

# Managing risks

Exploiting business opportunities relies on effective management and mitigation of risks. With a formalised governance structure on risk management and disclosure in place, Novo Nordisk is better positioned to respond promptly to events that may have a significant negative impact on the company’s ability to meet its objectives, both short term and long term.

There’s a fine balance between taking calculated, entrepreneurial risks and being overly cautious. This is particularly true for companies in the pharmaceutical industry, where the pipeline from hypothesis to successful market penetration typically runs over more than a 10-year period. To Novo Nordisk, risk management is about identifying and reducing risk to an acceptable level. Novo Nordisk defines risk as ‘any event that could have a significant negative impact upon our ability to meet our objectives’. Not just in terms of pursuing the Vision and meeting long-term financial targets, but also to protect employees and reputation. Hence, risk management considers both financial and non-financial risks, and reports on key risks through one integrated and systematic approach.

### Risk alert

In the wake of Enron, companies were alerted to improving not only their disclosure of business risks, but also internal control procedures. Novo Nordisk generally complies with current national and international codes of good corporate governance and also works to improve internal processes to identify risks, monitor trends and respond to emerging issues. However, in 2002 the Board of Directors and Executive Management took the opportunity to proactively address the emerging requirements on managing and reporting on risks. Against that background, the company established a process to standardise and optimise the company’s risk management system.

### Risk reporting

Today, a common, systematic risk reporting approach is in place which

identifies and assesses material risks associated with Novo Nordisk’s business. In quarterly reports to Executive Management and the Board of Directors, long-term and short-term risks are assessed and quantified in terms of reputational damage and financial impact. For each risk factor the potential impact is detailed, as are mitigating actions. This is being aligned with long-existing management processes such as the annual strategic planning, balanced scorecards and budgeting.

A Financial Corporate Governance and Risk Office has been established to handle implementation of the Sarbanes–Oxley requirements in Novo Nordisk and improve risk management. Reporting to the CFO and with links to the legal Corporate Governance function and Group Internal Audit, this office drives and consolidates risk reporting from each of the five business areas: discovery and development; manufacturing, sales and marketing; quality, regulatory and business development; finance, legal and IT; and people, reputation and relations. This is done in a process of consultation with internal risk stakeholders to ensure monitoring, measuring and reporting of risks, as well as implementation of mitigating actions. Moreover, a thorough risk assessment is included in all major projects.

### Risk Management Group

Executive Management has established a dedicated Risk Management Group of senior executives, representing all key business areas, and reporting to Executive Management and the Board of Directors. It sets the strategic direction and challenges, and analyses the risk and control information generated by the individual business areas. This challenger function helps eliminate blind spots and that potential cross-functional impacts are considered.

### Current risk profile

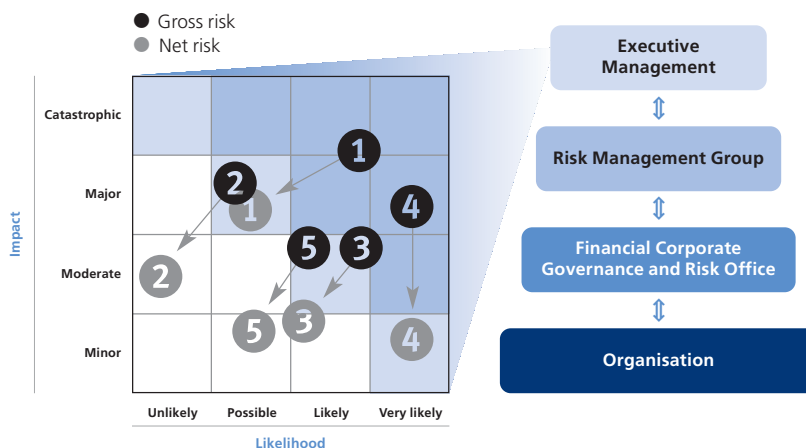
Key risks are mapped throughout the value chain of primary activities: from discovery and development, through manufacturing and logistics, and to marketing and sales. In addition, risks related to

## Risk management process

Examples of risk areas:

- ❶ Development of new drugs: strategic candidates in pipeline
- ❷ Manufacturing and quality: insufficient capacity
- ❸ Competition: new and stronger competitors
- ❹ Financial risks: foreign exchange rates
- ❺ Business ethics: reputational damage

Novo Nordisk’s risk reporting matrix is updated on a quarterly basis. Two factors are considered: what is the likelihood of a negative event occurring, and what is the calculated impact on the business. Impacts are quantified and assessed in terms of potential financial loss and reputational damage.



support activities such as quality, regulatory and business development, finance, legal, IT and human resources are included. Below are examples of current key risks.

### Development of new drugs

Delays in the development of new drugs or failure to obtain approval from regulatory authorities could have a significant negative impact on Novo Nordisk's ability to maintain its position as a market leader in diabetes care and to reach its long-term financial targets. On the other hand, drug development requires taking calculated risks; statistically the industry must carry a 45% risk that drugs tested as far as into phase 3 studies will never reach the market.

An example of a current risk in this area is Novo Nordisk's investments in the development of the new pulmonary delivery system AERx®. To mitigate this risk, Novo Nordisk has expanded its licensing rights to AERx® iDMS inhaled insulin programme from Aradigm, and obtained full development and manufacturing rights. Under the agreement, Novo Nordisk has assumed all further responsibilities for AERx® iDMS development and funding.

### Manufacturing and quality

The major part of Novo Nordisk's manufacturing capacity is concentrated at a few sites in Denmark. While this entails a relatively low risk in terms of access to a skilled people base, natural disasters and political instability, the geographical concentration in itself poses a potential risk. Contingency planning includes preventive measures against major exposures, for example alternative stock facilities. In 2004 Novo Nordisk announced new investment projects in production facilities outside Denmark – in the US and China. This will not only reduce exposure in terms of production capacity, but will also facilitate better access to strategic markets and reduced currency risk exposure.

Based on the samples taken during internal quality audits and inspections by health authorities in 2004, Novo Nordisk's production is found to be in general compliance with international standards for good manufacturing practice (cGMP). In 2004 Novo Nordisk received four inspections by the FDA; only one of these resulted in written observations. Regulatory approval of production sites as well as of products for the market is a precondition for the company's long-term ability to supply medicines to the market. A global strategy to obtain and maintain market authorisation will mitigate risks in this area, for example in relation to approvals for Levemir® and future indications of NovoSeven®.

### Competition

The diabetes market is highly competitive and increasingly so. On the one hand, Novo Nordisk is facing increased competition with strong entrants to the market, while on the other hand the company is gaining market shares in the attractive US market. In addition, there is government-mandated pressure on prices, particularly in Europe. Here, current healthcare reforms are putting pressure on the industry's ability to produce pharmacoeconomic assessments.

### Security, litigation and financial risks

Non-compliance with international and local legislation is also a risk factor. One example is the ongoing dispute with Polish customs authorities, who have claimed that pharmaceutical companies that have

imported products to Poland in the period 1999–2001 have misstated customs values. This dispute concerns a number of pharmaceutical importers, including Novo Nordisk. Another example would be the tax risk related to fixing and approval of transfer pricing.

Novo Nordisk is involved in some legal proceedings, and risks related to these are closely monitored. One such example is claims on alleged product liability on HRT. Novo Nordisk Inc., together with the majority of hormone therapy product manufacturers, is a defendant in 16 product liability lawsuits. Since the initiation of the lawsuits in July 2004, three cases against Novo Nordisk Inc. have been dismissed by the courts (see page 92).

Foreign exchange risk is the principal financial risk factor for Novo Nordisk, as a major part of costs are being paid in euro and significant income in non-euro currencies, primarily US dollars and Japanese yen. To mitigate this exposure, financial hedging instruments are used (see Note 36 on page 90 and management report on page 41). In addition, the company's global expansion strategy entails carrying a higher share of production costs in foreign currencies.

### Business ethics and people

In a highly competitive business environment, protecting employees and reputation is vital. Novo Nordisk relies on its ability to attract and retain talented individuals, and this is known to be a function of the company's external reputation and stakeholder trust.

In 2004, Novo Nordisk's ethics were challenged on a number of occasions (see page 18). However, none of these constitute major financial or reputational issues. The introduction of a business ethics policy and guidelines for employees will serve as mitigation of such risks. There have been no incidents of problematic relationships with key non-financial stakeholder groups that posed any significant risk to the company. ✱

## Quantitative and qualitative measures

The assessment of risks to financial stakeholders involves in-depth financial analysis of earnings, cash flows, balance sheets and off balance sheet risk exposures. Much of this analysis is quantitative in nature. At the same time a more qualitative analysis is often conducted, which focuses on other aspects of company performance, including country influences, industry factors, competitive dynamics, and company management and policy – all with regard to their impact on the quality and sustainability of a company's operating and financial performance.

Novo Nordisk's qualitative risk analysis aims to maximise shareholder value and enhance the quality of the company's transparency and disclosure. However, the company acknowledges that despite systematic risk identification, reporting, monitoring and mitigation, unforeseen adverse events can still occur. See page 47.