PERFORMANCE IN THE 2022 INDEX

Johnson & Johnson is a leading company and demonstrates strong performance across all three Technical Areas. The company performs strongly across all assessment criteria including access strategies, R&D access planning and capacity building.

Governance of Access: 2nd place. Johnson & Johnson has a strong performance in this area. It has an access-to-medicine strategy integrated into its overall corporate strategy and a robust set of compliance controls to mitigate the risk of non-compliance in countries in scope of the Index. It also incentivises its senior executives, the CEO and in-country and regional managers to perform on access-to-medicine goals and discloses the outcomes of its access-to-medicine activities.

Research & Development: 2nd place. Johnson & Johnson is a leading company in this area. The company has a large-sized priority pipeline compared its peers with access plans in place for all late-stage pipeline candidates. It also performs strongly in R&D capacity building and has an access planning framework that covers all projects in the pipeline.

Product Delivery: 3rd place. Johnson & Johnson performs strongly in this area. The company engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply chain and health systems strengthening). The company applies access strategies broadly, with several products having strategies across all country income classifications. It leads in its approach to access strategies for supranationally procured products.

OPPORTUNITIES FOR JOHNSON & JOHNSON

Improve the quality of access plans for R&D projects for non-communicable diseases. Johnson & Johnson has access plans in place for all its late-stage R&D projects in the pipeline. The company can plan beyond registration by including more access components such as equitable pricing plans for each project, including cetrelimab, a monoclonal antibody in development for bladder cancer, and apocitentan, an investigational treatment for hypertension.

Expand supply chain process reviews to more countries. Johnson & Johnson’s Global Public Health unit conducted supply chain process reviews in sub-Saharan African countries including Kenya, Uganda and Nigeria. These reviews revealed a gap in leadership skills in the supply chain. In response, the company launched the Public Health Supply Chain CEO Forum. The company can conduct needs assessments in further countries in sub-Saharan Africa and expand the forum to additional countries where supply chain leadership gaps are seen.

File patented medicines for HIV for registration in more countries. Johnson & Johnson’s antiretrovirals darunavir/cobicistat (Prezista®/Rezolsta®) and darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symbi™) have been filed in 12 and 5 countries in scope of the Index respectively. Both products can be filed for registration in countries with a high burden of disease, such as Mozambique, South Africa and Zimbabwe.

Expand access to patented products in countries with the highest burden of disease. Johnson & Johnson has access strategies in some LMICs for canagliflozin (Invokana®), indicated for type 2 diabetes mellitus, and for ibritunib (mbruvica®), indicated for leukaeemia. The company can apply access strategies such as equitable pricing and/or non-exclusive voluntary licensing to expand patient reach, particularly in countries in scope of the Index where the burden of disease is the highest, such as Sri Lanka (for diabetes) and Afghanistan (for leukaeemia).

CHANGES SINCE THE 2021 INDEX

- Expanded the scope of its Global Public Health organisation to include a focus on Global Surgery, including obstetric fistula.
- Launched new Health for Humanity 2025 Goals, including a goal on Global Access Plans.
- Shipped approximately 270 million doses of the Johnson & Johnson COVID-19 vaccine to Africa at a not-for-profit price.
- Entered into IP licensing agreements and conducted voluntary technology transfers for its COVID-19 vaccine across 10 manufacturing facilities, including in India and South Africa.
- Announced an agreement to provide its COVID-19 vaccine technology to South Africa-based Aspen SA Operations (Pty) Ltd to manufacture its own branded vaccine.
- Received WHO Prequalification for its Ebola vaccine (Ad26.ZEOB-GP) (Zabdeno®) and Ebola vaccine (MVA-BN-Filo) (Mvabea®).
- Announced several initiatives to help find the ‘Missing Millions’ of undiagnosed people living with TB, including with the Global Fund.
- Launched a network of Global Health Discovery Centers to accelerate innovation and tackle pandemic threats.
- Completed Phase 1 clinical study evaluating dengue-specific antiviral for treatment and prophylactic use.
- Invested USD 100 million into the newly launched Antimicrobial Resistance (AMR) Action Fund.
- Commenced the first interventional clinical trial for schizophrenia in Africa.
- Marked over 2 billion doses of mebendazole (Vermox®) donated since 2006.
SALES AND OPERATIONS

Business segments: Consumer health, medical technologies and pharmaceutical.
Therapeutic areas: Cardiovascular, immunology, infectious diseases, metabolism, neuroscience, oncology, pulmonary hypertension and other diseases.
Product categories: Consumer health products, innovative medicines, medical technologies and vaccines.

M&A news: Johnson & Johnson acquired Momenta Pharmaceuticals, Inc. in October 2020 for USD 6.5 billion.
Johnson & Johnson’s products are sold in 95 out of 108 countries in scope of the Index.
Johnson & Johnson has sales offices in 24 countries and sells via suppliers and/or pooled procurement in an additional 71 countries.

Sales by segment (2021) – in USD
- Consumer health: 14.64 bn
- Pharmaceutical: 52.08 bn
- Medical technologies: 27.06 bn
- Total: 93.78 bn

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases in scope
Johnson & Johnson has a total of 101 R&D projects in scope with 64 of these projects targeting priority diseases. The other 37 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on viral hepatitis (B and C) (12 projects), HIV/AIDS (11 projects), and tuberculosis (11 projects). Of the projects targeting other diseases in scope, the focus is on oncology (25). Forty R&D projects are in late-stage development. These target either a priority disease (19) or address a public health need in LMICs (21).* Evidence of access planning was in place for 100% of these projects.

PORTFOLIO as selected for analysis by the Index
Johnson & Johnson has 26 medicines in scope, 19 of which are on patent, and two vaccines. 42% of the medicines (11) are on the WHO EML. The off-patent medicines target the neglected tropical diseases soil-transmitted helminthiasis and echinococcosis and the non-communicable diseases (NCDs) (6) relating to cancer (3), mental health conditions (2) and kidney diseases. The on-patent medicines target communicable diseases such as HIV/AIDS (8) and tuberculosis, and NCDs such as cancer (5), mental health conditions (2), diabetes (2) and Alzheimer’s disease. The company also has two vaccines targeting Ebola and COVID-19.

Breakdown of projects

<table>
<thead>
<tr>
<th>Category</th>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration/approval</th>
<th>Other***</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targets established R&amp;D priorities</td>
<td>23</td>
<td>9</td>
<td>9</td>
<td>8</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>64</td>
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<tr>
<td>Addresses needs of LMICs*</td>
<td>4</td>
<td>7</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>25</td>
<td></td>
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<td>Other projects in scope</td>
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<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td></td>
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</tbody>
</table>

*50 diseases and 243 product gaps in scope have been established as a priority by global health stakeholders. For other diseases, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Only projects in the clinical phase of development were included for this analysis.
**Neglected tropical diseases, while also communicable, are highlighted separately throughout the Index.
***Other includes projects that have a technical lifecycle and projects that follow a different development cycle (e.g. diagnostics).
†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus.
‡Other includes vector control products.
Company report cards

Johnson & Johnson

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Johnson & Johnson performs strongly. Its access strategy, embedded in its Global Public Health unit and Janssen Access and Pricing Principles, covers all therapeutic areas in which the company is involved. The highest responsibility for access lies directly with the board, namely with the Science & Technology Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Johnson & Johnson performs strongly. It incentivises its senior executives, including its CEO and members of the Executive Committee, and regional managers to take action on access to medicine with financial and non-financial rewards. Senior management, including the CEO, have enterprise-level targets as well as access-related performance indicators, including KPIs to improve access to medicine, as part of their annual goals and objectives.

Publicly discloses outcomes of its access-to-medicine activities. Johnson & Johnson performs strongly in transparency of access activities. It publicly discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities in a centralised manner within its annual Health for Humanity Goals Progress Scorecard.

Performs above average in responsible promotional practices. Johnson & Johnson’s sales agents are not solely incentivised on sales volume targets. The company, however, sets sales incentives at the individual level for agents. It does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope of the Index (e.g. payments for attending events or promotional activities) except as required by law or national/regional trade associations (e.g., EFPIA), though it has policies and procedures in place limiting transfers of values to healthcare professionals in countries in scope of the Index. In addition, the company reports not using sales and marketing representatives for some products related to diseases in scope, such as HIV/AIDS medicines.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Johnson & Johnson performs strongly, demonstrating evidence of all components looked for by the Index: fraud-specific risk assessment, country risk-based assessment, a continuous system to monitor activities, audits (both internal and external, covering third parties and in all countries where it operates) and has formal processes to ensure third-party compliance with company standards. No breaches in countries in scope of the Index were publicly found in the period of analysis.

Publicly supports international agreements, such as the Doha Declaration on the TRIPS agreement. Johnson & Johnson publicly recognises and supports international agreements including the TRIPS Agreement, and states that it advocates for strong intellectual property (IP) systems that promote innovation. The company expresses reservations on compulsory licensing, namely that it should be limited to certain circumstances when alternatives are exhausted. There is evidence of industry association lobbying on IP and the usage of TRIPS flexibilities, namely of compulsory licensing, by national governments in some countries in scope of the Index. As a member of the industry association, Johnson & Johnson, like all other member companies in scope of the Index, is by default connected to this activity.

Access planning processes encompass all projects in the pipeline. Johnson & Johnson has a structured process in place to develop access plans during R&D. The process is intended to be applied to all R&D projects (both in-house and collaborative) for diseases in scope of the Index. In general, Johnson & Johnson begins developing access plans for R&D projects in Phase II of clinical development.

A large-sized priority R&D pipeline compared to peers, with access plans in place for 100% (19/19) of the late-stage candidates. Johnson & Johnson has a priority R&D pipeline of 64 projects, including 19 late-stage projects that target a priority gap. The company focuses on various priority areas, including viral hepatitises (B and C), HIV/AIDS and tuberculosis. Of Johnson & Johnson’s 19 late-stage candidates targeting a priority product gap, all have evidence of an access plan in place. It provides evidence of access plans with a range of components including equitable pricing strategies and plans for registration in countries in scope of the Index. Notably, the access plan for the two-shot regimen Ebola vaccine (Adz26, ZEBOV-GP) (Zabdeno®) and Ebola vaccine (MVA-BN-Filo) (Makavel®) is multifaceted, comprising of WHO prequalification, health systems strengthening and capacity building initiatives through the Johnson & Johnson vaccination monitoring platform VxnaID™, and product donations.

Many projects address a public health need in LMICs; with 100% (21/21) of late-stage projects covered by access plans. In this analysis, Johnson & Johnson has 21 late-stage R&D projects that target a disease and/or product gap that are yet established as a priority by global health stakeholders. These projects are all deemed by the Index to offer a clear public health benefit for people living in LMICs. Primarily, these projects have clinical trials in countries in scope of the Index and/or are first-in-class molecules. The projects mainly target cancer. Johnson & Johnson provides evidence of access plans for all 21 eligible projects.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. However, Johnson & Johnson does disclose fully disaggregated R&D investment data to Policy Cures Research.

All five R&D capacity building initiatives included for analysis meet all Good Practice Standards. Johnson & Johnson leads in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards than what is average for this indicator. For example, the Johnson & Johnson Global Public Health R&D Fellowship Program provides training in drug development to mid-career African doctors and scientists.
Public commitment not to enforce patents in countries in scope. Johnson & Johnson has had a specific policy since 2012 not to enforce the patents it owns and controls on the antiretroviral drug darunavir (PréziSta®) in sub-Saharan Africa and Least Developed Countries. In 2015, it expanded the geographical scope of the policy for paediatric products used in LMICs.

Publicly discloses information on patent status. Like most of its peers, Johnson & Johnson discloses the patent statuses for small molecules in scope via the Pat-INFORMED database. Johnson & Johnson discloses patent information including filing date, grant number, grant date and jurisdiction.

Performs above average in terms of sharing intellectual property (IP) assets with third-party researchers. Johnson & Johnson engaged in two new IP-sharing agreements with third-party research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does have existing agreements of this nature in place that were established before the current Index cycle and meet all inclusion criteria for evaluation.

Uses licensing to enable generic supply. Johnson & Johnson has a non-exclusive voluntary licensing agreement for one compound (for diseases in scope). Its licence for lopinavir (Edurant®) encompasses 83 countries in scope, including 57 middle income countries. It has also issued a non-assert declarator for one patented compound in scope, darunavir (PréziSta®).

Filed to register new products in 15 countries in scope on average. Johnson & Johnson has filed six products in at least one country in scope of the Index with the highest burden of disease (for products that could be assessed with available global burden of disease data, which excludes COVID-19). Among new products, its most widely filed is the Johnson & Johnson COVID-19 vaccine, rapidly authorized in 41 countries within the scope of the Index, 15 of which are LICs. Examples include Somalia, Sudan and Uganda. Johnson & Johnson also received emergency use waivers or import permits in 31 countries in scope of the Index. Among old products, canagliflozin/metformin (Vokanamet®/Invokamet®) has been filed in 18 countries within the scope of the Index, including one high burden disease country.

Has access strategies for all supranationally procured products in scope for this analysis. Johnson & Johnson leads in securing access for products procured supranationally. For the four products assessed in this category, the company demonstrates strategies both in countries eligible for supply from such procurers, and also in at least one country not eligible for such supply. For example, the company supplied its Johnson & Johnson COVID-19 vaccine at a not-for-profit price via a supranational procurement agreement with the African Vaccine Acquisition Trust (AVAT) as well as two advance purchase agreements with the South African government.

Has access strategies for the majority of healthcare practitioner-administered products in scope of this analysis. Johnson & Johnson performs above average in this area. For three of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). The company makes efforts to reach additional patients using strategies considering relevant payers’ ability to pay. For example, Johnson & Johnson secured bendamustine hydrochloride (Ribomustin®) reimbursement in both public institutions and private health insurance in Brazil. The company provides evidence of how patient reach has been increased through the approaches used in some of the country examples provided.

Has access strategies for the majority of its self-administered products for countries in scope for this analysis. Johnson & Johnson performs above average in this area. For two of the five products assessed, the company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC). It makes efforts to reach additional patients through pricing strategies considering relevant payers’ ability to pay and patient assistance programmes. For example, in an LIC for one cancer product, it provided evidence of pricing and non-pricing strategies to ensure continuous patient care while implementing health systems strengthening initiatives. Johnson & Johnson provides evidence of patient reach.

Four of the five manufacturing capacity building initiatives included meet all Good Practice Standards. Johnson & Johnson’s performance is above average in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all Good Practice Standards (GPS) than what is average for this indicator. For example, the company collaborated with Aspen Pharmacare Limited, a manufacturer in South Africa to transfer technology to produce the Johnson & Johnson COVID-19 vaccine. This initiative meets all GPS.

All five supply chain capacity building initiatives included for analysis meet all Good Practice Standards. Johnson & Johnson is one of the leaders in this area. The number of initiatives meeting all inclusion criteria is higher than average and more initiatives meet all GPS than what is average for this indicator. For example, the company is involved in technology transfers with third-party manufacturers in LMICs, and has a system in place to work with relevant stakeholders to communicate issues that may affect the supply chain, works with several active pharmaceutical ingredient suppliers, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a procedure for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Johnson & Johnson has a procedure for reporting SF medicines to national health authorities within five days. The company reports aiming at reporting within two days if the case presents a direct and serious or life-threatening risk to patient or healthcare professional. It distinguishes quicker reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Johnson & Johnson has public policies and supply processes in place to ensure ad hoc donations are carried out rapidly in response to expressed need, and it monitors the delivery of donations.

Publicly commits to the achievement of elimination, eradication or control goals in one structured donation programme for neglected tropical diseases or malaria. Johnson & Johnson publicly commits to supporting the control of soil-transmitted helminthiasis as a public health problem through its donation of mebendazole (Vermodox®) until the end of 2025 in 51 countries in scope of the Index.