

OVERALL PERFORMANCE

41%

# Johnson & Johnson

Research-based pharmaceutical company

Stock exchange: NYSE • Ticker: JNJ • HQ: New Brunswick, New Jersey, USA • Employees: 138,100

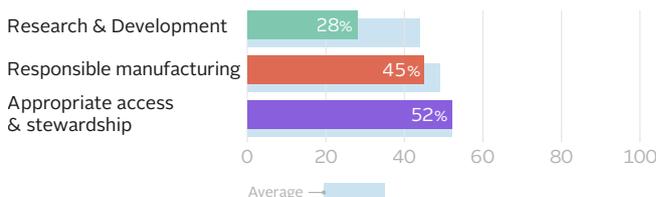
## PERFORMANCE IN THE 2026 BENCHMARK

**Mid-performing.** Johnson & Johnson's performance in R&D is low, with a significant decrease in projects, resulting in a small pipeline solely focused on *Mycobacterium tuberculosis*. Johnson & Johnson shows mixed performance across Responsible Manufacturing and Appropriate Access & Stewardship. Its environmental risk management strategy covers both its own and suppliers' sites, but the level of compliance is unclear for suppliers. It performs well in making bedaquiline, its sole product assessed, accessible through registrations and a comprehensive access strategy, and it shows Best Practice in supporting diagnostic capacity in India. However, it is no longer involved in AMR surveillance.

### How Johnson & Johnson was evaluated



### How score was achieved



## OPPORTUNITIES FOR JOHNSON & JOHNSON

**Advance bedaquiline (SIRTURO®) studies to address critical tuberculosis (TB) needs in LMICs.** Johnson & Johnson's closure of its R&D infectious disease & vaccine unit signalled a shift away from developing medicines and vaccines for diseases that disproportionately affect people in LMICs, leaving its antituberculosis drug, bedaquiline (SIRTURO®) as the only medicine assessed in this year's Benchmark. Despite this shift, the company can continue to advance clinical trials for bedaquiline (SIRTURO®) that are still in the pipeline. This includes studies in children under five years and a novel long-acting injectable formulation, with potential for TB prevention in populations at high risk of developing the disease. As development of the long-acting formulation – which could offer advantages in adherence in the treatment of latent TB infection – progresses beyond Phase I, Johnson & Johnson can develop an access and stewardship plan to ensure access in countries with a high burden of multidrug-resistant TB.

**Support AMR surveillance for bedaquiline (SIRTURO®).**

Johnson & Johnson does not report engaging in any AMR

surveillance programmes, following the completion of its post-marketing surveillance programme on bedaquiline – the Bedaquiline Drug Resistance Emergence Assessment in MDR-TB (DREAM) programme – in 2019. To help ensure continued monitoring and appropriate use of bedaquiline, the company can collaborate with other organisations to integrate the product into existing surveillance programmes, such as SENTRY.

**Ensure compliance with discharge limits directly in wastewater and improve transparency on levels of compliance achieved.** Johnson & Johnson publicly reports setting discharge limits in the receiving environment at its own and suppliers' sites, implementing mass balance estimations. 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 2023, the company closed its research and development (R&D) unit for infectious diseases and vaccines. Consequently, Johnson & Johnson no longer has any vaccines in development, and only one discovery project.
- In 2024, Johnson & Johnson's manufacturing site in Geel, Belgium received the BSI Kitemark™ for Minimized Risk of AMR Certification for the manufacture of bedaquiline.
- In February 2025, Johnson & Johnson and partner Sanofi announced the termination of the Phase III E.mbrace trial evaluating an extraintestinal pathogenic *E. coli* (ExPEC) vaccine candidate. The vaccine was not sufficiently effective in preventing invasive *E. coli* disease (IED) compared to the placebo. No safety signals related to the vaccine were identified.
- In July 2024, the US Food and Drug Administration (FDA) granted traditional approval for bedaquiline (SIRTURO®) for use, in combination therapy, in adults and children (≥5 years, ≥15 kg) with pulmonary multidrug-resistant TB. The FDA converted the approval from accelerated to traditional approval following confirmation of clinical benefit in a confirmatory trial.

# Johnson & Johnson

## SALES AND OPERATIONS

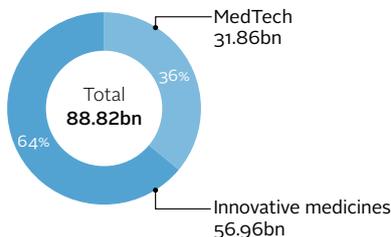
**Therapeutic areas:** Cardiovascular, immunology, infectious diseases, metabolic disorders, neuroscience, oncology, pulmonary hypertension

**Product categories:** Innovative medicines and MedTech

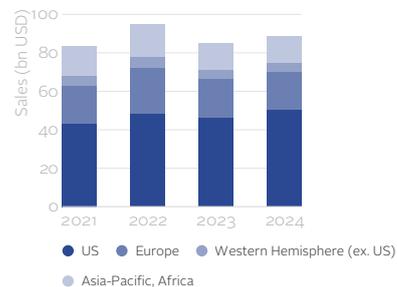
**Investments in AMR:** In 2020, Johnson & Johnson was a founding partner and invested USD 100mn in the AMR Action Fund, with the goal of bringing 2 to 4 new antibiotics to patients by the end of 2030.

**M&A news:** None identified in the antibacterial and/or antifungal sectors.

Sales by business segment (2024) – USD



Sales by geographic region – USD



## SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE BENCHMARK

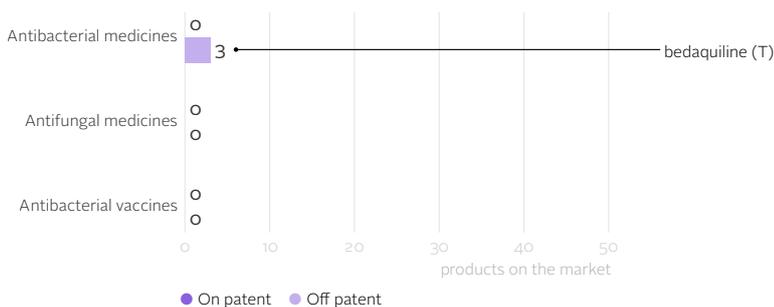
### PIPELINE for diseases in scope

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registered	Market approval	Total
Antibacterial medicine	1	0	1	3	0	0	0	5
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	1	0	1	3	0	0	0	5
Access plans			1*	0	0	0	0	0
Stewardship plans			0	0	0	0	0	0

### PORTFOLIO for diseases in scope

3 products in Johnson & Johnson's anti-infective portfolio

1 product selected for analysis



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

\*Access plans were assessed for only one project; consortium-led studies were not assessed.

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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
<p><b>Low-performing.</b> Johnson &amp; Johnson has a small pipeline, which has decreased significantly in size since the last Benchmark. All its remaining pipeline projects target <i>Mycobacterium tuberculosis</i>, a 'critical' priority pathogen, but the company no longer has any vaccines or innovative antimicrobial medicines in development. It has an access plan in place for its sole late-stage candidate but did not report any stewardship measures.</p>		●	●	●	●	●
<p><b>Small pipeline focused on adaptations of existing medicines targeting rifampicin-resistant <i>Mycobacterium TB</i>.</b> Johnson &amp; Johnson's small pipeline includes 5 antibacterial projects targeting pathogens in scope. Most projects are adaptations of its approved drug SIRTURO® (bedaquiline); its 2 self-developed projects include a long-acting formulation (Phase I) and a paediatric version (Phase II). In addition to its own trials, the company takes part in 2 consortia (PAN-TB and UNITE4TB) where the adult formulation of SIRTURO® (bedaquiline) – which is already approved as part of combination therapy for pulmonary multidrug-resistant TB (MDR-TB) – is being evaluated for new combination therapies. In addition, there is also published information on JNJ-2901, a novel Q203 analogue that shows activity against multidrug-resistant <i>Mycobacterium TB</i> clinical strains. All projects (5) target rifampicin-resistant <i>Mycobacterium TB</i>, a 'critical' pathogen as defined by WHO. The company no longer has any vaccines in its pipeline targeting pathogens in scope, nor does it have any medicines in its pipeline meeting any WHO innovation criteria. The company reports having an active in-house discovery programme for TB.</p>						
						<p><b>Above-average performance with comprehensive access plan but limited stewardship efforts.</b> Johnson &amp; Johnson has an access plan for its late-stage project evaluating a dispersible formulation of bedaquiline for MDR-TB for children under 5, with the aim of expanding registration to age groups for which it is not yet approved. The paediatric clinical trial is ongoing in 3 countries in scope of the Benchmark. As SIRTURO® (bedaquiline) is already approved for MDR-TB and widely registered in countries in scope, the Benchmark did not evaluate access plans for consortium-led studies involving the product. Johnson &amp; Johnson did not report a stewardship plan for its paediatric bedaquiline project.</p>

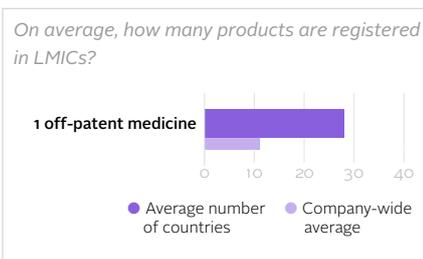
RESPONSIBLE MANUFACTURING	Indicators evaluated	B.1	B.2
<p><b>Mid-performing.</b> Reports an environmental risk management strategy aimed at mitigating AMR at both its own and suppliers' sites. It reports compliance levels achieved at its own sites (under an NDA) but not at its suppliers' sites, nor whether AMR provisions are included in supplier contracts. Johnson &amp; Johnson publicly discloses its quantification methods but not the level of compliance achieved across its supply chain.</p>		●	●
<p><b>Mitigates AMR risk at both its own sites and suppliers' sites; reports antibacterial compliance with discharge limits for its own sites and tracks compliance for suppliers'.</b> Johnson &amp; Johnson's comprehensive environmental risk management strategy incorporates the AMR Industry Alliance Antibiotic Manufacturing Standard (Industry Standard). It quantifies antibacterial discharge levels at its own sites using mass balance estimation verified by chemical analysis, if applicable, with audits conducted every 3 years. Its underlying quantification details (i.e., dilution factors and timeframe) are unclear. The company reports the level of compliance achieved at its own sites under an NDA. However, it did receive a BSI Kitemark™ for Minimised Risk of Antimicrobial Resistance Certification for bedaquiline at its manufacturing site in Geel, Belgium. The company requires antibacterial suppliers to follow the Industry Standard, including mass balance estimation, verified by chemical analysis. It conducts supplier audits at least once every 3 years using PSCI principles, including PNEC-based limits. It is unclear whether AMR provisions are in contracts or how many supplier products</p>			
			<p>meet discharge limits. Information on its practices regarding external waste treatment plants is provided under an NDA.</p> <p><b>Publicly discloses basic details of its AMR mitigation strategy but is not transparent about compliance with discharge limits.</b> Johnson &amp; Johnson publicly reports implementing the Industry Standard, quantifying discharge levels using mass balance estimation and verifying levels by chemical analysis. For both its own sites and its suppliers' sites, the company publicly reports conducting onsite audits on PNEC compliance. However, audit results – including the actual discharge levels – are not publicly disclosed; nor are the number of products complying with PNECs, or the names and locations of manufacturing sites for each antibacterial product.</p>

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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 by registering its sole in-scope medicine, bedaquiline (SIRTURO®), in more countries than peers and implementing access and stewardship strategies. Its support of improved diagnostics for bedaquiline in India is highlighted as a Best Practice in the Benchmark. The company takes steps to mitigate stockouts, maintaining buffer stocks of critical APIs and finished products. It addresses appropriate access through its business practices by not deploying sales agents for selected products, ensuring ethical interactions with healthcare professionals and fair market value transfers. However, it lacks efforts on surveillance, with no AMR programme participation.

**Johnson & Johnson registers its sole product, bedaquiline, more widely than peers' off-patent medicines.**



Johnson & Johnson registers its off-patent medicine targeting MDR-TB, bedaquiline (SIRTURO®), in 28 countries,\* including 11 countries where the corresponding disease burden is high. It also registers a paediatric formulation of bedaquiline in 11 countries. The company engages in multiple procedures to facilitate registration, including WHO's Collaborative Registration Procedure for WHO-Listed Authorities.

**Above-average performance, with comprehensive access strategy and some stewardship efforts for bedaquiline (SIRTURO®), the only off-patent/generic product assessed.** Johnson & Johnson provides bedaquiline, a key component in the treatment regimen for MDR-TB, for

supranational procurement across all countries served by the Stop TB Partnership's Global Drug Facility (GDF). Johnson & Johnson also granted GDF a licence to tender, procure and supply generic versions in the majority of LMICs. The company also does not enforce patents on bedaquiline in 134 LMICs; as such, bedaquiline was assessed as an off-patent product. The company reports the number of patients reached with bedaquiline. The company also ensures some level of responsible promotion and is working to address underdiagnosis of TB at a community level in India.

**Some efforts to mitigate stockouts/shortages. Some reported evidence of systems to ensure product quality.** Johnson & Johnson implements demand planning and data sharing by forecasting demand of bedaquiline (SIRTURO®) based on local tender patterns and utilisation trends in countries with high burdens, and distributor demand forecasts. The company also maintains buffer stocks of critical APIs and finished products and implements an automated inventory management system to prevent stock disruptions. However, the forecasting horizon or any supplier diversification efforts are not disclosed. It mitigates substandard and falsified products by verifying suppliers through GMP audits, reporting incidents to relevant authorities and implement-

ing security features. It reports that all its own and suppliers' sites are GMP compliant, however, it is unclear whether the company takes additional mitigation steps in countries with evolving regulatory systems.

**Includes elements to address appropriate use across its business practices.** Johnson & Johnson partly decouples incentives for its sales agents from sales volume targets, but these targets are set at the individual level. The ratio of quantitative and qualitative targets, the former including sales volume targets, was disclosed under an NDA. However, the sales incentive plan is not applicable for bedaquiline (SIRTURO®), as it does not deploy sales agents for the product. Through its global public positions/policy, Johnson & Johnson ensures all interactions with HCPs are ethical by specifying the legitimate need for such interactions and how to mitigate potential conflicts of interest. It also ensures that transfers of value (ToVs) are made at fair market value. While Johnson & Johnson abides by transparency requirements, it does not voluntarily disclose ToVs publicly in countries where it is not mandated to by law, or by other codes of practice. Johnson & Johnson applies its public policy to third parties working on its behalf. For its sales incentive plan, this is handled on a case-by-case basis.

**No activities in AMR surveillance.** Johnson & Johnson was not involved in any AMR surveillance programmes during the period of analysis. Its previous surveillance programme 'Bedaquiline Drug Resistance Assessment in MDR-TB (DREAM)' ended in 2019.

\*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'.