

# Fresenius Kabi AG

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><b>Integrate AMR in environmental risk-management strategy and increase public disclosure.</b></p> <p>Fresenius Kabi reports an environmental risk management strategy that includes auditing processes and recently became a member of the AMR Industry Alliance. The company can integrate AMR in its 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, Fresenius Kabi can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.</p>	<p>Fresenius Kabi publicly reports to be in the process of fully integrating the manufacturing standards of the AMR Industry Alliance into its environmental risk-management strategy. The company requires all its own sites to quantify discharge levels through mass balance calculations, with certain locations also conducting chemical analysis on wastewater samples. Fresenius Kabi reports that approximately one-third of its own manufacturing sites are compliant with discharge limits in the receiving environment. In instances where discharge limits are exceeded, investigation and improvement plans to reach compliance are developed. Additionally, the company publicly reports that, since 2021, it has introduced new methods and systems for treating wastewater, aiming to control discharge levels of antibiotics.</p> <p>Fresenius Kabi revised its Third-Party Code of Conduct (CoC) to specify that suppliers are expected to make reasonable efforts to meet discharge limits. The company is in the process of evaluating all its suppliers. Currently, approximately half of the company's assessed supplier sites are reported to be compliant with discharge limits in the receiving environment.</p>
<p><b>Expand availability and ensure continuous supply of antibacterial and antifungal medicines to more access countries.</b></p> <p>Fresenius Kabi expands access through direct selling contracts or tenders and reports a set of cost-containment measures. It also reports to ensure accurate demand planning and data sharing. Fresenius Kabi can ensure equitable access and adequate supply of its antibiotics and antifungals listed on the 2021 WHO EML in more access countries. For example, Fresenius Kabi can build on capacity or mitigate against shortages by working with several API suppliers.</p>	<p>Fresenius Kabi did not report any updates on expanding the availability of antibacterial and antifungal medicines in countries in scope of the Benchmark. The company expanded Active Pharmaceutical Ingredient (API) production capacity at its manufacturing site in Italy. Yet, the extent to which this has increased the availability in countries in scope remains unclear.</p> <p>Fresenius Kabi reports on several challenges it encounters in ensuring a continuous supply of essential medicines, including economic factors such as rising production costs, increasing environmental standards which require additional resources and European Union's legal proposals lacking incentives for strengthening the generics industry.</p>
<p><b>Expand registration of antibacterial and antifungal medicines.</b></p> <p>Fresenius Kabi reports developing generic IV formulations that are ready to launch directly after the patents of the branded products expire. It can apply this policy in access countries and register its antibiotics and antifungals listed on the 2021 WHO EML, (e.g. daptomycin and caspofungin), in more countries, including in low-income countries with a high burden of disease.</p>	<p>Fresenius Kabi reports it has received approvals for ten antibacterial medicines across seven low- and middle-income countries (LMICs) cumulatively. Among these, two products are listed on the 2023 World Health Organization (WHO) Model List of Essential Medicines (EML).</p>

**Overall Performance**

2020	2021
55%	63%▲

# Fresenius Kabi AG

Generic medicine manufacturer

Stock exchange: XFRA • Ticker: FRE (Fresenius SE & Co KGaA)\* • HQ: Bad Homburg, Germany • Employees: 40,519

## PERFORMANCE

Fresenius Kabi performs above average overall in its evaluated Research Areas when compared to the other generic medicine manufacturers in scope.

**Responsible Manufacturing:** Middle-performing. Reports environmental risk-management strategy for own sites; limited information on whether AMR and discharge limits are taken into account.

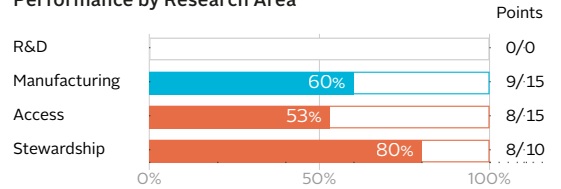
**Appropriate Access:** Middle-performing. Files some of its off-patent/generic medicines for registration in access countries. Reports some strategies to expand access and ensure continuous supply of its relevant products.

**Stewardship:** Performs well. It decouples incentives for sales agents from sales volumes by using tender sales for most sales. It reports broad conflict of interest mitigation for its educational programmes.

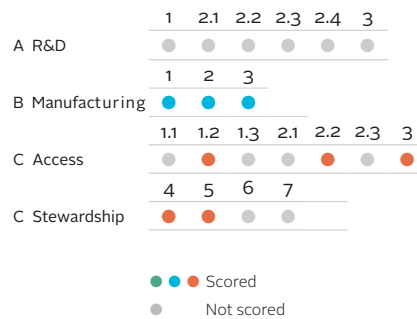
### Performance in the Benchmark



### Performance by Research Area



### How Fresenius Kabi was evaluated



## OPPORTUNITIES FOR FRESENIUS KABI

**Integrate AMR in environmental risk-management strategy and increase public disclosure.** Fresenius Kabi reports an environmental risk management strategy that includes auditing processes and recently became a member of the AMR Industry Alliance. The company can integrate AMR in its 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, Fresenius Kabi can publish information on how it manages environmental risk related to antibacterial manufacturing to curb AMR. The company currently publishes limited information.

**Expand availability and ensure continuous supply of antibacterial and antifungal medicines to more access countries.** Fresenius Kabi expands access through direct selling contracts or tenders and reports a set of cost-containment measures. It also reports to ensure accurate demand planning and data sharing. Fresenius Kabi can ensure equitable access and adequate supply of its antibiotics and antifungals listed on the 2021 WHO EML in more access countries. For example, Fresenius Kabi can build on capacity or mitigate against shortages by working with several API suppliers.

**Expand registration of antibacterial and antifungal medicines.** Fresenius Kabi reports developing generic IV formulations that are ready to launch directly after the patents of the branded products expire. It can apply this policy in access countries and register its antibiotics and antifungals listed on the 2021 WHO EML, (e.g. daptomycin and caspofungin), in more countries, including in low-income countries with a high burden of disease.

## CHANGES SINCE 2020

- Fresenius Kabi increased the number of registration filings in access countries for eight out of 10 of its relevant off-patent/generic antibacterial and antifungal medicines, compared to four out of 10 in 2020, meeting the opportunity provided in the 2020 Benchmark. They also increased registration to seven access countries on average from four on average since 2020.
- In 2020, Fresenius Kabi became a member of the AMR Industry Alliance stating a commitment to apply its corresponding guidelines for manufacturing going forward.

\* Fresenius Kabi AG is a business segment of Fresenius SE & Co. KGaA

## SALES AND OPERATIONS

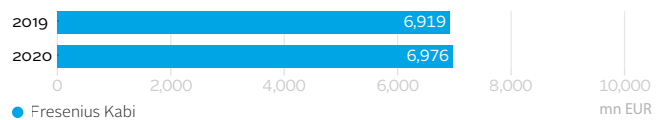
**Therapeutic areas:** Anaesthesia, Critical illness, Fluid management, Liver insufficiency, Maldigestion / malabsorption, Oncology, Paediatrics, Transfusion medicine.

**Business segments:** Fresenius Kabi

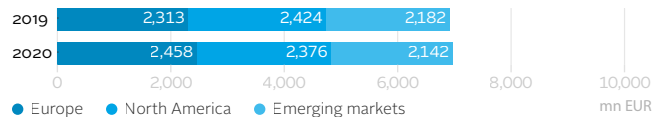
**Product categories:** Biosimilars, Generic medicines, Medical devices

**M&A since 2020:** None in the antibacterial and/or antifungal sectors

### Sales by business segment



### Sales by region (Fresenius Kabi)



## PORTFOLIO for pathogens in scope

**Mid-sized portfolio:** At least 51 products: 48 antibacterial medicines; 3 antifungal medicines

**Off-patent/generic medicines:** 10 of 51 were selected for analysis\*\* (aztreonam [R], caspofungin [F], clindamycin [A], daptomycin [R], fluconazole [F], isoniazid [T], linezolid [T], meropenem [W], metronidazole [A], piperacillin/tazobactam [W])

**AWaRe medicines\*\*\*:** 16 Access group; 22 Watch group; 5 Reserve group

**Anti-TB medicines\*\*\*:** 3

### Products on the market



## PERFORMANCE BY RESEARCH AREA

### A RESEARCH & DEVELOPMENT

As a generic medicine manufacturer, 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; questionnaire-based assessments of all suppliers

Fresenius Kabi reports a strategy to minimise the environmental impact of wastewaters and solid waste from antibacterial manufacturing at its sites, including audits every 1-4 years. It became a member of the AMR Industry Alliance in 2020 and plans to set discharge limits and quantify levels at its sites in the near future.

There is limited information on the requirements that Fresenius Kabi makes of third-party suppliers of antibacterials with respect to AMR. It reports conducting a questionnaire-based CSR assessment of all suppliers which includes questions on how antibacterial waste is processed by suppliers. It does not report requiring suppliers to set discharge limits or quantify discharge levels.

There is also limited information on the requirements Fresenius Kabi makes of exter-

nal private and public waste-treatment plants, in terms of environmental strategy, audits and antibacterial discharge limits and levels. It reports external waste disposal companies are regularly audited but exact audit parameters are defined locally by each site.

#### B.2 Publicly discloses some information on environmental risk management

Fresenius Kabi publishes some components of its environmental risk-management strategy, without specific references to AMR. It does publicly disclose that non-recyclable hazardous waste including antibiotics is mainly incinerated. Since 2020, it is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. Fresenius Kabi 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 sup-

pliers and plants; or (3) the levels of antibacterial discharge from its own or suppliers' sites.

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

Fresenius Kabi reports 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. It also reviews, as part of its external audit process, the results of audits that suppliers conducted with their own suppliers. 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 that manufacture antibacterials.

\*\* 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†

*Fresenius Kabi 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 Filed to register off-patent/generic medicines in 7 access countries on average

Fresenius Kabi has an average performance, filing eight of its 10 relevant off-patent/generic medicines for registration in seven access countries on average. Its most widely filed relevant product is the antifungal metronidazole filed in 21 access countries. Seven of its relevant products are filed in less than ten access countries. Two of its relevant products are filed for registration in at least one LIC.

### C.2.2 Some strategies to expand access to off-patent/generic medicines

Fresenius Kabi has an average performance. It expands access to its off-patent/generic medicines in access countries through direct sales contracts or tenders. Fresenius Kabi reports a set of cost-containment measures applied on its generic medicines, leading to lower prices. It provides some evidence of patient reach. Details were provided under the basis of confidentiality.

### C.3 Some strategies to ensure continuous supply

Fresenius Kabi has an average performance, with strategies reported in all four areas assessed. It ensures accurate demand planning and data sharing and mitigates against shortages risks.

Details were provided under the basis of confidentiality. It conducts internal or external audits of its suppliers, ensures compliance to the ISO and GMP standards, evaluates its supply performance through KPIs and has a Supplier Code of Conduct. Fresenius Kabi reports, subject to confidentiality, where it produces antibiotics in low- and middle-income countries. To mitigate against substandard and falsified products, Fresenius Kabi has implemented a Global Serialization Program.

## C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

### C.4 Broad COI mitigation strategies in place for its educational programmes

Fresenius Kabi performs well in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. Four programmes have all three COI mitigation strategies looked for by the Benchmark: (1) content is developed 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. The remaining programme has two COI mitigation strategies: the content is developed by Fresenius Kabi's marketing department.

### C.5 Engages in sales and marketing practices to address appropriate use

Fresenius Kabi performs above average in sales practices. It 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.

Fresenius Kabi engages in marketing prac-

tices that aim to address the appropriate use of its antibacterial and/or antifungal medicines. Its marketing materials include emerging resistance trends and/or include treatment guidelines for healthcare professionals: for a range of its intravenous antibacterial medicines used in intensive care units.

### C.6 Stewardship-Oriented Adaptations for Patients

*Fresenius Kabi is not eligible for this indicator as its medicines are administered by healthcare professionals in the hospital setting so there is no need to adapt 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, Fresenius Kabi 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.