Fresenius Kabi AG

Generic medicine manufacturer
Stock exchange: FRA • Ticker: FRE (Fresenius SE & Co KGaA) • HQ: Bad Homburg, Germany • Employees: 37,843

PERFORMANCE

Fresenius Kabi performs well overall in its evaluated Research Areas compared to other generic medicine manufacturers in scope.

Responsible Manufacturing: Middle-performing. Reports environmental risk-management strategy for own sites and plans for evaluation of suppliers but limited information on the extent to which AMR and discharge limits are taken into account.

Appropriate Access: Middle-performing. Files for registration for relevant off-patent products in access countries. Reports some information on its strategies for pricing and ensuring continuous supply.

Stewardship: Performs well. It has decoupled incentives for sales agents for most of the volume it sells. Its educational programmes have comprehensive conflict of interest (COI) mitigation.

SALES AND OPERATIONS

Therapeutic areas: Anaesthesia; Malabsorption; Oncology
Business segments: Biosimilars; Clinical Nutrition; Devices; Infusion Therapy; Intravenously Administered Drugs; Transfusion Medicine and Cell Therapies
Product categories: Biosimilars; Generic medicines; Medical devices; Nutritional; Transfusion technology
Manufacturing & supply: Fresenius Kabi reports having 17 manufacturing sites that produce antibacterial APIs and/or drug products. It reports selling its antibacterial and antifungal medicines across 44 countries, 10 of which are low- and middle-income countries.

M&A since 2018: None in the antibacterial and/or antifungal sectors

MID-SIZED PORTFOLIO for diseases in scope

Mid-sized portfolio: At least 51 products (46 unique INNs): 47 antibacterial medicines; 4 antifungal medicines

Essential medicines: 53% (27) of products are on the 2019 WHO EML

AWaRe medicines*: 13 Access group; 6 Watch group; 1 Reserve group

Anti-TB medicines*: 5 (incl. 2 Watch group, 1 Reserve group)

PORTFOLIO for diseases in scope

Therapeutic areas: Anaesthesia; Maldigestion; Oncology
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How Fresenius Kabi was evaluated

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

Revenues by product (2018)

Pharmaceuticals
Medical devices
Other

Revenues by region (2018)

Europe
North America
Asia Pacific
Latin America & Africa

The number of products is based on data from public sources, IQVIA, and data submitted by the company. It may not account for Fresenius Kabi’s entire portfolio.
**OPPORTUNITIES FOR FRESENIUS KABI**

Expand registration and ensure adequate supply of antibacterial medicines to more access countries. Fresenius Kabi can file for registration and ensure adequate supply of antibacterial medicines on the 2019 WHO EML within its current portfolio (e.g. the forgotten antibiotics benzylpenicillin, chloramphenicol and cloxacillin) in more access countries.

Deepen and expand its environmental risk-management strategy. Fresenius Kabi currently has an environmental risk-management strategy that includes auditing processes and is applied to its own manufacturing sites. The company can ensure that its strategy (1) includes specific antibacterial discharge limits and discharge-monitoring processes and (2) extends fully to the sites of third-party suppliers and to external private waste-treatment plants. The AMR Industry Alliance has developed a list of discharge limits that can serve as a starting point for this endeavour.

Adapt brochures and packaging. In order to promote the appropriate use of its antibacterial and/or antifungal medicines by all patients, Fresenius Kabi can make brochure and/or packaging adaptations that take account of language, literacy, paediatric use, adherence to treatment and the environment.

**CHANGES SINCE 2018**

- Initiated prioritisation of API suppliers for environmental risk assessments.
- Received the Drug Shortage Assistance Award in 2018 by the FDA recognizing its efforts in shortage mitigation.
- Engaged since 2018 in AMR-related educational programmes aimed at healthcare professionals (HCPs) that includes comprehensive conflict of interest (COI) mitigation.
- Sells most of its antibacterial and/or antifungal medicines through tenders and does not have sales incentives linked to the sales volume of these tenders.

**PERFORMANCE BY RESEARCH AREA**

### A RESEARCH & DEVELOPMENT

*As a generic medicine manufacturer (GMM), Fresenius Kabi is not evaluated in this Research Area.*

### B RESPONSIBLE MANUFACTURING

**Evaluated: antibacterials manufacturing (APIs and drug products)**

#### B.1 Environmental risk-management for own sites; no information on discharge limits

Fresenius Kabi reports a general strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites. This includes audits every 1-4 years. The company reports that antibacterial-contaminated wastewater is either incinerated, treated or disposed of via a external third parties. It does not report setting antibacterial discharge limits for its own sites with the aim of limiting AMR.

There is limited information on the requirements that Fresenius Kabi makes of third-party suppliers of antibacterial APIs and/or drug products with respect to AMR. It expects suppliers to follow its code of conduct, which includes general provisions on environmental protection. It has also recently established a supplier evaluation programme that prioritises antibacterial API suppliers for environmental impact assessment, but it is not clear how this takes account of the risk of AMR. There is also limited information on the requirements Fresenius Kabi makes of external private waste-treatment plants, in terms of environmental strategy, audits and antibacterial discharge limits. The company reports requiring each site to regularly audit its external waste disposal companies but states that exact audit parameters are defined locally by each site.

#### B.2 Limited publicly available information on environmental risk management

Fresenius Kabi 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; no requests for official corrective action

Fresenius Kabi reports having a system to maintain high-quality antibacterial production, consistent with international GMP standards. This includes risk-based internal audits and tracking of corrective and preventive actions. The company reports requiring suppliers to abide by regulatory and company quality standards. This includes submitting suppliers to a qualification process, after which a quality agreement is established and periodic risk-based audits are conducted to re-assess compliance. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Fresenius Kabi’s own sites or any subsidiaries.**

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**Including only wholly-owned direct subsidiaries of the company. More information in Appendix I.**
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
Fresenius Kabi 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 Registering off-patent products
Fresenius Kabi is a middle-performing company when it comes to filing relevant off-patent products† for registration. Further details were provided on the basis of confidentiality.

C.2.1 Pricing strategies for on-patent products
Fresenius Kabi 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. Fresenius Kabi reports that the pricing of its products is controlled by governments through mechanisms such as claw backs, paybacks, rebates and external reference pricing to public procurement/tendering. It reports that it participates in various tender programmes.

C.3 Some strategies to ensure the continuous supply of relevant products
Fresenius Kabi is a middle-performing company, compared to other generic medicine manufacturers evaluated, when it comes to taking steps to ensure the continuous supply of its relevant products to access countries. It performs forecasting and has a defined stock buffer to ensure market supply. To reduce the introduction of falsified medicines in the supply chain, it has implemented a Global Serialization Program which handles the implementation and roll-out to all countries where serialization is required by law. It is one of the co-founders of the European Medicines Verification Organisation (EMVO), that aims to prevent the entry of falsified medicines into the European pharmaceutical supply chain. Fresenius Kabi also takes steps to help ensure its forgotten antibiotics are available in access countries.

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

C.4 Strategy in place to mitigate COI for all of its educational programmes
The Benchmark analysed four AMR-related educational programmes for HCPs from Fresenius Kabi. Fresenius Kabi reports comprehensive COI mitigation for all four programmes. These programmes have all three COI mitigation strategies looked for by the Benchmark: (1) a policy of developing content independently from its marketing department; (2) a pledge not to provide financial or material incentives to participants; and (3) a policy of not using branded materials.

C.5 Adapts sales practices to address appropriate use
Fresenius Kabi engages in practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines via its sales practices. It does not disclose marketing materials that aim to address appropriate use of its antibacterial and/or antifungal medicines. Fresenius Kabi reports that it sells most of its antibacterial and/or antifungal medicines through hospital tenders, and does not have sales incentives linked to the sales volume of these tenders. After the period of analysis, the company shared marketing materials that include guidelines for HCPs to raise awareness of AMR and address appropriate use for a range of its intravenous antibacterial medicines used in intensive care units.

C.6 Does not adapt brochures and/or packaging to facilitate appropriate use
The majority of Fresenius Kabi’s portfolio is composed of IV drugs, which are administered in hospitals by HCPs. The company does not provide evidence of adapting its brochures and/or packaging to facilitate appropriate use of its self-administered antibacterial and/or antifungal medicines by patients beyond regulatory requirements.

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

*** 102 low- and middle-income countries where better access to medicine is most needed. See Appendix VI.
† See Appendix VII.