# The pharmaceutical industry - Summary of sector profile

## Products and business description

This sector profile covers pharmaceutical end products only. These can be divided into three categories:

- **Prescription drugs**, based on chemical compounds and prescribed or administered by healthcare professionals
- **Over the counter (OTC) drugs**, based on chemical compounds and freely sold
- **Vaccines**, based on bacteria and viruses

The distinction between branded and generic products is also important. A branded product is the original version, produced by the innovative company that developed the product. A generic product is a copy of the original by another company. Many innovative companies have divisions that produce generics as well.

R&D for new drugs requires high investments. After the discovery of new chemical compounds with a therapeutic effect, a patent is filed. This protects the potential new drug against generic competition, usually for 20 years. The drug then still has to be tested in several phases of clinical trials. The total development process costs several hundred million dollars and takes over 10 years. If the new drug is finally proven safe and effective, it is approved by a regulatory authority. As long as a branded product is protected by a patent, companies charge high prices to recover R&D investments and make high profits. After patent expiry, competition from cheap generics usually causes a large drop in prices.

R&D investments for vaccines are comparable to those for drugs. However, the production process of vaccines is more complicated and their delivery requires an advanced infrastructure ('cold chain'). Furthermore, the new vaccines currently used in high income countries are of a different type than those recommended for poor countries. They are much more expensive, but are preferred due to the lower risk of adverse reactions.

The largest pharmaceutical markets are the US, Europe and Japan. Together, these account for 84% of the $460 billion of global drug and vaccine sales in 2003. Cardiovascular and central nervous system (CNS) medicines are the largest selling therapeutic classes.

## Companies and business strategies

Over the last years, there have been many large mergers and acquisitions in the sector, while many companies have divested non-core activities. Although R&D investment has strongly increased over the past decade, many large companies do not have promising R&D pipelines and increasingly pursue growth through enhanced marketing. Outsourcing of production and alliances for R&D, distribution or marketing are common business strategies.

**Key figures for 2003 of largest companies, ranked by market value (in $ billion)**

| Company (country) | Market value[1] | Sales | Net profit |
|---|---|---|---|
| Pfizer (US) | 262 | 45.2 | 3.9 |
| Johnson & Johnson (US) | 149 | 41.9 | 7.2 |
| Novartis (Switz.) | 116 | 24.9 | 5.0 |
| GlaxoSmithKline (UK) | 116 | 35.2 | 7.8 |
| Merck & Co (US) | 97 | 22.5 | 6.6 |
| Roche (Switz.) | 90 | 25.5 | 2.5 |
| AstraZeneca (UK) | 77 | 18.8 | 3.0 |
| Amgen (US) | 76 | 8.4 | 2.2 |
| Eli Lilly (US) | 74 | 12.6 | 2.6 |
| Aventis (France)[2] | 60 | 17.8 | 1.9 |

## Corporate Social Responsibility (CSR)

CSR refers to the responsibility of a company for the social, ecological and economic impacts of its operations. Some sector-

[1] (Number of shares) x (share price at 25-03-04)
[2] Aventis merged with Sanofi-Synthélabo in 2004.

specific critical CSR issues are outlined below.

- **Clinical trials**. This includes adequate protection of volunteers, also in poor countries, and disclosure of test results.
- **Drug safety**. This is heavily regulated and official manufacturing standards apply.
- **Drug promotion**. Drugs are sometimes promoted in irresponsible ways, e.g. misrepresenting drug safety. Related to this, some companies have bribed doctors to prescribe more of their products.
- **Tax payments**. Several companies have recently been charged with underpaying more than $1 billion of taxes.
- **Workplace health, safety and environment**. These are very important because of the processing of chemical compounds.

**Access to medicines for poor people** is also highly important. **Intellectual property rights**, which protect a drug against generic competition, can be an obstacle to access to medicines. The agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) of the World Trade Organizations (WTO) forms an international framework for these rights. It specifies minimum standards for intellectual property protection in national legislation, but allows exemptions to ensure access to medicines in the case of a public health crisis. The Pharmaceutical Research and Manufacturers of America (PhRMA), an industry organization to which all major pharmaceutical companies are affiliated, has been pressing governments to offer stronger intellectual property protection than is currently required by the TRIPS agreement. This is against the interests of poor people.

Access to medicines can be enhanced by setting **preferential prices**, far below the retail prices in the US or EU, for supplies to poor countries. In some cases companies set a single reduced price, often at cost, for a group of countries. However, in other cases deals that were unfavourable for poor countries have been negotiated with individual governments.

**R&D for drugs and vaccines of special importance to poor countries** is also a central issue. Because of the poor target populations, the returns on such research are relatively low. As a consequence, only 10% of R&D investment goes to developing countries' diseases and some companies continue to neglect this area.

## Global Public-Private Initiatives (GPPIs)

GPPIs bring together different partners to address health problems in poor countries. They serve to bring together complementary expertise and to bring in additional funding. Different types of GPPIs include partnerships to increase R&D for a specific disease, to deliver drugs at low prices or for free, to strengthen local healthcare systems and to coordinate the efforts of various partners. Depending on the approach, some GPPIs are closely related to the core business of a company (e.g. R&D) while others are mere charity (e.g. donations).

There are a number of concerns about GPPIs and the role of pharmaceutical companies in them. Regarding the governance of GPPIs, transparency can be low, there may be conflicts of interests and recipient countries have sometimes little influence. Furthermore, GPPIs sometimes operate parallel to existing health systems, do not address underlying poverty-related causes of health problems, fail to reach the poorest people or may be unsustainable. Some companies use contributions to GPPIs to create a positive public image, while they do not pay attention to access to medicines or behave responsibly in day-to-day operations. They may be lobbying for stronger patent protection against public health interests, or the high profits enabling donation programmes can be partly based on excessive drug pricing or tax evasion.

**This sector profile was written by SOMO (Centre for Research on Multinational Corporations). The full report is available at http://www.somo.nl.**