Hainan Hailing Chemipharma Corp Ltd

Generic medicine manufacturer
Stock exchange: Privately held • Ticker: N/A • HQ: Haikou, China • Employees: 600

PERFORMANCE

Hainan Hailing 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

<table>
<thead>
<tr>
<th>Performance Area</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall score</td>
<td>15%</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>0/0</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>20%</td>
</tr>
<tr>
<td>Access</td>
<td>20%</td>
</tr>
<tr>
<td>Stewardship</td>
<td>0/30</td>
</tr>
</tbody>
</table>

How Hainan Hailing was evaluated

A R&D
● 2.1 2.2 2.3 2.4 3

B Manufacturing
● 1 2 3

C Access
1.1 1.2 1.3 2.1 2.2 2.3 3

C Stewardship
4 5 6 7

OPPORTUNITIES FOR HAINAN HAILING

Develop an AMR-specific environmental risk-management strategy and increase public disclosure. Hainan Hailing 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, Hainan Hailing 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. Hainan Hailing can expand registration and ensure equitable access of its antibiotics and antifungals listed on the 2021 WHO EML, such as cefepime and ceftazidime, to more countries, including low-income countries. It can improve transparency on where its medicines are registered and made available.

Apply responsible sales practices for antibacterial and antifungal medicines. Hainan Hailing 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 Hainan Hailing.

* 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, Hainan Hailing declined to submit data to the Antimicrobial Resistance Benchmark.
SALES AND OPERATIONS

Therapeutic areas: Antifungal, Anti-infective, Angiomyocardiac, Anti-diabetics, Gastrointestinal, Nervous system
Business segments: Pharmaceuticals
Product categories: Generic medicines
M&A since 2020: None in the antibacterial and/or antifungal sectors

SALES AND OPERATIONS

PORTFOLIO for pathogens in scope

Mid-sized portfolio: At least 43 products: 41 antibacterial medicines; 2 antifungal medicines
Off-patent/generic medicines: 8 of 43 were selected for analysis** (amoxicillin [A], amoxicillin/clavulanic acid [A], caspofungin [F], cefepime [W], cefotazidime [W], faropenem [R], luliconazole [F], rifandine [T])
AWaRe medicines***: 11 Access group; 25 Watch group; 1 Reserve group
Anti-TB medicines***: 1

PERFORMANCE BY RESEARCH AREA

A  RESEARCH & DEVELOPMENT

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

B  RESPONSIBLE MANUFACTURING

B.1 No AMR-specific environmental risk-management strategy
Hainan Hailing states a general commitment to manufacture its products in an environmentally responsible manner, supported by a discharge monitoring system to ensure compliance with local regulations. 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.

B.2 Limited publicly available information on environmental risk management
Hainan Hailing publishes limited information on its approach to environmental risk-management, without specific references to AMR. It 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 sites; limited information on suppliers; no requests for official corrective action
Hainan Hailing reports that its own sites have a system to maintain high-quality antibacterial production consistent with international GMP standards. There is limited information on audits, corrective actions 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 Hainan Hailing's own sites or any subsidiaries.

** 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†

Hainan Hailing 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.2.2 No information on strategies to expand access to off-patent/generic medicines
Hainan Hailing’s performance is low, as it discloses no information on how it expands access to its eight relevant off-patent/generic medicines, beyond China. It does not provide evidence of patient and geographic reach.

C.3 No information on strategies to ensure continuous supply
Hainan Hailing’s performance is low, as it discloses no information on how it ensures the continuous supply of its relevant products to access countries, beyond China.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP
Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4 Educational Stewardship Activities
There is no information regarding Hainan Hailing’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
Hainan Hailing 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. Hainan Hailing 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 Does not report adapting brochures and/or packaging to facilitate appropriate use by patients
Hainan Hailing 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, Hainan Hailing 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.