

RANK	SCORE
11	2.97
10 (2021)	

Novo Nordisk A/S

Stock exchange: Nasdaq Copenhagen • Ticker: NOVO-B • HQ: Bagsværd, Denmark • Employees: 48,478

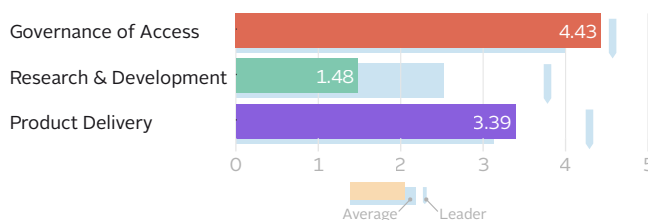
PERFORMANCE IN THE 2022 INDEX

11th place. Novo Nordisk has an average overall performance. It performs strongly in Governance of Access where it has an access-to-medicine strategy integrated into its overall corporate strategy. The company also engages in some high-quality capacity building initiatives. However, it performs comparatively poorly in Research & Development, where it has a small pipeline.

Governance of Access: 2nd place. Novo Nordisk 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 incentivises its senior executives, including 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: 19th place. Novo Nordisk performs poorly in this area. The company has a general process

How score was achieved



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.

Product Delivery: 10th place. Novo Nordisk has an average performance in this area. Novo Nordisk engages in high-quality capacity building initiatives across all fields (i.e., manufacturing, supply chain and health systems strengthening). It has access strategies for most of its products in all country income classifications but does not share IP assets with third-party researchers.

OPPORTUNITIES FOR NOVO NORDISK

Develop a structured access planning framework and ensure all late-stage R&D projects have comprehensive access plans. Novo Nordisk has access plans in place for 78% of late-stage projects analysed. It can develop a structured framework for access planning and ensure these plans cover all late-stage R&D projects. For example, the access plan for its once-weekly Insulin icodex, can be expanded to include access components such as equitable pricing.

Measure and share outcomes of iCARE. The iCARE initiative was launched in 2021 as a business-integrated model aimed towards improving access to diabetes treatment in 49 countries in sub-Saharan Africa. To scale up this initiative and support integration into local health systems, Novo Nordisk can track and share short and long-term patient outcomes as part of its impact evaluation of this programme, in addition to outcomes such as patient reach and volumes of insulin sold.

Expand access to innovative products. Novo Nordisk has an equitable pricing strategy, that applies to recombinant human insulins for all Least Developed Countries, all low-income countries (LICs), and some middle-income countries with large low-income populations. It can expand this equitable pricing strategy to long-acting analogue insulins, such as insulin degludec (Tresiba®), and to other innovative diabetes medicines, such as liraglutide (Victoza®).

Expand registration to insulins listed in the WHO Model List of Essential Medicines. Novo Nordisk has filed long-acting analogue insulin degludec (Tresiba®) for registration in 48 countries within the scope of the Index. The company has not filed this product for registration in any additional countries in scope since 2017. The company can expand registration for this product, especially in countries such as Bolivia and Cameroon, where human insulins have already been filed. In addition, Novo Nordisk can expand registration of human insulins in LICs, such as Sierra Leone, Somalia and South Sudan.

CHANGES SINCE THE 2021 INDEX

- Embedded social responsibility criteria (both access and environmental) into the R&D strategic processes across therapy areas, thereby ensuring such considerations and strategic decisions take place.
- Re-evaluated the thermal stability of short-acting and intermediate-acting human insulin products and will seek national approvals of more flexible storage conditions in relevant LMICs following the positive scientific opinion from the European Medicines Agency.
- Invested USD 50 million into the newly launched Antimicrobial Resistance (AMR) Action Fund through the Novo Nordisk Foundation and USD 25 million through the company itself.
- Extended the Changing Diabetes in Children initiative until 2030, launching the programme in ten new countries. Entered into a collaboration with Harvard University School of Public Health with the aim to improve data, research, innovation and capacity building in type 1 diabetes in LMICs.
- Launched the iCARE initiative based on learnings from the Base of the Pyramid Program. iCARE is a sustainable and fully integrated business model aimed at improving access to affordable diabetes treatment in the Novo Nordisk Middle Africa region.
- Expanded its humanitarian programme with the launch of the Senselet project in Ethiopia and DonateAble.

All companies were assessed based on information that was valid in the latest period of analysis (ending at 31 May 2022). This data was either submitted by companies, found in the public domain or was accessible through other sources.

The term LMICs is used to denote all low- and middle-income countries in scope of the Index, except when analysing companies' access strategies where the use of LMIC refers to lower-middle income countries as per the World Bank

income groups classification. Likewise, the terms LIC and UMIC refer to low income countries and upper-middle income countries.

SALES AND OPERATIONS

Business segments: Biopharm, diabetes and obesity care.

Therapeutic areas: Biopharmaceuticals, diabetes care, obesity care and other serious chronic diseases.

Product categories: Innovative medicines.

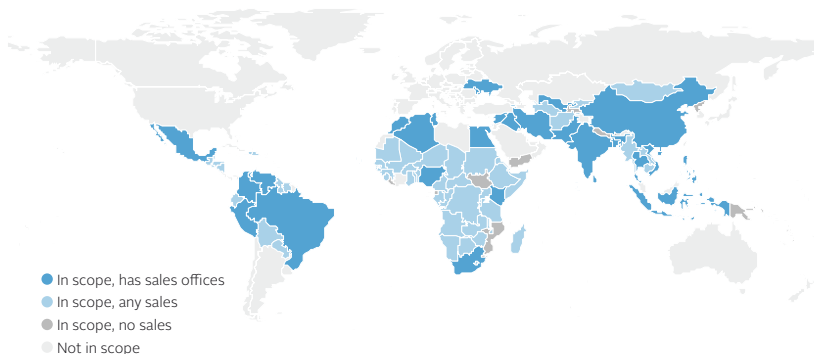
M&A news: Novo Nordisk acquired Dicerna Pharmaceuticals, Inc. in December 2021 for DKK 573 million.

Novo Nordisk's products are sold in 87 out of 108 countries in scope of the Index. Novo Nordisk has sales offices in 28 countries, and sells via suppliers and/or pooled procurement in an additional 59 countries.

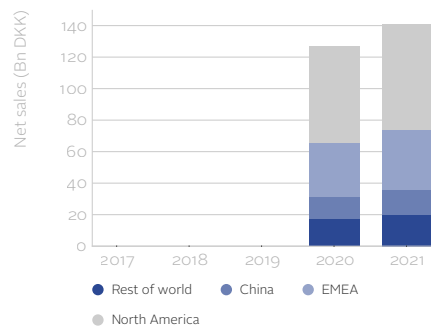
Net sales by segment (2021) – in DKK

Diabetes and obesity care	121.60 bn
Biopharm	19.20 bn
Total	140.80 bn

Sales in countries in scope



Sales by geographic region



SAMPLE OF PIPELINE AND PORTFOLIO ASSESSED BY THE INDEX

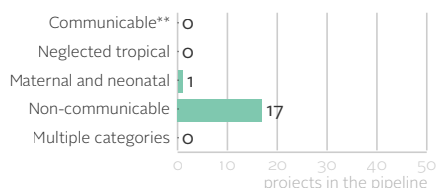
PIPELINE for diseases in scope

Novo Nordisk has a total of 18 R&D projects in scope with one project targeting a priority treatment gap. 17 projects target other diseases in scope. The focus of these projects is on diabetes (11 projects). Nine R&D projects are in late-stage development that target either a priority disease (1) or address a specific need in LMICs (8).^{*} Evidence of access planning was in place for 78% of these projects: one targeting a priority disease and six addressing a public health need in LMICs.

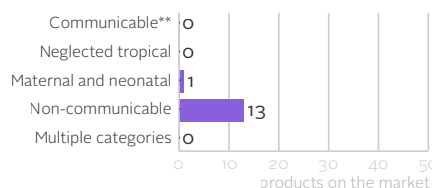
PORTFOLIO as selected for analysis by the Index

Novo Nordisk has 14 medicines in scope, eight of which are on patent. 36% of these medicines (5) are on the WHO EML. Most medicines are indicated for the treatment of diabetes.

18 projects in the pipeline



14 products as selected for analysis by the Index[†]



Breakdown of projects

	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Registration/approval	Other***	Total
Targets established R&D priorities	0	0	0	0	0	1	0	1
Addresses needs of LMICs*			0	2	5	1	0	8
Other projects in scope			5	4	0	0	0	9

Breakdown of products

	WHO EML	Non-EML	WHO EDL	Other	Total
Medicines on patent	2	6	0	0	8
off patent	3	3	0	0	6
Vaccines	0	0	0	0	0
Contraceptives	0	0	0	0	0
Diagnostics	0	0	0	0	0
Other [†]	0	0	0	0	0

^{*}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 fol-

low 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.

Novo Nordisk A/S

GOVERNANCE OF ACCESS

RANK 2

SCORE 4.43

Has an access-to-medicine strategy with measurable objectives, integrated within its overall corporate strategy. Novo Nordisk performs strongly. Its Defeat Diabetes strategy is structured around three focus areas: Prevention, Innovation and Access and Affordability, and includes an Access to Insulin Commitment focused on lowering the ceiling price for LMICs and humanitarian settings globally. The strategy covers all therapeutic areas in which the company is involved. 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 performs strongly. It incentivises its senior executives and in-country leaders to deliver 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 of the Index. It facilitates accountability and transparency by consistently sharing the outcomes of its access-to-medicine activities, including its Changing Diabetes in Children programme, in a centralised manner within its Year in Review report.

Performs above average in responsible promotional practices. Novo Nordisk's sales agents are not solely incentivised on sales volume targets. However, the company sets sales incentives at the individual level for agents. Novo Nordisk publicly discloses 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), where required by law and/or by local regulations, including consent related regulation, and it has policies and procedures in place governing transfers of values to healthcare professionals.

Has a robust set of compliance controls designed to ensure that governance efforts are not undermined by non-compliant or corrupt activities. Novo Nordisk 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.

Does not publicly support the Doha Declaration on TRIPS and Public Health. Novo Nordisk does, however, publicly state that health emergencies requiring exceptions to intellectual property (IP) rights can and should be accommodated under the international legal framework, but only under extraordinary circumstances. It does not support the routine use of compulsory licensing (e.g. absence of local manufacturing should never be a ground for issuing compulsory licenses). 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, Novo Nordisk, like all other member companies in scope of the Index, is by default connected to this activity.

RESEARCH & DEVELOPMENT

RANK 19

SCORE 1.48

A general process for access planning is disclosed. Novo Nordisk has a general process in place to include access-oriented principles for its R&D projects targeting diseases and countries within the scope of the Index.

A small-sized priority R&D pipeline compared to its peers, Novo Nordisk has one late-stage project in its pipeline that targets a priority product gap. Eptacog alfa (NovoSeven®) was recommended for approval for the treatment of severe postpartum haemorrhage by the European Medicines Agency during the period of analysis. For this project, Novo Nordisk provides evidence that they are considering plans for registration in several countries in scope of the Index.

Some projects address a public health need in LMICs,* with 75% (6/8) of late-stage projects covered by access plans. In this analysis, Novo Nordisk has eight 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 are first-in-class molecules and/or they significantly reduce the administrative burden or healthcare costs compared with existing products. Most target diabetes mellitus or ischaemic heart disease. Novo Nordisk provides evidence of access plans for six of these projects. These plans focus mainly on registration preparation in countries in scope of the Index.

Does not publicly disclose R&D investment data disaggregated by disease category, product type or phase of development. Novo Nordisk does not disclose disaggregated R&D investment data to global health organisations.

No R&D capacity building initiatives included for evaluation. There is no evidence — in the public domain or disclosed to the Index — of R&D capacity building initiatives active during the period of analysis that met inclusion criteria for evaluation. Novo Nordisk's performance is below average in this area.

*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. Projects in the clinical phase of development were included for this analysis.

PRODUCT DELIVERY

RANK 10

SCORE 3.39

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

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

Performs below average in terms of sharing intellectual property (IP) assets with third-party researchers. Novo Nordisk does not report on any new IP-sharing agreements with public research institutions or drug discovery initiatives established during the current analysis period that meet all inclusion criteria for evaluation. The company does not have existing agreements of this nature in place that were established before the current period of analysis and meet all inclusion criteria for evaluation.

No use of licensing agreements. Novo Nordisk does not engage in voluntary licensing for products in scope of the Index.

Filed to register new products in 17 countries in scope on average. Novo Nordisk did not disclose evidence of filing for registration any of its new products in more than half of the top ten high burden countries. Among new products, none have been filed in LICs. Among old products, its most widely registered is isophane human insulin (Insulatard®), for diabetes mellitus, filed in 83 countries within the scope of the Index, including four of the top ten high burden countries (Guyana, Mexico, Sri Lanka and Suriname).

Novo Nordisk is not eligible for assessment of supranationally procured products.

Novo Nordisk is not eligible for assessment of healthcare practitioner-administered products.

Has access strategies for its self-administered products for the majority of countries in scope of this analysis. Novo Nordisk performs above average in this area. For four 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 using pricing strategies that consider relevant payers' ability to pay and donations. For example, the company's Access to Insulin Commitment involves the provision of biphasic human insulin (Mixtard®), insulin human (rdna) (Actrapid®) and isophane human insulin (Insulatard®) in 76 LMICs, including Ethiopia, Sudan and Congo, Dem. Rep. at ceiling prices set at USD 3 per vial. Novo Nordisk provides evidence of how patient reach has increased. For example, 76,740 patients in Ethiopia were reached in the current period of analysis, compared to 7,291 patients reached previously.

Both manufacturing capacity building initiatives included for analysis meet all Good Practice Standards. Novo Nordisk's performance is average in this area. The number of initiatives meeting all inclusion criteria is lower than average but an average number of initiatives meet all Good Practice Standards (GPS) for this indicator. For example, Novo Nordisk is actively working with governments in countries in scope of the Index to ensure access to affordable diabetes treatment. The company conducts detailed technical assessments and due diligence of potential partners as a foundation of the capacity building projects.

Two of the three supply chain capacity building initiatives included meet all Good Practice Standards. Novo Nordisk's performance is average in this area. The number of initiatives meeting all inclusion criteria is average and an average number of initiatives meet all GPS for this indicator. The Sustainable Healthcare Supply Chain Programme in Ethiopia aims to 1) strengthen long-term supply of Ethiopian specialists in pharmaceutical supply chain handling 2) enhance institutional capacity to handle supply chains of non-communicable disease medicines and 3) strengthen responsiveness of the humanitarian medical supply chain. This initiative meets all GPS.

Four of the five health systems strengthening initiatives included meet all Good Practice Standards. Novo Nordisk'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 GPS than what is average for this indicator. For example, Cities Changing Diabetes (CCD) is a partnership programme to accelerate the prevention of diabetes and obesity by addressing the systemic change in urban environments: which are home to two-

thirds of people with diabetes. This initiative meets all GPS.

Has engaged in both scaling up and piloting one inclusive business model. Novo Nordisk performs above average in the use of inclusive business model aimed at meeting the access needs of populations at the base of the income pyramid (including other underserved populations) in LMICs. iCARE is a sustainable and fully integrated business model aimed at improving access to affordable diabetes treatment in the Novo Nordisk Middle Africa region through capacity building, safeguarding affordable insulin, strengthening supply chains and patient support and education.

Performs above average in terms of ensuring continuous supply of medicines in LMICs. Novo Nordisk 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, produces in-house active pharmaceutical ingredients, manages a buffer stock of relevant products and is involved in supply chain capacity building initiatives.

Has a policy for reporting substandard and falsified (SF) medicines in countries in scope of the Index in less than ten days. Novo Nordisk has a policy for reporting SF medicines to relevant health authorities within seven days. It does not provide evidence of shortened reporting time frames for cases which only require visual inspection to be confirmed.

Donates in response to expressed need and monitors delivery. Novo Nordisk 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.

Has no long-term donation programmes for neglected tropical diseases or malaria that are eligible for analysis under this indicator. However, the company is engaged in another structured donation programme: Changing Diabetes in Children where it has donated insulin human (rdna) (Actrapid®), isophane human insulin (Insulatard®) and biphasic human insulin (Mixtard®) to 21 countries in scope of the Index since 2009.