Hainan Hailing Chemipharma Corporation Ltd

Generic medicine manufacturer
Stock exchange: Privately held • Ticker: N/A • HQ: Haikou, China • Employees: 380

PERFORMANCE

Hainan Hailing performs low overall in its evaluated Research Areas when compared to other generic medicine manufacturers.

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: Diabetes; Gastroenterology; Infectious diseases
Business segments: Hailing Pharm
Product categories: Generic medicines
Manufacturing & supply: Hainan Hailing reports having three manufacturing sites of which at least two produce antibacterial APIs and/or drug products.
M&A since 2018: None in the antibacterial and/or antifungal sectors

PORTFOLIO for diseases in scope

Mid-sized portfolio: At least 47 products (42 unique INNs): 46 antibacterial medicines; 1 antifungal medicine
Essential medicines: 23% (11) of products are on the 2019 WHO EML
AWaRe medicines*: 7 Access group; 4 Watch group
Anti-TB medicines*: None

Performance in the Benchmark

Overall score 6% 2/35

Performance by Research Area

<table>
<thead>
<tr>
<th>Research Area</th>
<th>Points</th>
<th>N/A</th>
<th>0%</th>
<th>50%</th>
<th>100%</th>
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<tbody>
<tr>
<td>R&amp;D</td>
<td>2/15</td>
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<tr>
<td>Manufacturing</td>
<td>13%</td>
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<tr>
<td>Access</td>
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<td>Stewardship</td>
<td>0%</td>
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How Hainan Hailing was evaluated

A R&D 1 2.1 2.2 2.3 2.4 3 4
B RM 1 2 3
C AA 1.1 1.2 2.1 2.2 3
C STW 4 5 6 7

Revenues (2018)

No data available

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. Hainan Hailing declined to submit data to the 2020 AMR Benchmark.
OPPORTUNITIES FOR HAINAN HAILING

Develop, implement and monitor an AMR-specific environmental risk-management strategy. Hainan Hailing has stated a commitment to manufacture its medicines in an environmentally responsible manner and a monitoring system to ensure compliance with local regulations. It is unclear how the strategy takes AMR 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) and monitoring of antibacterial levels in discharge. It does not publish the results of environmental audits, whether conducted at its own sites or any subsidiaries. Yet, it is unclear whether AMR is 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) and monitoring of antibacterial levels in discharge, at its own manufacturing sites, to the sites of third-party suppliers and to 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.

Step up engagement on AMR and increase disclosure of AMR strategies and activities. Hainan Hailing could 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. The company can develop a strategy that takes AMR into account, including discharge limits based on PNECs to limit AMR (or more stringent) and monitoring of antibacterial levels in discharge. It does not publish the results of environmental audits, whether conducted at its own sites, the sites of suppliers or external private waste-treatment plants; or (3) the levels of nor limits for antibacterial discharge from its own sites.

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, Hainan Hailing 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), Hainan Hailing is not evaluated in this Research Area.

B RESPONSIBLE MANUFACTURING

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

Hainan Hailing reports a 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 antibacterial APIs and/or drug products or external private waste-treatment plants. The company can develop a strategy that takes AMR into account, including discharge limits based on PNECs to limit AMR (or more stringent) and monitoring of antibacterial levels in discharge from its own sites.

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 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 Limited evidence of a system to maintain production quality

There is limited information on the systems implemented by Hainan Hailing to maintain high-quality antibacterial production, consistent with international GMP standards. 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.

C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS

C.1.1 Registering on-patent products

Hainan Hailing 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

Hainan Hailing 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

Hainan Hailing 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 Hainan Hailing 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

Hainan Hailing discloses no information on how it takes steps to ensure the continuous supply of antibacterial or antifungal medicines or vaccines to access countries.
CAPPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP
evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

C.4  Educational stewardship activities
Hainan Hailing 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 Hainan Hailing’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 Hainan Hailing’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, Hainan Hailing is not eligible for this indicator as GMMs have a limited role in AMR surveillance activities.