PERFORMANCE IN THE 2021 INDEX

3rd place. Johnson & Johnson takes a place among the top three companies of the Index. The company has a particularly strong performance in R&D, with a large-sized priority pipeline.

Governance of Access: 4th place. Johnson & Johnson performs strongly in this area. It has embedded access-to-medicine into its corporate strategy as part of the Global Public Health unit. The company has a robust set of compliance controls in place to safeguard its governance efforts.

Research & Development: 2nd place. Johnson & Johnson has a strong performance in this area with 16 late-stage priority R&D projects in its pipeline. The company leads in R&D capacity building and has an access planning process in place that covers all projects in the pipeline.

Product Delivery: 5th place. Johnson & Johnson performs well in this area. The company shares many IP assets with third-party researchers and leads in its approach to access strategies for supranationally procured products. The majority of its capacity building initiatives meet all Good Practice Standards.

OPPORTUNITIES FOR JOHNSON & JOHNSON

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 such as Kenya, Uganda and Nigeria for products it is responsible for such as HIV/AIDS medicines and vaccines. It can expand these supply chain reviews to more countries.

File patented HIV/AIDS medicines for registration in more countries. Johnson & Johnson’s antiretrovirals darunavir/cobicistat (Prezobrix®/Rezolsta®) and darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) can be filed for registration in the high-burden countries in scope of the Index such as Equatorial Guinea, Lesotho, Malawi, Mozambique, South Africa and Zimbabwe.

Apply access planning to more R&D projects and consider affordability. Johnson & Johnson has access plans in place for 79% of its late-stage R&D projects. It plans for filing for registration for most of these projects. The company can plan for both registration and affordability as well as availability for all its late-stage R&D projects, e.g. for hepatitis B virus and for daratumumab (Darzalex®) for cancer.

Expand access to patented products. Johnson & Johnson can apply further access strategies to expand access for more patients using equitable pricing and/or non-exclusive voluntary licensing for on-patent products for Type 2 diabetes mellitus (e.g. canagliflozin (Invokana®), canagliflozin/metformin (Vokanamet®/Invokanamet®) and for MDR-TB, bedaquiline (Sirturo®).

CHANGE SINCE THE 2018 INDEX

- Expanded its mental health initiative in Rwanda and completed the first-ever mental health survey in the country.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Expands donation programme of mebendazole chewable (Vermox®, Vermox® Chewable) for children until 2025.
- Received FDA approval for bedaquiline (Sirturo®) paediatric formulation and EMA approval of their Ebola vaccine regimen composing the two doses (Zabdeno® and Mvabea®).
- Engaged in nine IP sharing agreements via WIPO research (NTDs), the Pan-TB (Project to Accelerate New Treatments for TB) and the COVID-19 Therapeutics Accelerator initiative.
- Expanded HIV drug-resistance mapping from the Democratic Republic of Congo (DRC) to Kenya with KEMRI.
- Supported the building of active pharmaceutical ingredient (API) capacity of third-party manufacturers in Africa, including exploring local drug substance manufacturing.
- Active partner in the Pandemic Cold Chain System Coalition.
- Collaborated with Stop TB to reduce the price and enact a volume-based free goods framework for bedaquiline (Sirturo®).
- Supported by the Johnson & Johnson Foundation, the company partnered with Last Mile Health, Living Goods, the Bill and Melinda Gates Foundation, the Audacious Project and four pharmaceutical companies on the Africa Health Worker Training Initiative.
SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PORTFOLIO as selected for analysis by the Index
Johnson & Johnson has 28 medicines and contraceptives in scope, 19 of which are on patent. 32% of these medicines (9) are on WHO’s EML. The off-patent medicines target the neglected tropical diseases soil-transmitted helminthiasis and echinococcosis and the non-communicable diseases relating to cancer (3), mental health conditions and kidney diseases. The company also markets two off-patent contraceptive methods. The on-patent medicines mainly target HIV (7), cancer (5) and mental health (3). Furthermore, it targets diabetes (2), tuberculosis and Alzheimer’s disease. Access strategies were analysed for 13 products on Johnson & Johnson’s portfolio – supranationally procured (3) or nationally procured HCP-administered (5) and self-administered products (5).

SALES AND OPERATIONS

Business segments: Consumer Health; Pharmaceutical; Medical Devices
Therapeutic areas: Pharmaceutical; Immunology; Infectious Diseases; Neuroscience; Oncology; Cardiovascular and Metabolism; Pulmonary Hypertension
Product categories: Innovative medicines; Vaccines; Diagnostics; Consumer health products; Medical devices
M&A news: Acquired all rights to the investigational compound bermekimab (immunology) from XBiotech in Q1 2020; acquired Momenta (immune-mediated diseases) for USD 6.5 billion in Q4 2020.

Johnson & Johnson’s pharmaceutical products are sold in 94 out of 106 countries in scope. Johnson & Johnson has sales offices in 21 countries, sells via suppliers in 60 countries and via pooled procurement into 13 additional countries.

Sales in countries in scope

PIPELINE for diseases and countries in scope
Johnson & Johnson has a total of 95 R&D projects featuring a relatively large priority R&D pipeline compared to its peers: 51 projects. Remarkably, Johnson & Johnson has the second largest pipeline and more than half of its R&D projects target priority diseases. The other 44 R&D projects target other diseases in scope. Of the projects targeting priority diseases, the focus is on HIV/AIDS (10 projects). Of the projects targeting other diseases in scope, the focus is on oncology (17). 39 R&D projects are in late-stage development. Johnson & Johnson is involved in 16 projects, with 15 of them in own pipeline and one driven by ViV healthcare. These target either a priority disease (16) or address a public health need in LMICs (23). Evidence of access planning was in place for 79% of these projects: 10 targeting a priority disease and 21 addressing a public health need in LMICs.

Breakdown of projects∗ ViV Healthcare & Janssen’s long-acting injectable formulation of cabotegravir and rilpivirine (Cabenuva), it is the first complete long-acting regimen for the treatment of HIV-1 infection in adults. The product is currently only approved in Canada.

Breakdown of products

Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

Access to Medicine Foundation

†Products included in the analysis were selected using a set of criteria determined by stakeholder consensus. See Appendix I for a full breakdown of the criteria

‡Projects in the discovery phases and/or other drug development phases were not included in this breakdown.

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Johnson & Johnson

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Johnson & Johnson performs strongly. It has an access strategy integrated within its overall corporate strategy. The strategy, embedded in its Global Public Health unit, 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 & Sustainability Committee.

Provides evidence of financial and non-financial access-related incentives at the executive level. Johnson & Johnson performs well here. It incentivises its senior executives, including both Vice Chairpersons of the Executive Committee, and regional managers to take action on access to medicine with financial and non-financial rewards. There is limited evidence, however, that the CEO is also incentivised toward access goals.

Publicly discloses outcomes of its access-to-medicine activities. Johnson & Johnson performs strongly in transparency regarding access activities. It publically discloses commitments, measurable goals, objectives and targets for improving access to medicine in countries in scope. It consistently shares outcomes of its access-to-medical activities with its Health for Humanity 2020 Goals Progress Scorecard.

Has an average performance 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. Except for Ukraine where it discloses to EFPIA1 and some countries where it is required by local regulations, it does not publically disclose information related to transfers of values to healthcare professionals in countries in scope (e.g. payments for attending events or promotional activities). However, it reports not using sales and marketing representatives for some products related to diseases in scope, such as HIV 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 all the 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.

RESEARCH & DEVELOPMENT

Access planning processes encompass all projects in 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 for diseases in scope. In general, Johnson & Johnson begins developing access plans for R&D projects in Phase II of clinical development. The process is for both in-house and collaborative R&D projects.

A large-sized priority R&D pipeline compared to peers, with access plans in place for 67% of the late-stage candidates. Johnson & Johnson has 51 projects including 15 late-stage candidates in its pipeline that target a priority product gap. The company focuses mostly on HIV/AIDS. Of Johnson & Johnson’s 15 late-stage candidates targeting a priority product gap, ten have evidence of having an access plan in place. These plans range from commitments to register product in several countries in scope to equity-based tiered pricing strategies for some projects. Note, if the development of the investigational Janssen preventative HIV vaccine is successful, the company plans to implement a global access strategy.

Many projects address a public health need in LMICs, with 91% of the late-stage projects covered by access plans. In this analysis, Johnson & Johnson has 23 late-stage R&D projects that target a disease and/or product gap not yet established as a priority by global health stakeholders. Johnson & Johnson provides evidence of access plans for 21 of these projects. In general these access plans focus on registration plans in LMICs. The 23 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 and/or are first-in-class molecules. Most target asthma and cancer.

Public policy to ensure post-trial access; commits itself to registering trialled products. Johnson & Johnson has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants who have a severe or life-threatening condition. In general, once a product is initially approved, Johnson & Johnson commits to submit applications for product registration in countries where the clinical trials for the product have taken place. This policy does not consider affordability for the wider population in the country where the trial(s) took place.

Five R&D capacity building initiatives meet all Good Practice Standards. Johnson & Johnson leads in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all the Good Practice Standards. The initiatives all target R&D capacity building in sub-Saharan Africa, predominantly focusing on communicable diseases such as HIV, TB and malaria:
- The Johnson & Johnson Global Health R&D Fellowship Program for African scientists and doctors.
- The Ugandan Academy for Health Innovation and Impact, which has been running since 2015.
- UMURINZI, working the Rwanda Biomedical Centre (RBC) of the Rwanda Ministry of Health to deliver the Ebola vaccine regime, supporting Clinical trial management and Good clinical practices.
- Strengthening HIV resistance mapping in Kenya and the DRC.
- Visiting Scientist Program and Mentorship Program at the University of Cape Town (UCT) Drug Discovery and Development Center (H3D).

PRODUCT DELIVERY

Public commitment not to endorse patents in countries in scope. Johnson & Johnson publicly pledges not to endorse patents on darunavir (Prezista®). This commitment applies in sub-Saharan Africa and in Least Developed Countries.

Publicly discloses detailed 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. The information is periodically updated and includes detailed information about patents, including filing date, grant number, grant date and jurisdiction.

Shares many IP assets with third-party researchers. Compared to its peers, Johnson & Johnson has newly

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1 Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, member companies are required to disclose payments made to healthcare professionals, such as sponsorship to attend meetings or speaker fees, in European countries they operate in.

2 Addresses local needs, priorities and/or skills gaps; is carried out in partnership with a local university or public research institution; partnership has good governance structures in place; initiatives goals align with or support institutional goals; measures outcomes; has long-term aims/aims for sustainability.
shared many IP assets with third-party researchers developing products for diseases in scope. This includes nine IP assets shared with research institutions and the drug discovery initiative COVID-19 Therapeutics Accelerator launched by the Bill and Melinda Gates Foundation, Wellcome and Mastercard. Assets shared include molecule libraries and performing assay for drug discovery.

Uses licensing to enable generic supply. Johnson & Johnson has a non-exclusive voluntary licensing agreement for one compound (for diseases in scope). Its licence, which is for rifapentine (Edurant®), encompasses 84 countries including 62 middle-income countries in scope. It has also issued a non-assert declaration for one patented compound in scope, darunavir (Prezista®).

Filed to register some new products in the majority of high burden countries. Johnson & Johnson has filed 20% of its most recently registered products in more than half of the top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). For example, the oncology medicine ibritinib (Imbruvica®) has been filed for registrations/registered in, among others, six high-burden countries in scope.

Has access strategies for all supranationally procured products in scope for this analysis. Johnson & Johnson leads in accessing for products procured supranationally. For the three products assessed in this category, the company demonstrated strategies both in countries eligible for supply from such procurers, and also in at least one country not eligible for such supply. For example, Johnson & Johnson offers similar terms in South Africa for tuberculosis medicine Sirturo® as it does for eligible countries procuring through Stop TB Partnership’s Global Drug Facility.

Has access strategies for the majority of health-care practitioner-administered products in scope of this analysis. Johnson & Johnson performs above average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. The company makes efforts to reach additional patients using equitable pricing strategies. For example, in India, for the schizophrenia treatment paliperidone palmitate (Invega®), it applies tiered pricing, participates in tenders and has a Patient Access Programme which provides financial support to patient to increase access, while strengthening the health system by raising awareness around schizophrenia. Johnson & Johnson is able to provide evidence of how patient reach has been increased through the approaches used.

Has access strategies for its self-administered products for some countries in scope for this analysis. Johnson & Johnson performs on average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMIC, LMIC, LIC) for one of the five products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategy and licensing. For example, in Kenya, for the oncology medicine Abiraterone acetate (Zytiga®), the company uses a tiered pricing strategy and provides additional support through patient assistance programs to address affordability and access for patients. Johnson & Johnson is able to provide evidence of how patient reach has been increased through the approaches used.

Two manufacturing capacity building initiatives meet all Good Practice Standards. Johnson & Johnson performs well in this indicator, with five manufacturing capacity building initiatives included for analysis. Johnson & Johnson submitted the maximum of five and all met inclusion criteria. Two initiatives met all Good Practice Standards, including a technology transfer programme in China for darunavir (Prezista®) for the treatment of HIV, which started in 2018. For three initiatives, Johnson & Johnson does not demonstrate that it is measuring outcomes.

Four supply chain capacity building initiatives meet all Good Practice Standards. Johnson & Johnson performs well in this indicator, with five supply chain capacity building initiatives included for analysis. Johnson & Johnson submitted the maximum of five initiatives, which met all criteria for inclusion. Four initiatives met all Good Practice Standards. Examples include:
- Last Mile Health Medical Drone Project, using medical drones to overcome geographical barriers to deliver antiretroviral therapy for the treatment of HIV.
- Africa Resource Centre Secondments, enabling company employees to offer their expertise to improve public sector supply chain capabilities in South Africa and Kenya. For the JSI STAR programme, a six-month training course for supply chain professionals, Johnson & Johnson does not sufficiently demonstrate how it aims for sustainability.

Five health system strengthening initiatives meet all Good Practice Standards. Johnson & Johnson is one of the leaders in this area. The company submitted the maximum of five initiatives, which were all included for analysis and met all Good Practice Standards: i.e., they address local needs, have local partners, mitigate risk of conflict of interest, are guided by clear goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. Examples include:
- DREAMS, Thina Abantu Abasha, a youth-led peer-to-peer initiative aimed at reducing HIV infections in adolescent girls and young women in South Africa.
- In collaboration with the government of Rwanda, Johnson & Johnson co-developed and launched the first remote training system in the country, training over 48,000 community healthcare workers in 2019 on recognizing mental illness and the referral process.

Has engaged in the development and implementation of new inclusive business models. Johnson & Johnson improved performance since 2018 when it comes to implementing scalable inclusive business models that aim to meet the access needs of populations at the base of the pyramid in countries in scope. In 2019, the company launched Johnson & Johnson Impact Ventures, supported by the Johnson & Johnson Foundation, including the development of two new models: partnership with Jacaranda maternity and partnership with Southlake Medical Center Kenya on access to primary and secondary healthcare.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Johnson & Johnson performs well in this area, disclosing multiple strategies to ensure continuous supply in countries in the scope of the Index. For example, based on the insights from the Sales & Operations Planning process, the company takes various measures to ensure continuous supply, including holding sufficient safety stocks and dual/multiple sourcing of supply and inventory. In 2019, Johnson & Johnson redesigns the distribution network of their HIV portfolio, reportedly enhancing demand forecasting and last mile distribution.

Has a procedure for reporting substandard and falsified (SF) medicines in Index countries in less than 10 days. Johnson & Johnson has a procedure for reporting SF medicines to national health authorities within 5 days. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed. However, it reports that its aims at reporting within 2 days if the case presents a direct and serious or life-threatening risk to patient or healthcare professional.

Donates in response to an expressed need, and monitors delivery to end users. Johnson & Johnson has a process in place to ensure ad hoc donations are carried out in response to an expressed need, and it monitors the delivery until the end user. For example, it donated darunavir/cobicistat (Rezolsta®) for HIV/AIDS to the Ivory Coast in 2020 to project HOPE worldwide.

Publicly commits to the achievement of elimination, eradication or control goals in its structured donation programme for NTDs. One structured donation programme for NTDs was included for analysis where elimination, eradication or control goals are possible. Johnson & Johnson publicly commits itself to controlling soil-transmitted helminthiasis by donating mebendazole (Vermox®) from 2006 to 2025 in 33 countries.