PERFORMANCE

Rises 4 places to 6th. Novo Nordisk focuses on one disease covered by the Index: diabetes. It has strong management structures for access and exhibits robust performance in the application of good practice in both capacity building initiatives and donation programmes.

Management: Falls 3 places to 5th, but remains in the first quartile, due to the reassignment of board-level responsibility for its access-to-medicine approach.

Compliance: Falls 4 places to 6th, as its internal control framework does not meet the same criteria as leading peers.

R&D: Rises 6 places to 9th with a new publicly available policy for post-trial access.

Pricing: Falls 2 places to 7th. Solid registration performance, but outperformed in the degree to which socioeconomic factors are used to determine affordable prices.

Patents: Falls 1 place to 13th. Static performance compared to 2016, as it reports no instances of sharing IP during the period of analysis.

Capacity: Rises 3 places to 4th. Strong performance in capacity building with 11/13 initiatives meeting all good practice standards.

Donations: Rises 8 places to 2nd with a high-quality programme for paediatric diabetes, that considers longer-term access once the programme ends.

OPPORTUNITIES

Expand access to insulin by supporting local manufacture. Novo Nordisk reports manufacturing capacity building initiatives in Bangladesh, India, Iran, and Egypt. The company can leverage this expertise and look to work with other insulin manufacturers (e.g., on the African continent, and in Latin America) to build capacity to produce high-quality insulin and help to stabilise local supply.

Expand Base of the Pyramid to more countries in scope. An evaluation from University College London demonstrated that Novo Nordisk’s Base of the Pyramid has been successful in sustaining access to care and diagnosis, raising awareness and providing a stable supply of insulin in Kenya. The programme currently reaches Ghana, Kenya, Nigeria and Senegal. The positive evaluation shows that shared value can be achieved and scalability is possible. Additional countries in need of access to diabetes care can be brought within the ambit of this programme.

Establish access plans during development that go beyond registration. Novo Nordisk currently focuses on registration strategies for its pipeline. It can also plan for equitable pricing strategies and (where possible) WHO prequalification. By addressing multiple barriers to access, it can help make critical therapies not only available for purchase but also at an affordable price in low- and middle-income countries. This is especially true of its oral GLP-1 agonist semaglutide (Ozempic®), which is currently in Phase III of clinical development and could address the heat-stability issues that have reduced the utility of other GLP-1 agonists in low- and middle-income countries in the past.

Expand access to more diabetic children with no access to insulin. Over the period of analysis, Novo Nordisk reported that the Changing Diabetes in Children (CDiC) Programme reached over 2,000 additional children. Programmes such as these fill an important gap, especially where diagnosis and treatment of type 1 diabetes in children is not yet achieved through Universal Health Coverage. CDiC continues to successfully expand, and should seek to include additional countries where children at risk live.

CHANGE SINCE 2016

- Improved its governance structure by anchoring its responsibility and accountability for its global access to diabetes care strategy at the highest level within Novo Nordisk in 2017.
- Founding member of the new global multi-stakeholder partnership, the Defeat-NCD Partnership, which was formally launched in September 2018. The initial focus will be on hypertension and diabetes.
- Launched the Partnering for Change - Chronic Care in Humanitarian Crises initiative in April 2018 which aims to ensure basic healthcare and improve supply of insulin in humanitarian settings.
- Novo Holdings launched the REPAIR Impact Fund in February 2018 with $165 million USD to invest in early-stage drug development projects targeting antimicrobial resistant microorganisms.
- Expanded its Changing Diabetes in Children programme in 2016, newly including Cambodia, Ivory Coast, Myanmar, Senegal and Sudan.
- Launched its Access to Insulin commitment in 2017, helping to ensure availability of low prices for insulin in the poorest parts of the world.
**PIPELINE** for diseases and countries in scope

*Smallest pipeline:* 10 R&D projects (all medicines) for diseases in scope.

*Clinical candidates:* 5, including a beta-cell preservation treatment for patients with newly diagnosed type I diabetes mellitus and oral semaglutide for type II diabetes mellitus.

*Regulatory approvals:* 2, including a faster-acting insulin aspart (Fiasp®) for the treatment of diabetes mellitus.

*R&D focus:* non-communicable diseases (diabetes mellitus).

*Access provisions:* for 2 projects, both of which have registration strategies.

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**PORTFOLIO** for diseases and countries in scope

*Smallest portfolio:* 12 products for diseases in scope (all medicines).

*Portfolio focus:* non-communicable diseases (diabetes mellitus).

*Essential medicines:* 17% of Novo Nordisk's medicines are currently listed on the 2017 WHO Model List of Essential Medicines (WHO EML).

*First-line treatments:* 75% of Novo Nordisk's medicines have first-line indications for diseases in scope.

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Novo Nordisk is developing a Phase III oral formulation of Ozempic® (semaglutide) which could make the use of GLP-1 agonists for diabetes mellitus more feasible in countries where the cold chain is difficult to maintain.

Of its four late-stage projects, two are supported by access provisions: e.g., the company plans to register both of its market-approved diabetes mellitus drugs, Fiasp® and Ozempic®, in several countries in scope. Two of its four late-stage projects have provisions.

**BUSINESS CONTEXT**

*Two business units:* Diabetes and Obesity Care; and Biopharmaceuticals. The company also operates in two other therapeutic areas (haemophilia; and growth disorders).

*M&A news:* 2018 acquisition of Ziylo Ltd, a biotechnology company with a glucose binding molecule platform. Parts of Ziylo’s research were also spun out to a new company (Carbometrics).

**Presence in emerging markets:** In 2018, Novo Nordisk reports sale in 81 countries in scope; 2 more countries than in the 2016 Index.

**Net sales by segment (2017) - DKK**

- Diabetes and Obesity Care: 92,877 MN
- Biopharmaceuticals: 18,819 MN
- Total: 111,696 MN

**Net sales by geographic region**

- Rest of World: 2013 - 45; 2017 - 48
- China: 2013 - 10; 2017 - 14
- Japan/Korea: 2013 - 20; 2017 - 20
- Europe: 2013 - 90; 2017 - 92
- North America: 2013 - 20; 2017 - 22

*Statistics relate only to diseases and countries in scope.*

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**M&A news:** 2018 acquisition of Ziylo Ltd, a biotechnology company with a glucose binding molecule platform. Parts of Ziylo’s research were also spun out to a new company (Carbometrics).

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75% of Novo Nordisk’s medicines are listed on the WHO EML and/or as first-line treatments: e.g., three human insulins and the long-acting insulin analogue insulin detemir (Levemir®).
Novo Nordisk A/S

**PERFORMANCE BY TECHNICAL AREA**

### GENERAL ACCESS TO MEDICINE MANAGEMENT

**RANK 5**  **SCORE 3.88**

Has a strong access-to-medicine strategy with board-level responsibility. Novo Nordisk is one of 14 companies that performs strongly with regard to its access-to-medicine strategy, which includes access-related goals and aligns with its corporate strategies. For example, its strategy on improving access to diabetes care focuses on availability and affordability, building capacity in health systems and increasing access for the most vulnerable. The highest level of responsibility for access sits with a board-level committee.

Financial and non-financial access-related incentives to reward employees. Novo Nordisk performs strongly in encouraging employees to work towards access-related objectives. It is one of 14 companies to have both financial and non-financial incentives in place to motivate employees to perform on access-related issues. These incentives include bonuses for employees who perform remarkably and a long-term share-based incentive programme. Senior management has a separate incentive that supports the company’s long-term access oriented objectives.

One of 16 companies working on impact measurement. Novo Nordisk measures and monitors progress and outcomes of access-to-medicine activities. It also publicly reports on commitments and performance information. For example, for its Changing Diabetes in Children initiative, the company reports on its performance, and its access to insulin commitments. Furthermore, it is one of the companies that is measuring impact by evaluation of its Base of the Pyramid initiative.

Discloses who it engages with, incorporates local perspectives into strategies. Novo Nordisk publicly discloses which stakeholder groups it engages with on access issues, as well as its progress. Neither of these are being conducted in partnership.

Above average transparency regarding access-related practices. Novo Nordisk publicly discloses its policy positions on access-related topics (e.g., it publicly supports the WHO’s Action Plan for Prevention and Control of NCDs). It is one of the few companies in scope to have a policy that forbids political contributions. It publicly discloses its membership and financial support of patient groups in countries in scope. It includes guidance for responsible interactions with stakeholders in its business ethics code of conduct. It does not, however, publicly disclose its policy approach to payments made to health-care professionals in countries in scope.

### MARKET INFLUENCE & COMPLIANCE

**RANK 6**  **SCORE 3.03**

Has measures to ensure third-party compliance with ethical marketing and anti-corruption standards. Novo Nordisk has a code of conduct relating to ethical marketing and anti-corruption. It provides annual compliance training for employees. The company provides evidence of having formal processes in place to ensure compliance with standards by third parties. Sales agents’ rewards are not solely based on sales targets. Instead, it rewards other qualities such as technical knowledge and leadership competencies.

Internal control framework meets some Index criteria. Novo Nordisk’s internal control framework to ensure compliance meets some of the criteria looked for by the Index. Namely, it has an auditing and review mechanism in place, involving both internal and external resources, that also applies to third parties. It does not, however, report fraud-specific risk assessments, nor does it demonstrate evidence of a monitoring system for non-compliance in the workplace, or procedures to segregate duties, to ensure decisions are checked by another party.

### RESEARCH & DEVELOPMENT

**RANK 9**  **SCORE 2.09**

Projects: 10 in clinical development: 5

R&D commitment has limited public health rationale. Novo Nordisk has made a specific commitment to R&D for diabetes, a disease in scope, but this is not publicly available. Its R&D strategy for low- and middle-income countries lacks evidence-based public health rationale including internal assessments and calls for action from external sources like WHO. It lacks time-bound strategies for completing R&D projects for diseases in scope. Novo Nordisk has the smallest pipeline in the Index with 10 projects. Novo Nordisk is active in R&D for diabetes, for which a globally accepted priority list does not exist.

Access provisions in place for 50% (2/4) of late-stage candidates. Novo Nordisk does not have a clear process in place to develop access plans during R&D. While Novo Nordisk considers access for all insulin products at some point, it is unclear whether or not this takes place during the clinical development stage. To date, Novo Nordisk has project-specific access provisions in place for two of its late-stage R&D projects, both of which have received market approval. Neither of these are being conducted in partnership.

### PRICING, MANUFACTURING & DISTRIBUTION

**RANK 7**  **SCORE 2.42**

Products: 12

Commits publicly to equitable pricing but does not report a commitment to file to register new products in scope. Novo Nordisk does not commit to filing its newest products for registration in countries in scope within one year of first market approval. However, it does publicly commit to implement inter-country equitable pricing strategies for a minority of its products for diseases in scope, including for future products. This does not explicitly apply to future products. It also commits to implementing intra-country pricing strategies.

Half of new products in scope filed for registration in the majority of relevant priority countries. Novo Nordisk has filed 50% of its newest products for registration to date in more than half of the relevant priority countries (disease-specific subsets of countries with a particular need for access to relevant products). However, it does not publicly share registration
25% of products have equitable pricing strategies targeting priority countries. Novo Nordisk's overall performance is average compared to peers in equitable pricing. It demonstrates evidence of having equitable pricing strategies for 25% of its products for diseases in scope. These strategies apply to all priority countries. All of the strategies apply inter- and intra-country pricing; these take into account an average of one socioeconomic factor.

Globally consistent recall guidelines for countries in scope but no processes to track products. Novo Nordisk has guidelines for drug recalls that apply to all countries in scope. It does not demonstrate evidence of having processes to track the distribution of products in countries in scope to facilitate rapid and effective recalls.

No use of non-assert or licensing arrangements. Novo Nordisk does not engage in voluntary licensing nor has it issued non-assert declarations for products in scope.

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.

Public commitment not to enforce patents in countries in scope. Novo Nordisk commits publicly to neither file for nor enforce patents related to diseases within the scope of the Index. This commitment applies in Least Developed Countries and low-income countries.

13 initiatives included for evaluation. Novo Nordisk has 13 capacity building initiatives that were included for analysis by the Index: i.e., the initiatives demonstrably address a specific local need and involve local partners. Companies could submit a maximum of 25 initiatives across all areas for assessment; Novo Nordisk submitted 16.

Strong focus on local manufacturing and strengthening health systems. Novo Nordisk has initiatives that meet inclusion criteria in all areas of capacity building, except pharmacovigilance. It performs strongest in manufacturing capacity building and health system strengthening. Its initiatives are focused on diabetes care.

11 initiatives meet all applicable good practice standards:
- The Base of the Pyramid (BoP)
- No Empty Shelves
- The Defeat-NCD Partnership
- Changing Diabetes in Children (CDiC)
- Cities Changing Diabetes

A full list of Novo Nordisk’s capacity building initiatives that meet all good practice standards can be found online. Novo Nordisk has only two included initiatives which do not meet all good practice standards. These two fall short on measuring progress and outcomes.

Timely approach to reporting substandard or falsified medicines to relevant authorities. Novo Nordisk provides evidence that it systematically reports confirmed cases of substandard or falsified medicines to relevant authorities or WHO Rapid Alert within the period recommended by stakeholders (maximum seven days).

Responds to emergencies and humanitarian crises and tracks delivery. Novo Nordisk donated medicines on the request of relief agencies. For example, during the period of analysis, it donated insulin in response to the 2017 earthquake in Mexico. The company discloses that such ad hoc donations are aligned with international guidelines (issued by WHO, PQMD), and it works, for example, with humanitarian organisations to ensure products are rapidly delivered. It also monitors the delivery of the product until received by end user.

One donation programme covering diseases and countries in scope. Novo Nordisk’s programme is focused on non-communicable diseases, namely diabetes. The programme Changing Diabetes in Children (CDiC) is carried out in partnership with the World Diabetes Foundation (WDF), Roche and the International Society for Paediatric and Adolescent Diabetes (ISPAD), Ministries of Health, National Diabetes Associations as well as other local partners. The programme supplies human insulin (rDNA (Actrapid®), isophane human insulin (Insulatard®) and biphasic human insulin (Mixtard®) in 14 countries and has been ongoing since 2009. During the period of analysis, the company reports that more than 2000 additional children were enrolled in the programme.

Ensures long-term access through transition planning. Novo Nordisk has transition plans in place for its CDiC programme to ensure ongoing access for patients once a programme ends. The company will ensure that the completion of the programme will occur gradually over time as it continues to work with local stakeholders to ensure communities retain access to the medicine once a programme ends. The company will continue to supply insulin to children enrolled in the programme.