Overall Performance

2020	2021
68%	68%=

Johnson & Johnson

Large R&D-based pharmaceutical company

Stock exchange: NYSE • Ticker: JNJ • HQ: New Brunswick, NJ, USA • Employees: 136,400

PERFORMANCE

Johnson & Johnson performs above average overall in its evaluated Research Areas compared to the other large research-based pharmaceutical companies in scope.

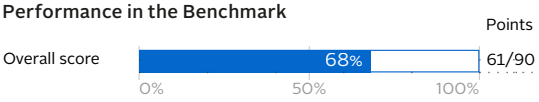
R&D: Johnson & Johnson is a middle-performing company in the R&D Research Area. Its 14-project pipeline has two vaccines. It has projects that target critical and/or urgent pathogens. Its two late-stage development projects are covered by project-specific access plans.

Responsible Manufacturing: Performs strongly. Reports comprehensive environmental risk-management strategy for own sites and suppliers; quantifies discharge levels at all own sites.

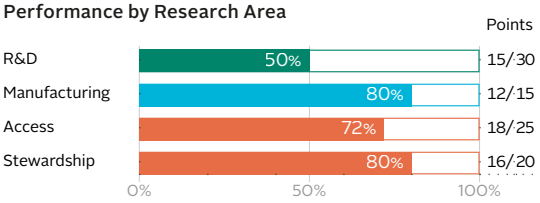
Appropriate Access: Performs well. Files some of its on- and off-patent medicines for registration in access countries. Reports some strategies to expand access and ensure continuous supply of its relevant products.

Stewardship: Performs well. It generally does not promote bedaquiline (Sirturo®) to healthcare professionals. It shares raw data of its DREAM surveillance programme in a restricted manner. It reports comprehensive conflict of interest mitigation for its educational programmes. It adapts brochures and packaging for patients.

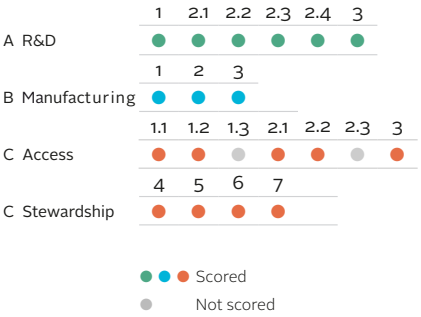
Performance in the Benchmark



Performance by Research Area



How Johnson & Johnson was evaluated



OPPORTUNITIES FOR JOHNSON & JOHNSON

Diversify access plans for late-stage R&D projects. Johnson & Johnson has one medicine and one vaccine in late-stage development. It can improve access to these new products, by developing plans for registration, affordability and sustainable supply. For example, for their phase III vaccine, ExPEC9V, Johnson & Johnson can define the access countries where they will file for registration, based on burden of disease, and where it considers ability-to-pay in its pricing strategy. Johnson & Johnson can also engage with external partners with the expertise to help boost availability of the vaccine in relevant territories once approved.

Ensure compliance with antibacterial discharge limits at own sites and suppliers by tracking and publicly disclosing progress and results. Johnson & Johnson reports to set limits and to quantify the discharge levels at its own sites and suppliers' sites. To provide clear evidence of its progress, it can track compliance at all sites and publicly disclose the results. Disclosure of information, including the results of audits and antibacterial discharge levels of its own sites and suppliers' sites, is important. It can also publicly disclose the names and locations of its suppliers and waste-treatment plants for increased transparency.

Expand reach of bedaquiline (Sirturo®) for eligible MDR-TB patients. Johnson & Johnson has continued to reach more patients with MDR-TB through tenders, patient assistance programs, access price settings and public or private partnerships. It can further apply these mechanisms to expand access and ensure diagnosed patients are treated, especially in countries where gaps remain between diagnosis of MDR-TB and treatment.

Fully decouple incentives for sales agents from sales volumes. Johnson & Johnson does not promote bedaquiline (Sirturo®) in most countries. Johnson & Johnson can apply the practice of not promoting this product globally. Further, it can fully decouple incentives for sales agents from sales volumes of all antibacterial and antifungal medicines.

Publicly share raw data from surveillance programme. Johnson & Johnson runs the multinational Drug Resistance Emergence Assessment in MDR-TB (DREAM) programme, which is focused on resistance against bedaquiline (Sirturo®). It can publicly share raw data from this surveillance programme, anonymised and in a freely accessible format.

CHANGES SINCE 2020

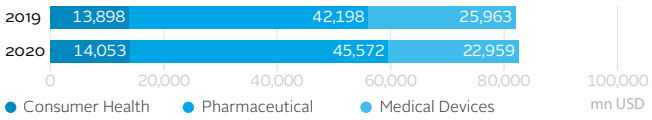
- Johnson & Johnson launched its inaugural satellite center for Global Health Discovery hosted at LSHTM focused on addressing the threat of AMR and TB.
- In February 2020, Johnson & Johnson joined the Project to Accelerate New Treatments for Tuberculosis (PAN-TB), a collaboration among philanthropic, non-profit and private sectors partners that aims to develop an investigational drug regimen capable of treating all forms of TB.
- Johnson & Johnson is funder and member of the consortium VALUE-Dx. VALUE-Dx is the first Innovative Medicines Initiative project initiated by six *in vitro* diagnostic companies who work with 20 non-industry partners to combat AMR and improve patient outcomes.
- Johnson & Johnson received two FDA indication extension approvals for bedaquiline (Sirturo®)* for MDR-TB in adolescents (12 - <18years) and pediatrics indications (5 - <12years).
- In 2020, Johnson & Johnson collaborated with the GDF Stop TB to reduce the price of bedaquiline in eligible low- and middle-income countries.

* As part of combination therapy of pulmonary tuberculosis due to multi-drug resistant *M. tuberculosis*.

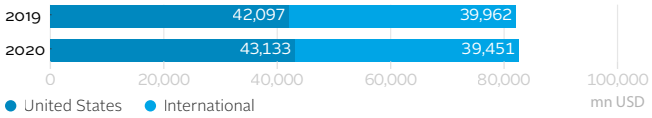
SALES AND OPERATIONS

Therapeutic areas: Cardiovascular/metabolism/(other), Immunology, Infectious diseases, Neuroscience, Oncology, Pulmonary hypertension.
Business segments: Consumer health, Medical devices, Pharmaceutical
Product categories: Consumer health products, Medical devices, Innovative medicines, Vaccines
M&A since 2020: None in the antibacterial and/or antifungal sectors

Sales by business segment



Sales by region



PIPELINE *for pathogens in scope*

Pipeline size: 14 projects targeting pathogens in scope** (12 antibacterial medicines; 2 antibacterial vaccines).
Development stages: 1 clinical project, ExPEC9V (formerly ExPEC10V) a Phase III, 9-valent vaccine for the prevention of invasive extraintestinal pathogenic *E. coli* disease in adults; and 12 discovery/preclinical projects.
Novelty: 0 novel clinical-stage medicine projects.
'Critical' and/or 'urgent' pathogens: Projects targeting invasive extraintestinal pathogenic *E. coli* (ExPEC) and *P. aeruginosa*.
Regulatory approvals: 2 approvals. In August 2019, marketing authorisation by the FDA was granted for the adolescent indication (12 - <18 years) of the MDR-TB drug bedaquiline (Sirturo®)* and in May 2020, for the paediatric indication (ages 5 - < 12 years).

PORTFOLIO *for pathogens in scope*

Comparatively small portfolio: At least 8 products: 3 antibacterial medicines; 5 antifungal medicines
On-patent medicines: 1 bedaquiline (Sirturo®)
Off-patent/generic medicines: 3 of 7 were selected for analysis** (itraconazole [F], levofloxacin [W], miconazole [F])
AWaRe medicines*:** 1 Watch group
Anti-TB medicines*:** 1

Pipeline for priority pathogens

Products on the market

PERFORMANCE BY RESEARCH AREA

A RESEARCH & DEVELOPMENT Evaluated: medicine & vaccine pipelines for priority** bacteria & fungi

A.1 Investments in R&D

Johnson & Johnson does not disclose publicly, or to the Benchmark, its R&D investments during 2019 and 2020 in antibacterial and antifungal medicines and/or vaccines for pathogens in scope. Johnson & Johnson has pledged USD 100 mn to the AMR Action Fund over the next ten years.

A.2.1 Medium-sized pipeline

The company has 14 projects targeting pathogens in scope: 12 medicines and two vaccines, all targeting bacterial pathogens. Out of the 14 projects, eight are in discovery stage, four are in preclinical stage, one is in clinical development and one received marketing approval during the period of analysis.

A.2.2 No clinical-stage novel medicines

Johnson & Johnson's clinical-stage medicine pipeline consists of one candidate, the paediatric adaptation of bedaquiline (Sirturo®). Johnson & Johnson does not currently have any medicine candidate that is considered novel in clinical development.

Pipeline targeting priority pathogens: 14† *As at 24 September 2021*

Discovery	Pre-clinical	Phase I	Phase II	Phase III	Approval
	♦ *S. aureus* vaccine			♦ Extraintestinal pathogenic *E. coli* vaccine (ExPEC9V)‡	Bedaquiline (Sirturo®) [*M. tuberculosis*] [FDA/Aug-19]: additional population: adolescent (12 - <18 years) [FDA/May-20]: additional population: paediatric (5 - <12 years)
				♦ Vaccine	

† Includes 11 confidential projects not shown in the figure.
‡ Progressed to Phase III after the end of the period of analysis.

**See Appendix V for information about eligibility for R&D projects and Appendix VII for eligibility criteria of products.
***Listed on the 2019 WHO EML.

A.2.3 Two vaccine candidates

Johnson & Johnson reports two vaccine projects in its pipeline. Its clinical-stage candidate, ExPEC9V is a Phase III vaccine targeting extraintestinal pathogenic *E. coli*. Johnson & Johnson also has a vaccine candidate against *S. aureus* in preclinical stage.

A.2.4 Candidates targeting critical and/or urgent priorities

Johnson & Johnson has projects targeting pathogens defined as 'critical' by WHO's list of priority pathogens and/or characterised as 'urgent' threats by the US Centers for Disease Control and Prevention (CDC). In clinical development, Johnson & Johnson has a vaccine candidate, ExPEC9V, that targets extraintestinal pathogenic *E. coli*. Johnson & Johnson also has projects that target *P. aeruginosa*.

A.3 Access and stewardship plans for late-stage projects

Johnson & Johnson has one vaccine (ExPEC9V) and one medicine in late-stage development [bedaquiline (Sirturo®)]. They are both covered by project-specific access plans.

The current stewardship activities ongoing for the adult indication of bedaquiline (Sirturo®) will extend to the new pediatric approval: for use in patients aged 5 - < 12 years and weighing at least 15 kg.

There are no clinical trials running in access countries[§] for the EXPEC9V vaccine, but Johnson & Johnson is planning to expand its Phase III trial to access countries.

B RESPONSIBLE MANUFACTURING Evaluated: antibacterials manufacturing (APIs and drug products)

B.1 Comprehensive environmental risk-management for own sites and suppliers; sets limits at own sites and suppliers

Johnson & Johnson reports a comprehensive strategy to minimise the environmental impact of wastewaters and solid waste generated from antibacterial manufacturing at its sites, including conducting audits every three years. It reports setting discharge limits in the receiving waters for all antibacterials manufactured at its sites, based on PNECs to limit AMR, as recommended by the AMR Industry Alliance. Johnson & Johnson also reports quantifying discharge levels at all its own sites using a mass balance approach, verified by chemical analysis if applicable.

Johnson & Johnson requires third-party suppliers of antibacterial APIs and drug products to follow the same standards, including limits based on PNECs. It reports conducting on-site audits of its suppliers typically every three years. Johnson & Johnson requests and reviews the discharge levels of its suppliers. It does not report how many suppliers have quantified discharge levels and are compliant with limits.

Johnson & Johnson expects external private waste-treatment plants to comply with its general environmental standards. Johnson & Johnson reports that it audits private waste-treatment plants based on risk and region. It also employs conservative measures for effluents sent to external public wastewater treatment plants.

B.2 Publicly discloses some information on environmental risk management

Johnson & Johnson publishes some components of its environmental risk-management strategy. It is a member of the AMR Industry Alliance, which publishes a list of recommended antibacterial discharge targets. It discloses that it has completed audits and an environmental risk assessment of all its pharmaceutical suppliers located in China and India, which also covers antibacterial discharge levels. Johnson & Johnson does not publish: (1) the results of environmental audits, conducted at its own sites, the sites of suppliers and/or external private and public waste-treatment plants; (2) a list of these suppliers 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

Johnson & Johnson reports that its 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. In general, Johnson & Johnson also requires its pharmaceutical suppliers to audit their own supplier sites based on risk. The Benchmark found no requests for official corrective action from the FDA or EMA related to non-conformities with cGMP at Johnson & Johnson's own sites or any subsidiaries that manufacture antibacterials.

C APPROPRIATE ACCESS & STEWARDSHIP – ACCESS

Evaluated: access activities relating to antibacterial & antifungal medicines & vaccines in 102 access countries[§]

Johnson & Johnson is not eligible for indicators: C.1.3 and C.2.3. For more information, see Appendix VII.

C.1.1 Filed to register on-patent medicines in 30 access countries

Johnson & Johnson performs above average, filing its one relevant on-patent medicine for registration in 30 access countries, including eight LICs. The medicine is the MDR-TB medicine bedaquiline (Sirturo®). Johnson & Johnson publicly discloses on its company's website where bedaquiline was filed for registration.

C.1.2 Filed to register off-patent/generic medicines in 29 access countries on average

Johnson & Johnson performs above average, filing all its three sample off-patent/generic medicines for registration in 29 access countries on average. All its three sample products are filed for registration in at least one LIC.

C.2.1 Several strategies to expand access to its on-patent medicine

Johnson & Johnson performs above average. It aims to expand access to its one relevant on-patent medicine in access countries through tenders, patient assistance programs, access price settings and public or private partnerships. It collaborates with the GDF-Stop TB Partnership to provide 100 mg bedaquiline at a global access price of USD 340 per 6-month treatment course to GDF-eligible countries. The GDF-Stop TB Partnership also provides the paediatric formulation of bedaquiline (20 mg) at a price of USD 200 per 6-month treatment course. Johnson & Johnson provides evidence of patient reach and geographic reach for all its reported approaches. It publicly commits to providing its MDR-TB medicine to a cumulative 700,000 patients worldwide by 2025. Bedaquiline is available in all 30 WHO high-burden countries for MDR-TB.

C.2.2 Limited information on strategies to expand access to off-patent/generic medicines

Johnson & Johnson has an average performance. It has set equitable tiered-pricing principles and publicly states to apply equitable pricing policies to its antifungal itraconazole and antibiotic levofloxacin. Johnson & Johnson provides evidence of patient reach and geographic reach for two of its three relevant products in scope. Details were provided under the basis of confidentiality.

[§] 102 low- and middle-income countries where better access to medicine is most needed.

C.3 Several strategies to ensure continuous supply

Johnson & Johnson performs above average, with strategies reported in all four areas assessed. It ensures accurate demand planning and data sharing by forecasting demand of bedaquiline (Sirturo®) based on local tender patterns and utilization trends in high burden MDR-TB countries, distributor demand forecasts and global donor grant budgeting cycles. It mitigates against shortage risks by keeping a buffer stock for APIs and finished products. Both bedaquiline API and finished product are manufactured in India with flexibility to scale production. It reports several capacity building or technology transfer initiatives including a technology transfer for the formulation, filling, and packaging processes of bedaquiline including with Pharmstandard (Russia). It mitigates substandard and falsified products by having a dedicated team. It uses packaging security features and digital technologies to detect illicit trade.

C APPROPRIATE ACCESS & STEWARDSHIP – STEWARDSHIP

Evaluated: stewardship activities relating to antibacterial & antifungal medicines globally

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

Johnson & Johnson performs strongly in conflict of interest (COI) mitigation for the five AMR-related educational programmes for HCPs assessed by the Benchmark. To mitigate COI for all five programmes, it provides financial resources to independent third parties (The Union, the Chinese and Indonesian governments) to carry out the programme.

C.5 Engages in sales practices but does not engage in marketing practices to address appropriate use

Johnson & Johnson performs above average in sales practices. It does not deploy any sales agents to promote bedaquiline (Sirturo®) to healthcare professionals except in one country. However, for the remaining antibacterial and/or antifungal medicines it does not report whether it decouples incentives for sales agents from sales volumes to help prevent the inappropriate use of such medicines.

Johnson & Johnson does not engage in marketing practices that aim to address the appropriate use of its antibacterial and/or antifungal medicines as its marketing materials do not reflect emerging resistance trends or include treatment guidelines for healthcare professionals.

C.6 Makes two types of brochure and/or packaging adaptations to facilitate appropriate use by patients

Johnson & Johnson adapts brochures and packaging to facilitate the appropriate use of bedaquiline (Sirturo®) by patients. Johnson & Johnson performs well, taking account of language and adherence to treatment. It produces a package insert with information in four languages to streamline distribution. Further, it packaged a 6-month treatment regimen in a single bottle to facilitate patient adherence to treatment.

C.7 Active in one AMR surveillance programme; shares raw data in a restricted manner

Johnson & Johnson runs the multinational Drug Resistance Emergence Assessment in MDR-TB (DREAM) programme, which is focused on resistance against bedaquiline (Sirturo®) in 11 countries and has been running since 2015. Johnson & Johnson shares the raw data (from its clinical trials) through the Yale University Open Data Access (YODA) platform, which can only be accessed via approval through an independent scientific committee.