INNOVATION
FOCUS
ACCESS
COMMITMENT

NUSAYBAH ABU HADID
from Jordan
has type 1 diabetes

Access to Health:
Our approach

About Novo Nordisk

Novo Nordisk is a global healthcare company with 88 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth-hormone therapy and hormone-replacement therapy.

The Novo Nordisk Way

In 1923 our Danish founders began a journey to change diabetes. Today, we have thousands of employees across the world with the passion, skills and commitment to continue this journey to prevent, treat and ultimately cure diabetes.

The Novo Nordisk Way describes who we are, where we want to go and the values that characterise our company. It connects our history and our future. It sets direction for and applies to all employees in Novo Nordisk – no matter what you do or where you work. It is a promise we make to each other and our external stakeholders.

Access to health is grounded in our ambition to strengthen our leadership in diabetes. Our key contribution is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.

Our Triple Bottom Line

We are committed to operating in a way that is financially, environmentally and socially responsible. Managing our business using the Triple Bottom Line principle helps us balance short-term profitability with longer-term societal interests. This approach is anchored in the company's by-laws, the articles of association and the Novo Nordisk Way.

Top line figures:

- Group revenue 2010: $10,806 million USD[1]
- Group profit 2010: $3,359 million USD[1]
- Global diabetes market share: 51% of the insulin market measured by volume (2010)[1]
- Countries products are marketed in: 180[1]
- Number of employees: More than 30,000 in 74 countries[1]
- Headquarters in Denmark

USD amount based on average exchange rate: 5,62 DKR per $1 USD.

September 2011

What is in this document

Our approach to improving access to health builds on the experience gained during the past 10 years of work through several initiatives. This document reviews the challenges and barriers we face in improving access to diabetes care, and describes the areas where we can make the most difference through our core business activities, skills and resources.

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Lars Rebien Sørensen in Nairobi, Kenya, 2007

Welcome

As a world-leading diabetes-care company, **Novo Nordisk is firmly committed to our vision of changing diabetes – for good.** On the occasion of the United Nations High-level Meeting on Non-Communicable Diseases it is important for me to underscore this commitment.

The potential for significant change persists. Diabetes represents a significant portion of the expanding non-communicable disease health crisis – one that does not recognise geographic borders and disproportionately affects low and middle-income countries. Today, 285 million people live with diabetes. In another 20 years, this number is expected to grow to 438 million, with the sharpest increase set to happen in China, South-east Asia, on the African continent and in the Middle East. **We have to try harder and reach further!**

Ten years ago, Novo Nordisk launched its Access to Health Strategy. At the same time, we introduced our differential pricing policy for least-developed countries, making insulin available at a very affordable price. The year after, in 2002, we launched the World Diabetes Foundation through a donation granted by our shareholders. Since then, many more global as well as national access-to-health initiatives have followed, some of which are detailed in this publication.

This publication provides me with the opportunity to thank the people in Novo Nordisk, as well as our many partners at the global and national levels, for their hard work, passion and skill in improving access to health. We may still have a long way to go, but we should allow ourselves the opportunity to take stock and reflect on what we have achieved and learned so far. This publication does exactly that. Through it I hope that we can facilitate conversation and build on our collective knowledge to do better and at a larger scale in years to come.

We will continue to accelerate our global efforts to reach more people with our products and our support activities. Diabetes has been our business and our passion for more than 85 years.

In the months leading up to the UN High-level Meeting there has been much discussion about the role of the private sector. Some have even questioned our motives and licence to operate on this high-level agenda. I can only say that we remain committed to being part of the solution in driving change for people with diabetes.

With that said, I would also like to remark on where our responsibility starts and where it ends. **Our key contribution is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.** Today, Novo Nordisk has the broadest portfolio of diabetes products in our sector. This means that we can accommodate virtually any market, from the high-end market to the market at the base of the economic pyramid. As an example, the average realised price for an insulin vial from Novo Nordisk in least-developed countries in 2010 was $4.2 USD or 15 US cents per day per patient. In other low- and middle-income countries we also offered insulin at similarly low prices through government-run tendering processes. Unfortunately, we cannot guarantee that the patient benefits from such schemes.

We have had to recognise that some challenges cannot be overcome by us alone. Mark-ups and other barriers throughout the distribution chain may significantly distort the general picture of affordability. While we focus efforts on dealing with such defects in the healthcare system, we naturally rely on the active participation of local, national and global policy makers, healthcare providers and patient organisations.

So, what can the global health community expect from us in the years to come?

Our ultimate goal is to find a cure for diabetes. In the meantime, **we will continue investing significant resources into the improvement of diabetes care through our research and development efforts.**

At the same time, we also recognise that there will always be a need for low-priced insulin. That is why I regard it as a basic building block in our business model that **low-priced insulin will always be part of our portfolio.**

Novo Nordisk can and will contribute to leading a change in diabetes. But, as said, a key lesson from our past engagement is that we will only succeed through collaboration. **I welcome the opportunity to learn from partners and stakeholders how we can reach out and support more people living with diabetes** – no matter where they live in the world.

Lars Rebien Sørensen
President and chief executive officer (CEO)
Novo Nordisk A/S

What is diabetes?

Diabetes is characterised by abnormally high levels of blood glucose due to defects in insulin production, resistance to insulin, or both. Diabetes is a chronic disorder that currently has no cure.

Diabetes can lead to serious complications and premature death, but people with diabetes can take steps to control the disease and lower the risk of complications.[2]

Type 1 diabetes is an autoimmune disease characterised by insulin deficiency resulting from destruction of beta-cells in the pancreas.[2] This form of diabetes usually affects children and young adults, but it can occur at any age.[2]

Type 2 diabetes accounts for approximately 85-95% of all diagnosed cases of diabetes.[2,3] Once thought to be an adult disease, type 2 diabetes is increasingly being diagnosed in children and adolescents[2], and is rapidly becoming a global public-health issue.[3]

The challenge of the diabetes pandemic

Once considered a condition confined to affluent nations, diabetes now touches every region of the world, and disproportionately affects poorer populations.[3] There is scientific consensus that in recent years the condition has grown dramatically into a global pandemic of alarming proportions, the potential size of which is not yet clear. Estimates suggest that global prevalence increased from 135 million in 1995[4] to 285 million in 2010 and will grow to 438 million by 2030[3]. The major burden is borne by low- and middle-income countries[3]. Close to 4 million adults worldwide die of diabetes-related causes annually.[3] By comparison, 1.8 million people died from HIV/AIDS-related illnesses in 2009.[6]

The economic costs are staggering. The World Health Organization (WHO) estimates that global healthcare expenditures to treat and prevent diabetes and its complications reached a total of $376 billion USD in 2010, and in 2030 this number could exceed some $490 billion.[3] Besides healthcare expenditure, diabetes also imposes large economic burdens in the form of lost productivity and foregone economic growth.[3]

Diabetes is a chronic, debilitating disease that requires life-long treatment. If untreated, or poorly treated, it carries the risk of serious, long-term complications, including blindness, amputation of limbs, heart disease, kidney failure and stroke.[3] The level of care needed for these types of complications carry far greater costs than the life-long medical treatment.[3] In many low- and middle-income countries people with diabetes are not diagnosed until the disease has progressed and complications have developed.[7]

Diabetes often has devastating consequences for the affected families' livelihood and hampers the economic development of nations without adequate health systems.

While people in the developing world continue to be ravaged by infectious diseases, they now face a double threat with the rise of diabetes, for which already over-burdened health-care systems are ill-prepared.[8] Constraints for patients include a lack of education about diabetes, and resistance to healthier diets and lifestyles.[9] On a policy level, low attention to chronic diseases, a focus on short-term costs rather than long-term implications, and limited health-care coverage work against effective diabetes management.

Family in their home in Dar es Salaam, Tanzania. The woman has had her foot amputated due to diabetes complications.

The call for concerted action

The Universal Declaration of Human Rights pledges that all humans have a right to medical care and proclaims that "every individual and every organ of society" has a responsibility to promote respect for this and other human rights.[10] We want to drive our business in respect of this statement, and recognise that we can contribute.

There have been many international calls for concerted action to address the acutely growing burden of diabetes. Some important global milestones in this respect include:

- In 2006 the UN passed a resolution on diabetes. With this, nations recognised the severity of the diabetes pandemic and committed to take urgent action.[11]
- Diabetes is a focus area in the World Health Organization (WHO) Global Strategy for the Prevention and Control of Non-Communicable Diseases.[12] The WHO puts special emphasis on low- and middle-income countries and vulnerable populations.
- The UN High-Level Meeting on Non-Communicable Diseases in 2011 gathered heads of states and governments to address the prevention and control of non-communicable diseases worldwide, with a particular focus on developmental and other challenges, as well as social and economic impacts, particularly for developing countries.[13]

The UN Millennium Development Goals (MDGs), defined by world leaders in 2000, also call for global partnerships between governments, civil society and businesses.[14]

The MDGs provide a framework for the international community to work together towards a common purpose – to ensure that human development reaches everyone, everywhere – and sets targets to be reached by 2015. If the goals are achieved, world poverty will be cut by half and millions of lives will be saved due to improved health conditions.[15]

As a leading provider of diabetes treatments, Novo Nordisk will take part in this global effort to address the challenges of the diabetes pandemic and improve access to health.

However, addressing the fast-growing problem of diabetes successfully depends on the participation of a wide range of stakeholders. Healthcare providers, governments, the education system, food manufacturers and retailers, pharmaceuticals companies and patients must all work together in order to produce the system-wide change required.

Recognising this reality, Novo Nordisk has for many years based its business conduct on a multi-stakeholder approach by engaging in dialogue with key parties such as NGOs, governmental regulators, healthcare professionals and patients. For Novo Nordisk, systematic stakeholder engagement helps us understand multiple agendas and helps us prioritise our actions.

What we have learned so far

This document is based on 10 years of experience from working to improve diabetes care in the developing world. As such, it is an important milestone in the process that we began in 2001.

In that year, we introduced differential pricing for insulin, discounting human insulin products to the governments of the Least Developed Countries (LDCs), as defined by the United Nations.[16] Also, in 2001, we began introducing three additional initiatives to provide appropriate systems-based solutions aimed at closing some of the biggest gaps in diabetes care.[16]

Contributing to improved health-care systems

Even significantly discounted insulin may be out of reach for the poorest people. To help meet their needs, Novo Nordisk established the World Diabetes Foundation (WDF). This independent and non-profit foundation supports the prevention and treatment of diabetes where it is needed most, providing funding for local initiatives that improve healthcare system capacity. Since it was founded by Novo Nordisk in 2001, it has supported 270 projects in 100 countries.[17] In financial terms, this is our biggest single commitment to the improvement of diabetes care in low- and middle-income countries, with a total commitment of $195 million USD during the period 2001 - 2017.[17]

Enhancing understanding of the needs of people with diabetes

To better understand the needs of people living with diabetes, and to better inform national diabetes programmes, we conducted a pioneering study to measure the psychosocial aspects of the disease. This effort, called Diabetes Attitudes, Wishes and Needs (DAWN™), was initiated in 2001. It involved more than 9,000 people with diabetes, healthcare professionals and policy makers worldwide.[18] The aim of DAWN™ was to identify ways to diagnose diabetes earlier, and to promote better health outcomes through treatment adherence and lifestyle changes.

Development of National Diabetes Strategies

Through National Diabetes Programmes, we collaborated with healthcare professionals, patient organisations and authorities in some 40 countries to set up projects aimed at developing or implementing national diabetes strategies.[18]

While developed countries often have a foundation on which to build better diabetes care, this is frequently not the case in developing countries. For this reason, we also investigated the design of a best-practice model for diabetes care in resource-poor settings. Through a programme called the World Partner Project, we undertook 31 initiatives to improve diabetes care in eight developing countries, in partnership with local, national and international players in the healthcare field.[18]

More global, more focused

Our approach has evolved over the past 10 years from focusing on the poorest to taking a more global view and a systematic approach to documenting performance. We believe these new additions to our approach will enhance our impact.

They are evident in two recent partnerships, focused on improving care for vulnerable groups:

- Changing Diabetes® in Children, was initiated in 2009 and aims to establish improved care for children with type 1 diabetes in developing countries.[19]
- Changing Diabetes® in Pregnancy, established in the same year, looks at building knowledge and solutions in the field of gestational diabetes.[20]

Dilemmas to tackle

Through these programmes we have learned that the challenge of tackling diabetes poses numerous dilemmas for the governments of all countries as they struggle to identify priorities, define policies and, not least, ensure funding to meet a growing number of competing health needs for their citizens.

Furthermore, our experiences in many countries indicates that accessibility and affordability of insulin is a complicated issue that cannot be solved simply by offering discounted prices. Efficient distribution and procurement practices, and adequate facilities for transportation and storage of insulin are additional challenges, and securing cooperation and commitment from governments – and/or other partners – is crucial to improving treatment of diabetes.

Even though our core business philosophy requires us to make a difference where we can, there are significant dilemmas involved for us as a company. What role should we assume in developing countries? How can we develop new sustainable business models? How will our investors respond to such business models? How do we avoid creating unhealthy dependencies between us and our project partners?

Our ambitions leading up to 2015

Novo Nordisk views our global task in the years ahead as continuing to expand access to diabetes care in all countries.

As a world leader in diabetes care, and the leading supplier of insulin, we know we have a unique ability to help society address an exploding global health crisis. We fully recognise how broad the challenge of preventing diabetes is, not to mention that of ensuring adequate care with successful outcomes.

A steady supply of safe and effective insulin is an essential component of treating diabetes, but not the only one. Our approach to health-care access remains rooted in the Universal Declaration of Human Rights, particularly article 25, which defines the four key elements in the right to health: availability, accessibility, affordability and quality. This was our starting point 10 years ago, and it continues to frame our thinking on this subject.

Building on what we have learned so far, the focus areas and approaches presented in this document are enhancements on our experience.

We will continue to evolve and grow our approach as we learn from new experiences, and as other actors and partners make their contributions. As part of this process we engage with stakeholders to refine our approach. A clear objective for this work in the near future is to define targets and indicators for each of the focus areas presented here.

Thus, the approach presented here will not serve as our reporting framework on our performance. It is an action framework, setting direction for what we will do.

We organise our key ambitions within the four elements in the right to health. Each ambition is supported by a number of focus areas and the approach currently applied as the way we conduct our business. The focus areas and approaches are presented in section 2 of this document, and a full summary overview of all can be seen on pages 46-47.

Ambition	Focus area
Availability of treatment: Develop quality-assured diabetes treatment for all	1. Make insulin available to people with diabetes globally 2. Address distribution challenges at the base of pyramid (BOP) 3. Facilitate technology transfer
Accessibility of healthcare: Work with partners to make diabetes care more accessible for those in need	4. Support strengthening of health-care systems 5. Improve accessibility to insulin in remote areas 6. Improve access to diabetes care for women and children
Affordability of treatment: Work to improve affordability of treatment for patients, particularly in resource-poor settings	7. Improve funding for diabetes healthcare 8. Improve affordability of insulin
Quality for patients: Quality assurance in diabetes treatment for patients	9. Conduct responsible and ethical clinical trials 10. Work for safe medicines 11. Empower people with diabetes to achieve better health and quality of life

A history of action

Year	2001	2002	2003	2004	2005
External	September 2000 – World leaders came together to adopt the **United Nations Millennium Declaration**, committing their nations to a new global partnership to reduce extreme poverty, and setting out a series of time-bound targets – with a deadline of 2015 – that have become known as the Millennium Development Goals.		Adoption of the **WHO Framework Convention on Tobacco Control (FCTC)** by the World Health Assembly	**The Global Strategy on Diet, Physical Activity and Health** endorsed by the World Health Assembly	**WHO report "Preventing chronic diseases – a vital investment"** September 2005, world leaders came together at a summit in New York to review progress since the Millennium Declaration
Milestones	**Novo Nordisk develops an Access to Health Strategy** A multi-initiative approach aimed at improving diabetes care in developing countries **Introduction of a differential pricing policy for LDCs**	**Establishment of the World Diabetes Foundation** Supports projects for the improvement of diabetes care in developing countries WORLD DIABETES FOUNDATION	**Establishment of the Oxford Health Alliance** Formed as an alliance between the University of Oxford and Novo Nordisk to foster a co ordinated approach, involving all stakeholders, with the aim of preventing epidemic chronic disease by addressing major risk factors	**The Rule of Halves** Launch of a new socio-economic forecast model to project long-term costs of diabetes	**Changing Diabetes®** platform launched changing diabetes®
Programmes	**Initiation of DAWN™ Study** A survey-study to investigate the status of psychosocial aspects of diabetes Roll-out of STAR project initiated with Steno to increase health-care-professional knowledge about diabetes	**Initiation of the World Partner Project** A public-private partnership to improve diabetes care in developing countries			**FAIR Programme** exploring improved care for minority populations
Key Novo Nordisk supported events		1st DAWN™ Summit United Kingdom	2nd DAWN™ Summit United Kingdom		

2006	2007	2008	2009	2010	2011
UN Resolution on Diabetes On 21 September 2006 the UN General Assembly adopted a landmark resolution that brought the global threat of the diabetes epidemic to the forefront of policy makers' thoughts **The Diabetes Declaration and Strategy for Africa:** A call to action, was launched on 4 December in 2006 by the IDF Africa Region	**WHO Resolution on Diabetes Prevention and Control:** A Strategy for the WHO African Region **WHO's Framework for Action** Strengthening health systems to improve health outcomes	**2008 High-level Event on the MDGs** Governments, foundations, businesses and civil society groups rallied around the call to action to slash poverty, hunger and disease by 2015, by announcing new commitments to meet the Millennium Development Goals, at a high-level event at UN Headquarters on 25 September 2008		**UN Resolution on NCD High-level Meeting**. On 13th May 2010, the UN General Assembly unanimously passed a resolution on the prevention and control of NCDs, calling for a UN Summit on NCDs to be held in September 2011 **EVERY WOMAN, EVERY CHILD:** The UN released a Global Strategy for Women's and Children's Health which sets out a plan to save the lives of millions of women and children.	**UN High-level Meeting on NCDs** The UN General Assembly, has decided to hold a UN Summit on Non-Communicable Diseases (NCDs) in order to bring global attention to these diseases and agree on a plan of action to address them
	Launch of the **Changing Diabetes® Leadership Initiative** (Leadership Forums, Barometer)	**Novo Nordisk handed a MDG3 Champion Torch** "To Do Something Extra" in support of gender equality and women's economic empowerment		Establishment of the **Steno Health Promotion Center**	Novo Nordisk makes additional donation of $4,45 million USD to WDF to fund additional activities in relation to and as a follow up to the UN High-level-Meeting on NCDs
Launch of the **Changing Diabetes® World Tour**	Initiation of **DAWN™ Youth WebTalk Survey**		Launch of the **Changing Diabetes® in Children** programme changing diabetes® in children	Launch of the **Changing Diabetes® in Pregnancy** programme changing diabetes® in pregnancy	Release of the **Blueprint for Change report on China** Initiation of DAWN 2™ Study
Supported UN Resolution on Diabetes and the "unite for diabetes" campaign 3rd DAWN™ Summit Italy	**Global Changing Diabetes® Leadership Forum NYC** Changing Diabetes® mobile clinic launched in China and Egypt	**Changing Diabetes® Leadership Forums** in Denmark and Russia 4th DAWN™ Summit Hungary	**Changing Diabetes® Leadership Forum** in China	**Changing Diabetes® Leadership Forums** in sub-Saharan Africa and MENA region	Launch of project in Ifakara Tanzania with objective to establish quality and comprehensive care in this rural community Establishment of **Early Origins of Health initiative**

Novo Nordisk research facility at Novo Nordisk Park located in Måløv, Denmark

Availability of treatment

Our ambition is to strengthen our leadership in diabetes, and our key contribution is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.

Novo Nordisk has contributed to key breakthroughs in diabetes treatments, such as the introduction of modern insulin in the 1990s and GLP-1 in 2009.[20] We invest in R&D to constantly improve therapies and feed the cycle of innovation so that more products become more available, to more people, over time.

To advance the availability of insulin treatment, we also support the transfer of technology and knowledge among others through building local production capacity, and have taken it upon ourselves to explore new business models for providing treatments for people living at the base of the income pyramid.

Ambition: Develop quality diabetes treatment for all

Area of focus	Approach
Make treatment available to people with diabetes globally	Ensure continued supply of human insulin to low- and middle-income countries for at least another 10 years
	Support research to document the consequences and implications of diabetes
	Share discoveries and knowledge that could have applications in infectious-disease areas
Address availability of treatment at the base of the pyramid	Explore business models for people living with diabetes at the base of the pyramid
Facilitate technology transfer in the countries where we operate	Work with public and private institutions in low- and middle-income countries to enhance healthcare provision, to the benefit of all patients

Research and development: make treatment available to people globally

Since the discovery of insulin in 1921,[21] Novo Nordisk has been one of the pharmaceutical companies to transform the treatment and care of diabetes through continued investment into research and development (R&D).

Beginning with the first patients our company treated with insulin in the 1920s,[20] we have been dedicated to improving continuously the safety, efficacy and convenience of diabetes treatment. Today, as the only company with a full portfolio of human and modern insulins,[1] we are uniquely positioned to address the issues at the core of the diabetes pandemic: insulin deficiency and the complexities of treating it. For those millions of people who must live with diabetes, our goal is to offer individualised treatment options so that they can lead their lives in full.

Diabetes represents 80% of our business and we are the world's largest private investor in diabetes-related R&D, with an annual investment of close to $2 billion USD.[1,14]

While there is not yet a cure for diabetes or a means of reversing diabetes progression, we are conducting research in cooperation with leading academic centres to tackle the roots of the condition. Through two key projects at our Hagedorn Research Institute involving stem-cell biology and beta cell regeneration, we are making progress towards preventing and ultimately curing diabetes.

Close to 90 years after the discovery of insulin, we continue to invest in the expansion of insulin-innovation leadership with research activities aimed at continuous improvement for all types of insulin. We hope to be able to radically change insulin delivery, offering tablets in addition to injectable treatments. The development of oral formulations for both insulin and Glucagon-like peptide-1 (GLP-1) is still at an early stage and many technological challenges remain.

Our research and development priorities for device innovation are guided by customer-insight studies. The ultimate goal is convenient and simple device technology that supports treatment compliance, with positive implications for patients' health.

In view of the developing diabetes pandemic, focus and funding is also required to adequately understand and address the rise of diabetes in low- and middle-income countries – not only to inform future research and development, but also to address prevention. Urbanisation, unhealthy lifestyles and poor nutrition are causing a rapidly growing pandemic in the large segments of the global population that live on a relatively low income.[8] Some major issues need to be delved into, such as what causes the high number of undiagnosed or untreated patients. There is a need to encourage more research and to provide information on the costs and benefits of prevention, diagnosis and treatment, as well as to identify areas for improvement.

In 2010 the Steno Diabetes Centre inaugurated a new Health Promotion Centre. The vision is to position the centre as a leading research and development institute in the fields of patient education, prevention and health promotion. The aim is to generate new knowledge, methods and approaches that show health professionals and other stakeholders how to create sustainable human and social change.[22]

Our position

Novo Nordisk will continue to invest significant resources into diabetes research and drug development. We will continue to improve diabetes therapy, to directly improve the lives of the millions of people with diabetes around the world.

Our approach

Ensure continued supply of human insulin to low- and middle-income countries for at least another 10 years

While our business model is based on discovering and developing innovative treatments, and making them accessible throughout the world, we realise that the newest generations of insulins are often out of reach for people living in low- and middle-income countries. Therefore Novo Nordisk is therefore committed always to making low-priced insulin available.

Support research to document consequences and implications of diabetes

Novo Nordisk will support research to document consequences and implications of diabetes. We do so in collaboration with experts in this field to better understand the benefits of prevention, diagnosis and treatment as well as to identify opportunities for cost-effective interventions.

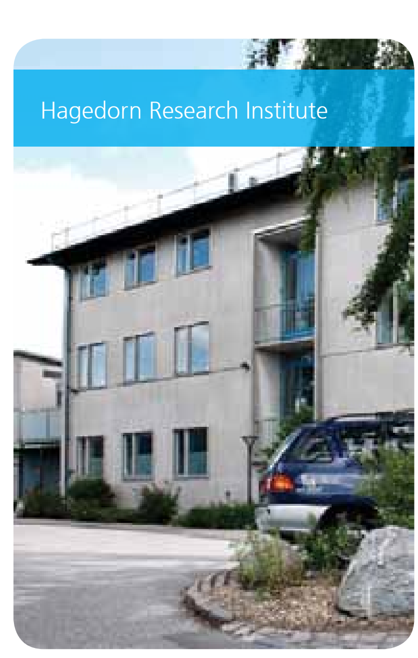
Share discoveries and knowledge that could be used in infectious disease areas

Novo Nordisk's capacity and expertise in insulin and other protein-based therapies is less relevant for novel research addressing infectious diseases and many of the diseases contained on the WHO's list of neglected diseases. However, if in the course of our research, discoveries are made that apply to infectious tropical disease areas, we will share that knowledge with interested stakeholders to benefit patient needs.

Production of insulin, Nordisk, c 1930

Finding a Cure: Hagedorn Research Institute[22]

Improving medicines are not our only concern. For more than five decades, Novo Nordisk's Hagedorn Research Institute (HRI), a world-class early applied research centre, has focused on discovering a cure for diabetes and its complications, as well as on identifying new opportunities for treating diabetes. HRI is a fully integrated part of Novo Nordisk. Close to 100 scientists work diligently at the institute to uncover the scientific clues that might one day lead to a cure.


Hagedorn Research Institute

Research and Teaching: Steno Diabetes Center[23]

Steno Diabetes Center , established in 1932, is a highly specialised and internationally renowned research and teaching hospital owned by Novo Nordisk.

Steno consists of four centres:

Steno Research Center
Steno Diabetes Center is a research hospital in the classical sense, where research and development go hand in hand with patient care, and basic research matches high international standards.

Steno Health Promotion Center
Steno Health Promotion Center aims to generate new knowledge, methods and approaches that show health professionals and other stakeholders how to create sustainable human and social change.

Steno Patient Care Center
Steno Diabetes Center is a specialised hospital that treats people with diabetes. For us it is important to offer high-quality treatment and service, and to teach and guide our patients so they are able to manage their diabetes. The centre treats about 6,200 patients, with about 25,000 visits annually. On average, each patient sees 2-3 different cross-disciplinary therapists at each visit.

Steno Education Center
Steno Education Center delivers education in diabetology for diabetes teams based in Denmark and other countries.

Donation of small-molecule compound library[24]

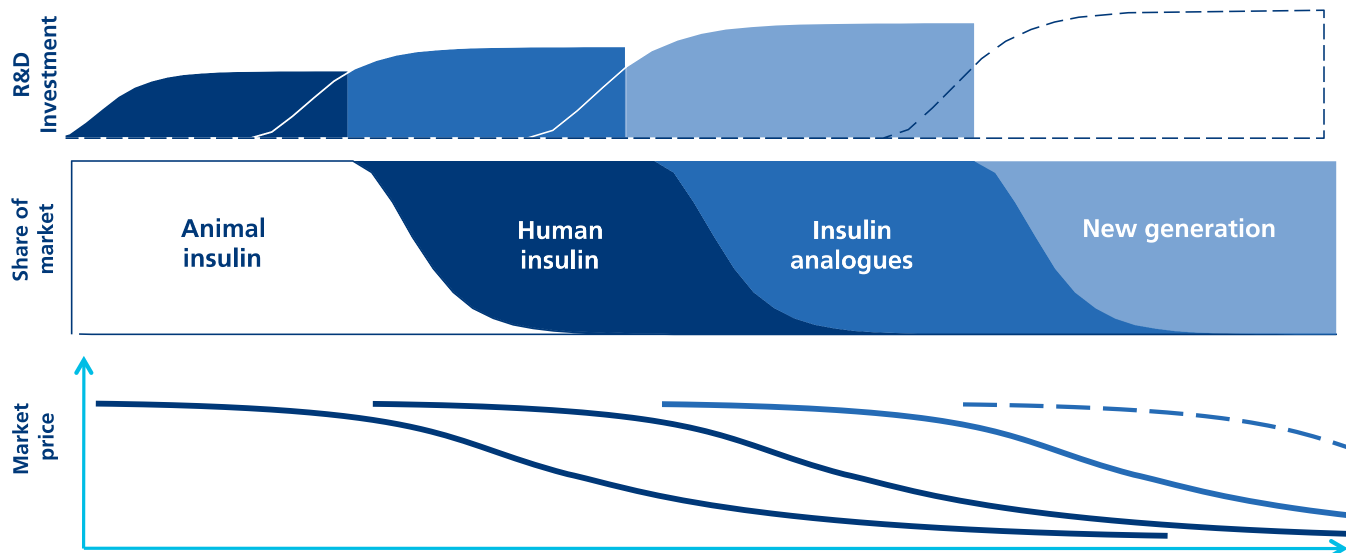
In 2008, Novo Nordisk donated a licence for our small-molecule compound library to the National Centre for Drug Screening in China. The library, consisting of 325,000 different chemical structures and with an estimated value of $53-70 million USD, is being used for screening activities to identify new drug candidates for infectious tropical diseases that affect people in developing countries.

Addressing the inter-linkages between TB and diabetes

In collaboration with the International Union Against TB and Lung Diseases, the World Diabetes Foundation is actively supporting advocacy and grass-roots initiatives to address the inter-linkages between TB and diabetes and support the recently launched the WHO Union's Collaborative Framework for Care and Control of Tuberculosis and Diabetes.

The link between innovation and price

The history of innovation shows that access to a product or product type increases over time. When a new-generation product is introduced, it attracts a smaller, higher-paying segment and the result is that prices of older-generation products decline, thus reaching wider markets. In diabetes therapies, this was certainly the case when human insulin replaced animal insulin in the 1980s, and again when insulin analogues were first introduced in the 1990s. The price of new products is higher to recoup R&D investments, and the price of older products declines.



The challenge of intellectual property rights

Pharmaceutical companies are largely responsible for discovering and developing new medicines, which is a time-consuming and expensive process. Only one out of every 5,000-10,000 new product ideas will be effective and safe enough to receive approval for use by patients.[25] The whole process, from discovery in a laboratory to marketplace, can take on average 12 years.[26] In order to retain the incentives for this massive investment, the patent system allows companies to recoup the cost of past and current research and development. Patents protect the intellectual property rights to new inventions, and incentivise research and development to make new medicines available. They are a critical component of the pharmaceutical industry's sustainable business. Without the income, pharmaceutical companies would not be able to invest sufficiently to maintain robust pipelines, and continue the search for new and improved treatments.

However, in developing countries patents may become a barrier to the affordability of medicines. The purpose of the patent system is to protect the originator of a new drug from unfair competition from companies that are able to make cheap replicates without investing in research and development. In most cases, patents concern newer and improved treatments. If effective older generations of treatments are off-patent, it is not a barrier to access to medicines if there are also patented alternatives on the market. In the case of diabetes, products like Metformin and human insulin are without patents and provide good treatment options for many patients suffering from diabetes. However, in other cases there may be no alternative to the patented products. It is therefore sometimes argued that companies should give away their rights to the innovations in which they have invested.

This is a dilemma between the short-term needs of the poorest parts of the world and the longer-term interests of ensuring continued improvements in treatment. The challenge today is to balance the current pharmaceutical patent system with the needs of developing countries. This has been attempted in the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) from 1994,[27] which provides minimum standards for global protection of patents.

Free trade resolving conflicting needs

Article 31 of TRIPS identifies flexibilities that open a door for the use of a drug without the authorisation of the patent holder, under certain conditions, such as protecting public health in emergencies, urgencies or in cases of public non-commercial use.[28] Prior to 2005, Article 31f stated that a compulsory licence should be predominantly for the local market. This was widely viewed as a barrier to access because many countries that would qualify for and could issue such a licence did not have local manufacturing capacity and would not benefit from it.[28] In December 2005, the World Trade Organization countries reached a consensus that allowed for the granting of Compulsory Licences (CL) for export.[28]

This means that, even if medicines are patented in a specific country, a CL granted for export would allow production in this country for export to countries where the medicines are urgently needed to protect public health, as defined in Article 31 of TRIPS.[28]

Our position

Novo Nordisk is committed to advancing the responsible use of intellectual property rights for the benefit of human health.

Novo Nordisk sees patent rights as a very important tool for promoting innovation, leading to new and better products and processes, and stimulating long-term economic growth and job creation.

Novo Nordisk believes that it is important to harmonise the patent system in order to create clear and operational patenting criteria, and to ensure fair and effective administration of the patent system.

Novo Nordisk will license its patents on genes for use as research tools and diagnostic agents on a non-exclusive basis under fair terms consistent with the advancement of biomedical research.

In cases of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use, Novo Nordisk supports the flexibilities outlined in TRIPS, in particular Article 31f and the 2005 agreement granting the right for countries to produce or import patented medicines without the authorisation of the patent holder to protect public health.

Novo Nordisk does not enforce patents in least-developed countries as defined by the UN.

Address distribution challenges at the base of the pyramid

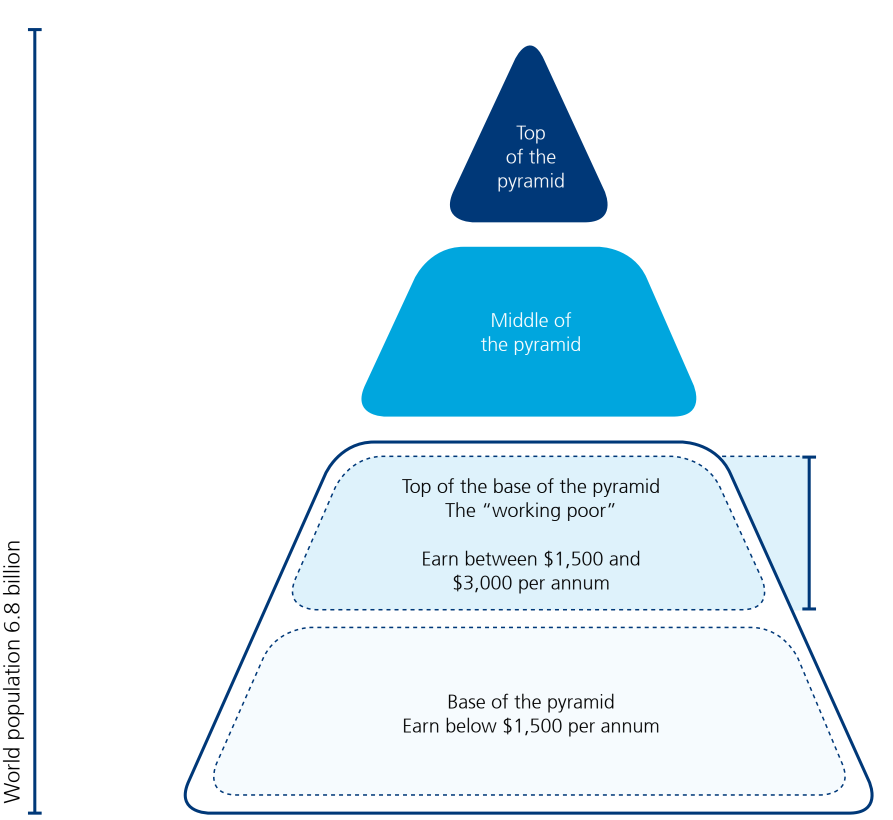
For many years, the world has focused on the healthcare needs of the poorest of the poor – the 1 billion people with incomes below $1,500 per year. However, more than four billion low-income people – the majority of the world's population – constitute the base of the economic pyramid (BOP). And the working poor – those who earn between $1,500 and $3,000 annually – have largely been ignored as a viable market segment by most multinationals, including pharmaceutical companies and others operating in the healthcare market.[29]

From a financial point of view, the business case for developing products specifically for this segment has been weak and faced with challenges of securing all-round sustainability.[29] Many companies have struggled to find the right products, prices, and distribution routes through which to attain profitability in this segment. With the exception of a tenacious few, most companies have not been able to make their projects in low-income markets work.[29]

Key to success is understanding the drivers of the entire value chain and in so doing develop business ecosystems, create new distribution channels, and design multi-sector partnerships to yield meaningful growth in revenues. These models tend to require a complete rethink of the product offering as well as how that product reaches the consumer.

Access to public healthcare is often very limited for the working poor, and even finding medicines to buy – especially ones that work – can be difficult. In addition, travel to a hospital or health clinic often costs more in cash or lost wages than the service itself, therefore BOP households defer treatment until a condition is relatively serious.[30]

In 2010, we established a corporate innovation project to identify solutions that will lead to an integrated approach to diagnosis, treatment and diabetes control for the working poor at the BOP. Our aim is to develop patient-centred solutions that may create new value for both the community and our company. Related to this project, in 2011 we commissioned a comprehensive market review to determine whether or not there is a commercially viable market for diabetes care within the large population that is socioeconomically defined as being at the "base of the economic pyramid". The analysis indicates that there is a significant market for insulin among the approximately 42 million people with diabetes globally who earn between $1,500 and $3,000 per annum.



Base of the pyramid

- 1,1 billion people
- Under-served
- Informal economy
- Inefficient and little competition

People with diabetes

- 2010: 42 million*
- 2030: 73,5 million*

*Based on a market analysis commissioned by Novo Nordisk from BroadReach consultancy in 2011

Our position

We believe it is important to explore solutions that will better meet the needs of the working poor in low-and middle-income countries (LMICs). At the same time, we are faced with significant uncertainties and challenges in trying to develop solutions for people with diabetes in this sector. Within chronic diseases there are no proven sustainable market approaches and business models. We do know, however, that this opportunity for creating both commercial success and a positive social impact includes a broad mindset, attacking the multiple challenges of significant lack of awareness and education, diagnosis and the often inadequate basic infrastructure needed to support a whole supply chain.

Our approach

Explore a business model to address the needs of people with diabetes living in the BOP segment.

We will complete our corporate innovation project with dedicated resources. The key question that we hope to address is: How can we generate profitable, sustainable, and scalable solutions to provide diabetes treatment to low-income people with limited access to care?

This project looks at two interlinked areas. The first area explores opportunities regarding suitable product offerings for the BOP segment. The second area deals with the non-product related obstacles in this segment, and may require local partners who are capable of creating solutions alongside Novo Nordisk.

A successful business model for achieving this will take time and significant long-term investment to develop, and can only be found through testing and learning. If Novo Nordisk succeeds it can change the lives of millions of people and, over time, this segment could have the potential to contribute to our growth.

Changing Diabetes® mobile clinic in Cambodia

Piloting one-stop diabetes care in Cambodia

In 2011 Novo Nordisk's initiated a BOP pilot to explore an innovative solution for the self-sustainable delivery of diabetes care in the BOP segment.

The pilot involves a mobile clinic that travels into rural areas according to a fixed and locally advertised schedule. The clinic is run by a team from the district hospital and a local distributor, and offers screening to those at risk, medical examinations, doctor consultations and medication on site.

To date, the clinic has screened 2,058 people at risk of diabetes and diagnosed 580 people. Essential medication for managing diabetes and hypertension is made available for less than $5 USD per month, including insulin from Novo Nordisk.

Ultimately, the objective of the project is to use the income generated to self-finance the mobile clinic operations.

Incremental innovation in Pakistan

Currently, more than 80% of the total insulin market in Pakistan is in vials, mainly because the cost for insulin device treatment has been too high for people on a very low income.

In 2011 Novo Nordisk launched a pilot project in Pakistan to test the viability of a single-packed product for people with diabetes in developing countries. The idea is to lower the one-time purchase price of a pen, and provide better comfort and convenience. The pilot will be evaluated to assess its cost-effectiveness, scalability and sustainability.

Facilitate technology transfer

The spread of technology can directly drive and often accelerate a country's economic and social development.[31] Technology transfer in pharmaceuticals – from training to manufacturing and clinical trials – has flourished in the last few decades. The pharmaceutical industry has set up collaborations with governments, and public-private partnerships with institutions to determine priorities for R&D and conduct research to address public health needs. In this way, research-based pharmaceutical companies have built up a credible track record of providing technology transfer to help improve recipient countries' ability to produce innovative medicines.

Novo Nordisk entered China more than 50 years ago and was the first international pharmaceutical company to establish R&D in the country.[32] We have set up research initiatives globally and in low- and middle-income countries, most notably in China and India. A large proportion of our clinical trials are now conducted in low- and middle-income countries. As we continue to enter new markets, we are exploring more technology transfer arrangements. Currently Novo Nordisk has factories and licence partners in the following LMICs: Algeria, Bangladesh, Brazil, China and India.

Our contribution to technology transfer lies in the transferring of not only manufacturing technology but also other forms of acquired expertise. Examples include:

- Sharing of knowledge through clinical trials, training and management
- Screening/sharing of compound libraries
- Scientific knowledge transfers via research collaborations
- Building public health capacity through training and education
- Imparting management skills/expertise
- Diffusing knowledge through direct investments
- Raising local production quality through joint ventures and licensed manufacturing
- Training in regulatory and quality standards
- Education in supply chain / logistical management
- Training of local healthcare workforces
- Sharing of intellectual property and other knowledge

In addition, we also transfer technology through outsourcing, increasingly using suppliers located in low- and middle-income countries. In doing so, we apply our global standards for responsible sourcing, according to which vendors must comply with the UN Global Compact principles to which Novo Nordisk is a signatory. Novo Nordisk conducts regular audits of vendors, and in some instances helps vendors to build capacity and live up to the required standards. Our responsible sourcing programme currently covers 1,100 vendors, closely related to Novo Nordisk's drug research and production, but is being expanded to cover more than 40,000 vendors worldwide.

While the viability of technology transfer tends to vary from country to country, several factors contribute to successful and sustainable technology transfers. For Novo Nordisk, technology transfers need to be coherent with our Triple Bottom Line approach, and be financially as well as socially and environmentally sustainable. We also maintain several preconditions, such as quality of the end product and stability of the local producers.

Our position

Novo Nordisk acknowledges the need and our responsibility to contribute to the transfer of knowledge and capacity in research and clinical development as essential for economic development. However, we believe there are a number of enabling conditions that need to be in place for successful technology transfer. Included in these are market scale and accessibility, political stability, good transparent governance and government policy.

Our approach

Work with public and private institutions in low- and middle-income countries countries to enhance healthcare provisions to the benefit of all patients

We build and enhance capacity in the countries where we operate by focusing on our core therapeutic expertise. A prerequisite is that we can find suitable partners allowing us to adhere to our global quality standard and the Triple Bottom Line.

Novo Nordisk will continue to enable access to appropriate therapies and technical know-how by implementing programmes to improve the health of patients and build capacity around the world, as well as transferring not only manufacturing technology but also other forms of acquired expertise.

Insulin manufacturing plant in Bangladesh[33]

In 2009 we entered into an agreement with Eskayef Bangladesh Limited to produce insulin. A bulk amount of insulin corresponding to 5 million vials per year will be produced at the newly opened high-tech manufacturing plant to serve the local market.

In addition to transferring technology and educating healthcare professionals, through this project we anticipate increasing the number of jobs in the area, growing local awareness of diabetes and improving local health-related infrastructure.

R&D in China[32]

China is one of the fastest-growing economies in the world. This development is accompanied by an increase in lifestyle-related chronic diseases. Diabetes poses a growing social, educational and economic challenge for Chinese society, and the people and families affected by diabetes. An estimated 40 million people in China have type 2 diabetes and this number is expected to reach 80 million in the next 15 years .

Novo Nordisk was the first international biopharmaceutical company to establish R&D in China. Expanding on this, the Novo Nordisk R&D Centre China in Zhongguancun Life Science Park in Beijing was established in 2002, and has evolved into a centre of excellence for Novo Nordisk in molecular biology, protein chemistry and cell biology. Currently, the R&D Centre China employs around 100 scientists and, in 2010, we announced plans to expand this to 200 employees by 2015. The expansion will mainly be dedicated to a new Diabetes Research Unit.

Adri van der Wielen, occupational health nurse, tends to a patient in a hospital in Pretoria, South Africa

Accessibility of healthcare

Today there are not enough health clinics and trained diabetes care providers to meet the needs of diabetes patients – a majority of whom live in low- and middle-income countries.[3,31] Weak and inadequate health systems prevent progress on a number of urgent health priorities, and improving healthcare systems is now widely recognised as a necessary foundation for achieving the UN Millennium Development Goals.[14]

In the diabetes context, too many cases go undiagnosed and too few people living with diabetes receive adequate care.[7] This presents particular problems for vulnerable populations and those in remote and conflict-affected areas. As part of our contribution, Novo Nordisk will expand partnerships, help train healthcare professionals, increase awareness through campaigns and continue to finance healthcare infrastructure through our donations to the World Diabetes Foundation.

Ambition: Work with partners to make diabetes care more accessible for those in need

Area of focus	Approach
Strengthen health systems as a long-term investment	Contribute to the training of healthcare professionals
Improve accessibility to insulin in remote areas	Continue to reach out to people with diabetes in remote areas
Improve access to diabetes care for women and children	Establish partnerships for the improved delivery of care to children with diabetes in low- and middle-income countries
	Establish partnership-based interventions as part of a long-term commitment to the improvement of health of women and the next generation

Strengthen health systems as a long-term investment

Inadequate local health systems constitute perhaps the biggest single obstacle to achieving the health improvement targets in the United Nations' Millennium Development Goals.[34] The countries most severely affected by non-communicable diseases are those with the greatest need for strengthened health systems. In many developing countries the additional burden of diabetes and other non-communicable diseases places new, long-term demands on healthcare systems that have traditionally focused more on acute, infectious diseases.[7]

Effective management of diabetes requires a sufficient number of well-trained professionals to ensure adequate prevention, diagnosis, treatment and follow-up.[35] For populations where there is no access to healthcare professionals on a regular basis, there is little chance of detecting diabetes before severe complications have emerged. Once detected, diabetes requires life-long care and the healthcare professional plays a key role in the management of diabetes. Besides coordinating treatment, they must also be part of the process of educating the person with diabetes on how to care for themselves. Since diabetes potentially impacts multiple organ systems (eyes, kidneys, blood and heart, for example) proper care involves services and medical specialists in all of these areas, as well as in diabetes itself.

The lack of reliable health systems is a major barrier against Novo Nordisk's efforts to deliver effective treatments to people with diabetes. We wish to drive a sustainable business and provide our insulin products under conditions that provide a prospect of regular treatment with a good outcome. The challenge for Novo Nordisk is to find ways to use our expertise to support the efforts of governments, international organisations and NGOs in strengthening the capacity of existing health systems. It is an important part of our business model to partner between and across private and public sectors globally and locally to address common agendas for improvements.

Our position

We regard it to be an essential extension of our role as the leading provider of diabetes care to use the special expertise we have to contribute to strengthening the capacity of health systems.

While we respect that it is the primary responsibility of governments and local organisations to provide healthcare in their countries, our aim is to play an active role in global health governance, supporting in selected areas where there are critical un-met needs.

We view these contributions as a long-term investment, in line with our Triple Bottom Line principles, that will contribute to sustainable development. Simply put, without the proper systems in place, our products will not be able to reach people with diabetes. Our effort to contribute to the building of reliable health systems is therefore a long-term investment in the development of future business.

Our approach

Contribute to the training of health-care professionals

Novo Nordisk supports diabetes-specific training for all levels of healthcare workers, including improving delivery of care and extending coverage of services. We do so, because it is a precondition for our sustainable business that products are used in regular treatment under proper supervision.

Our business presence locally helps improve the infrastructure for the delivery of diabetes care. This ranges from the establishment of cold chains to training of healthcare professionals, and engaging with ministries of health on issues of procurement and distribution. In addition, we work through the implementation of programmes like Changing Diabetes® in Children to boost specific capacity of local systems.

Expanding diabetes knowledge among healthcare professionals[23]

In 2000, Novo Nordisk, together with the Novo Nordisk Foundation and Steno Diabetes Center made the decision to support diabetes education in developing countries through the establishment of the STAR Programme (Steno Training and Application Resources courses). The aim of the programme is to update the knowledge of diabetologists with the latest information about the disease. The programme was initially rolled out in China and India due to the explosive development of diabetes in those countries, but is now also active in the Middle East and North Africa. To date, the STAR programme has seen the training of over 5,986 healthcare professionals in China, India, Tunisia and Turkey.

The World Partner Project: Identifying a model for improved diabetes care in LMICs[36]

In 2001 Novo Nordisk established the World Partner Project (WPP) as a complex of 31 public-private partnership initiatives across eight countries to ensure standards of diabetes care and improve quality of life for people with diabetes. The project started with a gap analysis of the diabetes situation in six developing countries on three continents: Bangladesh, Malaysia, Tanzania, Zambia, Costa Rica and El Salvador.

The work resulted in a model for improving access to diabetes care in these resource-poor settings. In 2003 the model was put into practice in all six original focus countries – plus India and China – with the world's two largest diabetes populations. We selected partners, typically national diabetes associations and/or ministries of health, to help prepare action plans for each country.

A particular success of the project was the development and deployment of a distance-learning programme for doctors in Bangladesh. The programme has resulted in a significant expansion of diabetes capacity, with over 3,600 healthcare professionals trained in diabetes by the end of 2010. Today the programme continues as a self-sustainable cooperation with a local faculty. The development of an accredited physician programme, with the ambition of extending care to rural areas of the country, is underway.

Improve accessibility of diabetes care in remote areas

The WHO predicts that resource-poor settings will bear the brunt of the diabetes epidemic in the 21st century. Currently, more than 80% of diabetes-related deaths occur in low- and middle-income countries.[37]

In spite of increased migration to urban areas in LMICs, there are still great numbers of people living in rural areas, where people in need of health care must travel long distances to health centres, sometimes for many hours or days. Once patients reach facilities, these can be poorly staffed and lack adequate equipment. It is difficult to attract doctors, specialists and other service providers to rural areas, and achieving reasonable country-wide coverage is a major challenge for any healthcare programme.

One way to improve accessibility to healthcare in these areas is to use mobile clinics or mobile healthcare teams. These units can play an important role in prevention by increasing awareness of lifestyle issues, and can work to improve diagnosis and provide health checks and patient education. However, diabetes (and other chronic diseases) often requires ongoing medical care under regular supervision and can only be treated effectively in a more permanent infrastructure. Without timely diagnoses and adequate treatment, complications and morbidity from diabetes rise exponentially.

The dilemma for health-care authorities, NGOs and companies in using mobile clinics is that, while they may be the only way to reach remote areas, their use risks leaving some patients with a diagnosis without providing a reasonable prospect of treatment. But even if people diagnosed with diabetes do not receive proper medical treatment they may still be able to manage their condition in a way that improves their health perspective, for example through the right lifestyle changes and nutrition.

Our position

We believe that care needs to be extended to all people, regardless of their geographical location. One of the most effective ways to ensure that basic supplies of medicine reach patients is through Novo Nordisk's cooperation with our partners who have the experience and capacity to provide healthcare in the region.

In addition, Novo Nordisk believes mobile clinics can be used to promote awareness, prevention and diagnosis of diabetes. Even if such clinics cannot meet the need for regular care of diabetes they may significantly improve access to important health information for people living outside the reach of normal health systems.

Our approach

Continue to reach out to people with diabetes in remote areas

In a number of LMICs Novo Nordisk has launched mobile clinics, in conjunction with local governments and NGOs, to reach the rural populations. The range of services each bus offers varies according to local requirements and regulations, but visitors are given information about diabetes and, in some cases, are screened for diabetes and, if appropriate, are offered free or affordable treatments and other medical services such as laser treatment for diabetic retinopathy. Mobile clinics have been launched in countries including Algeria, China, Egypt, India, South Africa, Cambodia and Tanzania.

Novo Nordisk continues to support the use of mobile clinics as a means to promote awareness, prevention and diagnosis of diabetes. We acknowledge that such clinics cannot provide consistent or regular diabetes care. However, awareness and screening campaigns are important tools in the effort to ensure earlier diagnosis, thereby empowering people to self-manage their condition to the extent possible through behavioural changes.

School children walking home in northern Tanzania

Extending diabetes care to rural Tanzania

In cooperation with Médécins du Monde, the University of Athens and the local government of Ifakara, Novo Nordisk in 2011 launched a project with the objective of reducing morbidity and mortality of diabetes in the rural community of Ifakara, Tanzania. The project will establish quality and comprehensive care for diabetes in this area, decentralising services to points of care in the districts and developing a referral system. A diabetes outpatient clinic has been established and the use of a mobile clinic is in scope. It is estimated that the project will have an impact on an estimated 60,000 people in the local population.

Mehedi Hassan has type 1 diabetes and receives treatment from a clinic in Faridpur, Bangladesh, under the Changing Diabetes® in Children programme

Gestational diabetes

Gestational diabetes (GDM) is a particular type of diabetes that is first detected in pregnancy.[40] It increases the risk of pre-eclampsia*, preterm delivery,[41] large babies and obstructed labour, increasing the need for caesarean section or assisted delivery.[42]

Women developing GDM are about 7-8 times more likely to develop type 2 diabetes within 10 years than those without GDM,[43] and are at greater risk of cardiovascular problems.[44] Up to 50% of women with a history of GDM go on to develop type 2 diabetes in the future, and babies born to mothers with GDM have a 4-8 times higher risk of developing type 2 diabetes or pre-diabetes later in life.[45]

* pre-eclampsia is raised blood pressure associated with elevated protein in the urine

Improve access to diabetes care for women and children

As demonstrated by the 2010 UN Global Strategy for Women's and Children's Health, the world is increasingly recognising the importance of investing in women's and children's health because addressing these areas can have profound societal and economic benefits.[38] But despite progress made over the past few years, there are still millions of preventable deaths among women and children every year, and more attention must be paid to these vulnerable populations.[38]

The same is true in the context of diabetes. Today, there are 480,000 children under the age of 15 years with type 1 diabetes in the world.[3] About half of these children live in resource-poor settings, often without necessary diabetes treatment facilities.[3] Children with type 1 diabetes have high mortality rates, with life expectancies of less than one year in some countries in sub-Saharan Africa.[39] This is the result of poor accessibility and affordability of medicines and diabetes care, especially in rural areas.[39] On top of this, families with a child with type 1 diabetes living in resource-poor settings often must choose between buying insulin and supplies for a child or food for the entire family.[39]

An estimated 143 million women live with diabetes today but, by 2030, this number is expected to rise to 222 million.[46] Women are the cornerstone of their families and communities, and when they suffer from diabetes it has far-reaching, profound economic consequences.[44] Additionally, although diabetes affects about the same number of women as men, women are often more severely affected by the complications of diabetes.[45] A number of factors contribute to this:

- Women in many parts of the world tend to receive less adequate care than men, especially for complications[47]
- Diabetes care for women is very variable and access is poor in low- and middle-income countries[44]
- Diabetes makes women suffer stigma and discrimination[44]

In recent years, attention has focused on the first 1,000 days of life – in the womb and early childhood – as being decisive in relation to lifelong risk of developing chronic diseases, particularly diabetes.[49,50] That is why it is so important to ensure that women maintain good health during pregnancy, that babies are breast-fed for at least six months[51] and that diabetes, whether pre-existing or developing during pregnancy, is identified and properly treated. Without this care, the unborn child is at risk of developing a number of serious conditions, and both mother and baby are at risk of developing type 2 diabetes later in life.[52-54]

Since 2008, we have launched two partnership-based programmes addressing exactly the issues of diabetes in children and women in LMICs.

Through these programmes we:

- support the development of new evidence and platforms for action by addressing critical research gaps
- mobilise key stakeholders at national and global levels to promote change with a positive health impact for women and children
- and engage key partners in exploring and co-creating innovative solutions targeting women, diabetes and pregnancy

Working on these programmes we take advantage of our past experience in developing concrete proposals for innovative and sustainable models of diabetes care for developing countries. A key lesson is that the starting point for improving care in these settings should be based on three basic intervention strategies:

- Support and strengthen local champions such as diabetes associations. Local champions are crucial for advocating the government and international agencies to create political will and obtain economic resources for diabetes programmes

- Support public-awareness programmes that focus on diabetes prevention. According to the WHO, reducing the incidence of diabetes and its complications through education and healthy lifestyle are cost-effective measure, as it will reduce the need for diabetes care

- Support training and education programmes directed not only at doctors, of which there are limited numbers in LMICs, but specifically at other groups of healthcare professionals such as nurses, medical officers, etc

Our position

At Novo Nordisk we believe that a sustainable and impactful approach to prevention, treatment and caring for people with diabetes requires a gender-based and life-course approach. We recognise that in many societies women and children are among the most vulnerable groups, with limited access to health, education and economic empowerment. We are committed to addressing the particular needs of women and children as part of our work to improve access to health and diabetes care.
Urgent action can help ensure that children with type 1 diabetes in resource-poor settings receive life-saving treatments and care. In 2008 Novo Nordisk decided to use the company's presence and capacity in resource-poor countries to bring relief, by working with our global and local partners to provide immediate treatment to children and find sustainable solutions that ensure they are also cared for in the future.

We believe that there is a significant link between women's health and the future development of diabetes. In 2011, Novo Nordisk established the Early Origins of Health initiative. The aim is to design timely early interventions that can reduce the risk of developing non-communicable diseases (NCDs) in adult life.

Our initiatives are in line with the UN Women's and Children's Health Strategy and we will use this as Novo Nordisk's frame of reference for further initiatives. We will continue to develop partnership-based programmes, as part of our long-term commitment to sustainable improvements in health.

Our approach

Partnerships for the improved delivery of care to children with diabetes in low- and middle-income countries

Novo Nordisk, through our Changing Diabetes® in Children programme, establishes partnerships at both the local and international level for the improved delivery of care to children with diabetes.

Continue to establish partnership-based interventions as part of a long-term commitment to improvement of health for women and the next generation

Through the Early Origins of Health initiative, we are building partnerships with members of industry, Steno Diabetes Center, the World Diabetes Foundation and the United Nations Foundation. Each will provide their expertise in the field of health literacy, nutrition, research, access to health, and connecting people, ideas and resources respectively.

In addition, under the umbrella of our Changing Diabetes® in Pregnancy programme we have set up local public-private partnerships in India, Colombia and Nicaragua. We work with local health authorities as well as academic and implementing partners to train health care professionals, build capacity in the health system for gestational diabetes screening and management, and test innovative ways to change the lifestyle of mothers with gestational diabetes and their families. The hope is to identify cost-effective ways of reducing the burden of diabetes-related disease both in the short and long term. The programme aims to reach 60,000 women with screening, treatment and follow-up and lifestyle education by 2013.

Supporting the treatment of childhood diabetes

In 2009 Novo Nordisk initiated the Changing Diabetes® in Children (CDiC) programme in partnership with the World Diabetes Foundation, Roche and the International Society for Pediatric and Adolescent Diabetes (ISPAD). The programme works through local partnerships to establish clinics within the existing healthcare system where children with diabetes can be diagnosed and receive specialised care. In addition to development of patient-education materials and the provision of free insulin and blood-glucose-monitoring equipment and supplies, the programme also addresses the need for training of healthcare professionals in the specific aspects of diagnosis, treatment and care of childhood diabetes.

CDiC has been rolled out in nine countries and 14 clinics have been established. To date 300 healthcare professionals have received training specific to childhood diabetes and more than 1,500 children are receiving treatment in the established clinics.

Building understanding of the long-term consequences of gestational diabetes

In 2011 we joined a research project in the Indian state of Tamil Nadu to build on an existing programme that is screening for gestational diabetes and providing free doses of insulin approved for use during pregnancy. National treatment, guidelines have been established, and advocacy targeted towards policy makers led to the inclusion of universal screening in national policy in 2010. Novo Nordisk is providing support for a new study to track the women diagnosed and treated and their children, to improve understanding of the long-term consequences of gestational diabetes. We are replicating this model in the state of Punjab in India, Nicaragua and Columbia.

Private pharmacy, Bangladesh

Affordability of treatment

In low-income and resource-poor settings, the cost of medicine and healthcare services presents a major hurdle to health.[55] These expenses are largely borne by patients as out-of-pocket expenses.[56] While the cost of medicine is a fraction of the overall cost of diabetes to health systems,[57] life-long treatment for diabetes still imposes a significant financial burden on patients and their families.[58]

To address this issue Novo Nordisk pioneered a differential pricing policy for human insulin in least-developed countries in 2001. A variety of other market factors – such as intermittent mark-ups – create additional costs and effectively add another layer to the access equation. The added cost burden to patients need to be addressed.

Ambition: Work to improve affordability of treatment for patients, particularly in resource-poor settings

Area of focus	Approach
Improve funding for diabetes healthcare	Continue our annual endowment to the World Diabetes Foundation
Improve affordability of insulin	Continue our differential pricing policy and provide insulin to the governments of LDCs at a maximum of 20 US cents per patient per day
	Work in partnership with governments and other organisations to increase the number of patients we reach in low- and middle-income countries

Improve funding for diabetes healthcare

The cost of diabetes medicines is a fraction of the impact of the disease on health budgets.[57] For a chronic disease such as diabetes, some of the highest costs result from associated health conditions that arise as the disease progresses.[60] Because of poor diagnosis, severe health problems like blindness, cardiovascular disease and amputations present themselves at the diagnosis of diabetes itself.[61]

This highlights the vicious cycle of disease and poverty in low- and middle-income countries. When someone lacks the means for regular treatment, he/she often ends up suffering from complications, which can have far more severe consequences for his/her health and livelihood,[62] as well as public health budgets.[63]

Public and private funding

The lack of public funding for diabetes is one of the main barriers to access to proper care for people with diabetes living in LMICs.[64]

For the poorest part of the world's population, funding for treatment can only be provided by government programmes or, when governments are unable, through international donors. This has been a successful model of global development aid for the last decade for leading infectious diseases, such as HIV/AIDS, TB and malaria, but it has yet to be applied to diabetes and other non-communicable diseases, which will soon present a double-burden to these developing countries.

For the many people with moderate incomes above the poverty threshold, treatment can be funded through private or public insurance. However, insurance systems increasingly struggle to cope with diabetes and often provide limited coverage. The result is that the majority of people with diabetes pay for most of their treatment out of their own pocket. [65]

Donations are often seen as a way of dealing with affordability issues in LMICs, especially in cases of national emergencies or natural disasters where supply of medicines is interrupted. In these instances, the willingness of private companies to donate medicines can play an important role.

Our position

We have developed a sustainable business model framework for our operations in developing countries and our pricing policy is a key example of our approach. Nonetheless, we recognise that even a significantly reduced price may be out of reach for the poorest people. To help meet their needs, Novo Nordisk established the World Diabetes Foundation. Its purpose is to support projects that will improve diabetes care in developing countries.

While we believe that product donations are not a sustainable way of improving access to healthcare, we maintain an active policy on emergency relief in disaster-struck areas. When appropriate, we donate products, in-kind services and sometimes cash to partner organisations that are equipped and experienced for operations under these circumstances. We always work in adherence with WHO's Interagency Guidelines for Drug Donations.

Our approach

Continue our annual endowment to the World Diabetes Foundation

Part of our contribution is our continued long-term financial commitment to the World Diabetes Foundation (WDF). In 2002 and 2008 our shareholders voted to contribute a portion of net insulin sales to the WDF over 15 years. These donations are reported annually on our income statement. The independent and non-profit WDF supports the prevention and treatment of diabetes where it is needed most, providing funding for local initiatives that improve healthcare system capacity. Since it was founded by Novo Nordisk in 2001, it has supported 270 projects in 100 countries.

Ensuring continued supply of insulin when disaster strikes

In 2010 Novo Nordisk emergency relief donations included:

- A donation of $177,000 USD to Pakistani flood victims, with $88,000 USD going to the Danish Red Cross, which cooperates with Pakistani Red Crescent. The other half went to supply insulin and medical supplies through Novo Nordisk's affiliate in Pakistan.
- A donation of 50,000 vials of insulin to victims of the earthquake in Haiti.

Novo Nordisk employees unload supplies for flood victims in Pakistan in 2010

World Diabetes Foundation

The establishment of the World Diabetes Foundation was announced by Novo Nordisk A/S on World Diabetes Day 2001. The foundation was legally established in February 2002. The foundation is registered as an independent trust and governed by a board of six experts in the field of diabetes care, access to health and development assistance.[66]

A donation of maximum DKK 650 million ($115,6 million USD) over a period of 10 years was approved by Novo Nordisk's General Assembly and shareholders in March 2002 (realised 2001-2010: DKK 528.8 million ($94,0 million USD). In March 2008, the shareholders approved an additional endowment of a maximum of DKK 575 million ($102,2 million USD) until 2017, a total of DKK 1,1 billion ($195,6 million USD).[67]

The World Diabetes Foundation supports prevention and treatment of diabetes in the developing world through funding of sustainable projects. The foundation creates partnerships and acts as a catalyst for other initiatives and helps others do more. Other focus areas are global education and advocacy, to create awareness, and bring care and relief to those impacted by diabetes. The World Diabetes Foundation has funded 270 projects in 100 countries with a total project portfolio of $255.5 million USD, of which $85.8 million USD has been donated by the foundation.[68]

The WDF in numbers*

Improved access to care	Presently, the World Diabetes Foundation has supported the training of 28,862 doctors, 23,158 nurses and 50,375 paramedics. To date, more than 6.5 million people have been screened for diabetes through 12,012 screening camps. Based on reports from project partners, more than 1 million documented cases have been treated at the 2,994 clinics and micro-clinics funded by the foundation
The Coming Generation (Primary prevention)	To date, the foundation has supported the training of 17,357 school teachers and educated 273,159 children. In addition, 156,796 parents and households have received information about healthy living and lifestyle behaviour
Eye care	To date, more than 593,724 people have been screened, and 113,724 cases of diabetic retinopathy detected. In addition, 40,248 people have been saved from unnecessary blindness through laser treatment
Foot care	The foundation has facilitated the training of 5,923 healthcare professionals in diabetic foot care, who have since screened more than 267,715 patients with high-risk feet, potentially saving 30,825 feet through appropriate treatment and care
Gestational diabetes	To date, 15,555 women have been screened for diabetes, and 354 clinics have been strengthened in providing care for gestational diabetes
Children with diabetes Advocacy building a global alliance	WDF provides care to 1,616 children living with type 1 diabetes. Over the last eight years, the World Diabetes Foundation has contributed to regional and global advocacy by providing funding and technical assistance to many initiatives. See our website www.worlddiabetesfoundation.org for more info.
DM/TB	New scientific evidence shows that people with diabetes are at an increased risk of tuberculosis. In support of the MDG's targets relating to tuberculosis control, the foundation has funded several pilot programmes to develop sustainable models for an integrated treatment approach in Malawi, India, China, Nigeria, Brazil and Cameroon.

*Numbers are accumulative from 2002 until end of 2010 and have been extracted from semi-annual reports and field-visit reports from partners and the Secretariat. USD number based on average exchange rate: 5,62 DKK per $1 USD.

For more information on the WDF visit www.worlddiabetesfoundation.org

Improve affordability of insulin

In 2001 we introduced differential pricing for Least Developed Countries (LDCs) as defined by the United Nations.[69] This industry-leading move significantly lowered the overall market price of insulin in these countries. In 2010 the average realised price for an insulin vial from Novo Nordisk in the LDCs was $4.2 USD and our insulin products were used by an estimated 8% of diagnosed patients (around 350,000 patients). This translates into a price per patient of approximately 15 US cents per day.*

In other low- and middle-income countries we also offer insulin at very low prices. In the public sector, government-run health programmes buy large volumes of product through a tendering process, which grants the contract to the pharmaceutical company offering the best bid. In 2010 we reached millions of patients with insulin at an average realised price of less than USD 15 cents per day per patient in many low- and middle- income countries like Brazil.

The supply chain of medicines like insulin is complex. These products are usually distributed through the public health system. Even if the manufacturer reduces the price to developing countries, mark-ups through the distribution chain are often much higher in low- and middle-income countries, and constitute a very significant part of the end-user price patients pay; the ex-manufacturers' price is not reflective of the price paid by the patients.[57]

In some instances, tariffs and taxes are added to the cost of pharmaceuticals.[57] The eventual end-user price also includes the cost of transportation, storage, import tariffs and taxes, and wholesale and retail mark-ups. These hidden costs can often more than double the ex-manufacturer's price. These situations can be avoided. In Tanzania and Uganda we have collaborated with the respective ministries of health and distributors, and successfully managed to remove import duties imposed on insulin.

In the private sector small private retail pharmacies cannot keep a large number of medicines in stock due to capital constraints and therefore rely on an extensive network of sub-wholesalers instead of buying directly from large manufacturer-appointed distributors. This leads to the existence of multiple third parties between the manufacturer and the dispensing pharmacists, resulting in increased retail price due to multiple distribution mark-ups.

Our position

The fundamental premise of the Novo Nordisk approach to access to health is the recognition that we need to make appropriate medicines affordable for patients according to their ability to pay. This is why we will always have a low-priced insulin in our product portfolio. We are also committed to working in partnership with governments and organisations to reach more patients with an affordable price in low- and middle-income countries.

We call on governments, international organisations and NGOs to improve distribution channels to ensure these discounted prices are passed on to the patients. We regard our affordable prices as one component of the wider partnership required to improve healthcare capacity for prevention, diagnosis and treatment.

Our approach

Continue our differential pricing and provide insulin to the governments in least-developed countries at maximum 20 US cents per patient per day[2]

Work in partnership with governments and other organisations to increase the number of patients we reach in low- and middle-income countries

We will take the initiative to identify and document the barriers against distribution that may hamper the supply and drive up the desk prices paid by patients. We will make these results public and develop suggestions for concrete actions.

We will seek to establish new partnerships with local and international organisations to develop better solutions for addressing these challenges.

*Note: The price per day per patient is calculated assuming 32 units per day and that the average person with type 2 diabetes needs 1 vial (10 ml) of human insulin per month.
Quoted prices are ex-factory prices and, in the case of low- and middle-income countries, ex-factory based on high-volume tender sales.

Private pharmacy, Bangladesh, 2008

Diabetes clinic in Bangalore, India, 2010

Fatma Tarek from Egypt has type 1 diabetes

Quality for patients: Quality assurance in diabetes treatments

All aspects of healthcare, including research and development, education of healthcare professionals, and measures for prevention and treatment of diseases, must meet scientific quality standards and be ethical and culturally acceptable.

Novo Nordisk has one stringent, global quality standard for all our products, ethical conduct of clinical trials, monitoring of short- and long-term side effects, and partnering with public health officials to monitor and preserve the cold chain for insulin. However, living well with diabetes is about much more than insulin. We have initiated patient-centered research to scientifically document the psycho-social aspects of life with diabetes to inform continued support of education for patients and healthcare professionals.

Ambition: Quality assurance in diabetes treatment for patients wherever they live

Area of focus	Approach
Conduct responsible and ethical clinical trials	Support and ensure full transparency of clinical trial activities and results
	Ensure that all persons enrolled in Novo Nordisk-sponsored research are protected by the same rights, high ethical standards and regulations, regardless of geography
Work for safe medicines for patients	Maintain one global quality standard
	Work against counterfeiting
	Work with ministries of health and distributors to establish effective supply chains for delivery of insulin
Empower people with diabetes to achieve better health and quality of life	Continue research into the understanding of patient needs, including the psychosocial barriers against adhering to treatment regimens
	Continue engaging with stakeholders, with a view to identifying areas for improvement in the management of diabetes
	Support healthcare professionals to deliver better-quality healthcare building on principles of patient involvement and ongoing support

Conduct responsible and ethical clinical trials

Clinical trials are conducted for all new medicines and represent the latest stage in a long process of development and testing before a new product can be marketed. Regulators only approve a new medicine for market authorisation if these trials, together with other research data, demonstrate health benefits significantly outweighing the potential risks.

Clinical trials are increasingly being conducted in low- and middle-income countries.[70] This is partly due to the fact that national health authorities are asking for greater numbers of participants in the total clinical development programme. Another reason is that more countries require that trials be performed on their own populations before a pharmaceutical product can be marketed in those countries.

Clinical trials in resource-poor settings involve additional challenges. Participants have a higher likelihood of dropping out and tracking them can be very difficult due to inadequate information systems. Cultural aspects – such as women's standing in society and the family – can also impede trial recruitment and participation. Such factors slow the process, increase costs and make it challenging to achieve the high scientific standards required.

However, the globalisation of clinical research can also bring global benefits, enabling pharmaceutical companies to potentially test new drugs more quickly and effectively for the simple reason that the more countries that participate, the greater the number of people who can potentially be recruited for the trials. Additionally, increased knowledge about drug effects in different populations ultimately benefits patients in these regions. For example, the existence of a large and genetically diverse population in India provides opportunities to rigorously assess drugs more efficiently. Clinical trials also bring resources and expertise to resource-poor countries.

Concerns have been raised that people in resource-poor settings may be easy targets for clinical trials and could be exploited. People who are deprived of basic healthcare services might enrol in a trial without a full understanding of the potential risks involved in testing an unapproved medicine. Another concern is whether or not, once approved, a medicine may be too expensive for the people who have been using it on a trial basis. The concern is that the pharmaceutical industry might use people from resource-poor countries as 'guinea pigs' for medicines that have more relevance for the Western world than for the countries hosting the trials. It is also argued that companies and research institutions cannot be held to account by poor, uneducated, people who participate in clinical trials.

It is hard to overstate the importance of conducting clinical trials in accordance with international guidelines and in compliance with the highest ethical standards.

Our position

Novo Nordisk supports transparency of all clinical trial activities and access to results, and is committed to a high ethical standard in all aspects of conducting clinical research. We support the fundamental belief that human rights need to be respected and also promoted when conducting clinical trials.

A substantial part of our clinical research takes place in developing countries.[70] We recognise that clinical research carried out in these areas can raise specific ethical concerns. Our internal procedures ensure that all persons enrolled in Novo Nordisk-sponsored research are protected by the same rights, high ethical standards and regulations, regardless of whether trial participants live in industrialised countries or the developing world. These procedures are continuously updated to integrate new regulatory demands and accommodate public concerns. We adhere to the Declaration of Helsinki, International Conference of Harmonisation (ICH) for current Good Clinical Practice (cGCP), and our own stringent policies and clinical trial procedures.

Novo Nordisk will only perform clinical trials in countries where the company intends to market the investigational product. Patients participating in clinical trials will, after the study has finished, be offered the best available treatment.

Informed consent

Participants in Novo Nordisk's clinical trials always sign an informed-consent form before any study procedure takes place. Those unable to give their consent, i.e. due to being underage, will only be included in a study activity when consent procedures in accordance with regulations are followed.

Information about a clinical trial is always provided in the patient's first language. By doing so we ensure that literacy, poverty or cultural barriers do not prevent a person's full understanding of the issues involved in participating in a clinical trial. Participation in a trial is always voluntary, with the ability for a person to withdraw at any time without giving a reason.

Ethics committee

Novo Nordisk only initiates trials in countries that can provide approval from an external local ethical committee and governmental body. This also means that Novo Nordisk only performs trials in countries where such a system is established. Ethical committees are constituted in accordance with ICH guidelines; they have independent board members, doctors and community representatives. The mandate of the ethical committees is to ensure that the ethical codes are followed. Health authorities conduct inspections of clinical trials, covering both investigators (external doctors that perform the studies) and companies, to ensure that trials are conducted in accordance with the Helsinki Declaration and ICH guidelines.

For more information see Novo Nordisk's bioethics policy: http://www.novonordisk.com/science/bioethics/bioethics-governance.asp

Our approach

Support and ensure full transparency of clinical-trial activities and results

Novo Nordisk strives to have all clinical-trial results published according to accepted international regulations and guidelines, and we ensure transparency of our studies by disclosing key protocol information on the external website: www.clinicaltrials.gov. Study results from trials involving marketed drugs can be accessed via the same site, www.clinicaltrials.gov, for studies that fall under the US law FDAAA. Furthermore, Novo Nordisk has its own online repository for clinical-trial activities: www.novonordisk-trials.com. This site contains information on all Novo Nordisk clinical studies and result summaries for studies conducted on marketed products. Novo Nordisk is collating all information about bioethics in the R&D area on www.novonordisk.com/R&D/bioethics.

Ensure that all persons enrolled in Novo Nordisk sponsored research are protected by the same rights, high ethical standards and regulations, regardless of geography

Clinical trials sponsored by Novo Nordisk will always be conducted according to the Helsinki Declaration, which describes human rights for patients participating in clinical trials, and similar international ethical guidelines such as the Nuremberg code, the Belmont report and Council for International Organizations of Medical Sciences (CIOMS), and the ICH guidelines for cGCP. We apply the same procedures wherever we sponsor clinical trials. This means that all people enrolled in Novo Nordisk trials are protected by the same rights, high ethical standards and regulations irrespective of the location of the study.

Novo Nordisk clinical trials[70]

The number of people participating in Novo Nordisk-sponsored clinical interventional trials increased by 74% from 11,130 in 2009 to 19,361 in 2010 and approximately 40% of the people live in developing countries.

In 2010 we also:

- Updated the company's clinical research ethics code of conduct to include observational studies, thereby ensuring these are also covered by the same ethical principles and in accordance with cGCP.
- Developed a documentary on clinical trial ethics in Novo Nordisk-sponsored trials with special focus on trials in India and China. The film documents the global ethical standard to which Novo Nordisk adheres.
- Developed a training programme on global clinical trial ethics, a new e-learning programme, a clinical trial brochure and slide decks.

Trial investigators: In trials sponsored by Novo Nordisk, all healthcare professionals have documented training to ensure they have the necessary competences. They must adhere to the Declaration of Helsinki, ICH Good Clinical Practice and Novo Nordisk's policies and clinical trial procedures.

Clinical results: Since 2005, Novo Nordisk has provided public access to the results of all its sponsored phase 1-4 clinical trials for marketed products and protocol information on all phase 2-4 clinical trials for drugs and devices in development. In addition, similar information is included on phase 1 trials initiated after 1 July 2008, and non-interventional studies initiated after January 2007.

Work for safe medicines for patients

Counterfeit healthcare products are becoming an increasingly important issue for the pharmaceutical industry and represent a public health risk, because the contents of counterfeit products are unknown.[72] Counterfeit products may lack active ingredients, so patients do not receive the treatment they expect and need, or worse yet, may contain other ingredients that could pose a safety risk.[73] Counterfeit and unsafe products also undermine confidence in the healthcare system, from the healthcare professionals who treat patients to the pharmaceutical industry.[74]

To ensure that only safe, effective and high-quality products are on the market, effective regulation is necessary. In industrialised countries, national drug-regulatory authorities approve medicines for use on the basis of their demonstrated safety, efficacy and quality. After a product has been registered, healthcare authorities monitor the market to detect and remove any poor-quality, falsified, or unregistered medicines. This requires significant governmental resources.[75]

A large number of low- and middle-income countries lack the means – financial resources, equipment and trained personnel – to regulate medicines effectively. The World Health Organization estimates that approximately 30% of countries are unable to maintain a registry of medicines. [76]

Counterfeiting is not the only problem with regard to diabetes products: insulin is heat sensitive and requires that temperature conditions are maintained both in transport and storage. Insulin loses its potency when exposed to temperatures above 10°C.

Our position

Ensuring the safety of patients is one of our main activities. If one of our products were shown to have harmful side effects, this could be devastating to our company. Therefore, we are on a constant high alert to ensure the production of high-quality products, compliance with regulatory requirements, and continuous improvement of how we work.

Insulin filling plant in Denmark

Our approach

Maintain one global quality standard

At Novo Nordisk we believe that all patients have the right to quality products regardless of where they live. Therefore, we have established one global quality standard for all of our products. To ensure this, we have a Quality Manual that covers all Novo Nordisk organisational units, products and devices, and outlines the processes performed by employees working in all organisational units of Novo Nordisk. We have also implemented and maintain a Quality Management System in accordance with: ISO 9001:2008 and ISO 13485:2003, external requirements set by laws and regulations and the Novo Nordisk Way.

Novo Nordisk also conducts ongoing internal quality audits in all countries. In 2010 we conducted 132 audits, with 22 of these taking place in developing countries.

In order to minimise any potential risk to patients and to meet regulatory requirements, Novo Nordisk has established a pharmaco-vigilance system. This allows us to continuously monitor the safe use of our insulin products and facilitate the timely reporting of detected adverse drug reactions to the relevant authorities.

Work against counterfeiting

At Novo Nordisk, we work against counterfeiting and work hard to find effective ways to stop counterfeiters via joint initiatives with peers and in industry organisations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Work with ministries of health and distributors to establish effective supply chains for delivery of insulin

We work closely with ministries of health and distributors to ensure the stability of insulin. This includes the establishment of cold-chain systems, quality audits and development of reports and action plans for countries to improve their systems. In addition, we strive to ensure that patient educational materials are available in all countries where our products are distributed.

Safeguarding patient safety

Three years ago, Novo Nordisk set an ambitious quality aspiration: To become the global quality leader within the pharmaceutical industry by 2020. Leadership is not an end in itself, but our work taking us towards achieving quality leadership, and ultimately succeeding, enables us to challenge ourselves and deliver a high-quality performance that ensures the safety of patients all over the world using Novo Nordisk's products.

Working against counterfeiting

Novo Nordisk works against counterfeiting by:

- having a quality-management system that investigates occurrences of counterfeited Novo Nordisk products
- working with scientific and trade organisations as well as regulatory bodies to develop legislation to counteract counterfeit products
- cooperating with regulators and other stakeholders to investigate counterfeit products and to develop new anti-counterfeit measures
- communicating efficiently and openly about cases of counterfeit products found in the Novo Nordisk supply chain to minimise the safety risk that use of such products may pose
- considering legal action against those involved in the counterfeiting of Novo Nordisk products
- being a member of the Pharmaceutical Security Institute (PSI), which collects information and coordinates investigations into counterfeit products within the pharmaceutical industry worldwide

Empower people with diabetes to achieve better health and quality of life

Improving quality of care for people with diabetes is not just about provision of medicine,[77] but about effectively addressing the many challenges they face. This involves qualified medical advice, patient education or support, and working against non-discrimination from their local communities and families.[78]

Even when medicines are fully available, most patients today do not achieve desired treatment outcomes, in part because healthcare systems do not meet the complex and changing needs patients have for multi-disciplinary care, education and support, in order to successfully self-manage their condition.[79]

Every single day for the rest of their lives, people with diabetes will make decisions[80] about their diet, exercise and medication management, and how they test their blood sugars, prevent or manage the risk of complications and worry how their day-to-day decisions influence this risk.[79]

A rethinking of how best to use existing human and financial resources is needed to better care for, educate and support people with diabetes to manage their condition in everyday life.

Sustainable improvements in chronic care require the involvement of all key stakeholders and must be based on patient involvement and understanding of the real treatment and self-management barriers that people with diabetes face.[81]

Healthcare professionals play a critical role in providing medical care for educating and empowering people to manage their diabetes. They also play a key role in prevention, awareness and earlier diagnosis of diabetes in society. They can only fulfil this role, however, with the necessary training, financial support and legislation, which supports a coordinated delivery of chronic care and prevention building on patient-centred principles.[82]

Family members, policy makers, non-governmental organisations, patient organisations, and other stakeholders each play essential roles in helping ensure that people with diabetes have the required social and community support they need. Stakeholders, however, require policy support and incentives to successfully mobilise change.[83]

Our position

At Novo Nordisk, our commitment to patients is at the centre of our actions and is fundamental to what we believe to be our most significant contribution to society: To discover and develop innovative biological medicines and make them accessible to patients throughout the world. In this way we share a common interest with all stakeholders to improve patients' health and quality of life.

Understanding the complex educational, psychological and cultural barriers people with diabetes face is key to finding better and more sustainable ways of enabling them to live full and productive lives.

Therefore, we support international, regional and local research initiatives that help shed light on the full range of un met needs of people with diabetes, their family members, as well as those of health-care professionals and other stakeholders in society in relation to achieving better chronic-illness care.

We take internal measures to ensure we apply all the insights from our extensive patient needs studies to our own research and development programmes and to the way we organise and prioritise our Changing Diabetes® programmes. We advocate the importance of putting patients firsts as we engage in partnerships for sustainable and cost-effective change.

We support training and education for healthcare professionals, non-governmental organisations and policy makers relevant for decision making and development of patient-centred national diabetes care programmes.

We facilitate an open dialogue and collaboration across all disciplines and sectors in society to help bring about change for more sustainable and cost-effective chronic-illness care according to the needs of patients and those who care for them.

We collaborate with our partners to improve access to quality diabetes education around the world and facilitate world-wide sharing of better practices amongst health professionals and educators in diabetes.

We undertake global initiatives to advance awareness, advocacy and research for diabetes education and self-management support. We also engage in local partnerships to support training of health professionals and education of patients as an integrated part of Changing Diabetes®.

Our approach

Continue international research into the unmet needs of people with diabetes and the barriers that they and those supporting them face against improving treatment outcomes

Continue facilitation of dialogue and collaboration among all stakeholders in diabetes, with a view to identifying new areas for sustainable improvement in the management of diabetes

Support healthcare professionals and communities at large to provide better care and community support to improve diabetes health, quality of life and self-management

Driving international efforts to improve self-management and psychosocial support in diabetes[84]

The DAWN™ (Diabetes Attitudes Wishes and Needs) study in 2001 was the largest study of its kind ever conducted to explore the wider non-medical aspects of diabetes management. Involving thousands of people with diabetes and their care givers from 13 countries around the world, the study revealed a number of critical psychological, social and educational factors that must be addressed in order to improve outcomes of diabetes care effectively. The international publications and training programmes derived from the DAWN study, have raised awareness on a global scale about the critical importance of issues such as stigma, public awareness, fear of medicines, anxiety, depression, and the importance of motivation, self-management education and social support.

The DAWN™ study provided the first milestone evidence to enable a wider acceptance in the international community of the importance of addressing the psychological and social barriers to effective self-management.

Today, more than a decade after the first DAWN™ study, many national and local diabetes programmes adopt principles of education and psychosocial support in their strategies. However, there is still a long way to go before all people with diabetes actually receive the kind of support they need.

To reconvene and revisit the international state of affairs of diabetes care from the perspective of people with diabetes, as well as of their family members and healthcare professionals, we are undertaking a second multi national DAWN™ study, "DAWN 2™". DAWN 2™ represents a 10-year follow-up on the first DAWN™ study and brings together key organisations and international and national experts, medical doctors, nurses, dieticians, psychologists, sociologists, educationalists and patient advocates from more than 18 countries.

The collective aim is to once again engage all key stakeholders in the global diabetes community to explore the real situation for people with diabetes, their full range of needs, and how each stakeholder around them can contribute to making their lives better and easier.

The first phase of the DAWN 2 study is a scientifically validated survey study in 18 countries: Algeria, Brazil, Canada, China, Denmark, France, Germany, India, Italy, Japan, Mexico, Netherlands, Poland, Russia, Spain, Turkey, the UK and the US. An estimated 16,200 will participate in three surveys targeting approximately 9,000 people with diabetes, 2,160 family members of people with diabetes and 5,040 healthcare professionals respectively.

Looking into the quality of life for diabetic patients in resource-poor settings[85]

In line with our commitment to applying the insights from the DAWN™ to study all aspects of our work, we conducted a survey-study on diabetes management, complications and psychosocial aspects of people with diabetes in sub-Saharan Africa countries in 2008. These countries had not participated in the original DAWN™ study. The study's key objective was to investigate the status of psychosocial management of diabetes and identify areas for possible improvements, as well as potentially providing a basis form measuring the quality of diabetes management moving forward.

The survey included 2,711 patients from 31 centres across six countries in sub-Saharan Africa and results revealed a number of critical gaps in care, such as inconsistent availability of insulin as well as inconsistent frequency of eye, feet, kidney and proteinuria examinations. Additionally, neuropathy was prevalent in at least 25% of patients, just as eye complications were common. Depression and anxiety were highly prevalent, again confirming the wider findings of the DAWN™ studies that psychosocial assessment and care must be considered as an integral part of diabetes care also in sub-Saharan Africa.

Representing a completely different but essential issue in Africa, several patient-research studies today confirm the importance of placing more emphasis on understanding the psychological, social and cultural determinants of acceptance of the disease and its treatment.

Novo Nordisk is committed to taking its lessons from the DAWN™ initiative into training programmes and care-improvement activities in the region to find local ways of addressing the challenges of self-management and mental health of people with chronic illnesses in that region.

Supporting health care professional training

Novo Nordisk will establish a scalable excellence model concept of regional diabetes training centres for healthcare professionals supported by the Steno Diabetes Center. At these centres healthcare professionals will obtain insights into the latest treatment guidelines and optimal standards of care, education and patient collaboration. It is our ambition that these centres deliver accredited diabetes education in collaboration with international key opinion leaders and contribute to developing a state-of-the-art curriculum for diabetes education on an ongoing basis.

Changing Diabetes® Village in Union Square, New York, World Diabetes Day, 14 November, 2007

Responsible advocacy and awareness: Bringing about change

High-level commitment and concrete action at a global, regional and national level is required to address the growing burden of diabetes in low- and middle-income countries. There is a need to generate awareness and consensus among payers and policy-makers about the impact of diabetes on individuals and society.

Today, diabetes and other non-communicable diseases (NCDs) represent a leading threat to social and economic development, with the mortality and disease burden set to increase substantially over the next 20 years, particularly in low- and middle-income countries.[86]

Still, governments and international organisations often lack commitment to address the issue appropriately, and a high level of public ignorance exists about diabetes,[87] its causes, risk factors and complications – in particular the extent to which a healthy lifestyle can prevent or delay the onset of type 2 diabetes and related medical complications.[88] This is especially true in low- and middle-income countries where access to information is often limited.

The Changing Diabetes® Leadership Initiative is part of Novo Nordisk's commitment to facilitating a worldwide response to the escalating diabetes pandemic. The global initiative was established following the adoption of the United Nations Resolution on diabetes. This requires us to extend our focus beyond treatment, and also challenge health systems and political priorities worldwide. We collaborate across advocacy platforms with global, regional and local organisations and governments to drive awareness, prevention, detection, equity in access to care and improved diabetes care.

Mobilising payers and policy-makers to maximise impact and sustainability of improved diabetes care

Novo Nordisk is actively engaged in the public debate around health-policy development to give appropriate priority to chronic NCDs such as diabetes. Through our advocacy work we aim to speak up for people with diabetes. This applies also for those living in developing countries, who otherwise would not have a voice or opportunity to influence public policy and resource allocation within political and health systems.

As a central part of the Changing Diabetes® initiative, Novo Nordisk collaborates with multiple partners to hold international, regional and national Diabetes Leadership Forums. The role of Novo Nordisk is generally that of sponsor and co-organiser, and titles and themes vary according to the partnership set-up and local priorities. The Leadership Forums are unique opportunities for public-health stakeholders to host or support high-level advocacy meetings to bring issues related to diabetes and NCDs on to the political agenda. They present opportunities to commit to sustainable action in the areas of prevention of diabetes and its complications, early detection and improved care for people with diabetes.

The Diabetes Leadership Forums aim to facilitate united responses on national levels and across regions, and gather relevant stakeholder groups (payers and policy-makers, patient groups, expert communities, private sector, NGOs, media, international health organisations and actors from outside the health community) to move diabetes up the public-health agenda and get them to commit to national targets for improved diabetes care. From 2007 - 2011, Leadership Forums have taken place in more than 40 locations worldwide, gathering more than 8,000 people, with international forums in New York, Moscow, Beijing, Johannesburg and Dubai.[89] We publish Changing Diabetes® Briefing Books to engage with stakeholders and raise awareness about diabetes. The books demonstrate how investments in diabetes can impact macroeconomic development and growth, as well as reduce the human suffering caused by the diabetes epidemic.

Working for universal quality care

Novo Nordisk strongly believes that the human and economic costs of diabetes can be significantly reduced through better treatment and earlier diagnosis of the disease, which can prevent many diabetes-related complications. Diabetes care is patchy and inconsistent, both between countries and between regional and local areas within countries. This is often due to a lack of knowledge and understanding of best practice in diabetes care across all stakeholder groups, from healthcare professionals and people with diabetes to governments and funding bodies. The missing link is greater collection and sharing of outcomes data that shows which approaches, systems, and treatments work and why.

Measurement of the full spectrum of diabetes care is the key. The Changing Diabetes® Barometer is a Novo Nordisk initiative that aims to collect the available data relating to prevalence, quality of care, cost of care, access to care and national plans worldwide, and to make the data more easily accessible. The Changing Diabetes® Barometer facilitates sharing of knowledge so that healthcare professionals, people with diabetes and others can interrogate the data and learn what works in which conditions.

This knowledge encourages investment and the adoption of best practices, which in turn will improve diabetes care and therefore outcomes. The virtuous circle is completed by more and better measurement of diabetes care as the value of measurement becomes more widely acknowledged.

In April 2009 Novo Nordisk launched the Changing Diabetes® Barometer website, which maps the diabetes situation around the world based on data and experiences collected from more than 70 countries. This site is a call to action to government policy makers, public-health officials, healthcare funders, as well as healthcare professionals and others who can make a difference and use the data to advocate for changes in policy.[90]

Visit the site at:
www.changingdiabetesbarometer.com

Driving public awareness and action

Novo Nordisk drives awareness campaigns at the global level and in all countries where we are present. These activities range from media engagement to the support of screening activities conducted together with local partners – usually the ministry of health and/or the local diabetes association. We actively support World Diabetes Day on 14 November, and in 2010 more than 2.6 million people were engaged in different Novo Nordisk-sponsored activities, including screening and educational programmes.

Changing Diabetes® Village Blue arch, New York

Supporting a new approach to healthcare

In 2010, we pledged to provide the World Diabetes Foundation with an additional DKK 25 million ($4,45 million USD) to be used for activities relating to the UN High-Level Meetings in 2011 and 2012. There have been 27 such meetings in the history of the UN, and HIV/AIDS is the only health topic to date. The UN High-Level Meeting on NCDs has the potential to mobilise action for a new type of collaboration that pursues a life-cycle approach to healthcare.

Driving awareness

In 2006, Novo Nordisk launched its Changing Diabetes® World Tour to create awareness about diabetes. After a three-year journey we expanded our scope to include diabetes screening, early detection and information. Through this programme, we have gained valuable insight into areas where screening and diagnosis often are not available and little is known about diabetes prevalence.

Changing Diabetes® Leadership Forums in Africa and the Middle East[91]

The Diabetes Leadership Forum Africa 2010, which was sponsored and co-organised by Novo Nordisk, took place in Johannesburg and focused on the social and economic challenges of the growing burden of diabetes in sub-Saharan Africa. The event was hosted by the Department of Health of the Republic of South Africa and the World Diabetes Foundation, and supported by the International Diabetes Federation.

The meeting was attended by more than 260 government representatives, international organisations, patient associations, non-governmental organisations, private-sector parties, academic institutions and healthcare professionals from 32 countries across sub-Saharan Africa and abroad. At the event, health ministers and senior ministerial representatives adopted a joint statement, which called for concrete actions to strengthen health systems and address non-communicable diseases, including diabetes, in sub-Saharan African countries.

In 2010, we also co-organised and sponsored a Forum in the Middle East and Northern Africa (MENA) region. At the event, more than 400 decision-makers from 22 countries in the region, including representatives of international and regional organisations, foundations, media, experts and leading members of the diabetes community, gathered to find solutions to the growing burden of diabetes on the region's people and healthcare systems. The main outcome of the forum was the adoption of the Dubai Declaration on Diabetes and NCDs in the MENA Region.

How we do business

Governance

Our response to the access-to-health dilemma is conducted within the frame of our general governance structure, under the responsibility of our executive management.

The basis for our corporate governance consists of the Novo Nordisk Way, and external regulation and codes, including compliance with applicable securities laws in Denmark and the US, and the Danish Recommendations on Corporate Governance.

The Novo Nordisk Way forms the foundation of our internal values-based framework. Our company is part of the Novo Group, a family of independent companies with a common history and shared values. The holding company of the Novo Group is Novo A/S, a Danish limited-liability company wholly owned by the Novo Nordisk Foundation, a commercial, profit-making foundation.

In today's interconnected economy the ability to manage the complexity of business and societal challenges helps ensure sustained growth. We believe that a healthy economy, environment and society are fundamental to long-term business success. This is why we build our business on the Triple Bottom Line principle, and make significant contributions to address global challenges such as the diabetes epidemic, climate change, natural resource constraints and imbalances of social development and economic prosperity.

Novo Nordisk has a formal governance function for access to health – the Health Policy Committee – to ensure accountability and determine the company's policy on access to health in developing countries. The committee reports to the chief operations officer and has representatives from senior line of business management in key regions and countries (i.e. Africa, Brazil, China, India and the Gulf) to ensure a consistent and integrated approach to increasing access in these countries.

Business ethics

A key part of our business is marketing pharmaceutical products to doctors, hospitals and governments. Maintaining and building trust is paramount to sustaining our licence to operate and innovate. This in turn requires that we operate ethically and with transparency in all aspects of our business, from conducting clinical trials to interacting with healthcare providers, patient organisations and other stakeholders.

Institutionalising ethical conduct requires more than codes and standards; it requires fostering a strong, values-based corporate culture. The Novo Nordisk Way outlines expectations for employee behaviour according to our corporate values, which include accountability. Adherence is monitored as part of our ongoing internal facilitation and investigation process. We have also implemented policies and procedures tailored to our operations and regulatory environment to provide guidance on standards of conduct for our employees, agents and contractors.

Our approach is based on global procedures, supported by regional/local procedures, as well as training, assurance reviews and investigations by internal auditors.

Novo Nordisk fully endorses the need for transparency in the field of public affairs, and supports the provision of clear information on who is engaging with policy makers and the interests they represent. Our public affairs work focuses on the tremendous un met need for better prevention, early detection, and better quality treatment in diabetes care.

Marketing practices

Novo Nordisk has a global procedure that ensures in-house legal counsel and regulatory-expert reviews, and approves marketing materials and activities. The review of promotional materials is documented in an electronic review system. The procedure, laying down the company's minimum requirements, also involves a second-tier review at the affiliate level to ensure compliance with local regulations in the market where materials will be used.

How we measure and evaluate

As we continue to develop our concrete responses to the global access to health challenge, we will define targets and indicators to measure our success, and we will report on our performance. Access to health is a key element in our Triple Bottom Line.

We will continue to evaluate our results, and refine our response and the way we carry it through. We regard this as an ongoing process of learning that is conducted in close dialogue with our local and global partners and stakeholders.

The Novo Nordisk Way

The Novo Nordisk Way forms the values-based governance framework for the company. From vision to policies, it describes how people at Novo Nordisk put values into action, and defines the principles for how the company does business. It sets direction for and applies to all employees in Novo Nordisk, and is about assuring and safeguarding the strong company culture of responsible and sustainable business practices and engaged employees and stakeholders.

Improving access to healthcare is entrenched in the Novo Nordisk Way in the following statement:

- Our key contribution is to discover and develop innovative biological medicines, and make them accessible to patients throughout the world.

Our Triple Bottom Line

We are committed to operating in a way that is financially, environmentally and socially responsible. Managing our business using the Triple Bottom Line principle helps us balance short-term profitability with longer-term societal interests. This approach is anchored in the company's by laws, the articles of association and the Novo Nordisk Way.

Applying the Triple Bottom Line principle in decision making serves two purposes. It builds trust and protects our licence to operate, and it helps drive innovation and long-term growth. This is how Triple Bottom Line management generates value.

Novo Nordisk employees from Princeton in the US form a "Unite for Diabetes" blue circle on World Diabetes Day

Summary of our ambitions

Throughout this document we have described our continuing priorities and how we approach each of them to provide an overview of how we aim to integrate access to diabetes care into the way we run our business.

Learning from our 20 years of working with the Triple Bottom Line as our business principle, we know that business integration requires a shared approach and concrete targets and indicators. The approach summarised here is our framework for action until 2015.

The framework will not define how we report publicly on our access to health activities. Through stakeholder engagement we will work to deliver targets and indicators for each focus area, and decide how we can best report on our performance externally. This is part of the continued process of refinement and integration we apply to our work.

Ambition 1: Develop quality diabetes treatment for all

Area of focus	Approach
Make treatment available to people with diabetes globally	Ensure continued supply of human insulin to low- and middle-income countries for at least another 10 years
	Support research to document consequences and implications of diabetes
	Share discoveries and knowledge that could have application in infectious-disease areas
Address distribution challenges at the base of pyramid (BOP)	Explore business models for people living with diabetes in the BOP segment
Facilitate technology transfer in the countries where we operate	Work with public and private institutions in low- and middle-income countries countries to enhance healthcare provision to the benefit of all patients

Ambition 2: Work with partners to make diabetes care more accessible for those in need

Area of focus	Approach
Strengthen health systems as a long-term investment	Contribute to the training of healthcare professionals
Improve accessibility to insulin in remote areas	Reach out to people with diabetes in remote areas
Improve access to diabetes care for women and children	Establish partnerships for the improved delivery of care to children with diabetes in low- and middle-income countries
	Establish partnership-based interventions as part of a long-term commitment to the improvement of health of women and the next generation

Ambition 3: Work to improve affordability of treatment for patients, particularly in resource-poor settings

Area of focus	Approach
Improve funding for diabetes healthcare	Continue our annual endowment to the World Diabetes Foundation
Improve affordability of insulin	Continue our differential pricing policy and provide insulin to the governments in least developed countries at maximum 20 US cents per patient per day
	Work in partnership with governments and other organisations to increase the number of patients we reach in low- and middle-income countries

Ambition 4: Quality assurance in diabetes treatment for patients wherever they live

Area of focus	Approach
Conduct responsible and ethical clinical trials	Support and ensure full transparency of clinical-trial activities and results
	Ensure that all persons enrolled in Novo Nordisk-sponsored research are protected by the same rights, high ethical standards and regulations, regardless of geography
Work for safe medicines for patients	Maintain one global quality standard
	Work against counterfeiting
	Work with ministries of health and distributors to establish effective supply chains for delivery of insulin
Empower people with diabetes to achieve better health and quality of life	Continue research into the understanding of patient needs, including the psychosocial barriers against adhering to treatment regimens
	Continue engaging with stakeholders, with a view to identifying areas for improvement in the management of diabetes
	Support healthcare professionals to deliver better quality healthcare, building on principles of patient involvement and ongoing support

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Ali Basem Arqoub from Jordan has type 1 diabetes

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