

RANK	SCORE
<b>3</b> ▼	<b>3.05</b>
2 (2016)	

# Johnson & Johnson

Stock Exchange: New York Stock Exchange • Ticker: JNJ • HQ: New Brunswick, New Jersey, United States • Employees: 134,000

## PERFORMANCE

Falls 1 place to 3<sup>rd</sup>. Remains a leader in access through both its Global Public Health unit and its strong approach to Capacity Building. It slips in part as its access approach focuses on a narrower set of diseases in scope compared to other companies.

**Management:** Rises two places to 4<sup>th</sup>, with a robust internal structure for ensuring senior responsibility for access.

**Compliance:** Falls three places to 9<sup>th</sup>, against stronger performance of peers in internal controls for compliance.

**R&D:** Falls 1 place to 4<sup>th</sup>, in part due to a lower proportion of late-stage projects with access plans compared to the other leaders, despite a solid performance overall.

**Pricing:** Falls from 2<sup>nd</sup> to 10<sup>th</sup> place due to comparatively small proportion of portfolio that is covered by equitable pricing strategies.

**Patents:** Rises from 7<sup>th</sup> to 5<sup>th</sup> place, supported by the increased transparency of its patents held in low- and middle-income countries.

**Capacity:** Rises to 2<sup>nd</sup> place, with initiatives meeting all good practice standards in all areas of capacity building.

**Donations:** Falls from 3<sup>rd</sup> to 9<sup>th</sup> place associated in part due to poorer public transparency for some donation programmes.

## OPPORTUNITIES

**Continue to expand its Global Public Health access approach.** During the period of analysis, Johnson & Johnson successfully incorporated an additional disease area (mental health) into the ambit of its Global Public Health unit. The company can continue to review its portfolio and pipeline to consider additional priority areas for action, e.g., diabetes, cardiovascular disease, and cancer.

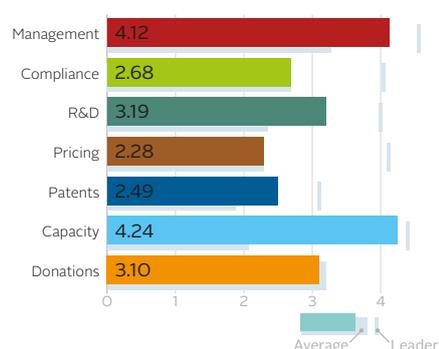
**Establish access plans for all late-stage R&D projects.** Johnson & Johnson can further apply the approach of its Global Public Health unit and establish access plans for all of its late-stage R&D projects, especially projects addressing a priority gap, to ensure broader access to more patients as soon as possible following market approval.

**Focus on registering key products in countries in scope.** The company's participation in the WHO's Collaborative Procedure for Accelerated Registration is a promising step towards faster registration of new products. The company can apply lessons from this pilot to help expedite registration of other recently launched products in more priority countries.

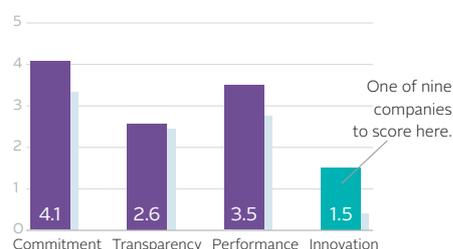
**Extend pledge not to enforce patent rights, and its engagement in voluntary licensing.** Johnson & Johnson can extend its pledge not to enforce IP rights to more high-need products beyond darunavir (Prezista®). Likewise, Johnson & Johnson can expand its use of non-exclusive voluntary licensing to ensure access to and supply of more of its on-patent products listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

**Scale up well-structured initiatives.** Johnson & Johnson's Born on Time initiative seeks to address the factors that can lead to preterm birth. It meets all good practice standards looked for by the Index. There is an opportunity for Johnson & Johnson to extend its commitment to this initiative, which is currently set to end in 2020, to support the expansion of activities to more countries which have expressed a need (the initiative is currently running in Bangladesh, Ethiopia, and Mali). Countries in scope with the highest burden of preterm birth are Nigeria, Pakistan and India.

### Performance by technical area



### Performance by strategic pillar



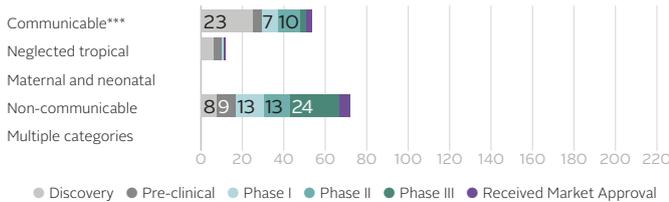
## CHANGE SINCE 2016

- Joined Access Accelerated with multiple initiatives such as Helping Babies Breathe and Born on Time.
- Published Health for Humanity report with progress on access-to-medicine initiatives, and with such data independently verified.
- Launched a new pilot programme in Rwanda focused on improving access to mental healthcare.
- Discloses publicly the patent statuses for small molecules in scope via the Pat-INFORMED platform.
- Strengthened its process to develop access provisions during development using a Value, Access and Pricing (VAP) framework to assess affordability of all R&D projects, with access plans being established from Phase II onwards.
- Expanded Johnson & Johnson Innovation for global public health to accelerate R&D for HIV/AIDS, tuberculosis, maternal and child health and other diseases through unique inter-sector partnerships.

**PIPELINE** for diseases and countries in scope

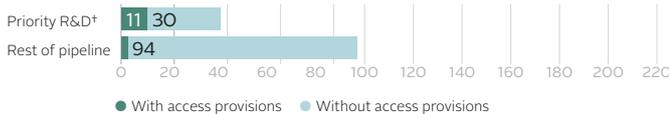
**Comparatively large pipeline:** 138\* R&D projects for diseases in scope (111 medicines; 17 preventive vaccines; 6 diagnostics; 4 therapeutic vaccines).  
**Clinical candidates:** 70, including a mosaic HIV-1 preventive vaccine candidate and pimodivir for the treatment of influenza type A, both in Phase II.  
**Regulatory approvals:** 9, including mebendazole (Vermox™ Chewable) for the treatment of soil-transmitted helminthiasis in children and adults.  
**R&D focus:** non-communicable diseases (cancer and diabetes mellitus), communicable diseases (lower respiratory infections and HIV/AIDS) and neglected tropical diseases (dengue).  
**Access provisions:** for 14 projects, most commonly registration commitments.

**Projects in the pipeline: 138\*\***



Johnson & Johnson's pipeline contains a Phase III preventive vaccine for Ebola and the only leprosy project in the collective company pipeline: a new indication for multidrug-resistant tuberculosis for bedaquiline.

**Projects for R&D priority targets with access provisions : 11**



Of Johnson & Johnson's 138 R&D projects, 14 are supported by access provisions: e.g., bedaquiline (Sirturo®) for the treatment of multidrug-resistant TB in children involves a commitment to register in high-burden countries in scope. Eight of its 58 late-stage projects have provisions.

**BUSINESS CONTEXT**

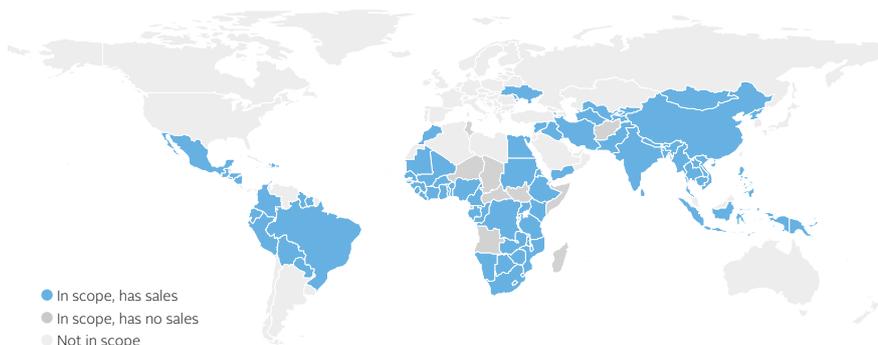
**Three business units:** Consumer Healthcare; Pharmaceuticals; and Medical Devices. The pharmaceutical segment has six therapeutic areas (immunology; infectious diseases and vaccines; neuroscience; oncology; cardiovascular diseases; and metabolism and pulmonary hypertension).  
**M&A news:** 2017 acquisition of Actelion Pharmaceuticals, a biopharmaceutical company specialising in drugs for unmet high priority medical needs.

**Presence in emerging markets:** In the 2018 Index, Johnson & Johnson is one of the companies with sales in the highest number of countries in scope. It reports sales in 85 countries in scope; 16 more countries than in the 2016 Index. It reports that almost 20% of its sales in 2017 came from Asia-Pacific and Africa.

**Sales by segment (2017) - USD**

Consumer	13,600 MN
Pharmaceuticals	36,300 MN
Medical Device	26,600 MN
<b>Total</b>	<b>76,500 MN</b>

**Sales in countries in scope**



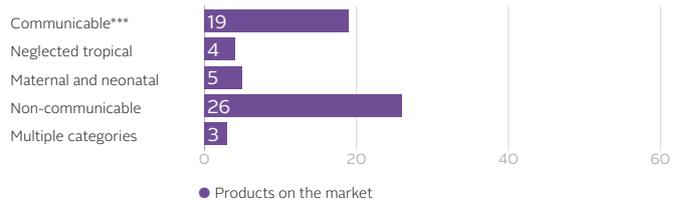
Statistics relate only to diseases and countries in scope.  
 \*Projects that target multiple product types are counted more than once.

\*\*Figure excludes 6 projects that do not fall into the listed phases of development: e.g., technical lifecycle projects, diagnostics, platform technologies, vector control products, investigator sponsored trials and Phase IV projects.

**PORTFOLIO** for diseases and countries in scope

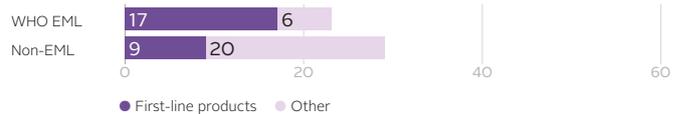
**Mid-sized portfolio:** 57 products for diseases in scope (45 medicines; 5 contraceptive methods; 5 diagnostics; 2 preventive vaccines).  
**Portfolio focus:** non-communicable diseases (diabetes mellitus and schizophrenia), communicable diseases (HIV/AIDS) and maternal & neonatal health conditions (contraceptive methods).  
**Essential medicines:** 44% of Johnson & Johnson's medicines and vaccines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).  
**First-line treatments:** 50% of Johnson & Johnson's medicines and vaccines have first-line indications for diseases in scope.

**Products on the market: 57**



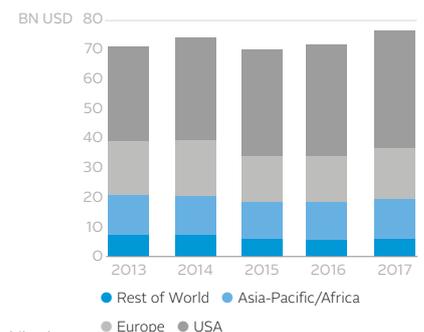
Johnson & Johnson's portfolio includes products such as bedaquiline (Sirturo®) for multidrug-resistant tuberculosis, fixed-dose dolutegravir/rilpivirine (Juluca®) and darunavir (Prezista®).

**Essential medicines with first-line indications: 17**



62% of Johnson & Johnson's medicines and vaccines are listed on the WHO EML and/or as first-line treatments: e.g., mebendazole (Vermox®) and the long-acting antipsychotic haloperidol decanoate (Haldol® Decanoate).

**Sales by geographic region**



\*\*\*Neglected Tropical Diseases, while also communicable, are highlighted separately throughout the Index. See Appendix II.  
 †See Appendix IV for definition.

# Johnson & Johnson

## PERFORMANCE BY TECHNICAL AREA

### GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 4 SCORE 4.12

**Has a strong access-to-medicine strategy with executive-level responsibility.** Johnson & Johnson is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals, and aligns with its corporate strategies. The strategy centres around promoting access to certain medicines within the company's portfolio, utilising strategies such as equity-based tiered pricing and partnerships with local organisations. The highest level of responsibility for access sits with the executive committee.

**Financial and non-financial access-related incentives to reward employees.** Johnson & Johnson performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include annual performance bonuses and long-term incentives based on individual performance. Senior management has a separate incentive that supports the company's long-term access oriented objectives.

**One of 16 companies working on impact measurement.** Johnson & Johnson measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on its commitments, objectives, targets and performance information. For example, it publicly shares its targets and independently verifies data in its Health for Humanity report. Furthermore, it is one of the companies that is measuring impact through a monitoring and evaluation framework that includes impact targets, for at least one access initiative, New Horizons.

**Clear and transparent stakeholder engagement approach that includes local stakeholders.** Johnson & Johnson publicly discloses which stakeholder groups it engages with on access issues, as well as its process for selecting who to engage with. It selects by using different processes for each stakeholder group. Johnson & Johnson does not share a specific policy for responsible engagement but it has some policies covering responsible interactions with stakeholders, namely guiding its interactions with stakeholders for improving access.

### MARKET INFLUENCE & COMPLIANCE

RANK 9 SCORE 2.68

**Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards.** Johnson & Johnson has a code of conduct relating to ethical marketing and anti-corruption, and provides regular compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Yet, expected performance for sales agents is based solely on sales targets. The company reports that for some products it does not deploy sales and marketing representatives to facilitate sales.

**Internal control framework meets some Index criteria.** Johnson & Johnson's internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place. It performs regular evaluations that also apply to third parties, and it has a monitoring system for compliance. However, Johnson & Johnson does not report conducting fraud-specific risk assessments, nor does it demonstrate having procedures to segregate duties, so that decisions are checked by another party.

**Above average transparency regarding access-related practices.** Johnson & Johnson publicly discloses its policy positions on access-related topics (e.g., its position on universal health coverage, and intellectual property). Johnson & Johnson reports that outside the US, it only makes political contributions in Australia, Canada and Japan; and these contributions are tracked at the local level. It discloses its membership and financial contributions to relevant organisations. It also discloses its policies for responsible engagement with its charter for general oversight. Johnson & Johnson does not publicly disclose its policy approach for payments made to healthcare professionals in countries in scope.

### RESEARCH & DEVELOPMENT

RANK 4 SCORE 3.19  
PROJECTS: 138 IN CLINICAL DEVELOPMENT: 70

**Publicly commits to R&D to meet public health needs.** Johnson & Johnson has publicly committed to R&D for diseases and countries in scope. Its R&D strategy for low- and middle-income countries is informed by an evidence-based public health rationale based on public health

targets. Further, it has time-bound strategies for completing R&D projects for diseases in scope and evaluates progress toward these targets. Johnson & Johnson has one of the largest pipelines in the Index with 138 projects. For diseases in scope where priorities exist, Johnson & Johnson is active in 58 projects; 41 of these target priority R&D gaps.

**Access provisions in place for 14% (8/58) of late-stage candidates.** Johnson & Johnson has a clear process in place to develop access plans during R&D. The process considers all R&D projects for diseases in scope using its Janssen Value, Access and Pricing (VAP) framework. In general, Johnson & Johnson begins to develop access plans for R&D projects in Phase II of clinical development. To date, Johnson & Johnson has project-specific access provisions in place for eight of its late-stage R&D projects. Of these, two are being conducted in partnership.

**Policy to ensure post-trial access; commits to registering trialed products.** Johnson & Johnson has a policy for ensuring post-trial access to treatments for clinical trial participants and has provided a detailed example of this policy in action in countries in scope. However, this policy is not publicly available. The policy is aligned with the standards set in the Declaration of Helsinki. Once a product is approved, Johnson & Johnson commits to registering it in all countries where clinical trials for the product have taken place.

### PRICING, MANUFACTURING & DISTRIBUTION

RANK 10 SCORE 2.28  
PRODUCTS: 57  
COVERED BY EQ. PRICING STRATEGIES WHICH TARGET AT LEAST ONE PRIORITY COUNTRY: 5

**Does not publicly commit to equitable pricing or report a commitment to file to register new products in scope.** Johnson & Johnson does not commit to filing its newest products for registration in countries in scope within one year of first market approval. Neither does it publicly commit to implementing equitable pricing strategies. However, it does have equitable pricing strategies for some products in scope of the Index.

**No new products in scope filed for registration in the majority of priority countries.** Johnson & Johnson has not filed any of its newest products for registration to date in more than half of the relevant priority countries (disease-spe-

cific subsets of countries with a particular need for access to relevant products). Its most widely registered product, for schizophrenia, is registered in five out of 12 possible priority countries. However, it publicly shares partial registration information for the majority of its products.

**9% of products have equitable pricing strategies targeting priority countries.** Johnson & Johnson's overall performance is below average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 9% of its products for diseases in scope. These strategies apply to an average of 70% of priority countries. All of these strategies apply inter-country pricing; these take into account an average of two socioeconomic factors.

**Globally consistent recall guidelines for countries in scope but no processes to track products.** Johnson & Johnson has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

## PATENTS & LICENSING

RANK 5 SCORE 2.49

**Publicly discloses detailed information on patent statuses.** Like most of its peers, Johnson & Johnson publicly discloses the patent statuses for small molecules in scope via the Pa-INFORMED platform. This will be periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

**Uses licensing and non-assert declarations to enable generic supply.** Johnson & Johnson has a non-exclusive voluntary licensing agreement in place for one compound (for diseases in scope). Its licence, for rilpivirine (Edurant®), encompasses 88 countries, including 58 middle-income countries in scope. It has also issued a non-assert declaration for one patented compound in scope, darunavir (Prezista®).

**Shares some IP assets with 3<sup>rd</sup>-party researchers.** Compared to its peers, Johnson & Johnson shares some IP assets with third-party researchers developing products for diseases in scope. This includes four shared with research institutions, such as the University of Toronto and the Walter and Eliza Hall Institute of Medical Research. The assets shared include molecule libraries.

**Public commitment not to enforce patents in countries in scope.** Johnson & Johnson commits publicly not to enforce certain patents related to diseases within the scope of the Index. This commitment is limited to darunavir (Prezista®), for the treatment of HIV/AIDS, in sub-Saharan Africa and in Least Developed Countries.

## CAPACITY BUILDING

RANK 2 SCORE 4.24

**23 initiatives included for evaluation.** Johnson & Johnson has 23 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Johnson & Johnson submitted the maximum.

**Strong focus on strengthening capacity of local R&D, manufacturing and health systems.** Johnson & Johnson has initiatives which meet inclusion criteria in all five areas of capacity building. It has at least one initiative in each area which meets all good practice standards. Johnson & Johnson performs strongest in manufacturing capacity building, R&D capacity building and health system strengthening.

**11 initiatives meet all applicable good practice standards:**

- GPH R&D Training Fellowship Program
- Asia Regional Pharmacovigilance Workshop
- Connect for Life™
- The Private Provider Interface Agency
- Born on Time

A full list of Johnson & Johnson's capacity building initiatives that meet all good practice standards can be found online.

Its remaining included initiatives typically have goals & objectives and good governance structures in place. However, it commonly falls short on measuring progress and outcomes in areas outside of health system strengthening.

**Does not provide evidence of reporting sub-standard or falsified medicines within the recommended timeframe.** Johnson & Johnson has a policy of reporting cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert. However, it does not require reporting to occur within the time frame of seven days looked for by the Index\*.

## PRODUCT DONATIONS

RANK 9 SCORE 3.10

STRUCTURED DONATION PROGRAMMES: 4

**Responds to emergencies and humanitarian crises and tracks delivery.** Johnson & Johnson donated medicines on the request of relief agencies. For example, during the period of analysis, it donated various products in response to the 2016 hurricane in Haiti. The company discloses that such *ad hoc* donations are aligned with international guidelines (issued by WHO, PQMD), and it works with various organisations to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

**Four donation programmes covering diseases and countries in scope.** Johnson & Johnson's programmes are focused on neglected tropical

diseases (NTDs), communicable and non-communicable diseases. All four programmes are carried out in collaboration with partners such as WHO, Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Fracarita International and USAID. Its programme for soil-transmitted helminthiasis supplies mebendazole (Vermox®) in 26 countries and has been ongoing since 2006. In 2017, Johnson & Johnson reports that 202 million doses of mebendazole (Vermox®) were donated.

**Ensures longer-term access through transition planning.** Johnson & Johnson has transition plans in place for two programmes to ensure ongoing access for patients once the programmes end. For example, its paediatric HIV donation programmes for darunavir (Prezista®) and etravirine (Intelence®), ensure that patients who are about to age out of the programme are able to transit into adult care without interruption of treatment. In addition to this, the company is working with the Paediatric HIV Treatment Initiative, to develop a generic fixed-dose combination of darunavir/ritonavir (120/20mg), to ensure affordability in the long term.

## BEST PRACTICES

**Leading platform to track access activities**

A system that enables it to track how local access strategies are implemented, and how activities progress.

**Global Public Health expands for better and wider access to healthcare**

A multidisciplinary unit with a strong business rationale for its access-to-medicine strategy.

**New Horizons addresses unmet needs in paediatric HIV care**

Collaborative initiative aimed at advancing paediatric HIV care, particularly for those failing treatment.

**Academy supports local scientists in Uganda**

A public institute that supports the development of scientists in Africa and conducts its own research.

## INNOVATIVE PRACTICES

**DREAMS learns from local young women to reduce HIV**

The collaborative partnership, to reduce new HIV infections among young women, uniquely engages directly with local young people to design learning activities.

**Combining data sources to map HIV resistance**

A modelling tool that blends multiple types of data to map HIV resistance.

**Cross-sector partnership drives early-stage R&D**

Extensive financial and on-site resources to enable groups behind early-stage projects to overcome limitations associated with development

\*Defined as a recommended time frame through consultation with stakeholders during Index methodology development.