

Risk management

Novo Nordisk has developed a dynamic approach to risk management to ensure that key risks are proactively identified, assessed and managed. Maintaining and monitoring a systematic integrated process to continually assess business risks is the responsibility of Executive Management. The Risk Management Board, with representatives of Senior Management from all parts of the business and chaired by the chief financial officer, sets the strategic direction for the risk management process and challenges the overall risk and control profile for Novo Nordisk.

Our policy for risk management is to proactively manage risk to ensure continued growth of our business and to protect our people, assets and reputation. This means that we:

- utilise an effective and integrated risk management system while maintaining business flexibility
- identify and assess material risks associated with our business
- monitor, manage and mitigate risks.

Our risk willingness is not one specific figure or formula, but varies depending upon the specific category of risk. The main characteristics of Novo Nordisk's risk willingness are:

- We innovate to help patients and to defeat diabetes by finding better methods of diabetes prevention, detection and treatment. We will offer products and services in other areas where we can make a difference. We accept the commensurate high level of risk involved in bringing new treatments or innovative products to market that meet the needs of patients.
- Because the safety of patients is paramount, vigorous efforts are made to reduce product safety risks to the lowest level possible.
- A conservative approach is taken to the management of financial risks.
- We strive to reduce supply chain risks through proactive business continuity planning, regular inspections and back-up facilities.
- We have a zero tolerance approach to unethical business conduct.

Risk management process

All major business areas are required to report their most significant financial and non-financial risks quarterly, along with plans or processes to manage these risks. The Risk Office, acting as the secretariat for the Risk Management Board, challenges business areas about reported risks. Reported risks are then consolidated into a ranking and assessment of the company's key risks. This information is presented to the Risk Management Board and then to Executive Management, the Audit Committee and the Board of Directors.

All assessments of risk take into account the likelihood of an event and its potential impact on the business. Impacts are quantified and assessed in terms of potential financial loss and reputational damage. Risks are assessed both as gross risk and

net risk. The assessment of gross risk assumes that no mitigating actions have been implemented, whereas net risk assessment takes into account mitigating actions already implemented and their anticipated effect. Enterprise risk management increases our ability to assess and understand risks separately and in relation to each other from a global perspective but with local control.

More information on our risk management process is available at annualreport2010.novonordisk.com.

The risks that we deem of greatest importance to our business are categorised and described below. They are not, however, ranked. Many of these issues are also discussed elsewhere in the report.

Market risks

Price pressures

As healthcare costs have risen, outstripping the pace of economic growth, there is increasing economic, political and regulatory pressure to contain pharmaceutical prices. The impact of the global economic recession has further exacerbated this trend.

In the US, healthcare reform legislation passed in 2010 is likely to impact Novo Nordisk's business. However, uncertainties regarding the implementation of specific aspects of the legislation remain. In Europe, the impact of the global economic recession coupled with budget deficits in many countries is increasing the pressure on governments to control healthcare spending even more tightly. As a result, we are operating in an increasingly challenging environment with significant price pressure.

It is increasingly imperative to document treatment benefits to ensure that innovation is properly valued. Novo Nordisk has therefore increased the number of clinical and health-economic studies to substantiate the benefits of our products for patients and society, particularly for improved diabetes treatment. For more information on how Novo Nordisk is addressing pricing challenges, see p 5.

Biosimilar competition

The market for therapeutic proteins is becoming more attractive to biosimilar producers as regulatory rules in Europe and the US are changing to allow producers to introduce biosimilar products when patents for branded products expire. This development is exacerbated by increasing pressures on governments to contain healthcare costs.

Novo Nordisk anticipates that the expiration of certain patents could impact sales within the next five years. However, with the continuing transition from human to modern insulins, an increasing proportion of Novo Nordisk's diabetes care sales in major markets are protected by patents.

Traditionally, earlier generations of insulin products have been off patent for years so this is a risk with which Novo Nordisk is familiar and has considerable experience addressing. Biosimilar products have been present on the European market for several decades but have had only a marginal impact. In countries such as India and China, where the company has long had biosimilar competition, Novo Nordisk has maintained an insulin volume market share of approximately 60%.

Research and development risks

Bringing new products to market

Continued growth in our business depends on the company's ability to develop and offer better treatments to patients. During each stage of the development process, which includes extensive non-clinical tests and clinical trials as well as an elaborate regulatory approval process, we may encounter serious obstacles which may delay our product initiatives and add substantial expense, or which could cause us to abandon a product initiative altogether. Delays in bringing new products such as Degludec and DegludecPlus to market would impact our ability to reach long-term financial targets.

In our experience, there is less than a 35% chance for a product candidate in phase 1 in the pipeline ultimately being approved for marketing, while the chance of success is around 40% for Phase 2 product candidates and rises to around 70% for Phase 3 but there remains significant uncertainty regarding the timing and success of the regulatory approval process. The reasons for delays or failure include, for instance: failure of the product candidate in non-clinical studies due to safety concerns; problems in completing formulation and other testing and work necessary to support a regulatory approval process; adverse reactions to the product candidate or indications of other safety concerns; failure in clinical trial data to support the safety or efficacy of the product candidate; inability to manufacture, in a timely and cost-efficient manner, sufficient quantities of the product candidate for development or commercialisation activities; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

Due to the risks and uncertainties involved in progressing through non-clinical development and clinical trials, and the time and cost involved in obtaining regulatory approvals, we cannot reasonably estimate the nature, timing, completion dates and costs of the efforts necessary to complete the development.

Production and quality risks

Supply disruptions

Failure or breakdown in any of the company's vital production facilities could adversely affect the results of operations, as well as possibly causing employee injuries or infrastructure damage. Fire-prevention design, alarms and fire instructions, annual inspections, back-up facilities and safety inventories are aimed at mitigating this risk. To spread this risk geographically and optimise costs and supply logistics, we have expanded production capacity beyond the company's European base to the US, Brazil and China. See the map of our production facilities on pp 26–27.

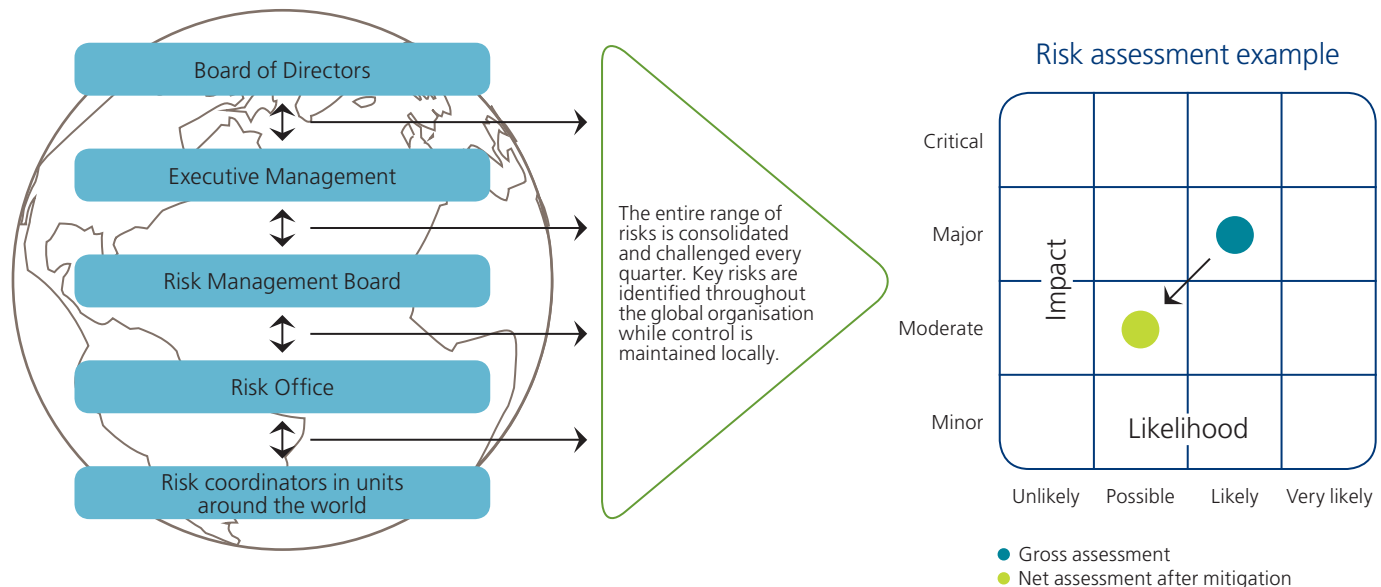
Continued growth depends on our ability to develop and offer better treatments to patients.

Risk of product recalls

Product safety is directly linked to patient well-being, so safety and product quality are paramount concerns from both financial and reputational perspectives. While the gross risk is very high, with product safety having the potential to adversely affect operations, we believe that our vigorous efforts to manage and mitigate this risk effectively reduce the company's net risk profile. We have a global corporate quality system in place, including quality audits, quality improvement plans and systematic Senior Management reviews.

For information on Novo Nordisk's product recalls during 2010, see p 10.

Managing risks throughout our business



Financial risks

Exchange rates

As a global business, fluctuations in currency exchange rates impact the reported performance. Novo Nordisk's reporting currency and the functional currency of corporate operations is the Danish krone, which is closely linked to the euro in a narrow range. However, the company has substantial exposure to other currencies, including the US dollar, Japanese yen, Chinese yuan and British pound. For information on how the company manages these risks, see note 27 in the financial statements on pp 80–81.

Tax disputes

During the ongoing course of business, tax disputes may arise in relation to different jurisdictions.

Ethical risks

Marketing practices

In a competitive environment with increasing public scrutiny and regulation, marketing practices can be the source of legal action or reputational risk. Our reputation as a trusted healthcare partner is integral to effectively maintaining and growing our business. At the same time, the regulatory context for marketing activity is constantly changing. A business ethics policy and global business ethics procedures, paired with close monitoring of performance and reporting requirements, all aim to mitigate these risks. Significant resources are also dedicated to training marketing and sales people around the world. Significant legal issues relating to marketing practices are included in note 31 on pp 87–88.

Legal risks

Intellectual property

Patent rights are a very important tool for promoting innovation, leading to new and better products and processes, and stimulating long-term economic growth and job creation. Governments may not recognise the validity of patents or may be unable or unwilling to uphold intellectual property rights.

We will enforce our patent rights in cases of infringement when this is deemed advisable by Executive Management after careful analysis of the commercial and legal aspects of enforcement. Similar analysis is applied to decisions to defend Novo Nordisk's patent rights against other legal challenges. Significant legal issues related to intellectual property are included in note 31 on pp 87–88.

Other legal risks

Novo Nordisk operates in a complex global legal and regulatory environment with diverse national, regional and international legislation. Legal issues may arise relating to product liability claims, company practices and government investigations.

In May 2009, Novo Nordisk entered into a Deferred Prosecution Agreement (DPA) for a three-year period with the US Department of Justice relating to certain actions undertaken by Novo Nordisk under the Oil For Food Programme for Iraq. We must comply with the terms of the DPA in order for the case to be dismissed. Novo Nordisk has subsequently enacted a detailed programme to ensure compliance with the DPA, including a reinforced governance structure, enhanced third-party due diligence systems and periodic testing of systems, policies and procedures.

Further information on significant legal issues related to product liability claims, business practices and government investigations is included in note 31 on pp 87–88.