strategy for global access to diabetes care

Closing the gap

Approved by the Health Policy Committee November 2013
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1. EXECUTIVE SUMMARY

Diabetes is a global health challenge. There are now an estimated 382 million people worldwide with diabetes and the number is expected to rise to over half a billion by 2035. Only a fraction has access to adequate treatment and care.

In Novo Nordisk, we believe that it should be an integrated part of our core business to improve access to diabetes care.

The purpose of the Novo Nordisk Strategy for Global Access to Diabetes Care is to:

• contribute to breaking the Rule of Halves by overcoming the barriers that inhibit access to care, in order to
• reach more people with quality treatments, and
• enable more people with diabetes to live better lives.

We have set a new long-term target of reaching 40 million people with diabetes with our diabetes care products by 2020 – also referred to as the Changing Diabetes® 40by20 ambition.

It will contribute to this long-term target if we work to break the Rule of Halves. As more people with diabetes are diagnosed, more will receive care, more will meet treatment targets and more will achieve improved health and quality of life that leads to a longer life expectancy.

The strategy is integrated into Novo Nordisk business planning processes. As part of their local Changing Diabetes® plans, Novo Nordisk affiliates are encouraged to assess which of their current activities can be scaled up or done differently to get more impact on the Rule of Halves.

The affiliates are also encouraged to set local patient targets, which will feed into the global goal of reaching 40 million people with diabetes by 2020, as well as comparable targets for their Changing Diabetes® activities relating to the pillars of the Rule of Halves.

The Changing Diabetes® 40by20 ambition will be part of the Novo Nordisk Regions’ budget presentations.

At the corporate level we will scale-up Novo Nordisk efforts in three key areas:

1. Reaching the base of the pyramid
2. Contributing to global education of healthcare professionals
3. Promoting health for the next generation

Novo Nordisk Health Policy Committee will be responsible for monitoring the progress of the strategy.
2. THE GLOBAL CHALLENGE

The diabetes epidemic

Since Novo Nordisk launched its first access to care strategy in 2001, diabetes has become a global health challenge. There are now an estimated 382 million people worldwide with diabetes and the number is expected to rise to over half a billion by 2035.\(^1\)

Only a fraction has access to adequate treatment and care.

The unfolding global diabetes epidemic is fuelled by rapid urbanisation, nutrition transition, and increasingly sedentary lifestyles. The human costs of the unchecked disease are measured in the loss of sight, amputated limbs and premature deaths due to diabetes-related complications.

In recent years, a new global understanding has emerged on the threat of diabetes and other non-communicable diseases (NCDs). The United Nations High-level Meeting on NCDs in September 2011 and the global targets of the WHO action plan on NCDs from May 2013 represent important breakthroughs in the global efforts to address the need for diabetes care. See appendix 1 for more information.

Diabetes has become a global issue:

- 80% of diabetes cases occur in middle- and low-income countries (LMICs).\(^4\) Only 20% of global healthcare expenditures due to diabetes are made in LMICs.\(^5\)

- The LMICs face a ‘double burden’ of infectious and chronic diseases and people in large numbers lack access to diabetes treatment and adequate health infrastructures. In high-income countries, indigenous and migrant populations suffer higher rates of diabetes and its complications.\(^6\)

- Harvard School of Public Health projects that diabetes and other NCDs will contribute to a stunning USD 47 trillion in lost economic output over the next 20 years.\(^7\)

- Childhood obesity is increasing at an alarming rate, particularly in urban areas. In 2010 the number of overweight children under the age of five was estimated to be over 42 million, close to 35 million of these living in developing countries. This development will continue to add to the growth of NCDs in LMICs.\(^8\)

As the leader in diabetes care, providing approximately half of the world’s insulin, Novo Nordisk has a responsibility to do more to help close the gap in access to diabetes care. For more than ten years we have been actively engaged in improving access to diabetes care. We have particularly focused on the least developed countries through our donation to the World Diabetes Foundation, the Differential Pricing Policy for Least Developed Countries and other initiatives. We have described these initiatives in the publication ‘Access to Health – Our approach’ from 2011.

This strategy draws on the experience gained through all the efforts we have made over the last 10 years and on our stakeholder dialogue. Until now, much has been achieved through different initiatives taken by our affiliates. With this strategy it is our ambition to bring these many good efforts together in a more coordinated framework that provides for more transparency and the consistent evaluation of our impact.

The diabetes epidemic requires a global concerted action to improve access to diabetes care. Novo Nordisk strategy is based on the premises that it should be an integrated part of our core business to improve access to diabetes care.

The Strategy for Global Access to Diabetes Care is an essential part of our corporate mission – Changing Diabetes\(^®\).

Changing Diabetes\(^®\)

In many countries there is only limited information on the prevalence and treatment of diabetes. The information available shows that diabetes generally follows the Rule of Halves:

- Only half of the people with diabetes are diagnosed
- Half of those diagnosed are untreated, and
- Half of those treated do not achieve treatment targets, and
- Half of those who meet treatment targets achieve a successful outcome in terms of improved health and quality of life.

As a result a large majority of all people with diabetes do not achieve successful health outcomes.

Novo Nordisk has made Changing Diabetes\(^®\) our corporate mission. As part of this mission, it is our aspiration to work with partners to break the Rule of Halves by overcoming the barriers that inhibit access to care. We will combine corporate priority programmes with local initiatives to address the specific conditions in the countries where we are present. In preparation for this strategy we have therefore made country profiles to identify the main barriers that lead to the Rule of Halves.


Actual rates of diagnosis, treatment, targets and outcomes vary in different countries.

3. BREAKING THE ‘RULE OF HALVES’

The purpose of the strategy
With our company values - The Novo Nordisk Way - we make it our key contribution to discover and develop innovative biological medicines and make them accessible to patients throughout the world. This is elaborated in our Global Health Policy, which defines how we will discover, develop and provide high-quality products and services within our areas of expertise to help people with diabetes live better lives throughout the world.

The purpose of the Novo Nordisk Strategy for Global Access to Diabetes Care is to:

- contribute to breaking the Rule of Halves by overcoming the barriers that inhibit access to care, in order to
- reach more people with quality treatments, and
- enable more people with diabetes to live better lives.

Novo Nordisk is calling for a joint effort by governments, international organisations, healthcare providers, civil society and industry to contribute to breaking the Rule of Halves. To break the Rule of Halves, more people with diabetes should be diagnosed; more people who are diagnosed should receive care; more people who receive care should achieve treatment targets; and more people who achieve their targets should achieve improved health and quality of life.

We will aim to address each pillar of the Rule of Halves through the most efficient means in the light of local circumstances:

- 1st pillar: Addressing the challenges associated with the level of awareness of diabetes requires the development and implementation of awareness and prevention strategies.
- 2nd pillar: Getting more people diagnosed is also a key challenge which calls for early detection initiatives in all countries and particularly in low- and middle-income countries where diagnosis rates are low.
- 3rd pillar: Receiving care is not only a question of treatment, it is also about having access to qualified healthcare professionals (HCPs). Training of HCPs is therefore a key contribution to addressing challenges within the third pillar.
- 4th pillar: Ensuring that more people with diabetes have access to treatments that meet their needs entails that people with diabetes have access to diverse, quality products with affordable solutions for all income groups.
- 5th pillar: Increasing the number of people achieving improved health and quality of life, requires an effort to strengthen patient engagement, education and support.
Changing Diabetes® 40by20 – a new ambition
As the key driver of the Strategy for Global Access to Diabetes Care, we have set a new long-term target of reaching 40 million people with diabetes with our diabetes care products by 2020—also referred to as the Changing Diabetes® 40by20 ambition.

We use the number of people reached as an overall indicator of our own contribution to addressing the global diabetes challenge. Activities within all five pillars of the Rule of Halves will contribute to our long-term target of 40 million people with diabetes: If we can break the Rule of Halves, more people with diabetes will be diagnosed, more will receive care, more will meet treatment targets and more will achieve an improved health and quality of life leading to a longer life expectancy. As a result we will also reach more people with diabetes care products in the quantities needed to provide for effective treatment throughout their life.

This long-term target will directly address the gap between the number of people with diabetes who need care and the number of people reached with Novo Nordisk products worldwide. It will also be Novo Nordisk contribution to the WHO goal of a 25% reduction in premature mortality from NCDs by the year 2025, called 25 by 25.

We have made the Changing Diabetes® 40by20 long-term target our key driver, because:

1. It puts the patient first: Novo Nordisk aims to reach more patients and contribute to the adequate management of their diabetes.
2. It clarifies that all access to diabetes care initiatives should contribute to the overall goal of reaching more people with diabetes: for example, early detection initiatives, HCP training and patient education should all be aimed at contributing to this goal.
3. It builds on Novo Nordisk sustainable business model by linking global health needs with our commercial offering. Access to diabetes care is an integrated part of our business.

We regard this to be a win-win approach that will capitalise on Novo Nordisk leadership, strengthen our business, contribute to solving the global diabetes challenges and, very importantly, help people with diabetes live better lives throughout the world.

All Novo Nordisk affiliates have a role to play in reaching the Changing Diabetes® 40by20 ambition by making our products available to more people with diabetes. Our diverse product portfolio offers an opportunity to address the diverse patient needs in terms of treatment – Novo Nordisk is therefore in a unique position to help close the gap between those who need diabetes care and those who receive it.
4. AN INTEGRATED PART OF OUR BUSINESS

Different focus in different countries

The nature of barriers that inhibit access to care differs around the world. The nature of our response will therefore differentiate between low-income, middle-income and high-income countries:

• In low-income countries (LICs), we work to improve access to care through our least developed country (LDC) pricing policy, the World Diabetes Foundation and through the Changing Diabetes® in Children Programme.

• In middle-income countries (MICs), we offer a broad portfolio of products, including human insulins, which are often sold through large government tenders to a price at or below the LDC price level. We explore innovative business models to reach patients at the base of the pyramid (BOP) as well as work to improve access to care through early detection, HCP training and patient education. The World Diabetes Foundation also supports local initiatives in MICs.

• In high-income countries, we work to improve access to care for underserved population groups who have unequal access to care, eg indigenous or migrant populations.

In continuation of this, the efforts of affiliates to improve access to diabetes care will be defined and anchored locally, depending on the maturity of the specific markets.

Integration into business planning processes

The strategy is integrated into Novo Nordisk business planning process. As part of the Changing Diabetes® plans process, Novo Nordisk affiliates are encouraged to assess which of their current activities can be scaled up or done differently to make a greater impact on the Rule of Halves, in turn positively impacting the long-term target of reaching 40 million people with diabetes by 2020. This entails a focus on activities with the greatest impact locally and allows for better practice sharing between affiliates.

As part of their business planning process, Novo Nordisk affiliates are encouraged to set local patient targets, which will feed into the global goal of reaching 40 million people with diabetes by 2020, as well as comparable targets for their Changing Diabetes® activities relating to the pillars of the Rule of Halves.

The Changing Diabetes® 40by20 ambition is also integrated into the annual budget process as part of the Novo Nordisk Regions’ Budget Presentations.
Complementary initiatives
The Global Access to Diabetes Care strategy will at the corporate level also focus on a scale-up of Novo Nordisk efforts in three key areas where both business and health needs will be served – and thus enable the company to provide treatment to more patients.

The three corporate focus areas are:

1. Reaching the base of the pyramid
   In LMICs, multiple mark-ups along the supply chain often prevent people with diabetes from having access to our medicines at affordable prices. “Base of the pyramid” initiatives aim at addressing these inefficiencies in product distribution through the implementation of innovative and sustainable partnership approaches involving a wide range of local stakeholders. In coming years, existing activities will be evaluated and, based on their success, scaled-up in countries where they have already been established or they will be implemented in new countries.

2. Contributing to the global education of HCPs
   Access to medicines is only one element of an integrated strategy aimed at improving access to diabetes care. It is also essential that healthcare professionals have the right level of qualifications to diagnose people with diabetes early and help them achieve their treatment targets and ultimately contribute to improving their quality of life. The need for high quality healthcare professional training remains a top priority in many countries, especially in LMICs. We will therefore scale-up our offering to train HCPs with partners such as the Steno Diabetes Center.

3. Promoting health for the next generation
   Maternal and child health remains a priority area of the global health agenda. New science has shown that our lifelong health and risk of developing diabetes, cardiovascular diseases and other chronic conditions are founded even before we are born. The health of the mother plays a central role in the health of future generations. Through focused, early intervention targeting maternal, newborn and child health, we can benefit the short term health of mother and child, while at the same time creating a good environment for the health of the future generation. The Changing Diabetes® in Children, Changing Diabetes® in Pregnancy and Changing Future Health programmes are the three pillars of Novo Nordisk contribution to promoting health for the next generation. We will scale-up existing activities and explore opportunities to expand their geographical scope in partnership with relevant stakeholders.

Measuring, monitoring and evaluating performance
The Health Policy Committee will be responsible for monitoring the progress of the updated Global Access to Diabetes Care strategy. Twice a year, the Health Policy Committee is updated on the progress towards reaching 40 million people with diabetes by 2020.

Novo Nordisk will monitor and evaluate the output of Changing Diabetes® activities along the Rule of halves using a standardised monitoring and evaluation framework across the company.

As the Changing Diabetes® 40by20 ambition is the key driver of the Global Access to Diabetes Care strategy, the estimated number of patients reached will be the main progress indicator. This number of patients is estimated based on our volume of sales. It will therefore contribute to the 40by20 ambition if:

- more people are diagnosed and start using our products
- more people receive regular treatment with adequate doses
- more people with diabetes live longer and continue treatment over a longer period.

The long-term target counts the entire Novo Nordisk diabetes care product portfolio, OADs, insulin and GLP-1, except devices and PrandiMet®, and uses the internationally recognised WHO-method to calculate the number of patients.

<table>
<thead>
<tr>
<th>Product</th>
<th>WHO_DDD</th>
<th>WHO_Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>NovoMix®</td>
<td>40 IU</td>
<td>40 IU</td>
</tr>
<tr>
<td>NovoRapid®</td>
<td>40 IU</td>
<td>40 IU</td>
</tr>
<tr>
<td>Levemir®</td>
<td>40 IU</td>
<td>40 IU</td>
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<td>Actrapid®</td>
<td>40 IU</td>
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<td>Insulatard®</td>
<td>40 IU</td>
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</tr>
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<td>Mixtard®</td>
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<td>40 IU</td>
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<td>Degludec®</td>
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<td>40 IU</td>
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<td>Metformin®</td>
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<td>2,000 MG</td>
</tr>
<tr>
<td>Victoza®</td>
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<td>1.2 MG</td>
</tr>
</tbody>
</table>

The 40by20 ambition means that we will increase our patient reach from approximately 20 million in 2011 to 40 million in 2020.

Governance
The Strategy for Global Access to Diabetes Care is governed by Novo Nordisk Health Policy Committee. The strategy will be rolled out in collaboration between Corporate Stakeholder Engagement, Operations Management and Global Marketing and executed through the Changing Diabetes Steering Group. See appendix for more information about the Health Policy Committee.
APPENDIX 1

OVERVIEW OF WHO GLOBAL ACTION PLAN FOR THE PREVENTION AND CONTROL OF NON-COMMUNICABLE DISEASES 2013–2020

Vision
A world free of the avoidable burden of non-communicable diseases.

Goal
To reduce the preventable and avoidable burden of morbidity, mortality and disability due to non-communicable diseases by means of multisectoral collaboration and cooperation at national, regional and global levels, so that populations reach the highest attainable standards of health and productivity at every age and those diseases are no longer a barrier to well-being or socioeconomic development.

Overarching principles:
• Life-course approach
• Empowerment of people and communities
• Evidence-based strategies
• Universal health coverage
• Management of real, perceived or potential conflicts of interest
• Human rights approach
• Equity-based approach
• National action and international cooperation and solidarity
• Multisectoral action

Objectives
1. To raise the priority accorded to the prevention and control of non-communicable diseases in global, regional and national agendas and internationally agreed development goals, through strengthened international cooperation and advocacy.
2. To strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of non-communicable diseases.
3. To reduce modifiable risk factors for non-communicable diseases and underlying social determinants through creation of health-promoting environments.
4. To strengthen and orient health systems to address the prevention and control of non-communicable diseases and the underlying social determinants through people-centred primary health care and universal health coverage.
5. To promote and support national capacity for high-quality research and development for the prevention and control of non-communicable diseases.
6. To monitor the trends and determinants of non-communicable diseases and evaluate progress in their prevention and control.

Voluntary global targets
(1) A 25% relative reduction in risk of premature mortality from cardiovascular diseases, cancer, diabetes, or chronic respiratory diseases
(2) At least 10% relative reduction in the harmful use of alcohol, as appropriate, within the national context
(3) A 10% relative reduction in prevalence of insufficient physical activity
(4) A 30% relative reduction in mean population intake of salt/sodium
(5) A 30% relative reduction in prevalence of current tobacco use in persons aged 15+ years
(6) A 25% relative reduction in the prevalence of raised blood pressure or contain the prevalence of raised blood pressure, according to national circumstances
(7) Halt the rise in diabetes and obesity
(8) At least 50% of eligible people receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes
(9) An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major non-communicable diseases in both public and private facilities
APPENDIX 2

HEALTH POLICY COMMITTEE

The Health Policy Committee (HPC) works on behalf of ExecMan and is responsible for the governance of the global health policy issues.

Mandate

- Ensure coordination of the efforts of Operations, Global Marketing and Corporate Stakeholder Engagement to promote access to diabetes care and haemophilia care as well as other relevant therapy areas
- Approve Novo Nordisk’s global access to diabetes care and haemophilia care strategies and guide their progress and updates
- Ensure line management back up and funding of activities within the scope of the global access to diabetes care and haemophilia care strategies, and evaluate Novo Nordisk’s performance in relation to their KPIs
- Follow new trends in companies’ global health policies and tracking Novo Nordisk against industry peers
- Approve public positions related to access to diabetes care and haemophilia care
- Identify and manage issues related to access to diabetes care and haemophilia care that may involve risks to the company
- Approve any future update of the Global Health Policy

Members

Kåre Schultz, President & COO, Executive Vice President (Chairman)
Lise Kingo, COS, Executive Vice President
Jakob Riis, Executive Vice President, Marketing and Medical Affairs
Christian Kanstrup, Senior Vice President, China
Jean-Paul Digy, Vice President, Business Area Africa
Federico Renzo Grayeb, Vice President, Business Area Latin America
Emil Kongshøj Larsen, Vice President, Business Strategy, International Operations
Anders Deijgaard, Managing Director, World Diabetes Foundation
Susanne Brandl, General Manager, Novo Nordisk Haemophilia Foundation
Sobia H. M. Akram, Operations Management
Charlotte Ersbøll, Corporate Vice President, Corporate Stakeholder Engagement
Soraya Ramoul, Director, Changing Diabetes Partnerships (Secretary)
REFERENCES

2. Patients reached with diabetes care products is estimated by dividing Novo Nordisk’s annual sales volume by the annual usage dose per patient for each product class as defined by the WHO. PrandiMet® is not included as no WHO-defined dosage exists.
9. Patients reached with diabetes care products is estimated by dividing Novo Nordisk’s annual sales volume by the annual usage dose per patient for each product class as defined by the WHO. PrandiMet® is not included as no WHO-defined dosage exists.
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