OVERALL PERFORMANCE

44%

Otsuka Pharmaceutical Co, Ltd

Research-based pharmaceutical company

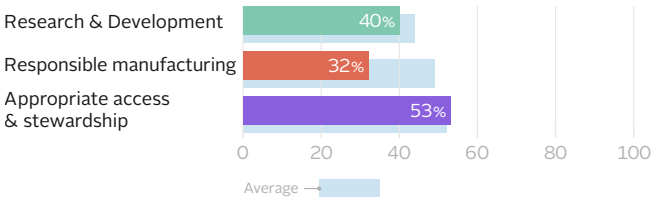
Stock exchange: TSE • Ticker: 4578 • HQ: Tokyo, Japan • Employees: 35,338

PERFORMANCE IN THE 2026 BENCHMARK

Mid-performing. Otsuka shows mixed performance across R&D and Appropriate Access & Stewardship. While it has a small pipeline, its innovative lead project, quabodepistat, targets a 'critical' priority pathogen and is accompanied by a comprehensive access plan. For delamanid, its sole product assessed, it exceeds peers in ensuring access through registrations and implementing a comprehensive access strategy, and it shows Best Practice by supporting diagnostic capacity in LMICs. It has potential to strengthen performance in Responsible Manufacturing, as it lacks public transparency on its strategy and only reports compliance at its own sites, but not at suppliers'.

How Otsuka was evaluated

How score was achieved



OPPORTUNITIES FOR OTSUKA

Expand access planning and paediatric development for projects targeting tuberculosis. Otsuka's pipeline solely focuses on projects that target *Mycobacterium tuberculosis* (RR-TB). The company has developed a comprehensive access and stewardship plan for its only late-stage R&D project, quabodepistat, an innovative tuberculosis treatment now in Phase III combination trials, which offers potential to shorten and simplify therapy compared to the standard of care. Once approved, Otsuka can ensure access to quabodepistat – which is identified as a priority for licensing by global health stakeholders – through multiple supply mechanisms, such as supranational supply, leveraging its already successful partnership with the Global Drug Facility (GDF) for delamanid, and/or through voluntary licensing to enable generic supply. In parallel, it can progress paediatric studies for quabodepistat – which is on WHO's paediatric TB (PADO-TB) watch list – to address critical treatment gaps and enable future use in children.

Expand appropriate access to delamanid for paediatric populations across LMICs. Otsuka provides access to both the adult and paediatric formulations of delamanid (Deltyba®), indicated for drug-resistant TB, through its collaboration with the GDF and via its technology transfer with a generic manufacturer. The adult formulation is registered in 14 LMICs. However, the paediatric formulation, indicated for children three years and older, is only registered in India. Otsuka can close the gap in registration and expand appropriate access in this age group by also registering delamanid's paediatric formulation in at least the same 14 LMICs, prioritising countries with a high unmet need.

Engage in AMR surveillance for delamanid. Otsuka does not report engaging in any AMR surveillance programmes and it did not report any progress on its plans to set up surveillance activities. Otsuka has an opportunity to start engaging in surveillance, particularly for its product delamanid, by either setting up its own surveillance programme or by collaborating with other organisations to integrate its product into existing surveillance programmes, such as SENTRY.

Formalise and publicly disclose comprehensive environmental risk management strategy to mitigate AMR. Otsuka does not report periodically quantifying antibacterial discharge from delamanid production at its own or its suppliers' sites. As a first step, it can begin periodic wastewater sampling to accurately quantify antibacterial discharge, in line with the 'stringent' WHO guidance, and ensure compliance with discharge limits directly in wastewater for both its own and its suppliers' sites. It can demonstrate progress by publicly reporting its antibacterial waste management practices, including compliance levels across its sites and suppliers', and the quantification methods used.

CHANGES SINCE NOVEMBER 2023 UPDATE REPORT ON PREVIOUS BENCHMARK OPPORTUNITIES

- In 2024, Otsuka agreed offering both its 50mg and 25mg delamanid (DELTYBA®) tablets to The Stop TB Partnership's Global Drug Facility's (GDF's) Strategic Rotating Stockpile (SRS) as consignment stock, enabling GDF to expand access to the drug in LMICs.
- In 2024, the World Health Organisation (WHO) recommended delamanid (DELTYBA®) as part of new oral, six- and nine-month regimens targeting multidrug-resistant or rifampicin-resistant tuberculosis (MDR/RR-TB). These regimens were also investigated in children, adolescents, pregnant and breastfeeding women – populations historically overlooked in TB clinical trials.
- PT Otsuka Indonesia and PT Amerta Indah Otsuka – subsidiaries of Otsuka Pharmaceutical Co., Ltd. (Japan) – received the Exemplar Award from Ending Workplace Tuberculosis (EWTB) for their efforts in curbing tuberculosis in the workplace through the FREE Tuberculosis at Workplaces programme. Since the launch of the programme in 2022, more than 70,000 employees have been screened for TB.

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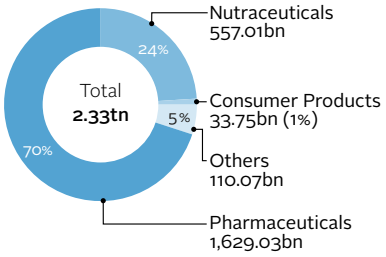
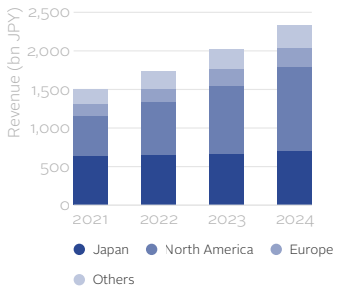
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular, gastroenterology, oncology, ophthalmology, psychiatry & neurology, renal diseases, tuberculosis
Product categories: Diagnostics, innovative medicines, medical devices
Investments in AMR: In 2023, Otsuka increased its spending on TB research and invested a further USD 30 million. As such, it is one of the two largest private-sector spenders in TB research, accounting, together with one other company, for 53% of all private sector spending.
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

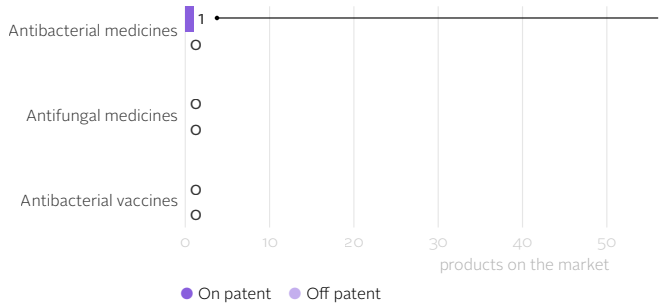
PIPELINE *for diseases in scope*

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	0	1	0	2	1	0	0	4
Antifungal medicine	0	0	0	0	0	0	0	0
Antibacterial vaccine	0	0	0	0	0	0	0	0
Antifungal vaccine	0	0	0	0	0	0	0	0
Total projects	0	1	0	2	1	0	0	4

Access plans			N/A*	1	0	0	1
Stewardship plans			N/A	1	0	0	1

PORTFOLIO *for diseases in scope*

1 product in Otsuka's anti-infective portfolio



1 product selected for analysis

delamanid (T)

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

*Access plans were not assessed for consortium-led studies.

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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
		●	●	●	●	●

Mid-performing. Although it has a small pipeline, Otsuka's lead candidate, quabodepistat, is an innovative medicine and targets a 'critical' priority pathogen (*Mycobacterium tuberculosis*). In addition, it has a comprehensive access plan in place for quabodepistat that addresses barriers to availability, affordability and sustainable supply in LMICs.

Small pipeline focused on multidrug-resistant *Mycobacterium TB*, with 1 innovative candidate in clinical development. Otsuka's small pipeline of 4 projects, all targeting multidrug-resistant (including rifampicin-resistant) *Mycobacterium TB*, a 'critical' priority pathogen as defined by WHO. Its 2 self-developed projects include an adult (Phase III) and paediatric (pre-clinical) development of the antibacterial medicine quabodepistat (OPC-167832). In addition, Otsuka collaborates with 2 consortia (PAN-TB and UNITE4TB) where its antibacterial medicines, delamanid and quabodepistat (OPC-167832), are being evaluated in new TB combination regimens. Its clinical-stage antibacterial, quabodepistat, meets all 4 WHO-defined innovation criteria: it has no known cross-resistance (to date), belongs to a new chemical class, and has both a new target and a new mode of action. Otsuka is not active in vaccine development. The company reports having an active in-house discovery programme for TB.

Above-average performance with comprehensive access and stewardship plan. Otsuka has an access plan and stewardship plan in place for its late-stage project – antituberculosis drug, quabodepistat. The access plan outlines measures for availability, affordability and sustainable supply. Clinical trials are currently ongoing in 5 countries in scope: China, Moldova, Peru, Philippines and South Africa. In addition, Otsuka has a stewardship plan in place to ensure the responsible use of quabodepistat. Access plans for consortium-led studies were not assessed.

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

Low-performing. Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. At its own sites, it reports compliance with discharge limits for delamanid's API but not for the drug product. It does not report on the level of compliance achieved at its suppliers' sites or whether it incorporates AMR provisions into supplier contracts. Otsuka does not publicly disclose the quantification methods implemented, or the level of compliance achieved across its supply chain.

Mitigates AMR risk at both its own sites and suppliers' sites through general environmental risk management strategy; reports compliance of antibacterials with discharge limits for its own sites but not for suppliers'. Otsuka adopts management and treatment practices for wastewaters and solid wastes from antibiotic manufacturing to minimise the impact of antibacterial discharge to the environment, but does not follow the AMR Industry Alliance Antibiotic Manufacturing Standard or WHO guidelines. Otsuka manufactures both the API and finished product for its sole in-scope medicine, delamanid, at its own sites. While the company confirms it does not regularly measure its discharge levels, it performed quantification for the first time during the period of analysis, reporting that the API was not compliant, but the drug product was. One intermediate used in delamanid production is manufactured by a third-party supplier, which Otsuka requests to adopt waste treatment practices aligned with its own. However, it is unclear whether contractual provisions have been implemented. Furthermore, it does not report measuring or reviewing discharge levels of a delamanid intermediate manufactured at its supplier's sites, and therefore it does not disclose whether it meets these discharge limits. Regarding external wastewater treatment plants, the company states that wastewater from delamanid production is treated in-house, with no involvement of external treatment facilities.

No publicly available information on environmental risk management to mitigate AMR. Otsuka does not publicly disclose practices to minimise the risk of AMR and ecological effects from antibacterial manufacturing at its own sites or its suppliers' sites. It therefore does not publicly disclose audit results, the number of products complying with PNECs, measured discharge levels or the names and locations of manufacturing sites per antibacterial product.

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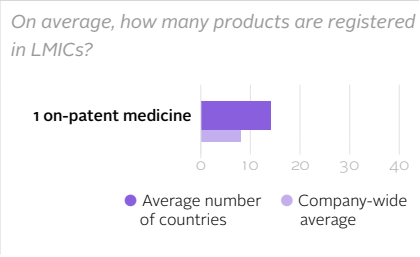
APPROPRIATE ACCESS & STEWARDSHIP	Indicators evaluated	C.1.1 ●	C.1.2 ●	C.1.3 ●	C.2.1 ●	C.2.2 ●	C.2.3 ●	C.3 ●	C.4 ●	C.5 ●

Mid-performing. Performs well in registering its sole in-scope medicine, delamanid (Deltyba®), in more countries than peers. Implements comprehensive access and some stewardship strategies, with its support for improved diagnostics in LMICs highlighted as a Best Practice in the Benchmark. It mitigates stockouts through demand planning and bi-weekly data sharing. Otsuka addresses appropriate use across its business practices and does not deploy sales agents for delamanid. It ensures ethical interactions with healthcare professionals, fair market value transfers, and discloses transfers of value in some countries. However, Otsuka lacks efforts on surveillance, with no active participation in AMR programmes during the analysis period.

Otsuka registers its sole product, delamanid, more widely than peers' on-patent medicines.



Otsuka registers its on-patent medicine targeting MDR-TB, delamanid (Deltyba®), in 14 countries,* including 4 countries where the corresponding disease burden is high (India, Kyrgyzstan, South Africa and Ukraine). In addition, Otsuka registers a paediatric formulation of delamanid in India. Otsuka has not reported engaging in mechanisms to facilitate registrations for delamanid; however, the product obtained WHO Prequalification through Viatris, one of its access partners.

Above-average performance, with comprehensive access strategy and some stewardship efforts for the only on-patent product assessed, delamanid (Deltyba®). Otsuka provides access to delamanid, a key component of 1 of WHO's recommended DR-TB regimens, through supranational procurement via the Stop TB Partnership's Global Drug Facility in 136 eligible countries. The company also operates a compassionate use programme for patients in countries where the drug is not yet marketed. Since 2023, Otsuka has set the price at $1,190[1] per treatment course of delamanid, which remains the main cost driver of the DR-TB regimen.[2] Otsuka monitors both the number of treatment courses supplied, and the countries reached. During the analysis period, over 120,000 adult courses were delivered to more than 135 countries, along with 1,469 paediatric courses across all channels. Finally, the company implements stewardship strategies to ensure the responsible promotion of delamanid and provides it free of charge for susceptibility testing through a third party in more than 50 countries.

Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality. Otsuka implements demand planning and data sharing through biweekly sales and operations planning meetings and a 1-month forecast horizon. Forecasting is cross-referenced with WHO's MDR-TB reports to ensure sufficient stocks are maintained. It does not report sharing forecasts with external stakeholders. Otsuka maintains a 1.5-year average buffer stock for all countries where it has market authorisation and its finished delamanid product is available in consignment stock for other countries. Otsuka's inventory is managed through annual onsite checks, but it is unclear whether it implements an automated inventory management system or supplier diversification strategies. It mitigates substandard and falsified medicines by verifying suppliers through GMP audits and implementing security features, such as serialised barcodes and track-and-trace systems. However, it is unclear whether it reports cases to relevant stakeholders. It does report that 2/2 of its own sites and its sole of its supplier site are GMP compliant. Delamanid is only manufactured in countries with stringent regulatory authorities. Therefore, it is not applicable for Otsuka to take additional quality measures in countries with less mature regulatory systems.

Clearly addresses appropriate use across its business practices. Otsuka does not deploy sales agents to sell and/or promote its antibacterial medicine Deltyba® (delamanid) to HCPs. Through its national policies in Europe and the US, Otsuka ensures all interactions with HCPs are ethical by specifying the legitimate need of such interactions. It also ensures that transfers of value (ToVs) are made at fair market value. A list of some of the countries where Otsuka discloses ToVs can be easily accessed on its website, and Otsuka voluntarily discloses information on ToVs publicly in Russia. Otsuka also applies its public policy to third parties working on its behalf.

No activities in AMR surveillance. Otsuka was not involved in any AMR surveillance programmes during the period of analysis. However, in multiple countries it supported national surveillance efforts by providing pure substance for drug susceptibility testing beyond routine clinical practice.

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

1. Results of the Global Drug Facility's 2024 Tender for Delamanid. (11 Nov 2024) https://www.stoptb.org/sites/default/files/documents/2024.11.11_DLM%20FAQ_FINAL_Posted%20with%20logo%20all%20pages.pdf

2. WHO Consolidated guidelines on tuberculosis. Module 3: Diagnosis. (April 2025) https://www.who.int/publications/i/item/9789240107984