OVERALL PERFORMANCE

66%

Shionogi & Co, Ltd

Research-based pharmaceutical company

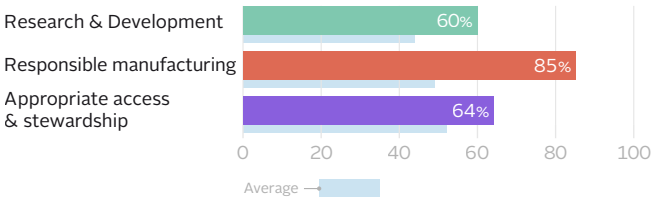
Stock exchange: TSE • Ticker: 4507 • HQ: Osaka, Japan • Employees: 4,959

PERFORMANCE IN THE 2026 BENCHMARK

Performs well. Shionogi performs well across all Research Areas, with specifically strong performance in Responsible Manufacturing. Here, Shionogi shows Best Practice in supporting supplier's wastewater management practices and demonstrates a comprehensive environmental risk management strategy at both its own and suppliers' sites. Across R&D and Appropriate Access & Stewardship, Shionogi is ahead of its peers in implementing access and stewardship plans and strategies; though performance is inconsistent across its pipeline projects. Its approach to stewardship is strong, including product-specific measures for its on-patent cefiderocol, though registrations for the product are limited.

How Shionogi was evaluated

How score was achieved



OPPORTUNITIES FOR SHIONOGI

Expand the depth of R&D access and stewardship plans for all late-stage projects. Shionogi has the most innovative pipeline across all large research-based companies in the AMR Benchmark, with access plans in place for two of its three late-stage candidates. It can strengthen its approach by ensuring that all late-stage projects are backed by comprehensive access and stewardship plans. For example, for its antifungal candidate, olorofim, developed in partnership with F2G, it can strengthen its plan by providing concrete details of access planning in countries with high burdens countries and demonstrate how affordability and supply are being addressed across the 20 LMICs where it holds commercialisation rights.

Improve access to and transparency around its surveillance data. Shionogi is active in three surveillance programmes, including its own 'Shionogi Cefiderocol Post-Marketing Japanese Surveillance Studies Programme'. While it publicly shares aggregated data from this programme, Shionogi has an opportunity to also provide public access to raw data, for example, through the AMR Register. In addition, Shionogi can report more information on the methods used to collect and analyse its surveillance data and disclose this information publicly.

Ensure compliance with discharge limits directly in wastewater. Shionogi publicly reports 100% compliance with discharge limits set in the receiving environment for its own products and 71% compliance for its suppliers' products, based on periodic sampling. 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' sites – 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

- In May 2024, the National Health Service (NHS) of England published guidance on the Antimicrobial Products Subscription Model to set out commercial arrangements for selected antimicrobials. This permanent model builds on a pilot programme launched in July 2022, where a subscription-style model was first awarded for Shionogi's cefiderocol (Fetroja®).
- In April 2025, Shionogi opened a US-based drug discovery laboratory to support antimicrobial research and development.
- In May 2025, Shionogi, Nagasaki University, Saraya, and Connect Afya signed a comprehensive partnership agreement aimed at supporting antimicrobial stewardship in Kenya.
- In July 2025, Shionogi and the Global Antibiotic Research and Development Partnership (GARDP) agreed to collaborate with Kenya's ministry of health to expand access to its antibiotic cefiderocol in the country. The initiative aims to support appropriate use of the drug in selected tertiary hospitals.
- In October 2025, Shionogi's Kanegasaki Plant received the BSI Kitemark™ for Minimized Risk of AMR Certification.

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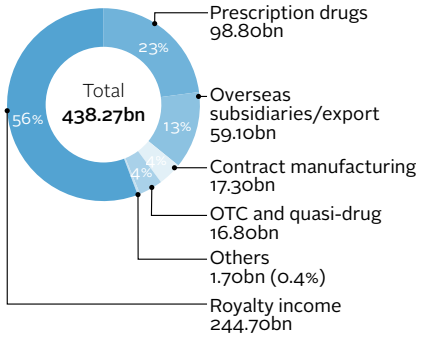
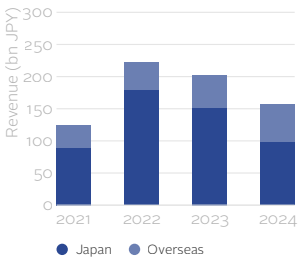
SALES AND OPERATIONS

Therapeutic areas: Analgesics, antibiotics, HIV, infectious diseases, rare diseases, women's health
Product categories: Diagnostics, innovative medicines, vaccines
Investments in AMR: In 2020, Shionogi was a founding partner and invested USD 20mn in the AMR Action Fund, with the goal of bringing 2 to 4 new antibiotics to patients by the end of 2030. It is unknown how much has been invested in the fund to date. In November 2024, it renewed its partnership with INCATE to support early-stage AMR innovators.
M&A news: None identified in the antibacterial and/or antifungal sectors.

Revenue by business segment (2024) – JPY



Revenue by geographic region – JPY



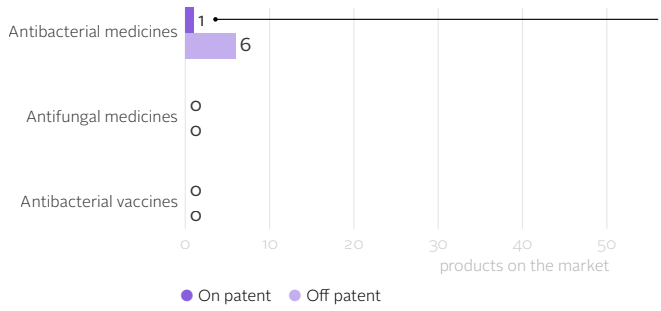
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	2	0	2	1	1	0	0	6
Antifungal medicine	0	0	0	0	1	0	0	1
Antibacterial vaccine	0	1	0	0	0	0	0	1
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	2	1	2	1	2	0	0	8
Access plans				0	2	0	0	2
Stewardship plans				0	2	0	0	2

PORTFOLIO *for diseases in scope*

7 products in Shionogi's anti-infective portfolio



1 product selected for analysis

cefiderocol (R)

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

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PERFORMANCE BY RESEARCH AREA

RESEARCH & DEVELOPMENT	Indicators evaluated	A.1.1	A.1.2	A.1.3	A.1.4	A.2
		●	●	●	●	●

Performs well. Shionogi has a mid-sized pipeline and stands out for having the most innovative projects targeting both 'high' and 'critical' pathogens. It performs above average in access and stewardship planning, however, its approach remains uneven across its three late-stage candidates.

Second largest and most innovative pipeline with diverse projects targeting high and critical priority pathogens. Shionogi's pipeline is the second largest among companies, with 8 projects targeting pathogens in scope: 6 antibacterial medicines, 1 antifungal medicine and 1 antibacterial vaccine. (See figure on previous page for Shionogi's pipeline breakdown, including phases). All 7 medicines in development target 'critical' or 'high' priority pathogens, as defined by WHO. This includes carbapenem-resistant *Acinetobacter baumannii* (critical) and carbapenem-resistant Enterobacterales (critical). Shionogi has the most innovative pipeline of all companies; with 4 medicines (3 antibacterial agents and 1 antifungal medicine) meeting at least 1 of WHO's 4 innovation criteria. For example, its project ORAvance, for complicated urinary tract infections, fulfils the criterion of no cross resistance, and its oral formulation offers a practical advantage for administration in LMICs. The company reports having an in-house discovery programme, focusing on the discovery of new beta-lactamase inhibitors.

Above average performance with some comprehensive access and stewardship plans, although not for all projects. Shionogi has access and stewardship plans for 2 of its 3 late-stage projects. Access plans include licensing agreements and technology transfers. For cefiderocol (Fetcroja®), an antibiotic for resistant gram-negative infections – currently under evaluation in paediatric populations – it has an early access programme and a licensing agreement with GARDP to provide the medicine in 135 countries, including LMICs. Stewardship planning for cefiderocol, is also integral to its GARDP partnership. In addition, it partners with F2G to develop the antifungal olorofim, where it is responsible for overseeing clinical trials, registration, supply and commercialisation in 79 countries, including 20 LMICs. Both companies have contractually committed to developing a joint access and stewardship plan within 60 days of the first global sale. However, specific details regarding access and affordability measures in LMICs remain unclear.

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

Performs strongly. Reports a comprehensive environmental risk management strategy aimed at mitigating AMR risk at both its own and suppliers' sites. It publicly reports product-specific levels of compliance achieved at its own and suppliers' sites, the quantification methods implemented, and the country-level locations of its antibacterial manufacturing sites. It incorporates AMR provisions into contracts with suppliers. Shionogi's hands-on approach to supporting suppliers' wastewater management practices is highlighted as a Best Practice in the Benchmark.

Mitigates AMR risk at both its own sites and suppliers' sites; reports 100% of antibacterials compliant with discharge limits for own sites and 71% for its suppliers' sites. Shionogi's comprehensive environmental risk management strategy is based on the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). Shionogi quantifies antibacterial discharges annually at its own sites using mass balance and chemical analysis. If PNECs are exceeded, CAPAs are implemented (e.g., diverting wastewater to holding tanks to prevent river discharge). It reports all 5 antibacterial products produced at its own sites are compliant with PNECs in the receiving environment, where wastewater is already diluted, which means that AMR risks present in wastewater may not be fully captured. It has received a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification for cefiderocol at its Kanegasaki Plant in Japan. Shionogi also requires antibacterial suppliers to follow the Industry Standard, including discharge quantification via mass balance estimation. It conducts annual supplier audits and enforces contractual provisions on discharge limit compliance. If PNECs are exceeded, it supports suppliers in developing CAPAs. It reports 5 of 7 supplier products are compliant in the receiving environment. Shionogi works with external waste treatment plants and ensures all solid waste and wastewater that it sends to plants is incinerated to mitigate AMR risk. It also audits these plants annually for technology suitability and contamination prevention protocols.

Publicly discloses comprehensive details of its AMR mitigation strategy, product-specific compliance information and country-level locations of all its manufacturing sites. Shionogi publicly reports implementing the Industry Standard, quantification through chemical analysis and achieving compliance with discharge limits for all 5 of its own products and 5 of its suppliers' 7 products. For both its own sites and its suppliers' sites, it publicly discloses aggregated product-specific audit results, including country-level locations of its manufacturing sites for each manufactured antibacterial, but the exact site names of its supplier sites are omitted. It also does not disclose the actual discharge levels measured.

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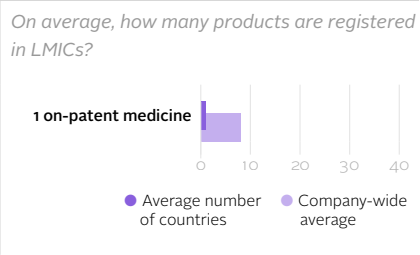
APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1 ●	C.1.2 ●	C.1.3 ●	C.2.1 ●	C.2.2 ●	C.2.3 ●	C.3 ●	C.4 ●	C.5 ●

Performs well. Demonstrates strong performance in ensuring continuous supply, with a comprehensive approach to mitigating stockouts and shortages and ensuring GMP compliance at its own and suppliers' sites. Shionogi clearly addresses appropriate use across its business practices by fully decoupling sales incentives from volume targets, ensuring ethical interactions with healthcare professionals, and setting limits on some transfers of value. It participates in three AMR surveillance programmes, sharing aggregated data. However, compared to peers, its sole product assessed, cefiderocol (Fetroja®), is registered in fewer countries on average.

Shionogi registers its sole product, cefiderocol, in fewer countries than peers' on-patent medicines.



Shionogi registers its on-patent Reserve antibiotic, cefiderocol (Fetroja®), in China,* which is not a country where the corresponding disease burden is high. However, it granted a voluntary licence to GARDP to supply the product in 135 countries, including LMICs in scope of the Benchmark. A specific paediatric formulation of cefiderocol is not approved yet, but currently in development. In addition, Shionogi engages in WHO's Prequalification process to facilitate registrations for cefiderocol.

Above-average performance, working towards broad access through a comprehensive access and stewardship strategy for the only on-patent product assessed, cefiderocol (Fetroja®). In 2022, Shionogi and GARDP signed a non-exclusive voluntary licensing agreement and, with CHAI, a collaboration agreement, to ensure broad access to the product. The licence covers 135 countries (106 in scope of the Benchmark). GARDP has entered a sublicensing agreement with Orchid Pharma, an India-based generic manufacturer, and Shionogi is currently conducting a technology transfer to Orchid Pharma to produce cefiderocol. As cefiderocol has not yet been launched in any GARDP territories, Shionogi is operating an early access programme in 3 countries in scope (Colombia, Guatemala and Mexico). The company does not report a methodology to monitor its access strategies, nor are any outcome metrics available at this stage. Shionogi implements a comprehensive stewardship strategy for the product, including responsible promotion activities and the SENTRY surveillance programme.

Strong efforts to mitigate stockouts/shortages. Strong reported evidence of systems to ensure product quality. Shionogi implements demand planning and data sharing by analysing historical market trends and monitoring public health and potential outbreaks. It provides monthly demand forecasts and uses sales and operations planning processes to communicate supply risks to internal and external stakeholders. Long-term forecasts are implemented for drugs with long lead times (i.e. cefiderocol >1.5 years), ranging from a 3- to 5-year forecasting horizon. It maintains 6-month buffer stocks of APIs and drug products and implements an automated inventory management system that updates inventory levels daily, providing regional supply chain teams with daily alerts on potential shortages. It also implements supplier diversification strategies through its Business Continuity Plans for each of its products, often involving sourcing from multiple upstream suppliers, though local sourcing is not specified. It mitigates substandard and falsified medicines by verifying suppliers through GMP audits and reports cases to relevant authorities. It reports that 2/2 of its own sites and 4/4 of its supplier sites are GMP compliant. Shionogi does not implement additional quality measures, as it does not manufacture in countries with less mature regulatory systems than stringent regulatory authorities.

Clearly addresses appropriate use across its business practices. Shionogi fully decouples incentives for its sales agents from sales volume targets. It does not specify any other qualitative targets that it links to its incentives. Through its global public policy, Shionogi ensures ethical interactions with HCPs, and for certain interactions it requires a defined legitimate need. It also sets limits on some transfers of value (ToVs). While Shionogi 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. Shionogi applies its sales incentive plan and its global policy to third parties working on its behalf.

Active in 3 multi/national AMR surveillance programmes. Shionogi runs the national 'Shionogi Cefiderocol Post-Marketing Japanese Surveillance Studies Programme', which is conducted by a third party on Shionogi's behalf, covering 11 genera of bacteria and 13 antibacterial medicines. Aggregated results from the post-marketing surveillance are shared on Shionogi's website and are accessible for HCPs. Shionogi reports submitting surveillance data from this programme to the Japanese Ministry of Health, Labour and Welfare. Additionally, Shionogi funds the national 'Four Academic Societies Joint Antimicrobial Susceptibility Surveillance Programme' and the multinational 'SENTRY Antimicrobial Surveillance Programme'. Aggregated data for both programmes is publicly available via their respective websites. For SENTRY, Shionogi specifically funds the testing of its own antibacterial medicine (cefiderocol). The methods used to collect surveillance data for SENTRY are largely clear, including: the type of surveillance; where the analysis is conducted and which breakpoints are used; and how deduplication is considered. The methods used for both other programmes are only partially clear.

*All registration numbers in this statement refer to the products selected for analysis and are based on the the 113 countries in scope for 'access metrics'.