PERFORMANCE IN THE 2021 INDEX

10th place. Novo Nordisk is a middle-performing company. It shows a strong performance in access strategies for its products in specific markets and launched the Defeat Diabetes Strategy, but has a small R&D pipeline with no priority projects.

Governance of Access: 5th place. Novo Nordisk performs well in this area. It has an access-to-medicine strategy integrated within the overall corporate strategy and publicly discloses the outcomes of its access-to-medicine activities.

Research & Development: 18th place. Novo Nordisk performs poorly in this area. The company does not have a structured process for access planning during R&D and does not engage in R&D capacity building initiatives. It has a small-sized R&D pipeline compared to its peers; no priority projects.

Product Delivery: 4th place. Novo Nordisk performs above average in this area. The company demonstrates engagement in high-quality initiatives in all fields of capacity building, i.e. manufacturing, supply chain and health system strengthening. It has access strategies for its products and multiple mechanisms to ensure continuous supply for some countries in scope. Yet, there is no evidence of new products filed for registration in the majority of high-burden countries and the company does not share IP assets with third-parties.

OCCUPORTUNITIES FOR NOVO NORDISK

Continue to expand capacity building for vulnerable populations. Novo Nordisk’s Changing Diabetes in Children (CDIC) initiative is active in 14 LDCs, LICs and LMICs in Asia and sub-Saharan Africa and was extended to 2030. It can scale up to additional countries, for example, in Latin America. It has scaled up its Base of the Pyramid model addressing diabetes-related access issues including awareness and health infrastructures in Kenya, Ghana, Nigeria, Senegal and Morocco. Novo Nordisk can apply this model in more countries with a high burden of diabetes and populations at the base of the pyramid such as Swaziland and Sri Lanka.

Expand access to innovative products. Novo Nordisk has an equitable pricing strategy, the ‘Access to Insulin Commitment’, that applies to recombinant human insulins for all LDCs, other LICs and MICs with large low-income populations. It can also apply equitable pricing strategies in LDCs and LICs to analogue insulins, such as insulin degludec (Tresiba®), and to other innovative anti-diabetic medicines such as liraglutide (Victoza®). Furthermore, it can expand filing for registration to most recently introduced products such as semaglutide injection (Ozempic®) and oral (Rybelsus®) and insulin aspart + niacinamide (Fiasp®).

Develop an access planning process and access plans for all R&D projects. Novo Nordisk can develop a formal access planning process and accordingly develop access plans for all clinical Phase II projects, especially for products addressing a public health need in low- and middle-income countries such as its once-weekly basal insulin analogue, and ensure a stronger access plan for oral semaglutide (Rybelsus®) that includes affordability.

CHANGE SINCE THE 2018 INDEX

- Launched the Defeat Diabetes Strategy.
- Strengthened its Access to Insulin Commitment to include 76 low- and middle-income countries and lowered the price ceiling of human insulin to USD 3.00 per human insulin vial.
- Extended Changing Diabetes in Children initiative to 2030.
- Extended Partnering for Change to support the efforts of ICRC and the Danish Red Cross to provide access to NCD care for the populations they serve.
- Increased capacity, with the formation of a Sustainable Supply Chain team, to supply insulin products to humanitarian organisations on preferential terms until at least 2030.
- Supports the clinical development of novel antibiotics via the AMR Action Fund.
- Donates via WHO insulin and glucagon for diabetes mellitus for use in 50 low- and middle-income countries in response to COVID-19.
- Partners with the Coalition for Access to NCD Medicines and Products to develop a demand forecasting tool.
- Set up an insulin production line in Iran.
SALES AND OPERATIONS

Business segments: Diabetes and Obesity care; Biopharm
Therapeutic areas: Diabetes; Obesity; Haemophilia, Growth disorders and Hormone replacement therapy.
Product categories: Innovative medicines
M&A news: Acquired Emisphere Technologies (drug delivery) for USD 1.35 billion.

Novo Nordisk’s products are sold in 81 out of 106 countries in scope. Novo Nordisk has sales offices in 25 countries and sells via suppliers in 56 additional countries.

Net sales by segment (2019) – DKK

<table>
<thead>
<tr>
<th>Segment</th>
<th>Sales 2019 (bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes and Obesity care</td>
<td>102.840 bn</td>
</tr>
<tr>
<td>Biopharm</td>
<td>19.181 bn</td>
</tr>
<tr>
<td>Total</td>
<td>122.021 bn</td>
</tr>
</tbody>
</table>

Sales in countries in scope

Sales by geographic region

SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

PIPELINE for diseases and countries in scope
Novo Nordisk has the smallest pipeline compared to its peers with 7 R&D projects targeting other diseases in scope (no priority R&D pipeline). The focus of these projects is on diabetes (5 projects). One project targets sickle cell disease and one is for ischaemic heart disease. 3 R&D projects are in late-stage development that address a public health need in LMICs.* Evidence of access planning was in place for 33% of these projects (1).

PORTFOLIO as selected for analysis by the Index
Novo Nordisk has 13 medicines in scope, 8 of which are on patent. 15% of these medicines (2) are on WHO's EML. All medicines in the off-patent portfolio target diabetes and are insulins (4) and glucagon. The medicines in the on-patent portfolio target diabetes, as well. Novo Nordisk has insulins (5) and GLP1 agonists (3) on its on-patent portfolio. Access strategies were analysed for 5 products on Novo Nordisk’s portfolio – nationally procured self-administered products (5).

7 projects in the pipeline

13 products as selected for analysis by the Index*

Breakdown of projects*

Breakdown of products

*50 diseases and 211 product gaps in scope have been established as a priority by global health stakeholders. For other diseases/product gaps, the Index used a set of criteria to determine which projects in the pipeline offer a clear public health benefit to patients in LMICs. Projects in the clinical phase of development were included for this analysis.

†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.
Novo Nordisk A/S

GOVERNANCE OF ACCESS

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novo Nordisk performs strongly. The Defeat Diabetes strategy, focused on prevention, innovation, access and affordability, covers all therapeutic areas in which the company is involved for diseases in scope. The highest responsibility for access lies directly with the board, namely with the CEO, under the supervision of the Board of Directors.

Provides evidence of financial and non-financial access-related incentives at the executive level. Novo Nordisk also performs strongly here. It incentivises its senior executives and in-country leaders for delivering on its access to care objectives. The CEO also has access-related incentives, linked to long-term social targets.

Publicly discloses outcomes of its access-to-medicine activities. Novo Nordisk performs strongly in transparency of access activities. It publicly discloses commitments including Access to Insulin, measurable goals, objectives and targets for improving access in countries in scope. It consistently shares outcomes of its access-to-medicine activities, including on the number people treated with insulin based on targets set and for its Changing Diabetes in Children programme.

Has an average performance in responsible promotional practices. Novo Nordisk's sales agents are not solely incentivised on sales volume targets. The company sets sales incentives at the individual level for agents. Novo Nordisk does not publicly disclose information related to transfers of values to healthcare professionals in countries in scope (e.g., payments for attending events or promotional activities), unless required by local regulations or industry association commitments e.g., in Brazil and in the Philippines.

Has a robust set of compliance controls to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novo Nordisk performs strongly here, demonstrating 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 compliance with company standards by third parties.

PUBLICALLY discloses its commitments not to enforce patents in low-income countries. Novo Nordisk states that health emergencies requiring exceptions to IP rights can and should be accommodated under the international legal framework. It expresses reservations on the use of compulsory licensing. It states that its positions are generally aligned with its industry associations.

RESEARCH & DEVELOPMENT

No structured process for access planning disclosed. Novo Nordisk does not have a structured process in place to develop access plans during R&D. The company did not disclose a structured timeline for the development of access plans for its R&D projects.

Novo Nordisk has no priority R&D projects in its pipeline. The company’s R&D projects focus mostly on diabetes mellitus (Type 2 and 2). Some projects address a public health need in LMICs, with 33% of the late-stage projects covered by access plans. In this analysis, Novo Nordisk has three late-stage R&D projects that target a disease and/or product gap not yet designated 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 concern clinical trials in countries in scope and/or are first-in-class molecules. Most target diabetes mellitus. Novo Nordisk provides evidence of access plans for one of these projects.

Public policy to ensure post-trial access; commits itself to registering trialled products. Novo Nordisk has a policy for ensuring post-trial access to treatments for clinical trial participants. This policy covers a subset of clinical trial participants on a case-by-case basis. Once a product is approved, Novo Nordisk commits to seek registration in all countries where clinical trials for the product have taken place. The policy does not consider affordability for the wider population in the country where the trial(s) took place.

No R&D capacity building initiatives included for evaluation. Novo Nordisk performs poorly in this area. The company submitted two R&D capacity building initiatives, but none met all criteria for inclusion.

PRODUCT DELIVERY

Public commitment not to enforce patents in countries in scope. Novo Nordisk publicly pledges to neither file for nor enforce patents. This commitment applies in Least Developed Countries and low-income countries.

Publicly discloses detailed information on patent status. Novo Nordisk both publicly discloses on its website the patent statuses for biologics and for small molecules in scope via the Pat-INFORMED database. Novo Nordisk’s disclosure includes detailed information about patents, including expiry date, patent number and jurisdiction.

Does not share IP assets with third-party researchers. Novo Nordisk reports no instances where it shares IP assets with third-party researchers developing products for diseases in scope during the period of analysis.

No evidence of new products in scope filed for registration in the majority of high burden countries. Novo Nordisk did not disclose evidence of filing any of its most recently registered products in more than half of the relevant top 10 high burden countries (disease-specific subset of countries with the highest burden of disease). Its most widely registered product, insulin human (rDNA) (Actrapid®) for diabetes mellitus is registered and has been filed for registration in 76 countries in scope, including Guyana and Central African Republic.

No supranationally procured products. Novo Nordisk has no products eligible for scoring in this indicator.

No healthcare practitioner-administered products. Novo Nordisk has no products eligible for scoring in this indicator.

Has access strategies for its self-administered products for some countries in scope of this analysis. Novo Nordisk performs above average in this area. The company provides examples of access strategies which consider affordability in countries of all assessed income levels (UMC, LIC, LIC) for three of the five products assessed. It makes efforts to reach additional patients through the use of equitable pricing strategies and donation. For example, in Kenya, the human insulin (rDNA) (Actrapid®) is covered by the Access to Insulin Commitment, an inter- and intra-country equitable pricing strategy. The company guarantees a price ceiling of $3 USD per vial under this commitment. Novo Nordisk also runs a programme that
covers capacity building, patient education and provision of insulin at a low price in faith-based health facilities for patients at the base of the economic pyramid. In addition, the company donates human insulin for children with Type 1 diabetes mellitus through the Changing Diabetes® in Children programme. Novo Nordisk is able to provide evidence of how patient reach has been increased.

Two manufacturing capacity building initiatives meet all Good Practice Standards. Novo Nordisk has an average performance in this area. The company submitted two initiatives, which were both included for analysis and met all Good Practice Standards. Both initiatives support partner manufacturing sites in India and Bangladesh in meeting Good Manufacturing Practice (GMP) standards, the qualification of equipment and the validation of manufacturing processes.

Three supply chain capacity building initiatives meet all Good Practice Standards. Novo Nordisk performs above average in this area. The company submitted four initiatives, which all met all criteria for inclusion. Three of them met all Good Practice Standards. Examples include:

- The Defeat-NCD Partnership, strengthening the supply and procurement of non-communicable disease (NCD) treatments.
- The Base of the Pyramid, improving diabetes care for people living at the base of the economic pyramid in Kenya.

For the partnership initiative with the Africa Resource Centre in Kenya to support the National AIDS and STD Control Program, Novo Nordisk did not sufficiently demonstrate how the initiative aims for sustainability.

Five health system strengthening initiatives meet all Good Practice Standards. Novo Nordisk 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, have defined goals and objectives, (plan to) measure outcomes, have a governance structure in place and aim for sustainability/integration in the local health system. For example, the Changing Diabetes in Children (CDiC) initiative aims to improve diabetes care for children by establishing clinics for Type 1 diabetes care, training healthcare workers, supporting patient education and donating free-of-charge human insulin. To date, the initiative has established 208 clinics in 14 countries, enrolled over 26,500 children and has been extended until 2030.

Has engaged in the development and implementation of a scaled up inclusive business model. Novo Nordisk performs well 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. It has scaled up its model Base of the Pyramid to address diabetes-related access issues including awareness and health infrastructures in five African countries.

The company has multiple mechanisms in place to ensure continuous supply in countries in scope of the Index. Novo Nordisk performs well in this area, disclosing multiple strategies to ensure the continuous supply in countries in the scope of the Index. In January 2020, Novo Nordisk rolled out a new demand planning platform ‘Demand Planning 4 Future’, which covers all markets and products and includes both commercial sales and humanitarian organisations sales. In February 2020, Novo Nordisk started a mapping project in 15 sub-Saharan African countries and India, identifying key agents in the value chain with the aim to improve processes and enhance availability.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope in less than 10 days. Novo Nordisk has a policy for reporting SF medicines to the relevant health authorities, including the FDA, within 7 days. It does not distinguish reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to an expressed need, and monitors delivery to end user. Novo Nordisk has a policy 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 insulin and glucagon for diabetes mellitus to at least 50 countries in 2020 in response to the COVID-19 pandemic.

Is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. Novo Nordisk is not engaged in structured donation programmes for NTDs where elimination, eradication or control goals are possible. However, it is engaged in another structured donation programme: the Changing Diabetes in Children programme where it donates human insulin (Actrapid®, Insulatard® and Mixtard®) to 14 countries since 2009.

† Addresses local needs, priorities and/or skills gaps; builds capacity of third party or unaffiliated partner; or works with external partners; guided by clear, measurable goals or objectives; measures outcomes; has long term aims; aims for sustainability.