

## **Novo Nordisk response to the preliminary report on the pharmaceutical sector inquiry**

1. Novo Nordisk makes the following submission in the framework of the public consultation on the preliminary findings of the EU pharmaceutical sector inquiry initiated on 15 January 2008 (the 'Sector Inquiry') under the EC competition rules (Articles 81 and 82 of the EC Treaty).
2. This submission complements the one submitted by the European Federation of Pharmaceutical Industries and Associations (EFPIA) in January 2009. Novo Nordisk fully endorses EFPIA's submission.

### **3. Executive summary**

- 3.1 Novo Nordisk requests the European Commission to clarify whether biosimilars are in the scope of the Sector Inquiry, as well as to clearly differentiate generics and biosimilars.
- 3.2 Novo Nordisk urges the European Commission to broaden the scope of the Sector Inquiry to address areas such as generic to generic competition, state controls, and regulatory requirements, in order to assess whether these factors are affecting innovation and generic entry.
- 3.3 Novo Nordisk would like to stress that it is legitimate and pro-competitive for pharmaceutical companies to protect innovation taking all the steps as listed in the Commission's so-called toolbox.
- 3.4 Novo Nordisk stresses the need for a fair reward for innovation, including incremental innovation, in order to support innovation in the EU pharmaceutical sector.
- 3.5 Novo Nordisk urges the Commission and Member States to ensure strong intellectual property protection, which stimulates R&D and thereby ensuring that many new life-improving and life-saving medicines come onto the market.
- 3.6 Novo Nordisk supports international efforts to harmonise the patent system in order to create clear and operational patenting criteria, and to ensure fair and effective administration thereof.

#### **4. Facts & figures about Novo Nordisk**

- 4.1 Novo Nordisk is a healthcare company and a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets life-improving and life-saving pharmaceutical products and services that make a significant difference to patients, the medical profession and society.
- 4.2 With headquarters in Denmark, Novo Nordisk employs approximately 27,000 employees in 80 countries, markets its products in 179 countries and its R&D and production facilities span five continents. 13,050 employees are based in Denmark and 14,018 abroad. Of the 27,068, 4,619 work in R&D, 8,182 in production, 9,064 in sales and distribution and 5,203 in administration.
- 4.3 Novo Nordisk's B shares are listed on the stock exchanges in Copenhagen and London. Its ADRs are listed on the New York Stock Exchange.

#### **5. Introduction**

- 5.1 Novo Nordisk welcomes the opportunity to comment on the preliminary findings of the Sector Inquiry. The company hopes that this consultation process will shed light on the European Commission's assumptions that innovation is in decline and that generics' market entry may be delayed.
- 5.2 Novo Nordisk is committed to ensuring that there is clear and open dialogue on all the issues of concern to the European Commission, as well as with other relevant stakeholders. Since the start of the Sector Inquiry, Novo Nordisk has fully cooperated with the European Commission services and has answered all questionnaires from DG Competition in due time.
- 5.3 Novo Nordisk agrees with the European Commission's vision that the pharmaceutical sector is vital to the health and wellbeing of Europe's citizens.
- 5.4 Novo Nordisk supports a competitive generics market and calls for the resultant savings to national healthcare budgets to be reinvested to further stimulate and reward innovation, thus ensuring that new life-improving and life-saving medicines come onto the market.

- 5.5 Novo Nordisk regrets that the report focuses solely on patents and that the Commission seems to ignore that patents incentivise innovation. In addition, the report has omitted the economic rationale behind the patenting system.

## **6. Differentiation between generics and biosimilars**

- 6.1 The European Commission states in its preliminary report that biosimilars are not the main focus of the Sector Inquiry. Regardless of this, the definition of “generics” (generic medicinal products) tends to include biosimilars (biosimilar medicinal products). Novo Nordisk requests the European Commission to clarify whether biosimilars are in the scope of the Sector Inquiry or not, as well as to clearly differentiate generics and biosimilars, and to adjust the definitions accordingly.
- 6.2 There are important differences between biosimilars - which include active, large and complex biological ingredients - and generics - which include active, small and simple chemical ingredients. Whereas generics have identical biological activity as they reference medicinal product, biosimilars have similar but not necessary identical biological activity as their reference medicinal product.
- 6.3 Due to the complexity of biological products and the impact of even minor changes to the manufacturing process can have on the human safety and efficacy, the generic approach is not scientifically appropriate for biosimilars to ensure that safe and effective medicines are delivered to patients. As a consequence, appropriately designed pre-clinical and clinical studies are needed to prove that a biosimilar product has the same clinical properties (efficacy and safety) as the original product.
- 6.4 The approval of biosimilars is regulated through Directive 2004/27/EC of 31 March 2004, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
- 6.5 Once the patents and data exclusivity of the original products expire, selected biosimilar medicines can be launched on the European market after appropriate testing to confirm their quality, safety and efficacy.
- 6.6 The EU legal provisions are supplemented by guidance documents of the European Medicines Agency. The Agency has adopted a case-by-case approach to the market authorisation of biosimilar products regarding size of pre-clinical and clinical data required for approval of each applied indication. As biosimilars are similar, but not identical to their respective reference medicinal product, the decision to treat a patient with a reference or a biosimilar medicine should only be taken following the opinion of a qualified healthcare professional.

## **7. Missing elements in the report**

- 7.1 Novo Nordisk urges the European Commission to broaden the scope of the Sector Inquiry so that the final report addresses the following areas in order to assess whether these factors are affecting innovation and generic entry:
- Generic to generic competition (i.e. why is the price differences between originator and generic drugs bigger in the US than in the EU)
  - National pricing and reimbursement approvals and controls
  - Regulatory requirements
  - Commercial requirements
- 7.2 Novo Nordisk urges the European Commission and Member States to improve the transparency and predictability of healthcare buyers' procedures, as they undermine investment decisions and shareholders' confidence.
- 7.3 Novo Nordisk calls upon the European Commission and Member States to guarantee transparent, objective, fair, swift and predictable pricing and reimbursement processes (including health technology assessments or similar methodologies) that are as close to a free market as possible, in line with the overall goals of the EU.

## **8. The alleged decline in innovation**

- 8.1 The European Commission's preliminary report finds that there has been a decline in innovation measured by the number of novel medicines. However, Novo Nordisk suggests that this could be due to a number of factors such as: industry retooling, increased regulatory requirements and State controls.
- 8.2 Novo Nordisk's commitment to innovation has never been stronger. R&D expenditure and the number of products in clinical trials are steadily increasing. Novo Nordisk's primary R&D objective is to develop new medications that help save people's lives or improve their quality of life. In terms of R&D investments, Novo Nordisk is the largest Danish company and ranks as number 30 on a European scale (in 2006 numbers), up from number 33. The increase in the share of R&D spending relative to sales revenue (from 16.3% in 2006 to 17.2% in 2007) reflects the fact that R&D expenditure has risen by 14% while sales have risen by 8%. Finally, the number of distinct molecules in clinical trials has increased from 11 in 2006 to 15 in 2007.

## 9. Alleged delayed generic entry

- 9.1 Novo Nordisk regrets that the European Commission's preliminary report has not taken into account the findings of the CRA International report 'Factors Affecting Generic Entry in Europe', which was part of the EFPIA submission of June 2008. This report sets out in detail many factors relevant to generic entry.
- 9.2 Novo Nordisk believes that the average time of generic entry identified in the preliminary report (a weighted average of seven months, and under four months for highest value medicines) is extremely fast, and that the data collected by the European Commission shows that entry time is becoming swifter.
- 9.3 Novo Nordisk would like to emphasize that the so-called "defensive" patent strategies and patent portfolios are essential to innovation and investment in the pharmaceutical industry as in any high technology sector. Calling into question the legality of these practices would have a negative effect on innovation, investment and employment in this sector. Such practices are fully legitimate and pro-competitive. They are an essential part of competition.
- 9.4 Novo Nordisk would like to stress that, according to existing ECJ and national courts' case law, it is legitimate and pro-competitive for pharmaceutical companies to protect innovation taking all the steps as listed in the Commission's so-called toolbox (patent portfolios, litigation, settlements, regulation, next generation technologies, and marketing). Patent litigation is essential for intellectual property protection and the right to litigation is a fundamental right deeply enshrined in the constitutional systems of all Member States. In addition, Community courts have never found an infringement of the competition rules based on a claim of vexatious litigation. Without strong intellectual property protection, no pharmaceutical company would make the considerable upfront investments that are necessary to bring new life-improving and life-saving medicines onto the market.
- 9.5 There are many ways for companies (both generics and originators) to "clear the way" before launching their products, e.g. by opposition procedures and non-infringement declaration. By choosing not to utilize these means such companies are naturally exposing themselves to litigation, which is the only means left to protect intellectual property rights. Novo Nordisk therefore calls upon the European Commission not to undermine the existing measures to protect innovation.
- 9.6 Novo Nordisk would like to remind the European Commission that the recourse to settlement agreements is a fully legitimate and pro-competitive practice, and often facilitates market entry. Such

settlement agreements remove uncertainties and allow companies to invest in conditions of business certainty. Restrictions in settlement agreements that go no further than the exclusionary effect of a patent do not restrict competition.

- 9.7 Patents have as their function to exclude others from copying their protected inventions. However, once the patent protection expires others are free to copy. No later patent can extend the term of an earlier patent.

## **10. Incentives – Rewarding innovation**

- 10.1 Innovative pharmaceutical companies must not only cover costs but also make a competitive return on the investment, by vigorously protecting their intellectual property and their development pipeline. In addition, the hugely risky nature of this business is simply not recognised by appropriate rewards from its customers.

- 10.2 Novo Nordisk therefore stresses the need for a fair reward for innovation, including incremental innovation, in order to support innovation in the EU pharmaceutical sector.

- 10.3 Novo Nordisk would like to address one possible reason explaining why fewer entities are being submitted for approval. As the European Commission has stated, cost of development, clinical trials including safety requirements and manufacturing, constitute major cost components for medicines, whatever the technology used to make them. However, under the current framework, a company that carries out the entire development for a completely new indication for a medicine that is already in the market for another indication, would be rewarded with no more than one year's additional data exclusivity. Novo Nordisk believes that this is clearly not sufficient for a company to undertake huge upfront investments in an entire new indication. Novo Nordisk therefore calls upon a more appropriate framework for the reward of such innovation efforts and the risks undertaken would thus be encouraged.

## **11. Strong intellectual property protection**

- 11.1 The patent system is a long-established and accepted means for stimulating R&D, ensuring that many new life-improving and life-saving medicines come onto the market. Novo Nordisk therefore urges the Commission and Member States to guarantee strong intellectual property protection.

- 11.2 The process of bringing new medicines to the market is long, complicated, and very expensive. On average it takes between 10 and 12 years to develop a new drug. The costs can amount up to one billion Euros, and it is essential to be able to not only recoup these

investments but also make a competitive return. Being a research-based pharmaceutical company that aspires to make a difference to the benefit of public health, patent protection is of vital importance to Novo Nordisk.

11.3 Novo Nordisk supports the United Nations Universal Declaration of Human Rights, according to which "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" (Article 27(2) of UN's Human Rights Declaration).

11.4 Novo Nordisk supports international efforts to harmonise the patent system in order to create clear and operational patenting criteria, and to ensure fair and effective administration thereof. In this sense, Novo Nordisk supports the creation of a European patent system where English is accepted as the single language and the establishment of a specialist Patent Court of First Instance and Appeal to decide issues relating to infringement and validity in a single action on pan-EU basis. Such a Court must be capable of producing high quality, cost-effective and timely judgements.