Alkem Laboratories Ltd

Generic medicine manufacturer
Stock exchange: NSE • Ticker: ALKEM • HQ: Mumbai, India • Employees: 14,115

PERFORMANCE

Alkem performs less well overall in all its evaluated Research Areas when compared to other generic medicine manufacturers in scope.

Responsible Manufacturing: Performs less well. Reports a 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: Dermatology; Gastroenterology; Infectious diseases; Pain management
Business segments: Pharmaceuticals
Product categories: Generic medicines
Manufacturing & supply: No information available
M&A since 2018: None in the antibacterial and/or antifungal sectors

PORTFOLIO for diseases in scope

Mid-sized portfolio: At least 92 products (51 unique INNs): 89 antibacterial medicines; 3 antifungal medicines
Essential medicines: 28% (26) of products are on the 2019 WHO EML
AWaRe medicines*: 8 Access group; 13 Watch group
Anti-TB medicines*: 4 (incl. 2 Watch group; 2 Reserve group)

How Alkem was evaluated

Performance by Research Area

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Points</th>
<th>Scored</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Manufacturing</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Access</td>
<td>0%</td>
<td></td>
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<tr>
<td>Stewardship</td>
<td>0%</td>
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</tbody>
</table>

Each indicator is worth a max score of 5. Indicators are not applicable to every company. See Appendix for full overview.

Revenues by product (2017-18)

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Total Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-Infectives</td>
<td>64.3 bn INR</td>
</tr>
<tr>
<td>Consumer healthcare</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
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</tbody>
</table>

Revenues by region (2017-18)

<table>
<thead>
<tr>
<th>Region</th>
<th>Total Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>64.3 bn INR</td>
</tr>
</tbody>
</table>

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. Alkem declined to submit data to the 2020 AMR Benchmark.
OCCUPATIONAL ACCESS FOR ALKEM

Step up engagement on AMR and increase disclosure of AMR strategies and activities. Alkem is one of the generic medicine manufacturers with the largest portfolio of antibacterial and/or antifungal medicines, including 26 products on the 2019 WHO EML. Alkem 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. Alkem 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 an 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, Alkem can decouple sales incentives from sales volumes and/or avoid deploying sales agents, as appropriate.

PERFORMANCE BY RESEARCH AREA

A  RESEARCH & DEVELOPMENT

As a generic medicine manufacturer (GMM), Alkem 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

Alkem reports a 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 antibacterial APIs and/or drug products or external private waste-treatment plants.

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 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 and suppliers’ sites; regulator requested official corrective action

Alkem reports having a system to maintain high-quality antibacterial production, consistent with international GMP standards, including periodic internal audits. In February 2019, an FDA drug quality inspection identified non-conformities with cGMP at an S&B Pharma site (an Alkem subsidiary), resulting in an official request for corrective action. It is unclear whether the site produces antibacterials. This suggests potential risks regarding how the system is being implemented at sites producing antibacterials. The company reports requiring suppliers to abide by regulatory and company quality standards. This includes submitting suppliers to a qualification process and periodic audits for re-qualification. It reports engaging with suppliers to implement corrective and preventive actions.

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

Alkem 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***

Alkem reports no evidence of filing 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

Alkem 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 Alkem considers affordability or socioeconomic factors when setting prices for off-patent antibacterial or antifungal medicines or vaccines.

C.3 No information on measures to ensure continuous supply of relevant products

Alkem discloses no information on how it takes steps to ensure the continuous supply of antibacterial or antifungal medicines or vaccines to access countries.

** 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
Alkem 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 Alkem’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 Alkem’s adaptations in its brochures and/or packaging to facilitate the appropriate use of its antibacterial and/or antifungal medicines by patients beyond regulatory requirements.

C.7 Antimicrobial surveillance
As a GMM, Alkem is not eligible for this indicator as GMMs have a limited role in AMR surveillance activities.