OVERALL PERFORMANCE

44%

Fresenius Kabi AG

Generic medicine manufacturer

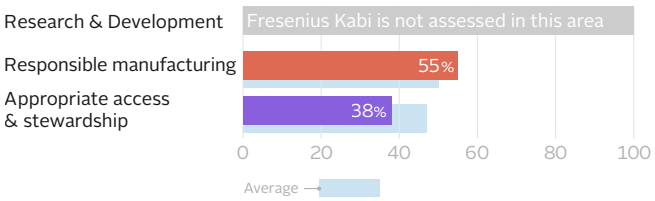
Stock exchange: XFRA • Ticker: FRE • HQ: Bad Homburg, Germany • Employees: 41,586

PERFORMANCE IN THE 2026 BENCHMARK

Low-performing. Fresenius Kabi is mid-performing in Responsible Manufacturing, where it reports partial compliance with discharge limits for the antibacterial products manufactured at its own and suppliers' sites. It has potential to strengthen performance in Appropriate Access & Stewardship, where its efforts are mixed. Although it registers its products in more countries than other assessed generic medicine manufacturers, it implements general but not product-specific stewardship strategies and reports limited measures to mitigate stockout and shortages of its products in LMICs.

How Fresenius Kabi was evaluated

How score was achieved



OPPORTUNITIES FOR FRESENIUS KABI

Expand registrations of its antibacterial and antifungal medicines. Fresenius Kabi registers its off-patent medicines in 12 LMICs, on average. It can expand appropriate access to its Reserve antibiotics, colistin and polymyxin b, which are registered in one country, by prioritising access in countries with high unmet need.

Track product-level patient reach for off-patent antibacterial and antifungal drugs. Fresenius Kabi has a general global strategy for expanding access to its medicines. However, it discloses an aggregate number of patients reached across its entire portfolio and does not disclose the methodology used to calculate it. Fresenius Kabi can improve this approach by reporting patient reach data at a more granular product- and country- level, which is essential for measuring both appropriate access and supporting responsible use of its medicines.

Implement wider strategies to mitigate stockouts and shortages. Fresenius Kabi reports implementing demand planning and maintaining buffer stocks of its products. To further mitigate shortage risks, the company can implement several strategies. These include establishing two-way data-sharing arrangements with local stakeholders – focusing specifically on regions with developing forecasting capabilities – to gather more accurate and reliable local demand indications. Furthermore, where feasible, it can strategically build supplier redundancies for critical antimicrobials and implement additional quality controls at manufacturing sites or supplier facilities when sourcing locally from LMICs with evolving regulatory systems.

Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved. Fresenius Kabi reports 49% compliance with discharge limits set in the receiving environment for its own products, based on mass balance estimations, and 86% compliance for its suppliers' products. To further safeguard AMR risk from antibacterial manufacturing, it can publicly report compliance with discharge limits directly in wastewater for all its own and suppliers' products and require supplier compliance through contractual provision – a step beyond its current practice of setting discharge limits in receiving waters – in line with the 'stringent' WHO guidance.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

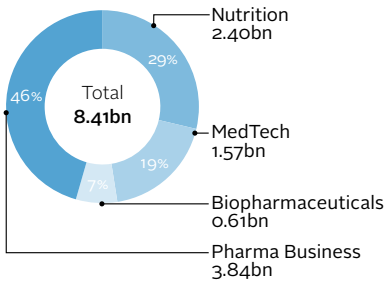
- As of 2025, Fresenius Kabi has earned four BSI Kitemark™ Certifications for Minimized Risk of AMR. These include certifications for ceftriaxone, manufactured at its site in Portugal; amikacin, manufactured at its site in Austria; and linezolid and amikacin, manufactured at its site in Poland.
- In November 2025, the US Food and Drug Administration (FDA) approved Dalbavancin for Injection (for single-dose regimen use only) – a generic formulation of the FDA reference-listed drug Dalvance® – for the treatment of acute bacterial skin and skin structure infections in adult and paediatric patients.

Fresenius Kabi AG

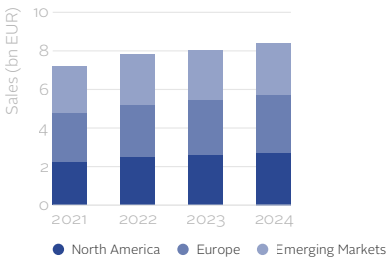
SALES AND OPERATIONS

Therapeutic areas: Anaesthetics & analgesics, anti-infectives, autoimmune diseases, critical care, cell therapies, diabetes, hematology, immunology, infusion therapies, oncology, osteoporosis
Product categories: Consumer health products, generic medicines & biosimilars, medical devices
Investments in AMR: No notable investments identified.
M&A news: In September 2024, Fresenius Kabi divested its subsidiary Laboratorio Sanderson in Chile, which manufactures and supplies hospital antimicrobial injectables across Chile and the wider Latin American region, to Medifarma.

Revenue by business segment (2024) – EUR



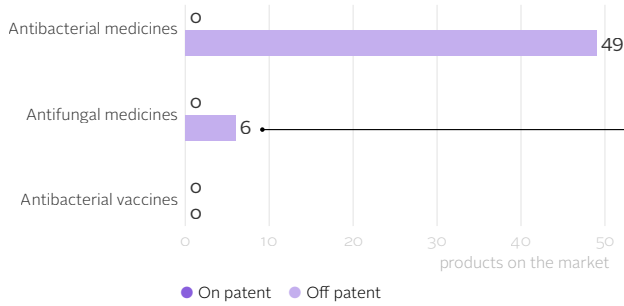
Sales by geographic region – EUR



SAMPLE OF PORTFOLIO ASSESSED BY THE BENCHMARK

PORTFOLIO *for diseases in scope*

55 products in Fresenius Kabi's anti-infective portfolio



10 products selected for analysis

- Antibacterial medicines: doxycycline (A), metronidazole (A), meropenem (W), piperacillin/tazobactam (W), colistin (R), polymyxin b (R), linezolid (T), moxifloxacin (T)
- Antifungal medicines: fluconazole (F), micafungin (F)

Key:
A - Access antibiotic, W - Watch antibiotic, R - Reserve antibiotic, F - Antifungal medicine, T - Antituberculosis medicine

PERFORMANCE BY RESEARCH AREA

RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
		●	●

Mid-performing. Reports an environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It reports the level of compliance achieved at its own and suppliers' sites but does not incorporate AMR provisions into supplier contracts. Fresenius Kabi publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own its sites and suppliers' sites; tracks compliance of antibacterials with discharge limits. Fresenius Kabi's environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). To measure discharge levels at its sites, it uses mass balance estimation, chemical analysis, or both – initially over 1 year, then at a risk-based frequency. If PNECs are exceeded, CAPAs are implemented. Fresenius reports 49% of its antibacterial products are compliant in the receiving environment. It has received 4 BSI Kitemark™ Certifications for Minimized Risk of AMR. The company requires its antibacterial suppliers to follow the Industry Standard and to implement estimation methods recommended by the PSCI. It conducts supplier audits based on PSCI compliance but does not include AMR provisions in its supplier contracts. It reports 86% of its suppliers' antibacterial products are compliant in the receiving environment. The company works with external wastewater treatment plants and reports requesting information from them to inform quantification of discharge levels. It also employs measures to treat wastewater it sends to external plants.

Publicly discloses basic details of its AMR mitigation strategy but is not transparent about compliance with discharge limits. Fresenius Kabi publicly reports implementing the Industry Standard and quantifying discharge levels using mass balance estimation. However, it does not disclose audit results, the number of products complying with PNECs, or the names and locations of manufacturing sites for each manufactured antibacterial.

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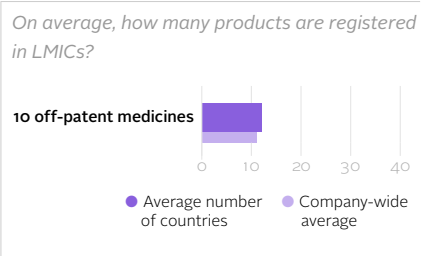
APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1	C.1.2	C.1.3	C.2.1	C.2.2	C.2.3	C.3	C.4	C.5
		●	●	●	●	●	●	●	●	●

Low-performing. Performs well in registration by registering its products in more countries on average compared to peers. It also does well in stewardship, as it considers appropriate use across its business practices. However, Fresenius Kabi can improve in implementing product-specific access and stewardship strategies, as it only follows a general global strategy for expanding access, and provides a patient reach number at an aggregated level. Its measures to mitigate stockouts and shortages are limited.

Fresenius Kabi registers its off-patent medicines more widely than its peers.



Fresenius Kabi registers its off-patent medicines in 12 countries.* No paediatric-specific products from the company were assessed. Its Reserve antibiotics and medicines targeting MDR-TB are registered in 6 countries, including 2 countries where the corresponding disease burden is high. Fresenius Kabi does not report engaging in any mechanism to facilitate registrations for the products selected for analysis.

Below-average performance, with a global access strategy but no reporting on any stewardship initiatives or outcomes data for off-patent/generic antibacterial and antifungal medicines. For all 10 products assessed Fresenius Kabi only discloses a general global strategy for expanding access, which includes participation in government tenders. The company does not report any country- or product-specific data for its access and stewardship strategies. Fresenius Kabi reports only an aggregated number of patients reached across its entire portfolio and provides no details on the methods or metrics used to monitor its strategies.

Limited action to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Fresenius Kabi implements demand planning and maintains buffer stocks of its products. However, it does not report on the inventory management system it uses, or any supplier diversification efforts to mitigate stockouts and shortages in the countries in scope. Fresenius Kabi reports conducting GMP audits to verify supplier credentials and reports cases of substandard incidents to relevant authorities. It also implements track-and-trace systems and smart labels, but this is mentioned in the context of streamlining the delivery process rather than mitigating instances of drug falsification.

Includes elements to address appropriate use across its business practices. Fresenius Kabi does not deploy sales agents to sell and/or promote the majority of its antibacterial and antifungal medicines in most countries. Where sales agents are deployed, Fresenius Kabi partly decouples incentives for its sales agents from sales volume targets and targets are set at the group or business segment level. 15% of variable pay is linked to achieving sustainability measures (ESG targets). Through its global policy, Fresenius Kabi ensures all interactions with HCPs are ethical by ensuring that transfers of value (ToVs) are made at fair market value. While Fresenius Kabi abides by disclosure requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Fresenius Kabi does not apply its public policy to third parties working on its behalf and it is unclear if this is the case for its sales incentive plan.

*All numbers in this statement are expressed as an **average** of the products selected for analysis and refer to registrations in the 113 countries in scope for 'access metrics'.