti-infective, Cardiac, Dermatology, Gastro-intestinal, Pain/analgesics, Neuro/CNS.

Business segments: Pharmaceuticals

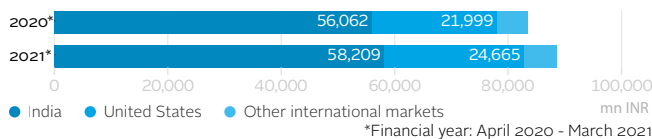
Product categories: Generic medicines

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: 49 antibacterial medicines; 3 antifungal medicines

Off-patent/generic medicines: 10 of 52 were selected for analysis** (amoxicillin [A], amoxicillin/clavulanic acid [A], caspofungin [F], cefixime [W], cefotaxime [W], colistin [R], isoniazid [T], itraconazole [F], linezolid [T], tigecycline [R])

AWaRe medicines*:** 5 Access group; 18 Watch group; 3 Reserve group

Anti-TB medicines*:** 2

Products on the market



PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT

As a generic medicine manufacturer, Alkem 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

Alkem states a general commitment to manufacture its products in an environmentally responsible manner, supported by a management system that includes periodic impact assessments. 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 sites, third-party suppliers of antibacterials or external private and public waste-treatment plants.

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.

EMA related to non-conformities with cGMP at Alkem's own sites or any subsidiaries that manufacture antibacterials.

B.2 Limited publicly available information on environmental risk management

Alkem publishes limited information on its approach to environmental risk-management, without specific references to AMR. It does not publish: (1) the results of environmental

B.3 System in place to maintain production quality for own and suppliers' sites; no requests for official corrective action

Alkem 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 Alkem requires its suppliers to audit their own suppliers. The Benchmark found no requests for official corrective action from the FDA or

** 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†

Alkem 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 No information on registration filings for off-patent/generic medicines

Alkem's performance is low. It reports no evidence of filing its ten relevant off-patent/generic medicines for registration in access countries, beyond India.

C.2.2 No information on strategies to expand access to off-patent/generic medicines

Alkem's performance is low as it discloses no information on how it expands access to its ten relevant off-patent/generic medicines, beyond India. It does not provide evidence of patient reach and geographic reach.

C.3 No information on strategies to ensure continuous supply

Alkem's performance is low as it discloses no information on how it ensures the continuous supply of its relevant products to access countries, beyond India.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Educational Stewardship Activities

There is no information regarding Alkem's involvement in AMR-related educational programmes aimed at healthcare professionals and it is therefore not eligible for this indicator as there is no conflict of interest mitigation to be assessed.

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

Alkem 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.

Alkem 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.

Alkem does not report adapting brochures and/or packaging to facilitate the appropriate use of its antibacterial and/or antifungal medicines by patients.

C.6 Does not report adapting brochures and/or packaging to facilitate appropriate use by patients

Alkem does not report adapting brochures and/or packaging to facilitate the appropriate use of its antibacterial and/or antifungal medicines by patients.

C.7 AMR Surveillance

As a generic medicine manufacturer, Alkem 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.