

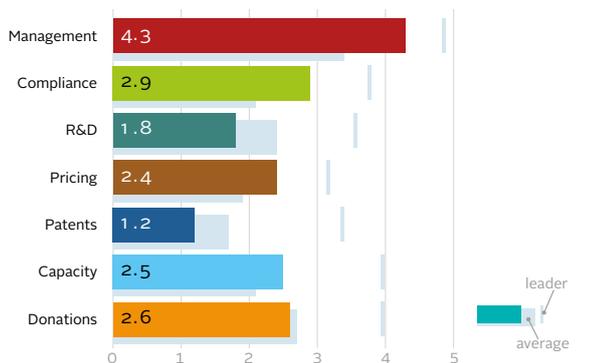
RANK	SCORE
10 ^v	2.35
2 (2014)	

Novo Nordisk A/S

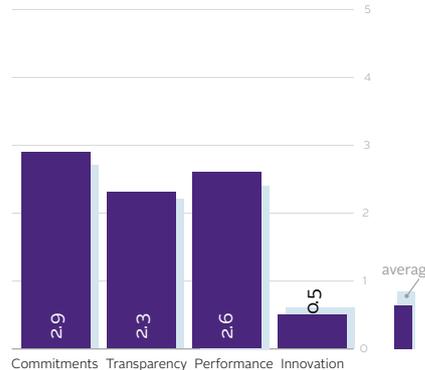


Stock Exchange: XCSE • Ticker: NOVOB • HQ: Bagsværd, Denmark • Employees: 41,122

Ranking by technical area



Ranking by strategic pillar



PERFORMANCE

Novo Nordisk has fallen in this Index, yet remains in the top ten. It maintains solid access management structures and compliance systems, but drops across other areas of measurement. It has a small relevant pipeline, and engages little in collaborative R&D. Its equitable pricing strategies only cover human insulin products, representing 27% of its portfolio for diseases in scope. Novo Nordisk has one structured donation

programme, which is limited in geographic and population scope. It now publishes the statuses of its patents, but has yet to agree a non-exclusive voluntary licence for one of its patented products. In Capacity Building, the company no longer leads but remains strong overall.

CHANGE SINCE 2014

- Has leading access management structures in place, supported by two systems for tracking and assessing access-related performance.
- Has not been found in breach of laws or regulations related to marketing and corruption since 2014.
- Has equitable pricing strategies for the same human insulin products as in 2014 but has updated its commitment to providing low-priced human insulin, to include more countries and humanitarian organisations.
- Has improved its accountability for its sales agents' pricing practices.
- Publishes information about all patents held worldwide.
- Launched the No Empty Shelves partnership with PATH in 2014 to identify capacity gaps in supply chain management for diabetes medicines and technologies in low- and middle-income countries.
- Launched Cities Changing Diabetes in 2014, a partnership programme designed to identify and address the root causes of the rise of type 2 diabetes in urban areas.
- Expands Changing Diabetes in Children donation programme, enrolling five additional countries in 2016.

OPPORTUNITIES

Work with partners to address access concerns for non-communicable diseases more broadly. Novo Nordisk can leverage its expertise in diabetes to support public and/or private partners in strengthening care for different non-communicable diseases.

Expand strong capacity building approach. Novo Nordisk can expand its capacity building activities and target local needs and skills gaps more strategically (e.g., in its R&D partnerships in China and Iran). The company can also share information with local stakeholders to help strengthen supply chains and pharmacovigilance systems.

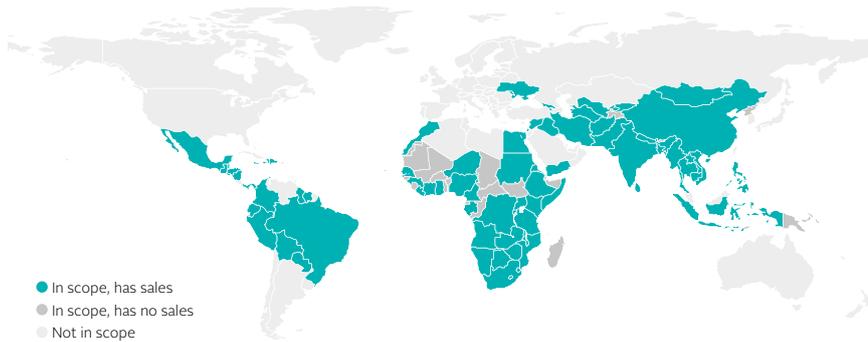
Ensure sustainable access to insulin. In addition to its pricing strategy for human insulin, Novo Nordisk can implement new measures to support sustainable and affordable access to new diabetes treatments (including insulin analogues) that are suitable for people in low- and middle-income countries. It can assess local needs per population segment when customising pricing. It can implement registration commitments to prioritise those markets where the product is urgently needed.

Consider a company-wide approach to voluntary licensing. Novo Nordisk can consider terms for voluntary licences of its patented innovative diabetes products (e.g., long-acting analogues such as insulin degludec (Tresiba®), a

second-line treatment for diabetes) to permit generic medicine manufacturers to produce biosimilars. This can help address issues of affordability and supply. Considering the complexity of biosimilar production, the company can consider additional technology transfer and support.

Use stakeholder engagement to inform its R&D priorities. Novo Nordisk can apply its existing model of engaging with health care professionals to ensure R&D priorities are based on the needs of patients in low- and middle-income countries. This includes ensuring specific access plans are in place for candidates currently in the pipeline (e.g., for its candidate oral formulation of insulin).

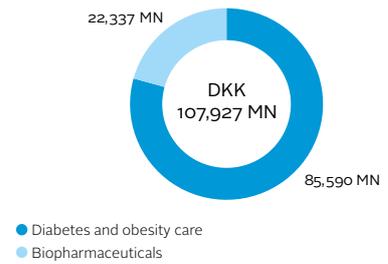
Sales in countries in scope



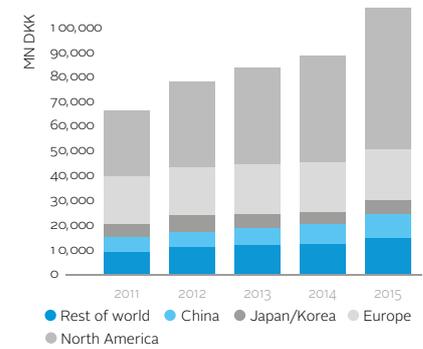
SALES AND OPERATIONS

Novo Nordisk operates in two divisions: Diabetes & Obesity Care, and Biopharmaceuticals. The company is active in five product areas: diabetes care, haemophilia, growth hormone therapy, obesity and hormone replacement therapy. Novo Nordisk has sales in 79 countries in scope, and over 20% of its sales come from emerging and frontier markets.

Net sales by segment (2015)



Net sales by geographic area



PORTFOLIO AND PIPELINE

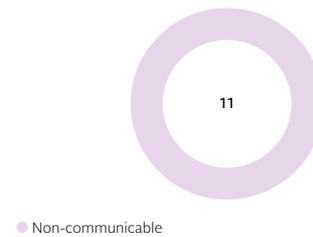
Novo Nordisk has the smallest relevant portfolio in the Index, with 11 medicines. It has a small pipeline of four R&D projects that address the needs of people in countries in scope. Its relevant portfolio and pipeline focus exclusively on diabetes.

Nine of its 11 medicines are insulins, including human insulin and insulin analogues. In 2015, its insulin degludec (Tresiba®) was approved for use by the FDA. Its remaining two products are liraglutide (Victoza®), a glucagon-like peptide-1 receptor agonist, and repaglinide (Novonorm®),

from the meglitinide therapeutic class. The company is developing four medicines, all in phase I clinical trials. These include a long-acting basal insulin analogue for once-weekly dosing, an appetite-regulating hormone peptide tyrosine and a liver-preferential prandial insulin analogue. The latter has progressed from discovery stage to phase I trials since 2014.

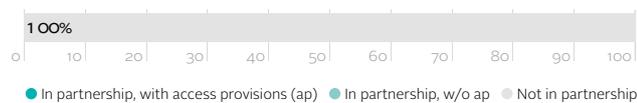
The company's focus is on diabetes. It is not targeting high-priority product gaps with low commercial incentive, for diseases that disproportionately affect low- and middle-income countries.

Products per disease category



Novo Nordisk's medicines all target diabetes: nine out of 11 are insulins and insulin analogues.

Pipeline projects



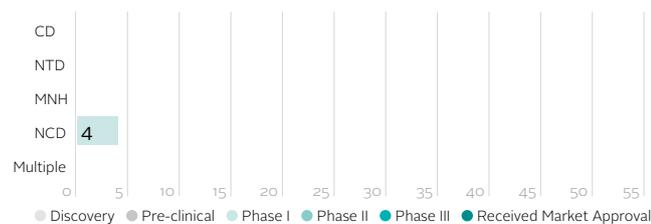
Novo Nordisk's relevant R&D projects are not being developed in partnership.

First-line treatments and essential medicines



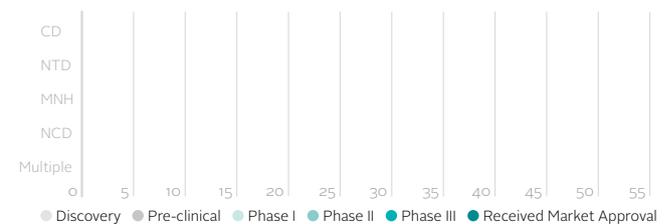
Human insulin is Novo Nordisk's only product on the WHO EML and/or listed as a first-line treatment. The company has two human insulins in its portfolio.

Pipeline by stage of development



Novo Nordisk's pipeline focuses on innovative medicines. It is developing a daily oral insulin tablet that will not require refrigeration, potentially improving access to insulin in settings without stable cold chains.

Adaptive medicines and vaccines



Novo Nordisk is not currently adapting any products to meet the needs of people living in low- or middle-income countries.

Novo Nordisk A/S

PERFORMANCE BY TECHNICAL AREA

GENERAL ACCESS TO MEDICINE MANAGEMENT

RANK 2 SCORE 4.3

A leader, due to a strong strategy and systems. Novo Nordisk once again performs well in this area, rising one place to 2nd. It has a strong access strategy, good performance management systems and an innovative initiative in governance and stakeholder engagement.

Access is integrated into corporate strategy, at global and local levels. Globally, the company aims to reach 40mn people with diabetes by 2020. This target is included in the company's annual strategic planning process. At the local level, Novo Nordisk assesses which of its activities can be scaled up or adapted to increase their impact.

Double performance management system. Novo Nordisk uses two performance management systems to monitor and measure progress towards access targets. The first is its Balanced Scorecard, used for tracking the company's goals, and the second is its People Performance Process system, for tracking employee targets.

Well-defined strategic stakeholder engagement. Novo Nordisk has a strategic approach to stakeholder engagement. The process is well defined, making it easier for subsidiaries to follow. The details are not publicly available.

► **Innovation: governance and stakeholder engagement approach.** Cities Changing Diabetes is a cross-disciplinary and cross-sector partnership programme designed to identify and address the root causes of the rise of type 2 diabetes in urban areas including in Johannesburg, Mexico City, Tianjin and Shanghai. It aims to support the implementation of sustainable solutions in urban areas.

► **Best practice: benchmarking targets.** Novo Nordisk is committed to systematically reviewing its contribution to each of the 17 Sustainable Development Goals, focusing on health and improving the well-being and lives of patients.

MARKET INFLUENCE & COMPLIANCE

RANK 2 SCORE 2.9

Top performer in market influence and compliance. Novo Nordisk is 2nd once again, with a strong compliance system, and no confirmed

breaches of laws and regulations during the period of analysis. Its transparency regarding lobbying and marketing is above average.

Goes beyond sales-linked incentives; has broad marketing code. Novo Nordisk has a marketing code that also applies to third parties. It rewards its sales agents for more than just sales, using product availability and stock maintenance as alternative performance metrics. Nevertheless, it does not disclose information about its marketing activities in countries in scope.

Relatively high transparency regarding lobbying. Novo Nordisk is transparent about its lobbying activities and public policy positions. It states it does not make any political contribution in countries in scope. It has a policy for mitigating conflicts of interest that is not publicly available.

Auditing system in place. Novo Nordisk plans its audits based on an independent risk assessment, to ensure certain units are visited every year and that all units are visited every third year. Two to three external audits of selected high-risk third parties are performed annually.

Compliance with laws and codes. As in 2014, Novo Nordisk has not been the subject of any settlements for criminal, civil or regulatory infractions relating to unethical marketing or corruption anywhere in the world during the period of analysis.

Enforcement process applies to third parties. Novo Nordisk has an enforcement process in place, including disciplinary measures. Sanctions include re-training, counselling, oral warnings and dismissal. Termination clauses are in place in contracts with third parties.

RESEARCH & DEVELOPMENT

RANK 15 SCORE 1.8

Drops in R&D, with a smaller pipeline for the poor. Novo Nordisk's performance fell, largely due to a decrease in the size of its adaptive pipeline that targets unmet medical or public health needs in countries in scope. The company was also overtaken by several peers whose performance improved.

Strong commitment to R&D for diabetes. One of Novo Nordisk's strategic aims is to build and maintain a leading position in emerging markets. The company engages with profession-

als to understand the hurdles to diabetes treatment. It does not provide evidence that it uses the insights gathered in order to base R&D strategies on public-health and product needs.

Significant investment in R&D for diabetes. A relatively high proportion of Novo Nordisk's R&D investments are relevant to the Index. It publishes its investments into diabetes and obesity care (DKK 19,793 mn annually), approximately 90% of which is relevant to the Index.

No commitment to access-oriented R&D partnerships. The company does not commit to ensuring access-oriented terms are systematically included in its research partnerships. Neither does it publish the relevant terms and conditions of its research collaborations. The company has no relevant R&D partnerships nor intellectual property sharing arrangements.

Takes measures to ensure clinical trials are conducted ethically. Novo Nordisk has policies in place and takes measures to ensure its in-house and outsourced clinical trials are conducted ethically.

High transparency around clinical trials. The company upholds high standards of clinical trial data transparency, including providing scientific researchers access to patient-level data upon request. Novo Nordisk has established an independent, expert-review governing body to review such requests.

PRICING, MANUFACTURING & DISTRIBUTION

RANK 5 SCORE 2.4

Drops two places due to a static performance. Novo Nordisk falls from 3rd place as its static performance in equitable pricing is outperformed by peers making improvements.

Same products with equitable pricing. Novo Nordisk has equitable pricing strategies for the same human insulin products as in 2014. It has expanded its commitment to providing low-priced insulin: in 2017, it will guarantee a ceiling price of USD 4 per vial of human insulin in Least Developed Countries. Some (27%) of its products have pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). These strategies reach the majority (70%) of corresponding priority countries. The

company currently only considers affordability in its intra-country equitable pricing strategies, overlooking other socio-economic factors.

► **Innovation: distribution project.** In 2015, Novo Nordisk Business Area Africa (BAAF) initiated the BAAF Distribution Optimisation project to reduce the price to patients of its full diabetes portfolio and to work with distributors to optimise the supply chain. This is an important step as, even with Novo Nordisk's ceiling price for Least Developed Countries, there are other barriers along the distribution chain that can increase the cost of insulin.

Pricing guidelines for all local sales agents.

Novo Nordisk provides guidelines on margins and distributor fees. Additionally, it conducts a formal bi-annual internal audit on pricing and pricing structures in all mid-sized and large markets.

Leader in the area of registration. Novo Nordisk only commits to registering products for a sub-set of diseases in some lower-middle income countries, but provides no timeframe. However, in practice, the company has filed to register all (100%) of its newest products in the majority of priority countries (disease-specific sub-sets of countries with a particular need for access to relevant products). The majority of these products were launched over 10 years ago.

Consistent recall guidelines and public disclosure of recalls. Novo Nordisk has consistent guidelines for issuing drug recalls in all countries relevant to the Index where its products are available. The company publicly discloses aggregate information on relevant recalls in its annual report and is the only company to make any public disclosure in this area.

Limited brochure & packaging adaptation for rational use. Novo Nordisk provides evidence of adapting brochure and packaging to address only language needs with the aim of facilitating rational use by patients.

PATENTS & LICENSING

RANK 12 SCORE 1.2

Patent disclosure. Novo Nordisk publishes information about the patent rights it holds. It indicates where the patent has been granted, whether extension has been applied for, and the patent number.

Public commitment not to file or enforce. Novo Nordisk has published a commitment not to file for or enforce patents in Least Developed Countries and low-income countries.

Lack of engagement in licensing. Novo Nordisk does not engage in non-exclusive voluntary licensing of its patented products, and has made no public offer to consider this.

Evidence of anti-competitive behaviour. During the period of analysis Novo Nordisk reached a settlement with the Michigan Federal court to settle an anti-trust action concerning repaglinide (Prandin®). At the time of analysis, there was no record of an appeal identified.

No public acknowledgement of the Doha Declaration.

Novo Nordisk does not publicly acknowledge the Doha Declaration, though it states that public health emergencies require exceptions to intellectual property rights in extraordinary circumstances.

CAPACITY BUILDING

RANK 7 SCORE 2.5

Previous leader, now outperformed. Novo Nordisk fell six places, losing its leading position. Although Novo Nordisk performed well, particularly in capacity building outside the pharmaceutical value chain. It has been outperformed by peers. This is particularly the case with regard to sharing information with stakeholders to strengthen local supply chains and pharmacovigilance systems.

Leader in building capacity outside the value chain. Novo Nordisk has a very strong approach to philanthropy, including targeting local needs, through the World Diabetes Foundation. The company discloses a number of relevant initiatives for building locally-needed capacities outside the pharmaceutical value chain, focusing on diabetes care.

Building R&D capacity in China and Iran. Novo Nordisk has local partnerships for building diabetes research capacity in Iran (with Tehran University of Medical Sciences), and China (with the Chinese Academy of Sciences). Both partnerships are long-term, but it is not clear how they target local skills gaps.

Strengthening supply chains in sub-Saharan Africa. Working in partnerships, Novo Nordisk is actively strengthening local supply chains in countries in scope, particularly in sub-Saharan Africa. However, the company did not demonstrate that it shares information with relevant stakeholders to improve supply chain management skills.

Average performance in strengthening pharmacovigilance systems. Novo Nordisk has a number of activities for building local pharmacovigilance skills: including a partnership with the Bangladesh Ministry of Health to improve capacity of the National Drug Control Laboratory. The company did not provide evidence that it voluntarily shares safety data with relevant authorities.

Manufacturing capacity building receives least attention. Novo Nordisk makes a general commitment to build manufacturing capacity in rele-

vant countries. It undertakes a number of capacity building activities, including permanently attaching an in-house expert to a third-party plant in India.

PRODUCT DONATIONS

RANK 10 SCORE 2.6

One of the biggest fallers. Novo Nordisk drops to 10th position. Novo Nordisk has one on-going structured donation programme, with comparatively limited geographic and population coverage.

Continues to donate insulin for children. In 2009, Novo Nordisk initiated its Changing Diabetes in Children (CDiC) programme. It is currently funded until the end of 2020, is implemented in nine countries and provides insulin to 13,516 children. Five more countries were slated to be enrolled in 2016.

Complies with WHO guidelines for donations. Novo Nordisk has internal guidelines for making emergency drug donations. These require adherence to WHO's Guidelines for Drug Donations.

Tailored monitoring structure. Within its CDiC programme, Novo Nordisk works with partners to ensure donated products are monitored and that they reach intended users. As part of the programme, each country has a system in place for monitoring whether the donated insulin is administered to the intended users. Each system is tailored to the local setting.

Makes ad hoc donations for emergency relief. Since 2014, Novo Nordisk has donated insulin for emergency relief. The company donated products during the 2014-2015 Ebola epidemic and the 2015 refugee crisis in Syria.