

# **THE PHARMACEUTICAL INDUSTRY IN FIGURES**

**2008 Edition**

**EFPIA (The European Federation of Pharmaceutical Industries and Associations) represents the research-based pharmaceutical industry operating in Europe.**

Founded in 1978, its members comprise **32** national pharmaceutical industry associations and **43** leading pharmaceutical companies involved in the research, development and manufacturing of medicinal products in Europe for human use.

Its mission is to promote pharmaceutical research and development and the best conditions in Europe for companies to bring to market medicines that improve human health and the quality of life around the world.

Through its membership, EFPIA represents the common views of 2,200 large, medium and small companies including the entire European research-based pharmaceutical sector whose interests also include an important part of the generics segment. Two specialised groups have been created within EFPIA to address specific issues relating to vaccines (EVM – European Vaccine Manufacturers) and the needs of biopharmaceutical companies (EBE - European Biopharmaceutical Enterprises).

Further details about the Federation and its activities can be obtained from:

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## **SUMMARY**

Europe has a great deal to gain in health and economic terms from a strong and competitive indigenous research-based pharmaceutical sector. The research-based pharmaceutical industry is one of the remaining leading high technology industries in Europe, amounting to about 19% of global business R&D investments and about 3.5% of the total EU manufacturing value added.

Since the early 1990s, the research-based pharmaceutical industry in Europe has been losing competitiveness with respect to its main competitors, in particular the US. Data for 2006 and preliminary figures for 2007 confirm the vulnerability of Europe's research-based pharmaceutical industry. Benchmarking and performance indicators show Europe's relative lack of attractiveness for pharmaceutical R&D investments.

- Between 1990 and 2007, R&D investment in United States grew 5.2 times whilst in Europe it only grew 3.3 times. The latest study released in 2007 estimated the average cost of researching and developing a new chemical or biological entity at € 1,059 million.
- There is rapid growth in the research environment in emerging economies such as China and India. The current tendency to close R&D sites in Europe and to open new sites in Asia will show dramatic effects in the next few years if nothing is done to maintain the pharmaceutical discovery expertise in the EU.
- The United States still dominates the biopharmaceutical field, accounting for the three quarters of the world's biotechnology revenues and R&D spending.
- In 2007 North America accounted for 45.9% of world pharmaceutical sales against 31.1% for Europe. According to IMS Health data, 65% of sales of new medicines launched during the period 2002-2007 were generated on the US market, compared with 24% on the European market.
- The fragmentation of the EU pharmaceutical market results in a lucrative parallel trade which benefits neither social security nor patients but deprives the industry from additional resources to fund R&D. Parallel trade was estimated to amount to € 4,300 million (value at ex-factory prices) in 2006.

### **Pharmaceutical R&D expenditure in Europe (€ million)**

|      |        |
|------|--------|
| 1980 | 2,331  |
| 1985 | 4,310  |
| 1990 | 7,766  |
| 1995 | 11,484 |

|      |            |
|------|------------|
| 2000 | 17,849     |
| 2005 | 21,778     |
| 2006 | 24,759     |
| 2007 | 26,000 (e) |

Source: EFPIA Member Associations (official figures) - (e): EFPIA estimate

**Pharmaceutical R&D expenditure** *Graph)*  
**Annual growth rate (%)**

|           | Europe | USA  |
|-----------|--------|------|
| 1993-1997 | 8.5    | 10.7 |
| 1998-2002 | 7.5    | 10.7 |
| 2003-2007 | 5.1    | 6.7  |

Source : EFPIA, P/RMA

## **MAIN TRENDS**

### **DETERIORATION OF EUROPE'S COMPETITIVE POSITION**

The benchmarking competitiveness report released by the European Commission in November 2000\* highlighted two main trends: 1) the European research-based pharmaceutical industry is losing competitiveness with respect to the US industry; and 2) there is a process of concentration of R&D into North America.

The United States has become the dominant player in the pharmaceutical sector. Whereas R&D investment in Europe grew by 3.3 times between 1990 and 2007, the corresponding increase in the U.S. was 5.2 times. According to the 2000 competitiveness report, "North America has become the main locus of innovation in pharmaceuticals, to which European companies turn to get knowledge". The report notes that the concentration of research and innovation in the U.S. is "worrying because Europe risks to be relegated into the fringe of the industry, surviving and even thriving through imitation, generics, marketing, but giving up a large share of the value added and becoming dependent on the USA for the development of new products."

\* Global Competitiveness in Pharmaceuticals - A European Perspective, A. Gambardella, L. Orsenigo, F. Pammolli, Report prepared for the Directorate General Enterprise of the European Commission, November 2000

#### **Pharmaceutical R&D expenditure in Europe, USA and Japan (million of national currency units\*), 1990-2007 (Main graph)**

|        | 1990  | 1995   | 2000   | 2005   | 2006   | 2007       |
|--------|-------|--------|--------|--------|--------|------------|
| Europe | 7,766 | 11,484 | 17,849 | 21,778 | 24,759 | 26,000 (e) |
| USA    | 6,803 | 11,874 | 21,364 | 30,969 | 34,468 | 35,394 (e) |
| Japan  | 5,161 | 6,422  | 7,462  | 10,477 | 11,735 | n.a.       |

\* Note: Europe: € million; USA: \$ million; Japan: ¥ million x 100

(e): estimate

Source: EFPIA member associations, P/RMA, JPMA

#### **Pharmaceutical R&D expenditure in Europe, USA and Japan (€ million, current exchange rates), 1990-2007 (Graph)**

|        | 1990  | 1995   | 2000   | 2005   | 2006   | 2007       |
|--------|-------|--------|--------|--------|--------|------------|
| Europe | 7,766 | 11,484 | 17,849 | 21,778 | 24,759 | 26,000 (e) |
| USA    | 5,342 | 9,078  | 23,121 | 24,893 | 27,451 | 25,826 (e) |
| Japan  | 2,809 | 5,221  | 7,499  | 7,656  | 8,037  | n.a.       |

Note: As these figures are converted into a common currency (€) they are significantly influenced by exchange rate movements.

(c): estimate

Source: EFPIA member associations, P/RMA, JPMMA

## CHANGING GLOBAL MARKET DYNAMICS

Over the past decade, the US pharmaceutical market has grown twice as fast as the European market in real terms. The year 2005 ended a decade of strong US market dominance, which led to a significant shift of economic and pharmaceutical research activity towards the US territory over the period.

In many respects the US pharmaceutical market has demonstrated that competitive market forces can drive research & development by providing the necessary rewards for innovation. According to IMS data, 65% of sales of new medicines marketed since 2002 are generated on the US market, compared to 24% on the European market.

### **Geographical breakdown (by main markets) of sales of new medicines launched during the period 2002-2007** *(graph)*

|       |                   |
|-------|-------------------|
| 65.2% | USA               |
| 24.3% | Europe            |
| 3.7%  | Japan             |
| 6.8%  | Rest of the World |

Note: New medicines cover all new active ingredients marketed for the first time on the world market during the period 2002-2007

Europe includes non-EU members and CIS markets

Source: IMS Health MIDAS MAT December 2007

The European pharmaceutical market is highly fragmented and remains driven by governments' forever-changing cost containment plans, resulting in a lack of predictability for companies' medium and long-term operational plans. Europe lacks a climate which favours and rewards innovation: cost-containment policies in Europe tend to focus at the beginning of the product life cycle rather than at the end of the product life cycle like in the US.

The fragmentation of the EU pharmaceutical market results in a lucrative parallel trade which benefits neither social security systems nor patients but deprives the industry from additional resources to fund R&D. Parallel trade was estimated to amount to € 4,300 million (value at ex-factory prices) in 2006.

### **Total pharmacy market (at ex-factory prices)** **Average growth rate for the period 1996-2006 (%)** *(graph)*

At current prices

At constant prices  
(adjusted for inflation)



|                           |      |     |
|---------------------------|------|-----|
| Europe (weighted average) | 6.1  | 4.1 |
| USA                       | 10.8 | 8.2 |
| Japan                     | 4.4  | 4.5 |

Source: EFPIA member associations, P/RMA, JPMA, IMS Health

### **Share of parallel imports in pharmacy market sales (%) - 2006**

|                |      |
|----------------|------|
| Denmark        | 15.2 |
| Finland        | 1.9  |
| Germany        | 7.7  |
| Netherlands    | 10.4 |
| Norway         | 5.9  |
| Sweden         | 13.3 |
| United Kingdom | 14.7 |

Source: EFPIA member associations

## BIOPHARMACEUTICALS

Biotechnology is delivering significant advances in healthcare. Entirely new medicines are being created, notably for rare or previously untreated diseases. Approximately one-fifth of the new molecular entities launched on the world market each year are now derived from biotechnology.

Biotech production methods also provide safer versions of existing treatments in unlimited quantities. Biotechnology has revolutionised research and development of new medicines and allows better product targeting for specific diseases and patient groups.

Although Europe's biopharmaceutical sector is growing steadily, it remains dominated by its American competitor. As Europe practically missed out on the first wave of biotech start-ups in the 1980s, most European biotech companies are significantly smaller than their US counterparts.

### Biopharmaceuticals - Europe versus USA (2006)

|  | Europe | USA     |
|--|--------|---------|
| Revenues (€ million)                           | 9,147  | 44,154  |
| R&D expenditure (€ million)                    | 2,891  | 18,205  |
| Net loss (€ million)                           | 896    | 2,760   |
| Number of public and private companies (units) | 1,621  | 1,452   |
| Number of employees (units)                    | 32,470 | 146,100 |

Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2007' (data relate only to publicly traded companies)

### Number of new molecular entities (NMEs) first launched worldwide 1990-2006 (Graph)

|      | Total NMEs<br>(including biologicals) | Biologicals |
|------|---------------------------------------|-------------|
| 1990 | 36                                    | 1           |
| 1991 | 51                                    | 7           |
| 1992 | 43                                    | 6           |
| 1993 | 40                                    | 2           |
| 1994 | 40                                    | 5           |

|      |    |    |
|------|----|----|
| 1995 | 41 | 7  |
| 1996 | 36 | 6  |
| 1997 | 46 | 5  |
| 1998 | 37 | 10 |
| 1999 | 41 | 9  |
| 2000 | 32 | 4  |
| 2001 | 31 | 11 |
| 2002 | 28 | 2  |
| 2003 | 26 | 4  |
| 2004 | 24 | 6  |
| 2005 | 28 | 6  |
| 2006 | 25 | 7  |

Source: CMR International

## THE ADDED VALUE OF MEDICINES IN HEALTHCARE

The research-based pharmaceutical industry in Europe plays a critical role in both the industrial and health fields. It invests billions of euros each year to develop innovative medicines that will meet patients' needs.

The mainstay of the European pharmaceutical industry's long-term competitiveness is its ability to pay for R&D. This ability largely depends on the success of products already on the market, and in particular on the attitude that Europe takes with respect to new products. Medicines remain the prime target of health cost containment policies, despite the fact that, on average, pharmaceutical spending accounts for only 16.6% of total health expenditure in Europe.

In most European countries, healthcare policies do not sufficiently take into account the therapeutic and economic value of medicines. However, there is growing evidence at macro and micro-economic level regarding the added value of medicines in the health care context, not only in terms of global cost savings but also in terms of increasing the quality of care. Medicines not only provide the best treatment for many diseases, but also generate savings by substantially reducing costs in other branches of health care (hospital stays, invalidity, etc.).

### **Breakdown of total health expenditure in Europe – 2005** *(pie chart)*

|  |      |
|--|------|
| In-patient care (hospital)                   | 35.6 |
| Outpatient care & others                     | 47.8 |
| Pharmaceuticals & other medical non-durables | 16.6 |

Source: OECD Health Data 2007, Statistics and Indicators for 30 countries, October 2007 – EFPIA calculations (non-weighted average for 17 EU & EFTA countries)

## **The annual impact of inadequate diabetes treatment in Germany**

Diabetes is one of the most common diseases of Western civilisation affecting more than 19 million people in the European Union. At least thirty percent of the 4 million patients suffering from diabetes in Germany are not treated with medicines at all. The inadequate treatment of diabetes in Germany results in: 6,000 cases of blindness, 8,000 patients becoming dependent on dialysis, 27,000 heart attacks, almost 28,000 amputations of limbs and 44,000 strokes annually. Medicines account for 27% of all costs in diabetes treatment, whilst hospital stays represent almost 60%. A large part of the hospitalisation costs – as with most other serious illnesses - could be avoided with proper outpatient treatment (especially by regulation of the blood sugar level).

- 6,000 cases of blindness
- 8,000 dialysis patients
- 27,000 heart attacks
- 28,000 amputations of limbs
- 44,000 strokes

***(graph)***

Source: CODE 2 study (Costs of diabetes in Europe, type 2), 1999

## **VALUE OF MEDICINES**

### **THE PHARMACEUTICAL INDUSTRY: A KEY ASSET TO SCIENTIFIC AND MEDICAL PROGRESS**

Science today offers more promise for finding better treatments than ever before,, thanks to new knowledge and new technologies. Today European citizens can expect to live 30 years longer than a century ago. Huge reductions in mortality (e.g. in HIV/AIDS, many cancers or cardiovascular diseases) and a significant progress in the quality of life are the results of some big and many small steps in biopharmaceutical research. Contrary to common belief, higher life expectancy does not inevitably lead to degenerative diseases and ever longer stays in nursing homes. European citizens cannot only expect to live longer but to live longer and healthier. Higher blood pressure and cardiovascular diseases can be controlled with antihypertensive drugs and cholesterol-lowering drugs, knee or hip replacements prevent patients from wheelchairs, and some cancers can be controlled or even cured thanks to newer targeted medicines. Yet, there remain huge challenges in disease areas such as Alzheimer, multiple sclerosis, many cancers or orphan diseases.

The research-based pharmaceutical industry's key contribution to medical progress is to turn fundamental research findings into innovative treatments that are widely available and accessible. Since aspirin was invented a century ago, scientific and technological breakthroughs in the pharmaceutical industry have enabled researchers to target increasingly complex diseases more closely, first, by exploring the biochemistry of tissues, and then by analysis of individual cells. Through the mapping of the human genome, today's research will enable scientists to target the causes of diseases rooted in man's molecular structure.

#### **Chronology of Drug Innovation (Chart)**

Source: Boston Consulting Group

#### **Life expectancy (years) Total population at birth, Europe (Graph)**

|      |      |
|------|------|
| 1960 | 69.3 |
| 1970 | 70.7 |
| 1980 | 72.8 |
| 1990 | 74.8 |
| 2000 | 77.1 |
| 2005 | 78.4 |

Source: OECD Health Data 2007, Statistics and Indicators for 30 countries, October 2007 – EFPIA calculations (non-weighted average for 23 EU & EFTA countries)

## **KEY FIGURES**

### **THE PHARMACEUTICAL INDUSTRY: A KEY ASSET TO THE EUROPEAN ECONOMY**

Besides driving medical progress and improving health within Europe and worldwide, the research-based pharmaceutical industry is a key asset to the European economy. The pharmaceutical industry is one of Europe's best performing high-technology sectors.

| <b>INDUSTRY (EFPIA total) (1)</b>                                     | <b>1990</b> | <b>1995</b> | <b>2000</b> | <b>2005</b> | <b>2006</b> | <b>2007</b> |
|---|-------------|-------------|-------------|-------------|-------------|-------------|
| Production  | 63,010      | 88,912      | 123,282     | 172,098     | 182,339     | 190,000 (e) |
| Exports (2)   | 23,180      | 44,188      | 90,935      | 181,575     | 202,316     | 210,000 (e) |
| Imports (2)   | 16,113      | 31,018      | 68,841      | 145,823     | 157,941     | 161,000 (e) |
| Trade balance   | 7,067       | 13,170      | 22,094      | 35,752      | 44,375      | 49,000 (e)  |
| R&D expenditure   | 7,766       | 11,484      | 17,849      | 21,778      | 24,759      | 26,000 (e)  |
| Employment (units)  | 500,879     | 506,052     | 538,438     | 635,937     | 643,138     | 645,000 (e) |
| R&D employment (units)  | 75,760      | 82,282      | 88,524      | 100,013     | 106,974     | 107,000 (e) |
| Pharmaceutical market value at ex-factory prices                      | 41,147      | 59,871      | 86,812      | 129,462     | 133,350     | 140,500 (e) |
| Pharmaceutical market value at retail prices                          | 64,626      | 93,032      | 136,627     | 188,109     | 194,524     | 205,000 (e) |
| Payment for pharmaceuticals by statutory health insurance systems (3) | 40,807      | 58,128      | 74,743      | 104,370     | 107,844     | 111,000 (e) |

Values in € million unless otherwise stated

(1) Data relate to EU-27, Norway and Switzerland since 2005 (EU-15 before 2005)

(2) Data relating to total exports and total imports include EU-27 intra-trade (double counting in some cases)

(3) Since 1998 data relate to ambulatory care only

Source: EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-27 trade data 1995-2007)

The research-based pharmaceutical industry accounts for approximately 3.5% of the total EU manufacturing value added and for 19% of the global business R&D expenditure. The pharmaceutical industry performs well on most standard indicators, such as:

- employment: more than 643,100 jobs in Europe, including 107,000 in R&D units;
- R&D investment: € 24,800 million in 2006 (up from € 7,800 in 1990);

- trade surplus: € 44,400 million in 2006 (up from € 7,100 in 1990).



## **MEMBERSHIP**

EFPIA represents the pharmaceutical industry operating in Europe. EFPIA brings together 32 European national pharmaceutical industry associations as well as 43 leading companies undertaking research, development and manufacturing of medicinal products for human use in Europe.

## **MEMBER ASSOCIATIONS**

### **Austria**

Fachverband der Chemischen Industrie Österreichs (FCIO)

### **Denmark**

Laegemiddelindustriforeningen  
The Danish Association of the  
Pharmaceutical Industry (Lif)

### **France**

Les Entreprises du Médicament (LEEM)

### **Greece**

Hellenic Association of Pharmaceutical  
Companies (SFEE)

### **Italy**

Associazione delle Imprese del Farmaco  
(Farmindustria)

### **Norway**

Legemiddelindustriforeningen  
Norwegian Association of Pharmaceutical  
Manufacturers (LMI)

### **Portugal**

Associação Portuguesa da Indústria  
Farmacêutica (Apifarma)

### **Sweden**

Läkemedelsindustriföreningen  
The Swedish Association of the  
Pharmaceutical Industry (LIF)

### **Turkey**

Arastirmaci Ilac Firmalari Dernegi (AIFD)

### **Founder member (Germany)**

Bundesverband der Pharmazeutischen  
Industrie (BPI)

### **Belgium**

Association Générale de l'Industrie du  
Médicament (pharma.be)

### **Finland**

Lääketeollisuus ry  
Pharma Industry Finland (PIF)

### **Germany**

Verband Forschender  
Arzneimittelhersteller (VFA)

### **Ireland**

Irish Pharmaceutical Healthcare  
Association (IPHA)

### **Netherlands**

Vereniging Innovatieve Geneesmiddelen  
Nederland (Nefarma)

### **Poland**

Employers Union of Innovative  
Pharmaceutical Companies (Infarma)

### **Spain**

Asociación Nacional Empresarial de la  
Industria Farmacéutica (Farmaindustria)

### **Switzerland**

Société Suisse des Industries Chimiques  
(SSIC)

### **United Kingdom**

The Association of the British  
Pharmaceutical Industry (ABPI)

## **ASSOCIATIONS WITH LIAISON STATUS**

**Bulgaria** Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM)

**Croatia** Croatian Pharmaceutical Association (CARP)

**Cyprus** Association of Pharmaceutical Companies (KEFEA)

**Czech Republic** Mezinárodní Asociace Farmaceutických Společností (MAFS)

**Estonia** Association of International Pharmaceutical Manufacturers in Estonia (AIPME)

|                  |   |
|------------------|---|
| <b>Hungary</b>   | Association of Innovative Pharmaceutical Manufacturers (AIPM)                       |
| <b>Iceland</b>   | Icelandic Pharmaceutical Association (Frumtök)                                      |
| <b>Latvia</b>    | Association of International Research-based Pharmaceutical Manufacturers (AFA)      |
| <b>Lithuania</b> | Association of Representative Offices of Ethical Pharmaceutical Manufacturers (EFA) |
| <b>Malta</b>     | Maltese Pharmaceutical Association (PRIMA)  |
| <b>Romania</b>   | Association of International Medicines Manufacturers (ARPIM)                        |
| <b>Slovakia</b>  | Slovak Association of Research Based Pharmaceutical Companies (SAFS)                |
| <b>Slovenia</b>  | Forum of International Research and Development Pharmaceutical Industries (EIG)     |

## MEMBER COMPANIES

### Full Members

|                                  |                         |
|----------------------------------|-------------------------|
| Abbott Laboratories              | USA                     |
| Almirall S.A.                    | Spain                   |
| Amgen                            | USA                     |
| AstraZeneca                      | United Kingdom / Sweden |
| Baxter                           | USA                     |
| Bayer Healthcare AG              | Germany                 |
| Biogen Idec                      | USA                     |
| Boehringer Ingelheim             | Germany                 |
| Bristol Myers Squibb             | USA                     |
| Chiesi Farmaceutici              | Italy                   |
| Eisai                            | Japan                   |
| Eli Lilly & Co                   | USA                     |
| Esteve                           | Spain                   |
| Genzyme                          | USA                     |
| Gilead Sciences                  | USA                     |
| GlaxoSmithKline                  | United Kingdom          |
| Grünenthal                       | Germany                 |
| Ipsen                            | France                  |
| Johnson & Johnson                | USA                     |
| H. Lundbeck A/S                  | Denmark                 |
| Menarini                         | Italy                   |
| Merck Serono                     | Germany                 |
| Merck & Co                       | USA                     |
| Novartis                         | Switzerland             |
| Novo Nordisk                     | Denmark                 |
| Orion Pharma                     | Finland                 |
| Pfizer                           | USA                     |
| Pierre Fabre                     | France                  |
| Procter & Gamble Pharmaceuticals | USA                     |
| Roche                            | Switzerland             |
| Sanofi Aventis                   | France                  |
| Schering-Plough                  | USA                     |
| Servier                          | France                  |
| Sigma-Tau                        | Italy                   |
| Solvay                           | Belgium                 |
| Takeda                           | Japan                   |
| UCB                              | Belgium                 |
| Wyeth                            | USA                     |

### Affiliate Members

|                          |          |
|--------------------------|----------|
| Bial                     | Portugal |
| Bracco                   | Italy    |
| Elan Pharmaceuticals Plc | Ireland  |
| Otsuka Pharmaceuticals   | Japan    |
| Recordati                | Italy    |

## NUMBER OF COMPANIES REPRESENTED BY EFPIA MEMBER ASSOCIATIONS

| <b><u>EFPIA 2007</u></b> | <b><u>Units</u></b> |
|--------------------------|---------------------|
| Austria                  | 64                  |
| Belgium                  | 142                 |
| Bulgaria                 | 22                  |
| Cyprus                   | 47                  |
| Czech Republic           | 29                  |
| Denmark                  | 38                  |
| Estonia                  | 22                  |
| Finland                  | 64                  |
| France                   | 262                 |
| Germany                  | 310                 |
| Greece                   | 64                  |
| Hungary                  | 26                  |
| Iceland                  | 18                  |
| Ireland                  | 52                  |
| Italy                    | 218                 |
| Latvia                   | 21                  |
| Lithuania                | 16                  |
| Malta                    | n.a.                |
| Netherlands              | 43                  |
| Norway                   | 44                  |
| Poland                   | 42                  |
| Portugal                 | 137                 |
| Romania                  | 23                  |
| Slovakia                 | 21                  |
| Slovenia                 | 20                  |
| Spain                    | 218                 |
| Sweden                   | 62                  |
| Switzerland              | 67                  |
| Turkey                   | 36                  |
| United Kingdom           | 74                  |
| <b>Total</b>             | <b>2,202</b>        |

Note: Number of members as of 1 January 2007  
Germany: VFA (45 members); BPI (265 members)

Source: EFPIA member associations

## **STRUCTURE OF THE PHARMACEUTICAL INDUSTRY**

More than 2,200 companies (separate legal entities) are represented by EFPIA and its member associations. These companies' activities range from groundbreaking R&D to top-quality manufacturing and marketing (information and sales). The industry's structure varies from country to country, reflecting differing national medical traditions, intellectual property protection standards and industrial policies.

From an international perspective, Europe's research-based pharmaceutical companies have performed well historically. European companies are well represented among the top firms in the world measured by sales, research investment and new product launches.

Since the mid-90's, US research-based companies have significantly increased their share in the world's top selling medicines. They launched 45.8% of the new chemical and biological entities over the period 2003-2007 against 33.3% for the European companies. Of the top 10 worldwide products in 2007, 6 originate from the US against 4 from Europe.

As shown by the report released by the European Commission on the competitiveness of the European pharmaceutical industry\*, European-based firms have faced a comparative disadvantage in selling their new medicines over the past decade. The difference in sales growth between European and American companies resulted mainly from the difference in demand growth between the two continents, rather than the inherent ability to develop new breakthrough medicines. American companies have better exploited the growing demand in their own country and have been more successful than European and Japanese companies in disseminating their new medicines at international level.

\* Global Competitiveness in Pharmaceuticals - A European Perspective, A. Gambardella, L. Orsenigo, F. Pammolli, Report prepared for the Directorate General Enterprise of the European Commission, November 2000

### **Origin of the top 20 companies by worldwide sales, 2007**

|        |   |                |
|--------|---|----------------|
| Europe | 8 | <i>(graph)</i> |
| USA    | 9 |                |
| Japan  | 2 |                |
| Others | 1 |                |

Note: American companies (Pfizer; Johnson & Johnson; Merck & Co; Abbott; Eli Lilly & Co; Amgen; Wyeth; Bristol Myers Squibb; Schering-Plough); European companies (GlaxoSmithKline; Novartis; Sanofi Aventis; AstraZeneca; Roche; Bayer; Boehringer Ingelheim; Novo Nordisk); Japanese companies (Takeda; Eisai); Others (Teva)

Source: IMS Health, MIDAS, MAT December 2007

### **Origin of the top 40 companies by R&D investment, 2006**

|        |    |                |
|--------|----|----------------|
| Europe | 13 | <i>(graph)</i> |
| USA    | 19 |                |
| Japan  | 7  |                |
| Others | 1  |                |

Source: UK Department of Trade and Industry, The 2007 R&D Scoreboard - EFPIA calculations

### **New chemical and biological entities launched during the period 2003-2007**

|        |    |                |
|--------|----|----------------|
| Europe | 48 | <i>(graph)</i> |
| USA    | 66 |                |
| Japan  | 15 |                |
| Others | 15 |                |

Source: SCRIP (2002-2005); CMR (2006) - EFPIA calculations

### **Origin of the top 10 medicines by worldwide sales, 2007**

|        |   |
|--------|---|
| Europe | 4 |
| USA    | 6 |

Source: IMS Health, MIDAS, December 2007

## PHARMACEUTICAL PRODUCTION

### **EFPIA 2006** **€ million**

|                |                |
|----------------|----------------|
| Austria        | 1,874          |
| Belgium        | 5,261          |
| Bulgaria       | n.a.           |
| Cyprus         | n.a.           |
| Czech Republic | n.a.           |
| Denmark        | 5,278          |
| Estonia        | n.a.           |
| Finland        | 857            |
| France         | 34,444         |
| Germany        | 23,699         |
| Greece         | 666            |
| Hungary        | n.a.           |
| Iceland        | n.a.           |
| Ireland        | 14,900         |
| Italy          | 22,317         |
| Latvia         | 95             |
| Lithuania      | n.a.           |
| Malta          | 34             |
| Netherlands    | 5,664          |
| Norway         | 709            |
| Poland         | 1,367          |
| Portugal       | 1,829          |
| Romania        | 223            |
| Slovakia       | n.a.           |
| Slovenia       | n.a.           |
| Spain          | 12,459         |
| Sweden         | 7,196          |
| Switzerland    | 18,618         |
| United Kingdom | 24,849         |
| <b>Total</b>   | <b>182,339</b> |

Note: All data based on SITC 54

Malta, Poland: 2004 data

Netherlands: 2005 data

Greece: 2006 provisional data

Denmark, France, Ireland, Italy, Norway, Portugal, Spain, Sweden, Switzerland: estimate

Germany, Ireland, Norway, Switzerland: veterinary products excluded

Source: EFPIA member associations (official figures)

## **PHARMACEUTICAL OUTPUT**

With an estimated share of 39.3% of the world pharmaceutical output, the US remains the primary manufacturing centre for medicines in the world, just ahead of Europe and Japan. Together, these three regions account for the bulk (approximately 84%) of the world pharmaceutical production. In 2006, EFPIA countries' pharmaceutical production was worth an estimated total of € 182,300 million.

According to EUROSTAT data, the pharmaceutical industry is the high technology sector with the highest value added per person employed, well above the average value for high-tech and manufacturing industries. The pharmaceutical industry is also the sector with the highest ratio of R&D investment to net sales. It amounts to approximately 3.5% of the total EU manufacturing value added and 19.3% of the total worldwide business R&D expenditure.

### **Ranking of industrial sectors by aggregate R&D from the world top 1,400 companies in the 2007 EU Scoreboard - 2006**

| <b>Sector<br/>(according to the ICB)</b> | <b>R&amp;D<br/>Investment<br/>(€ million)</b> | <b>Share in<br/>R&amp;D<br/>investment<br/>(%)</b> | <b>R&amp;D/Sales<br/>ratio (%)</b> |
|--|---|--|------------------------------------|
| Pharmaceuticals & biotechnology          | 70,523.5                                      | 19.3   | 15.9                               |
| Technology hardware & equipment          | 64,531.5                                      | 17.6   | 8.6                                |
| Automobiles & parts                      | 60,807.1                                      | 16.6   | 4.1                                |
| Electronic & electrical Equipment        | 27,138.9                                      | 7.4  | 4.4                                |
| Software & computer services             | 26,522.8                                      | 7.3  | 9.8                                |
| Chemicals                                | 17,186.0                                      | 4.7  | 3.1                                |
| Aerospace & Defence                      | 15,991.3                                      | 4.4  | 4.8                                |
| Leisure goods                            | 14,208.6                                      | 3.9  | 6.5                                |
| Industrial engineering                   | 9,319.3                                       | 2.5  | 2.7                                |
| General industrials                      | 8,867.6                                       | 2.4  | 2.1                                |
| Fixed line telecommunications            | 7,283.1                                       | 2.0  | 1.6                                |
| Health care equipment & services         | 6,446.1                                       | 1.8  | 6.8                                |
| Oil & gas producers                      | 4,923.7                                       | 1.3  | 0.3                                |
| Food producers                           | 3,918.5                                       | 1.1  | 2.2                                |
| Household goods                          | 3,911.9                                       | 1.1  | 1.6                                |
| Others (22 sectors)                      | 24,243.9                                      | 6.6  | 0.9                                |
| <b>Grand Total (37 sectors)*</b>         | <b>365,823.9</b>                              | <b>100.0</b>                                       | <b>3.4</b>                         |

\* Totals do not add due to rounding

Note: ICB: Industrial Classification Benchmark set up by FTSE (Financial Times Stock Exchange) & Dow Jones

Data relate to the top 1,400 companies with registered offices in the EU, Japan, the USA and the Rest of the World, ranked by the size of their R&D investment (over € 23 million)

Source: The 2007 EU Industrial R&D Investment Scoreboard, Joint Research Centre, Directorate General Research, European Commission



*(pie chart)*

**Breakdown of the world pharmaceutical production (at ex-factory prices), 2006**

|       |                   |
|-------|-------------------|
| 35.2% | Europe            |
| 39.3% | USA               |
| 9.5%  | Japan             |
| 16.0% | Rest of the World |

Source: EFPIA member associations, P/RMA, JPMA, OECD, IMS Health – Estimate (EFPIA calculations)

*(Graph)*

**European pharmaceutical production, 1980-2007 (€ million)**

|      |             |
|------|-------------|
| 1985 | 39,821      |
| 1990 | 63,010      |
| 1995 | 88,912      |
| 2000 | 123,282     |
| 2005 | 172,098     |
| 2006 | 182,339     |
| 2007 | 190,000 (e) |

Note: As these figures have been converted into a common currency, they are to some extent influenced by exchange rate movements.

Source: EFPIA member associations (official figures) – (e): EFPIA estimate

## PHARMACEUTICAL MARKET VALUE (at ex-factory prices)

### EFPIA 2006 € million

|                |        |
|----------------|--------|
| Austria        | 2,544  |
| Belgium        | 3,684  |
| Bulgaria       | 538    |
| Cyprus         | 177    |
| Czech Republic | 1,467  |
| Denmark        | 1,685  |
| Estonia        | 189    |
| Finland        | 1,740  |
| France         | 24,353 |
| Germany        | 24,353 |
| Greece         | 4,244  |
| Hungary        | 1,954  |
| Iceland        | n.a.   |
| Ireland        | 1,706  |
| Italy          | 16,472 |
| Latvia         | 213    |
| Lithuania      | 411    |
| Malta          | 80     |
| Netherlands    | 4,230  |
| Norway         | 1,312  |
| Poland         | 4,009  |
| Portugal       | 3,321  |
| Romania        | 1,352  |
| Slovakia       | 671    |
| Slovenia       | 468    |
| Spain          | 12,154 |
| Sweden         | 2,802  |
| Switzerland    | 2,673  |
| United Kingdom | 14,548 |

**Total** **133,350**

Note: Medicinal products as defined by Directive 2001/83/EEC

Denmark, Finland, Latvia, Norway, Slovenia, Sweden: pharmaceutical market value at pharmacy purchasing prices

Greece: including parallel exports

Belgium, France, Germany, Ireland, Italy, Norway, Spain: estimate

Source: EFPIA member associations (official figures) – Bulgaria, Cyprus, Hungary, Lithuania, Malta, Poland: IMS Health

The figures above are for pharmaceutical sales, at ex-factory prices, through all distribution channels (pharmacies, hospitals, dispensing doctors, supermarkets, etc.), whether dispensed on prescription or at the patient's request. Samples and sales of veterinary medicines are excluded.

## **PHARMACEUTICAL SALES**

The world pharmaceutical market was worth an estimated € 484,130 million (\$ 663,500 million) at ex-factory prices in 2007. The North American market (USA & Canada) remained the world's largest market with a 45.9% share, well ahead of Europe and Japan. In 2007 the European market outpaced the US market in terms of growth but the Asian region is by far the fastest growing market (the growth of the North American market was estimated at 4.2 % in 2007, compared with an estimated market growth of 6.7% for Europe and 13.1% for Asia).

*(pie chart)*

### **Breakdown of the world pharmaceutical market – 2007 sales**

|  |         |
|--|---------|
| North America (USA, Canada)                | : 45.9% |
| Europe                                     | : 31.1% |
| Japan                                      | : 9.4%  |
| Africa, Asia (excluding Japan) & Australia | : 8.8%  |
| Latin America                              | : 4.8%  |

Note: Europe includes non-EU members and CIS markets

Source: IMS Health, February 2008 (data relate to the 2007 audited market at ex-factory prices)

### **Breakdown of the total pharmaceutical market value (at ex-factory prices) by main distribution channels (in € million), 2006**

|                | Total  | Pharmacy | Hospital | Other channels |
|----------------|--------|----------|----------|----------------|
| Austria        | 2,544  | 1,753    | 791      | 0              |
| Belgium        | 3,684  | 3,176    | 508      | 0              |
| Bulgaria       | 538    | n.a.     | n.a.     | n.a.           |
| Cyprus         | 177    | n.a.     | n.a.     | n.a.           |
| Czech Republic | 1,467  | 1,042    | 425      | n.a.           |
| Denmark        | 1,685  | 1,066    | 600      | 19             |
| Estonia        | 189    | 166      | 23       | 0              |
| Finland        | 1,740  | 1,309    | 418      | 13             |
| France         | 24,353 | 19,762   | 4,591    | 0              |
| Germany        | 24,353 | 20,848   | 3,295    | 210            |
| Greece         | 4,244  | 3,231    | 1,013    | 0              |
| Hungary        | 1,954  | n.a.     | n.a.     | n.a.           |
| Iceland        | n.a.   | n.a.     | n.a.     | n.a.           |
| Ireland        | 1,706  | 1,395    | 291      | 20             |
| Italy          | 16,472 | 11,859   | 4,613    | 0              |
| Latvia         | 213    | 169      | 44       | 0              |
| Lithuania      | 411    | n.a.     | n.a.     | n.a.           |
| Malta          | 80     | n.a.     | n.a.     | n.a.           |

|                |          |        |        |       |
|----------------|----------|--------|--------|-------|
| Netherlands    | 4,230    | 3,109  | 756    | 365   |
| Norway         | 1,312    | 1,017  | 279    | 16    |
| Poland         | 4,009    | n.a.   | n.a.   | n.a.  |
| Portugal       | 3,321    | 2,416  | 902    | 3     |
| Romania        | 1,352    | 1,053  | 299    | 0     |
| Slovakia       | 671      | 597    | 74     | 0     |
| Slovenia       | 468      | 384    | 84     | 0     |
| Spain          | 12,154   | 9,259  | 2,895  | 0     |
| Sweden         | 2,802    | 2,400  | 402    | 0     |
| Switzerland    | 2,673    | 1,450  | 511    | 712   |
| United Kingdom | 14,548   | 10,215 | 3,613  | 720   |
| EFPIA total    | 126,181* | 97,676 | 26,427 | 2,078 |

\* Total excluding Bulgaria, Cyprus, Hungary, Lithuania, Malta and Poland (breakdown not available)

Note: Other channels include dispensing doctors, supermarkets, drugstores and other retail outlets  
Denmark, Finland, Latvia, Norway, Slovenia, Sweden: pharmaceutical market value at pharmacy purchasing prices  
Belgium, France, Germany, Ireland, Italy, Norway, Spain: estimate  
Greece: including parallel exports

Source: EFPIA member associations (official figures) – Bulgaria, Cyprus, Hungary, Lithuania, Malta, Poland: IMS Health

## GENERICIS

The term 'generics' is widely used but its definition is not always consistent between countries. Generics are usually produced by a manufacturer who is not the inventor of the original product and are marketed when intellectual property protection rights are exhausted.

The market share of generics cannot be analysed without taking market access conditions for new medicines in each country into consideration. In general there is a link between low levels of generic penetration and poor pricing conditions for innovative medicines on European markets. The market share of generics is significantly lower in price-controlled environments than in unrestricted ones, except in new EU Member States with historically low levels of intellectual property protection.

**Share (estimate - in %) accounted for by generics in pharmaceutical market sales value (at ex-factory prices), 2006**

### *Graph*

|                |      |
|----------------|------|
| Austria        | 17.1 |
| Belgium        | 10.0 |
| Denmark        | 21.1 |
| Finland        | 20.6 |
| France         | 8.7  |
| Germany        | 30.5 |
| Greece         | 11.6 |
| Ireland        | 8.0  |
| Italy          | 13.7 |
| Netherlands    | 18.4 |
| Norway         | 13.5 |
| Portugal       | 14.6 |
| Romania        | 30.8 |
| Slovakia       | 45.6 |
| Slovenia       | 32.9 |
| Spain          | 6.4  |
| Sweden         | 14.0 |
| Switzerland    | 11.6 |
| United Kingdom | 23.8 |

Note:

Denmark, Finland, Greece, Portugal, Romania, U.K.: share of generics in pharmacy market sales

Austria, Belgium, France, Germany, Ireland, Italy, Netherlands, Spain: share of generics in reimbursable pharmacy market sales

Switzerland: share of generics in total reimbursable market sales

Norway, Slovakia, Slovenia, Sweden: share of generics in total market sales

France: data relate only to those active substances listed on the official list of medicines

U.K.: pharmacy market sales at NHS reimbursement prices

Definition: 'generic' means a medicine based on an active substance that is out of patent and which is marketed under a different name from that of the original branded medicine (generics data do not include those generics marketed by the originator).

Source: EFPIA member associations

## **VAT RATES APPLICABLE TO MEDICINES**

Distribution margins, which are generally fixed by governments, and VAT rates differ significantly from country to country in Europe. On average, approximately 35.0% of the retail price of a medicine does not revert to the manufacturer but rather to distributors (pharmacists and wholesalers) and the State.

### **Price structure - Breakdown of the retail price of a medicine, 2006 (%)**

|                             |       |                    |
|-----------------------------|-------|--------------------|
| Manufacturer                | 64.98 | <i>(pie chart)</i> |
| Wholesaler                  | 6.35  |                    |
| Pharmacist                  | 19.79 |                    |
| State (VAT and other taxes) | 8.88  |                    |

Note: non-weighted average for Europe (estimate)  
Source: EFPIA member associations

As referred to in Directive 2006/112/EC the basic VAT rules require Member States to apply a standard VAT rate of at least 15% and two optional reduced rates of minimum 5% to a limited list of goods and services. The reduced rates apply to an exhaustive list of products and services, most of which are basic necessities or goods and services used for social or cultural purposes, provided they could be supplied with little or no risk of distorting competition. Pharmaceutical products are on this list. Reduced VAT rates are currently applied to pharmaceutical products in all EU-27 Member States except Austria, Bulgaria, Denmark and Germany. The table below shows the VAT rates applied to medicines in European countries on 1 January 2008.

| Country                   | Standard VAT rate (%) | VAT rates applied to medicines |           |
|---------------------------|-----------------------|--------------------------------|-----------|
|                           |                       | Prescription (%)               | OTC (%)   |
| <b>Austria</b>            | 20.0                  | 20.0                           | 20.0      |
| <b>Belgium</b>            | 21.0                  | 6.0                            | 6.0       |
| <b>Bulgaria</b>           | 20.0                  | 20.0                           | 20.0      |
| <b>Cyprus</b>             | 15.0                  | 0.0                            | 0.0       |
| <b>Czech Republic (1)</b> | 19.0                  | 9.0                            | 9.0       |
| <b>Denmark</b>            | 25.0                  | 25.0                           | 25.0      |
| <b>Estonia</b>            | 18.0                  | 5.0                            | 5.0       |
| <b>Finland</b>            | 22.0                  | 8.0                            | 8.0       |
| <b>France (2)</b>         | 19.6                  | 2.1 - 5.5                      | 2.1 – 5.5 |
| <b>Germany</b>            | 19.0                  | 19.0                           | 19.0      |

|                           |      |            |            |
|---------------------------|------|------------|------------|
| <b>Greece</b>             | 19.0 | 9.0        | 9.0        |
| <b>Hungary</b>            | 20.0 | 5.0        | 5.0        |
| <b>Ireland (3)</b>        | 21.0 | 0.0 - 21.0 | 0.0 – 21.0 |
| <b>Italy</b>              | 20.0 | 10.0       | 10.0       |
| <b>Latvia</b>             | 18.0 | 5.0        | 5.0        |
| <b>Lithuania</b>          | 18.0 | 5.0        | 5.0        |
| <b>Luxembourg</b>         | 15.0 | 3.0        | 3.0        |
| <b>Malta</b>              | 18.0 | 0.0        | 0.0        |
| <b>Netherlands</b>        | 19.0 | 6.0        | 6.0        |
| <b>Norway</b>             | 25.0 | 25.0       | 25.0       |
| <b>Poland</b>             | 22.0 | 7.0        | 7.0        |
| <b>Portugal</b>           | 21.0 | 5.0        | 5.0        |
| <b>Romania</b>            | 19.0 | 9.0        | 9.0        |
| <b>Slovakia</b>           | 19.0 | 10.0       | 10.0       |
| <b>Slovenia</b>           | 20.0 | 8.5        | 8.5        |
| <b>Spain</b>              | 16.0 | 4.0        | 4.0        |
| <b>Sweden</b>             | 25.0 | 0.0        | 25.0       |
| <b>Switzerland</b>        | 7.6  | 2.4        | 2.4        |
| <b>United Kingdom (4)</b> | 17.5 | 0.0        | 17.5       |

(1) Czech Republic: VAT increase from 5% to 9% for all medicines on 01/01/2008

(2) France: reimbursable medicines 2.1%; non-reimbursable medicines 5.5%

(3) Ireland: oral medication 0%; other medication 21%

(4) United Kingdom: 17.5% on medicines purchased by hospitals



## PHARMACEUTICAL INDUSTRY RESEARCH & DEVELOPMENT IN EUROPE

### EFPIA 2006 € million

|                |               |
|----------------|---------------|
| Austria        | 311           |
| Belgium        | 1,559         |
| Bulgaria       | n.a.          |
| Cyprus         | n.a.          |
| Czech Republic | n.a.          |
| Denmark        | 958           |
| Estonia        | n.a.          |
| Finland        | 180           |
| France         | 3,997         |
| Germany        | 5,393         |
| Greece         | 36            |
| Hungary        | n.a.          |
| Iceland        | n.a.          |
| Ireland        | 150           |
| Italy          | 1,115         |
| Latvia         | n.a.          |
| Lithuania      | n.a.          |
| Malta          | n.a.          |
| Netherlands    | 505           |
| Norway         | 122           |
| Poland         | n.a.          |
| Portugal       | n.a.          |
| Romania        | 25            |
| Slovakia       | n.a.          |
| Slovenia       | 100           |
| Spain          | 850           |
| Sweden         | 859           |
| Switzerland    | 2,806         |
| United Kingdom | 5,793         |
| <b>Total</b>   | <b>24,759</b> |

Note: The figures relate to the R&D carried out in each country.

Greece: 2003 data

Austria, France, Netherlands: 2004 data

Ireland: 2005 data

Belgium, Denmark, France, Greece, Ireland, Italy, Netherlands, Norway, Romania, Sweden (LIF members), Switzerland (Interpharma members): estimate

Source: EFPIA member associations (official figures)

## **PHARMACEUTICAL RESEARCH & DEVELOPMENT (R&D)**

### **PHARMACEUTICAL DEVELOPMENT COSTS**

All new medicines introduced on the market are the result of lengthy, costly and risky research and development (R&D) conducted by pharmaceutical companies. The rate at which R&D costs have risen over the last decade is illustrated by several recent studies. The latest study released in 2007 estimated the average cost of researching and developing a new chemical or biological entity at € 1,059 million (\$ 1,318 million in year 2005 dollars). Meeting these costs demands ever-increasing investment efforts, which in the pharmaceutical industry's case, are almost entirely financed from its own resources.

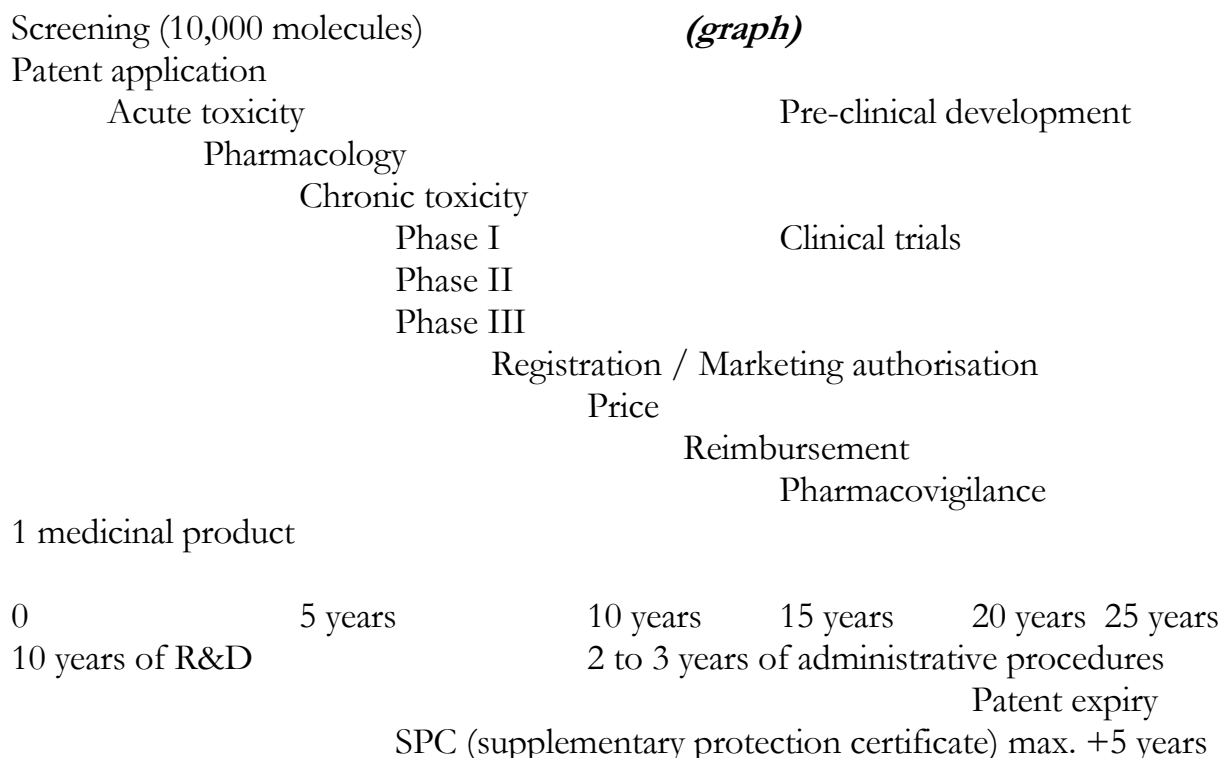
High failure rates, the significant cost of clinical trials and the amount of resources needed to get approval by regulatory authorities are the primary reasons for this exponential increase of R&D costs. Promising new substances frequently reach an advanced stage of clinical research before results demonstrate that they must be abandoned. The chances of new substances becoming a marketable medicine remain relatively small: several studies have produced figures ranging from 1 in 5,000 to 1 in 10,000. The financing of such R&D costs requires a sustained and substantial cash flow that the company is only able to generate if it launches new medicines on the various national markets as quickly as possible.

#### **Estimated full cost of bringing a new chemical or biological entity to market (\$ million - year 2005 \$)**

|      |       |
|------|-------|
| 1975 | 138   |
| 1987 | 318   |
| 2001 | 802   |
| 2006 | 1,318 |

Source: J.A. DiMasi and H.G. Grabowski, 'The Cost of Biopharmaceutical R&D: Is Biotech Different?', *Managerial and Decision Economics* 28 (2007): 469-479

## Phases of the research and development process



## IMPORTANCE OF PHARMACEUTICAL R&D

In 2006 the pharmaceutical industry invested about € 24,800 million in R&D on the European territory. Compared to the US, Europe is seen as a less attractive R&D investment location in terms of market size and incentives for the creation of new innovative biotech companies. Over the past ten years, Europe's research and development base has been gradually eroded, with new leading-edge technology research units being transferred out of Europe and mainly to the United States. Whereas R&D investments in Europe grew by 3.3 times between 1990 and 2007, the corresponding increase in the U.S. was 5.2 times.

There is rapid growth in the research environment in emerging economies such as China and India. The current tendency to close R&D sites in Europe and to open new sites in Asia will show dramatic effects in the next few years if nothing is done to maintain the pharmaceutical discovery expertise in the EU.

### R&D as percentage of sales, 1985-2007 (%)

|      |      |
|------|------|
| 1985 | 15.6 |
| 1990 | 18.9 |
| 1995 | 19.2 |
| 2000 | 20.6 |

|      |          |
|------|----------|
| 2005 | 16.8     |
| 2006 | 18.6     |
| 2007 | 18.5 (e) |

Source: EFPIA Member Associations (official figures) - (e): EFPIA estimate

As a whole, the research-based pharmaceutical industry invests about 18.5% of its sales into R&D in Europe. In terms of allocation of R&D investment, companies spend on average 27.2% of their R&D budgets on pre-clinical functions (synthesis and extraction, biological screening and pharmacological testing, toxicology and safety testing, pharmaceutical dosage/formulation and stability). Clinical trials (Phase I, II and III) required for medicine approval account for 47.8% of R&D budgets while an additional 12.9% of R&D is spent on additional trials (pharmacovigilance) once the medicine has been approved by the regulatory authorities. In addition, 6.1% of R&D is allocated to the approval process.

#### **Allocation of R&D investments by function (%)**

|                              |      |
|------------------------------|------|
| Pre-human/Pre-clinical       | 27.2 |
| Clinical trials              | 47.8 |
| <i>Phase I</i>               | 6.7  |
| <i>Phase II</i>              | 13.1 |
| <i>Phase III</i>             | 28.0 |
| Approval                     | 6.1  |
| Pharmacovigilance (Phase IV) | 12.9 |
| Uncategorized                | 6.0  |

Source: PhRMA, Annual Membership Survey 2008 (percentages calculated from 2006 data)

#### **Changes in Research Sites (2001 – 2006)**

#### ***Graph***

|        | New research Sites | Closed Research Sites |
|--------|--------------------|-----------------------|
| Europe | 2                  | 18                    |
| USA    | 6                  | 5                     |
| Asia   | 14                 | 1                     |

Note: data collected from 22 global companies

Source: IMI (EFPIA Research Directors Group & IFPMA)

**Pharmaceutical R&D expenditure  
Value & Annual growth rate (%)**

*Graph)*

|      | Europe            |                                    | USA                |                                    |
|------|-------------------|------------------------------------|--------------------|------------------------------------|
|      | Value (€ million) | Annual<br>percentage<br>change (%) | Value (\$ million) | Annual<br>percentage<br>change (%) |
| 1990 | 7,766             | 9.0                                | 6,803              | 13.0                               |
| 1991 | 8,361             | 7.7                                | 7,929              | 16.5                               |
| 1992 | 9,459             | 13.1                               | 9,312              | 17.4                               |
| 1993 | 10,404            | 10.0                               | 10,477             | 12.5                               |
| 1994 | 11,082            | 6.5                                | 11,102             | 6.0                                |
| 1995 | 11,484            | 3.6                                | 11,874             | 7.0                                |
| 1996 | 12,465            | 8.5                                | 13,627             | 14.8                               |
| 1997 | 14,203            | 13.9                               | 15,466             | 13.9                               |
| 1998 | 15,032            | 5.8                                | 17,128             | 11.0                               |
| 1999 | 16,827            | 11.9                               | 18,471             | 7.4                                |
| 2000 | 17,849            | 6.1                                | 21,364             | 15.7                               |
| 2001 | 18,976            | 6.3                                | 23,502             | 10.0                               |
| 2002 | 20,334            | 7.2                                | 25,655             | 9.2                                |
| 2003 | 20,448            | 0.6                                | 27,065             | 5.5                                |
| 2004 | 21,205            | 3.7                                | 29,556             | 9.2                                |
| 2005 | 21,778            | 2.7                                | 30,969             | 4.8                                |
| 2006 | 24,759            | 13.7                               | 34,468             | 11.3                               |
| 2007 | 26,000            | 5.0                                | 35,394             | 2.7                                |

2007: estimate

Source: EFPIA, P/RMA

**DEVELOPING NEW CHEMICAL OR BIOLOGICAL ENTITIES (NCEs/NBEs)** - The European pharmaceutical industry has for many years been the world's leading inventor of new medicines. However, over the past decade, the United States has become the dominant player in the pharmaceutical sector, including R&D where Europe is under-represented in some crucial research fields such as biotechnology.

Between 1960 and 1965, European companies invented 65% of new chemical entities (NCEs) placed on the world market. Forty years later their share had fallen to 33%. The latest data available (period 2003-2007) show the predominance of the United States which has now become the leading inventor of new molecules in the world.

Twenty-five new molecular (chemical and biological) entities reached the world market for the first time in 2007. According to Adis R&D Insight Database, the overall number of medicines in active development at the end of 2007 amounted to 6,400.

**New chemical or biological entities (1988-2007)**

*Graph*

|           | Europe | USA | Japan | Others |
|-----------|--------|-----|-------|--------|
| 1988-1992 | 97     | 52  | 63    | 5      |
| 1993-1997 | 90     | 66  | 61    | 6      |
| 1998-2002 | 68     | 77  | 29    | 4      |
| 2003-2007 | 48     | 66  | 15    | 15     |

Source: SCRIP – EFPIA calculations (according to nationality of mother company)

**Number of new active substances launched on the world market over the last five years (2003-2007)**

*Graph*

|      |    |
|------|----|
| 2003 | 31 |
| 2004 | 23 |
| 2005 | 30 |
| 2006 | 35 |
| 2007 | 25 |

Source: SCRIP

**Origin of the 25 new molecular (chemical and biological) entities launched on the world market in 2007**

*Graph*

|        |    |
|--------|----|
| Europe | 10 |
| USA    | 12 |
| Japan  | 1  |
| Others | 2  |

Source: SCRIP - EFPIA calculations (according to nationality of mother company)

## RESEARCH & DEVELOPMENT AS A PERCENTAGE OF GROSS DOMESTIC PRODUCT

According to the latest Eurostat data, Research and Development expenditure represented 1.84% of the European Union's Gross Domestic Product (GDP) in 2006 against 1.86% in 2000. The EU goal in R&D expenditure, as set by the Lisbon summit strategy, is to achieve by 2010 a R&D intensity of at least 3% for the EU as a whole.

The gap with regard to R&D expenditure in the United States and Japan remains significant since these countries spent respectively 2.62% and 3.33% of their GDP on R&D. Among European countries, the lowest R&D ratios were registered in the southern countries and the new Member States, whilst Sweden and Finland, with respective shares of their GDP of 3.82% and 3.45%, made the greatest research effort.

### *Graph*

#### **R&D expenditure as a percentage of GDP (2006)**

|                |      |
|----------------|------|
| Austria        | 2.45 |
| Belgium        | 1.83 |
| Bulgaria       | 0.48 |
| Cyprus         | 0.42 |
| Czech Republic | 1.54 |
| Denmark        | 2.43 |
| Estonia        | 1.14 |
| Finland        | 3.45 |
| France         | 2.12 |
| Germany        | 2.51 |
| Greece         | 0.57 |
| Hungary        | 1.00 |
| Iceland        | 2.83 |
| Ireland        | 1.32 |
| Italy          | 1.10 |
| Latvia         | 0.69 |
| Lithuania      | 0.80 |
| Luxembourg     | 1.47 |
| Malta          | 0.55 |
| Netherlands    | 1.72 |
| Norway         | 1.51 |
| Poland         | 0.56 |
| Portugal       | 0.81 |
| Romania        | 0.46 |
| Slovakia       | 0.49 |
| Slovenia       | 1.59 |
| Spain          | 1.16 |

|                |             |
|----------------|-------------|
| Sweden         | 3.82        |
| Switzerland    | 2.93        |
| United Kingdom | 1.76        |
| <b>EU – 27</b> | <b>1.84</b> |
| China          | 1,34        |
| Japan          | 3,33        |
| USA            | 2,62        |

Note: Iceland, Switzerland: 2004 data

China, Italy, Japan, Portugal, United Kingdom, USA: 2005 data

Austria, Cyprus, Denmark, Estonia, France, Germany, Greece, Luxembourg, Malta,  
Netherlands, Slovenia, Spain: provisional data

EU-27: estimate

Source: EUROSTAT News release, 34/2008, 10 March 2008; ‘Science, technology and innovation  
in Europe’, 2008 edition, EUROSTAT



## **BIOPHARMACEUTICALS**

The major health challenges facing Europe require new technologies. The application of human genomics knowledge to clinical practice and drug development will allow us to predict a patient's response to treatment and create new "personalised" medicines according to genetic variations. The introduction of these new medicines will not only affect the global burden of disease but also the pattern of care and patient management, with an operational shift from acute treatment to prevention and cure.

Approximately one-fifth of the new molecular entities launched on the world market each year are now derived from biotechnology. Europe's biotechnology sector is growing fast, although still not as fast as its US counterpart.

In this context, competitive research is the key. The development of a strong and viable biomedical industry in Europe goes hand in hand with the maintenance of a competitive and innovative research-based industry in Europe. Accounting for 19% of the global business R&D expenditure, the research-based pharmaceutical industry can make a major contribution to the strategic goal set by the March 2000 Lisbon Council of turning Europe into *"the most competitive and dynamic knowledge-based economy in the world by 2010"*.

### **Biopharmaceuticals (2006)**

| Year 2006                                      | Global  | USA     | Europe | Canada | Asia-Pacific |
|--|---------|---------|--------|--------|--------------|
| Revenues (€ million)                           | 58,501  | 44,154  | 9,147  | 2,581  | 2,619        |
| R&D expenditure (€ million)                    | 22,119  | 18,205  | 2,891  | 705    | 319          |
| Net loss (€ million)                           | 4,336   | 2,760   | 896    | 417    | 264          |
| Number of employees (units)                    | 195,820 | 146,100 | 32,470 | 7,440  | 9,810        |
| Number of public and private companies (units) | 4,275   | 1,452   | 1,621  | 465    | 737          |

Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2007' (data relate only to publicly traded companies)

#### **About EBE**

European Biopharmaceutical Enterprises (EBE) is the European trade association that represents biopharmaceutical companies of all sizes operating in Europe. EBE was established in 2000 as a specialised group of EFPIA and is headquartered in Brussels. EBE actively promotes a favourable economic, business, scientific and regulatory environment for biopharmaceuticals in Europe and also provides a wide

range of value-added services to its 66 member companies. Membership in EBE is open to all companies using biotechnology to discover, develop and bring new medicinal products to market. Further details about EBE and its activities are available on [www.ebe-biopharma.org](http://www.ebe-biopharma.org)

### **Share of global biotechnology revenues, public companies (2006)**

|              |       |
|--------------|-------|
| USA          | 75.5% |
| Europe       | 15.6% |
| Canada       | 4.4%  |
| Asia/Pacific | 4.5%  |

Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2007' (data relate only to publicly traded companies)

### **Share of global biotechnology R&D expenses, public companies (2006)**

|              |       |
|--------------|-------|
| USA          | 82.3% |
| Europe       | 13.1% |
| Canada       | 3.2%  |
| Asia/Pacific | 1.4%  |

Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2007' (data relate only to publicly traded companies)

## **VACCINES**

Europe is the main manufacturing and research location for human-use vaccines. About 88.8% of the total production of the worldwide vaccine manufacturers originated from Europe in 2006. In terms of market sales, North America is the leading market accounting for nearly half of the value of worldwide vaccine sales (which was estimated to amount to € 9,722 million in 2006).

### **Worldwide major vaccine manufacturers market value (€ million – 2006)**

|                              |         |         |
|------------------------------|---------|---------|
| North America                | 4,852.7 | (49.9%) |
| Europe                       | 3,081.2 | (31.7%) |
| Specific/Humanitarian groups | 338.0   | (3.5%)  |
| Rest of the world            | 1,450.3 | (14.9%) |

Source: European Vaccine Manufacturers (EVM), 2008

The number of R&D projects (from pre-clinical stage to Phase III development) by major international vaccine manufacturers amounted to a total of 137 as of 31 December 2006. More than two thirds of the total number of R&D projects were located in Europe in 2006 (Europe: 97 projects; North America: 39 projects; Other countries: 1 project). Major international vaccine manufacturers altogether had 20 manufacturing sites and 22 R&D sites based in Europe in 2006.

### **(Graph)**

#### **Total number of R&D projects by international vaccine manufacturers**

Pre-clinical: 49

Phase I: 22

Phase II: 21

Phase III: 45

Source: European Vaccine Manufacturers (EVM), 2008

### **Number and location of manufacturing and R&D sites by international vaccine manufacturers in Europe (2006)**

|                | <b>Manufacturing</b> | <b>R&amp;D</b> |
|----------------|----------------------|----------------|
| Austria        | 2                    | 2              |
| Belgium        | 4                    | 5              |
| Czech Republic | 1                    |                |
| France         | 2                    | 3              |
| Germany        | 2                    | 2              |
| Hungary        | 1                    | 1              |

|              |           |           |
|--------------|-----------|-----------|
| Ireland      | 1         |           |
| Italy        | 1         | 2         |
| Netherlands  | 1         | 3         |
| Spain        | 1         |           |
| Sweden       | 1         | 1         |
| Switzerland  | 2         | 2         |
| U.K.         | 1         | 1         |
| <b>Total</b> | <b>20</b> | <b>22</b> |

Source: European Vaccine Manufacturers (EVM), 2008

### **About EVM**

The European Vaccine Manufacturers (EVM) were established within EFPIA in 1991 in order to promote a favourable climate for expanded vaccine protection and improved vaccine coverage in Europe. EVM members companies are actively engaged in research and development of new vaccines. Among the illnesses targeted by vaccines which recently received a marketing authorization are rotavirus diarrhoea, pneumococcal disease and cervical cancer caused by the human papilloma virus. EVM companies are also engaged in pre-clinical and clinical research against major infections such as HIV and malaria, and other diseases including cancers. Further details about EVM and its activities are available on [www.evm-vaccines.org](http://www.evm-vaccines.org)

## PHARMACEUTICAL EXPORTS

| <b>EFPIA 2006</b> | <b>€ million</b> |
|-------------------|------------------|
| Austria           | 4,252            |
| Belgium           | 30,448           |
| Bulgaria          | 119              |
| Cyprus            | 117              |
| Czech Republic    | 660              |
| Denmark           | 5,203            |
| Estonia           | 24               |
| Finland           | 764              |
| France            | 20,059           |
| Germany           | 35,784           |
| Greece            | 909              |
| Hungary           | 1,496            |
| Ireland           | 14,175           |
| Italy             | 11,159           |
| Latvia            | 154              |
| Lithuania         | 76               |
| Luxembourg        | 43               |
| Malta             | 98               |
| Netherlands       | 10,912           |
| Norway            | 417              |
| Poland            | 598              |
| Portugal          | 346              |
| Romania           | 43               |
| Slovakia          | 225              |
| Slovenia          | 1,172            |
| Spain             | 6,076            |
| Sweden            | 6,933            |
| Switzerland       | 29,639           |
| United Kingdom    | 20,415           |
| <b>Total</b>      | <b>202,316</b>   |

Note: All data based on SITC 54  
Norway, Switzerland: veterinary products excluded

Source: Eurostat (COMEXT database – December 2007)  
Norway, Switzerland: EFPIA member associations (official figures)

## **PHARMACEUTICAL TRADE**

### **PHARMACEUTICAL EXPORTS**

The pharmaceutical trade data reflect changes occurring in the manufacturing and distribution pattern of medicines within Europe since 2000. Over the last years several companies have reorganised their manufacturing and distribution services, which resulted in a significant increase of trade exchanges between some European countries, e.g. Belgium, Germany and Ireland.

In 2006 EFPIA countries' pharmaceutical exports totalled € 202,300 million. This amount also includes the trade flows between the EFPIA countries, which were estimated to € 123,600 million in 2006. Exports to non-EFPIA countries amounted to € 78,700 million, i.e. 38.9% of total exports. The European Union's main trading partners are the USA and Switzerland.

#### **Exports, imports and trade balance with respect to non-EU countries (2006 - € million)**

|                | Exports | Imports | Trade balance |
|----------------|---------|---------|---------------|
| Austria        | 2,278   | 1,391   | 887           |
| Belgium        | 10,993  | 3,529   | 7,464         |
| Bulgaria       | 89      | 84      | 5             |
| Cyprus         | 72      | 30      | 42            |
| Czech Republic | 154     | 218     | - 64          |
| Denmark        | 2,481   | 310     | 2,171         |
| Estonia        | 2       | 5       | - 3           |
| Finland        | 542     | 107     | 435           |
| France         | 9,267   | 4,102   | 5,165         |
| Germany        | 12,049  | 6,848   | 5,201         |
| Greece         | 59      | 504     | - 445         |
| Hungary        | 681     | 278     | 403           |
| Ireland        | 4,055   | 746     | 3,309         |
| Italy          | 4,333   | 4,101   | 232           |
| Latvia         | 77      | 85      | - 8           |
| Lithuania      | 23      | 13      | 10            |
| Luxembourg     | 0       | 2       | - 2           |
| Malta          | 10      | 19      | - 9           |
| Netherlands    | 3,547   | 4,776   | - 1,229       |
| Norway         | 75      | 219     | - 144         |
| Poland         | 222     | 407     | -185          |
| Portugal       | 104     | 242     | - 138         |
| Romania        | 17      | 281     | - 264         |
| Slovakia       | 70      | 108     | - 38          |

|                |        |        |        |
|----------------|--------|--------|--------|
| Slovenia       | 682    | 103    | 579    |
| Spain          | 2,368  | 1,584  | 784    |
| Sweden         | 3,513  | 433    | 3,080  |
| Switzerland    | 11,582 | 2,233  | 9,349  |
| United Kingdom | 9,372  | 4,874  | 4,498  |
| EFPIA total    | 78,717 | 37,632 | 41,085 |

Note: All data based on SITC 54  
Norway, Switzerland: veterinary products excluded

Source: Eurostat (COMEXT database – December 2007)  
Norway, Switzerland: EFPIA member associations (official figures)

***(pie charts)***

**The European Union's top 5 pharmaceutical trading partners - 2006**

EU exports

|             |       |
|-------------|-------|
| USA         | 34.4% |
| Switzerland | 13.7% |
| Russia      | 5.3%  |
| Canada      | 4.8%  |
| Japan       | 4.5%  |
| Others      | 37.3% |

EU imports

|             |       |
|-------------|-------|
| USA         | 43.7% |
| Switzerland | 38.8% |
| Japan       | 3.5%  |
| China       | 2.5%  |
| Singapore   | 2.2%  |
| Others      | 9.3%  |

Source: Eurostat, SITC 54

## PHARMACEUTICAL IMPORTS

| <b>EFPIA 2006</b> | <b>€ million</b> |
|-------------------|------------------|
| Austria           | 3,914            |
| Belgium           | 28,102           |
| Bulgaria          | 405              |
| Cyprus            | 161              |
| Czech Republic    | 1,753            |
| Denmark           | 2,086            |
| Estonia           | 171              |
| Finland           | 1,580            |
| France            | 14,867           |
| Germany           | 27,591           |
| Greece            | 2,939            |
| Hungary           | 1,645            |
| Ireland           | 2,229            |
| Italy             | 12,419           |
| Latvia            | 310              |
| Lithuania         | 372              |
| Luxembourg        | 257              |
| Malta             | 77               |
| Netherlands       | 10,673           |
| Norway            | 1,134            |
| Poland            | 3,035            |
| Portugal          | 1,836            |
| Romania           | 1,254            |
| Slovakia          | 850              |
| Slovenia          | 499              |
| Spain             | 7,667            |
| Sweden            | 2,539            |
| Switzerland       | 13,695           |
| United Kingdom    | 13,881           |
| <b>Total</b>      | <b>157,941</b>   |

Note: All data based on SITC 54  
Norway, Switzerland: veterinary products excluded

Source: Eurostat (COMEXT database – December 2007)  
Norway, Switzerland: EFPIA member associations (official figures)



## PHARMACEUTICAL IMPORTS

In 2006 pharmaceutical imports of EFPIA countries totalled € 157,900 million, of which 23.8% originate from non-EU countries. The European Union's major trading partners are the USA, Switzerland, and Japan. In 2006 these three countries supplied 86.0% of the EU-27 imports, and purchased 53.4% of its exports.

Pharmaceuticals contribute significantly to reducing the European Union's trade deficit in high-tech products. Pharmaceuticals represented 5.8% of total EU manufacturing exports in 2006 against 2.1% in 1990.

### EU trade in high-tech products (2006 - € million)

|  | EU<br>exports | EU<br>imports | EU trade<br>balance |
|--|---------------|---------------|---------------------|
| Pharmaceutical products (SITC 54)                        | 67,028        | 35,177        | 31,851              |
| Power generating machinery and equipment (SITC 71)       | 45,837        | 28,837        | 17,000              |
| Office machines and computers (SITC 75)                  | 29,122        | 80,396        | -51,274             |
| Telecommunication, sound, TV, video (SITC 76)            | 40,843        | 71,040        | -30,197             |
| Electrical machinery (SITC 77)                           | 78,366        | 79,382        | -1,016              |
| Professional, scientific, controlling material (SITC 87) | 32,821        | 27,224        | 5,597               |
| Total high tech sectors                                  | 294,017       | 322,056       | 28,039              |
| Total manufacturing sectors                              | 1,159,211     | 1,351,445     | 192,234             |

Source: Eurostat, External and intra-European Union trade, Monthly statistics, Issue number 4/2008

### EU trade in high-tech products (1990 - € million)

|  | EU<br>exports | EU<br>imports | EU trade<br>balance |
|--|---------------|---------------|---------------------|
| Pharmaceutical products (SITC 54)                        | 7,728         | 4,121         | 3,607               |
| Power generating machinery and equipment (SITC 71)       | 13,644        | 9,522         | 4,122               |
| Office machines and computers (SITC 75)                  | 7,789         | 22,080        | -14,291             |
| Telecommunication, sound, TV, video (SITC 76)            | 5,969         | 14,044        | -8,075              |
| Electrical machinery (SITC 77)                           | 17,690        | 17,933        | -243                |
| Professional, scientific, controlling material (SITC 87) | 8,647         | 8,159         | 488                 |
| Total high tech sectors                                  | 61,467        | 75,859        | -14,392             |
| Total manufacturing sectors                              | 355,164       | 404,351       | -49,187             |

Source: Eurostat

*(pie chart)*

### Share of pharmaceuticals in high-tech products exports (2007)

|  |       |
|--|-------|
| Pharmaceutical products (SITC 54)                        | 23.7% |
| Power generating machinery and equipment (SITC 71)       | 16.9% |
| Office machines and computers (SITC 75)                  | 8.9%  |
| Telecommunication, sound, TV, video (SITC 76)            | 12.6% |
| Electrical machinery (SITC 77)                           | 26.7% |
| Professional, scientific, controlling material (SITC 87) | 11.2% |

Source: Eurostat, External and intra-European Union trade, Monthly statistics, Issue number 4/2008

*(pie chart)*

### Share of pharmaceuticals in high-tech products imports (2007)

|  |       |
|--|-------|
| Pharmaceutical products (SITC 54)                        | 11.1% |
| Power generating machinery and equipment (SITC 71)       | 9.9%  |
| Office machines and computers (SITC 75)                  | 21.3% |
| Telecommunication, sound, TV, video (SITC 76)            | 24.7% |
| Electrical machinery (SITC 77)                           | 24.7% |
| Professional, scientific, controlling material (SITC 87) | 8.3%  |

Source: Eurostat, External and intra-European Union trade, Monthly statistics, Issue number 4/2008

## PHARMACEUTICAL TRADE BALANCE

### EFPIA 2006 € million

|                |               |
|----------------|---------------|
| Austria        | 338           |
| Belgium        | 2,346         |
| Bulgaria       | - 286         |
| Cyprus         | - 44          |
| Czech Republic | - 1,093       |
| Denmark        | 3,117         |
| Estonia        | - 147         |
| Finland        | - 816         |
| France         | 5,192         |
| Germany        | 8,193         |
| Greece         | - 2,030       |
| Hungary        | - 149         |
| Ireland        | 11,946        |
| Italy          | - 1,260       |
| Latvia         | - 156         |
| Lithuania      | - 296         |
| Luxembourg     | - 214         |
| Malta          | 21            |
| Netherlands    | 239           |
| Norway         | - 717         |
| Poland         | - 2,437       |
| Portugal       | - 1,490       |
| Romania        | - 1,211       |
| Slovakia       | - 625         |
| Slovenia       | 673           |
| Spain          | - 1,591       |
| Sweden         | 4,394         |
| Switzerland    | 15,944        |
| United Kingdom | 6,534         |
| <b>Total</b>   | <b>44,375</b> |

Note: All data based on SITC 54  
Norway, Switzerland: veterinary products excluded

Source: Eurostat (COMEXT database – December 2007)  
Norway, Switzerland: EFPIA member associations (official figures)

## PHARMACEUTICAL TRADE BALANCE

Europe is a net exporter of medicines. The European pharmaceutical industry generates a substantial trade surplus, which amounted to € 44,400 million in 2006. Over the period 1990-2006 the total pharmaceutical trade surplus grew by 6.3 times, from € 7,100 million in 1990 to € 44,400 million in 2006.

In several European countries, the pharmaceutical industry ranks among the top five net exporters in the manufacturing sector. At European level, the pharmaceutical industry is the leading high-technology sector in terms of trade surplus.

### European total pharmaceutical exports, imports, and trade balance for 1990-2007 (€ million)

| Year | Total exports | Total imports | Trade surplus |
|------|---------------|---------------|---------------|
| 1990 | 23,180        | 16,113        | 7,067         |
| 1995 | 44,188        | 31,018        | 13,170        |
| 2000 | 90,935        | 68,841        | 22,094        |
| 2005 | 181,575       | 145,823       | 35,752        |
| 2006 | 202,316       | 157,941       | 44,375        |
| 2007 | 210,000 (e)   | 161,000 (e)   | 49,000 (e)    |

Note: (e): EFPIA estimate  
All data based on SITC 54  
Norway, Switzerland: veterinary products excluded

Source: Eurostat  
Norway, Switzerland: EFPIA member associations (official figures)

### EU-27 trade balance - High technology sectors (€ million) - 2007

|         |  |         |
|---------|--|---------|
| SITC 54 | Pharmaceutical products                        | 37,483  |
| SITC 71 | Power generating machinery and equipment       | 20,144  |
| SITC 75 | Office machines and computers                  | -41,003 |
| SITC 76 | Telecommunication, sound, TV, video            | -40,212 |
| SITC 77 | Electrical machinery                           | 3,204   |
| SITC 87 | Professional, scientific, controlling material | 8,233   |

Source: Eurostat, External and intra-European Union trade, Monthly statistics, Issue number 4/2008

## EMPLOYMENT IN THE PHARMACEUTICAL INDUSTRY

| <b>EFPIA 2006</b> | <b>Units</b>   |
|-------------------|----------------|
| Austria           | 9,593          |
| Belgium           | 29,155         |
| Bulgaria          | n.a.           |
| Cyprus            | n.a.           |
| Czech Republic    | n.a.           |
| Denmark           | 17,286         |
| Estonia           | n.a.           |
| Finland           | 6,110          |
| France            | 103,350        |
| Germany           | 113,200        |
| Greece            | 11,450         |
| Hungary           | n.a.           |
| Iceland           | n.a.           |
| Ireland           | 24,500         |
| Italy             | 74,726         |
| Latvia            | n.a.           |
| Lithuania         | n.a.           |
| Malta             | 445            |
| Netherlands       | 16,200         |
| Norway            | 4,691          |
| Poland            | 30,000         |
| Portugal          | 10,581         |
| Romania           | 20,000         |
| Slovakia          | 1,800          |
| Slovenia          | 6,500          |
| Spain             | 39,117         |
| Sweden            | 18,434         |
| Switzerland       | 34,000         |
| United Kingdom    | 72,000         |
| <b>Total</b>      | <b>643,138</b> |

Note: Malta, Poland: 2004 data

Austria, Netherlands: 2005 data

Belgium, France, Greece, Ireland, Italy, Netherlands, Norway, Poland, Romania, Slovenia, Sweden, United Kingdom: estimate

Source: EFPIA member associations (official figures)

## **PHARMACEUTICAL EMPLOYMENT**

The research-based pharmaceutical industry is one of Europe's major high-technology industrial employers. Recent studies carried out in some countries showed that the research-based pharmaceutical industry generates three to four times more employment indirectly - upstream and downstream - than it does directly, a significant proportion being high value added jobs (e.g. clinical science, universities, etc).

The industry directly employs about 643,100 people, of which 107,000 work in R&D. Through R&D activities carried out in close co-operation with universities and hospitals, the pharmaceutical industry funds the work of thousands of researchers in universities and healthcare centres.

### **Employment in pharmaceutical R&D (1985-2007)      *(Main graph)***

|      |             |
|------|-------------|
| 1985 | 63,000      |
| 1990 | 75,760      |
| 1995 | 82,282      |
| 2000 | 88,524      |
| 2001 | 93,572      |
| 2002 | 101,663     |
| 2003 | 100,062     |
| 2004 | 103,815     |
| 2005 | 100,013     |
| 2006 | 106,974     |
| 2007 | 107,000 (e) |

Note: Data include Slovenia (since 2004) and Romania (since 2005)  
Bulgaria, Cyprus, Czech Republic, Estonia, Greece, Hungary, Iceland, Latvia, Lithuania, Malta, Poland, Portugal, Slovakia: data not available

Source: EFPIA member associations - (e): EFPIA estimate

### **Employment in the pharmaceutical industry (1985-2007)      *(graph)***

|      |             |
|------|-------------|
| 1985 | 439,090     |
| 1990 | 500,879     |
| 1995 | 506,052     |
| 2000 | 538,438     |
| 2005 | 635,937     |
| 2006 | 643,138     |
| 2007 | 645,000 (e) |

Note: As of 2005 data include Malta, Poland, Romania, Slovakia and Slovenia

Source: EFPIA member associations (official figures) - (e): EFPIA estimate

**PAYMENT FOR PHARMACEUTICALS BY COMPULSORY HEALTH INSURANCE SYSTEMS AND NATIONAL HEALTH SERVICES (ambulatory care only)**

| <b><u>EFPIA 2006</u></b> | <b><u>€ million</u></b> |
|--------------------------|-------------------------|
| Austria                  | 1,809                   |
| Belgium                  | 2,633                   |
| Bulgaria                 | n.a.                    |
| Cyprus                   | n.a.                    |
| Czech Republic           | 1,196                   |
| Denmark                  | 933                     |
| Estonia                  | 62                      |
| Finland                  | 1,100                   |
| France                   | 20,340                  |
| Germany                  | 25,874                  |
| Greece                   | 3,193                   |
| Hungary                  | 1,147                   |
| Iceland                  | n.a.                    |
| Ireland                  | 1,547                   |
| Italy                    | 12,327                  |
| Latvia                   | 62                      |
| Lithuania                | n.a.                    |
| Malta                    | n.a.                    |
| Netherlands              | 4,353                   |
| Norway                   | 1,101                   |
| Poland                   | 1,351                   |
| Portugal                 | 1,425                   |
| Romania                  | 477                     |
| Slovakia                 | 709                     |
| Slovenia                 | 211                     |
| Spain                    | 10,504                  |
| Sweden                   | 1,870                   |
| Switzerland              | 2,733                   |
| United Kingdom           | 10,887                  |
| <b>Total</b>             | <b>107,844</b>          |

Note: France, Greece, Ireland, Netherlands, Norway, Sweden, United Kingdom: estimate  
Hungary, Poland: 2004 data

Source : EFPIA member associations (official figures)

## **PHARMACEUTICAL REIMBURSEMENT**

Pharmaceutical reimbursement refers to the share of medicine costs paid by the state through a compulsory social security system or by health insurance funds, according to the statutory national system.

In most European countries only prescribed products are reimbursed, although arrangements differ widely from country to country. Not all medicines are reimbursed, and few are reimbursed in full (except, in most countries, when they are dispensed in hospitals). Some countries limit reimbursement to a proportion of the price of the prescribed medicine whilst others reimburse a flat-rate amount according to packaging or prescription. Most countries operate a co-payment system, which requires patients to meet part of the cost of their prescribed treatment. There are also over-the-counter (OTC) products, which are bought by patients at their own initiative and expense.

**Estimated costs paid by the patient in the total reimbursed pharmacy market value at retail prices (in %) – 2006** *(graph)*

|                                     | Costs paid by the patient (%) | Costs paid by compulsory health insurance systems (%) |
|-------------------------------------|-------------------------------|---|
| Austria                             | 17.0                          | 83.0  |
| Belgium                             | 15.9                          | 84.1  |
| Denmark                             | 40.4                          | 59.6  |
| Estonia                             | 36.7                          | 63.3  |
| Finland                             | 30.7                          | 69.3  |
| France                              | 1.0                           | 99.0  |
| Germany                             | 7.1                           | 92.9  |
| Greece                              | 13.6                          | 86.4  |
| Hungary                             | 19.9                          | 80.1  |
| Ireland                             | 9.4                           | 90.6  |
| Italy                               | 3.2                           | 96.8  |
| Netherlands                         | 0.5                           | 99.5  |
| Norway                              | 10.7                          | 89.3  |
| Portugal                            | 33.3                          | 66.7  |
| Romania                             | 39.4                          | 60.6  |
| Slovakia                            | 13.4                          | 86.6  |
| Slovenia                            | 38.3                          | 61.7  |
| Spain                               | 7.0                           | 93.0  |
| Sweden                              | 22.4                          | 77.6  |
| Switzerland                         | 10.0                          | 90.0  |
| United Kingdom                      | 6.7                           | 93.3  |
| <b>EFPIA (non-weighted average)</b> | <b>17.9</b>                   | <b>82.1</b>   |

Note: France: costs paid by compulsory health insurance system include costs paid by supplementary insurance (mutual or private), which amount to about 20.1% of total costs.



Hungary: 2004 data  
Greece: 2005 data  
EFPIA calculations – Estimate

Source: EFPIA member associations

## PERCENTAGE OF ELDERLY PEOPLE (65 AND OVER) IN TOTAL POPULATION

| Country        | 1960       | 1970        | 1980        | 1990        | 2000        | 2010        | 2020        |
|----------------|------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Austria        | 12.0       | 14.1        | 15.4        | 14.9        | 15.5        | 17.5        | 19.8        |
| Belgium        | 12.0       | 13.3        | 14.4        | 14.9        | 16.9        | 17.6        | 20.5        |
| Bulgaria       | 7.5        | 9.6         | 11.9        | 13.1        | 16.6        | 17.7        | 20.6        |
| Cyprus         | 5.9        | 10.1        | 10.3        | 10.9        | 11.3        | 13.0        | 15.5        |
| Czech Republic | 9.3        | 12.1        | 13.4        | 12.5        | 13.8        | 15.6        | 20.5        |
| Denmark        | 10.6       | 12.3        | 14.4        | 15.6        | 14.8        | 16.7        | 20.2        |
| Estonia        | 10.5       | 11.7        | 12.5        | 11.4        | 15.0        | 16.7        | 18.3        |
| Finland        | 7.2        | 9.2         | 12.0        | 13.4        | 14.9        | 17.1        | 22.2        |
| France         | 11.6       | 12.9        | 14.0        | 14.0        | 16.3        | 16.5        | 20.2        |
| Germany        | 11.5       | 13.7        | 15.6        | 15.0        | 16.4        | 20.5        | 22.4        |
| Greece         | 8.3        | 11.1        | 13.1        | 13.7        | 16.7        | 18.8        | 21.1        |
| Hungary        | 9.0        | 11.6        | 13.4        | 13.3        | 14.7        | 16.1        | 19.5        |
| Iceland        | 8.0        | 8.8         | 10.1        | 10.6        | 11.7        | 12.7        | 16.1        |
| Ireland        | 11.2       | 11.2        | 10.7        | 11.4        | 11.2        | 11.3        | 13.6        |
| Italy          | 9.3        | 10.9        | 13.1        | 15.3        | 18.2        | 20.6        | 23.2        |
| Latvia         | 10.5       | 11.9        | 13.0        | 11.6        | 15.3        | 17.6        | 18.7        |
| Lithuania      | 7.7        | 10.0        | 11.3        | 10.9        | 13.9        | 16.2        | 17.7        |
| Luxembourg     | 10.8       | 12.7        | 13.7        | 13.5        | 14.2        | 14.1        | 15.2        |
| Malta          | 7.4        | 8.9         | 9.9         | 10.6        | 12.3        | 14.8        | 19.7        |
| Netherlands    | 9.0        | 10.2        | 11.5        | 12.8        | 13.6        | 15.4        | 20.0        |
| Norway         | 11.1       | 12.9        | 14.8        | 16.3        | 15.2        | 15.3        | 18.4        |
| Poland         | 5.8        | 8.2         | 10.1        | 10.1        | 12.2        | 13.6        | 18.5        |
| Portugal       | 8.0        | 9.2         | 10.5        | 13.4        | 16.1        | 17.5        | 19.8        |
| Romania        | 6.7        | 8.6         | 10.3        | 10.4        | 13.5        | 14.9        | 17.5        |
| Slovakia       | 6.7        | 9.2         | 10.4        | 10.3        | 11.4        | 12.3        | 16.4        |
| Slovenia       | 7.8        | 9.9         | 11.4        | 11.1        | 14.1        | 16.5        | 20.8        |
| Spain          | 8.2        | 9.8         | 11.2        | 13.5        | 16.8        | 17.3        | 19.5        |
| Sweden         | 12.0       | 13.7        | 16.3        | 17.8        | 17.2        | 18.4        | 21.1        |
| Switzerland    | 10.1       | 11.3        | 13.8        | 14.4        | 14.6        | 17.0        | 20.0        |
| Turkey         | 3.4        | 4.3         | 4.6         | 4.0         | 5.2         | 5.9         | 7.6         |
| United Kingdom | 11.9       | 13.2        | 15.1        | 15.9        | 15.8        | 16.6        | 18.9        |
| <b>EU-27*</b>  | <b>9.9</b> | <b>11.6</b> | <b>13.3</b> | <b>13.9</b> | <b>15.7</b> | <b>17.5</b> | <b>20.3</b> |
| USA            | 9.2        | 9.8         | 11.2        | 12.2        | 12.3        | 12.8        | 15.8        |
| Japan          | 5.7        | 7.1         | 9.0         | 12.0        | 17.2        | 22.5        | 28.4        |
| <b>World**</b> | <b>5.3</b> | <b>5.4</b>  | <b>5.9</b>  | <b>6.1</b>  | <b>6.9</b>  | <b>7.7</b>  | <b>9.4</b>  |

\* weighted average for EU-27 countries

\*\* weighted average

Note: Figures for the years 2010 and 2020 are United Nations projections.

Source: World Population Prospects (United Nations), OHE

## **PHARMACEUTICAL SPENDING**

On average, total pharmaceutical spending accounts for 16.6% of total health expenditure in Europe. According to OECD figures, the share of pharmaceutical spending in total health expenditure shrank by one fourth between 1970 and 1980. Since then, pharmaceutical spending has grown at a slightly higher rate than that of health spending as a whole.

### **Share of total pharmaceutical spending in total health spending (%)**

|               | <b>1970</b> | <b>1980</b> | <b>1990</b> | <b>1995</b> | <b>2000</b> | <b>2005</b> |
|---------------|-------------|-------------|-------------|-------------|-------------|-------------|
| <b>Europe</b> | <b>17.3</b> | <b>13.4</b> | <b>13.2</b> | <b>15.0</b> | <b>16.1</b> | <b>16.6</b> |
| United States | 12.3        | 9.0         | 9.2         | 8.9         | 11.7        | 12.4        |
| Japan         | -           | 21.2        | 21.4        | 22.3        | 18.7        | 19.0*       |

\* 2004 data

Source: OECD Health Data 2007, Statistics and Indicators for 30 Countries, October 2007 – EFPIA calculations (non-weighted average for 17 EU & EFTA countries)

Factors related to both supply and demand explain the growth in pharmaceutical spending. On the supply side, the industry has added to, and substantially improved, its range of treatments. On the demand side, a combination of socio-economic factors, in particular population ageing, has fuelled a steady increase in this spending.

Medicines remain a prime target of Member States' healthcare cost-containment policies. Most of these policies take little account of the structural factors underlying the growth in health care and pharmaceutical spending. For example, several European countries fix an overall budget or seek to impose percentage limits on growth in pharmaceutical spending. These budgets or growth targets for medicines spending are at levels which do not take into consideration the ageing population and the desire of patients to have access to new innovative treatments.

## Percentage of very elderly people (75 and over) in total population

|                | 1960       | 1970       | 1980       | 1990       | 2000       | 2010       | 2020       |
|----------------|------------|------------|------------|------------|------------|------------|------------|
| <b>EU-27*</b>  | <b>3.3</b> | <b>3.9</b> | <b>5.0</b> | <b>6.1</b> | <b>6.8</b> | <b>8.3</b> | <b>9.4</b> |
| USA            | 3.1        | 3.8        | 4.5        | 5.0        | 5.8        | 6.0        | 6.5        |
| Japan          | 1.8        | 2.1        | 3.1        | 4.8        | 7.0        | 10.8       | 14.6       |
| <b>World**</b> | <b>1.6</b> | <b>1.7</b> | <b>1.9</b> | <b>2.2</b> | <b>2.4</b> | <b>3.0</b> | <b>3.5</b> |

\* weighted average for EU-27 countries

\*\* weighted average

Note: Figures for the years 2010 and 2020 are United Nations projections.

Source: World Population Prospects (United Nations), OHE

## TOTAL SPENDING (PUBLIC AND PRIVATE) ON HEALTH CARE AS A PERCENTAGE OF GDP AT MARKET PRICES

|                | 1960       | 1970       | 1980       | 1990       | 2000       | 2005       |
|----------------|------------|------------|------------|------------|------------|------------|
| Austria        | 4.3        | 5.2        | 7.5        | 7.0        | 10.0       | 10.2       |
| Belgium        | -          | 3.9        | 6.3        | 7.2        | 8.6        | 10.3*      |
| Czech Republic | -          | -          | -          | 4.7        | 6.5        | 7.2        |
| Denmark        | -          | -          | 8.9        | 8.3        | 8.3        | 9.1*       |
| Finland        | 3.8        | 5.5        | 6.3        | 7.7        | 6.6        | 7.5        |
| France         | 3.8        | 5.4        | 7.0        | 8.4        | 9.6        | 11.1       |
| Germany        | -          | 6.0        | 8.4        | 8.3        | 10.3       | 10.7       |
| Greece         | -          | 4.7        | 5.1        | 5.8        | 9.3        | 10.1       |
| Hungary        | -          | -          | -          | -          | 6.9        | 8.1*       |
| Iceland        | 3.0        | 4.7        | 6.3        | 7.8        | 9.3        | 9.3        |
| Ireland        | 3.7        | 5.1        | 8.3        | 6.1        | 6.3        | 7.5        |
| Italy          | -          | -          | -          | 7.7        | 8.1        | 9.0        |
| Luxembourg     | -          | 3.1        | 5.2        | 5.4        | 5.8        | 7.4*       |
| Netherlands    | -          | -          | 7.5        | 8.0        | 8.0        | 9.2        |
| Norway         | 2.9        | 4.4        | 7.0        | 7.6        | 8.4        | 8.7        |
| Poland         | -          | -          | -          | 4.8        | 5.5        | 6.2*       |
| Portugal       | -          | 2.5        | 5.3        | 5.9        | 8.8        | 10.2       |
| Slovakia       | -          | -          | -          | -          | 5.5        | 7.1        |
| Spain          | 1.5        | 3.5        | 5.3        | 6.5        | 7.2        | 8.3        |
| Sweden         | -          | 6.8        | 9.0        | 8.3        | 8.4        | 9.1        |
| Switzerland    | 4.9        | 5.5        | 7.4        | 8.3        | 10.4       | 11.3*      |
| United Kingdom | 3.9        | 4.5        | 5.6        | 6.0        | 7.3        | 8.3        |
| <b>Europe</b>  | <b>3.5</b> | <b>4.7</b> | <b>6.8</b> | <b>7.0</b> | <b>8.0</b> | <b>8.9</b> |
| USA            | 5.1        | 7.0        | 8.8        | 11.9       | 13.2       | 15.3       |
| Japan          | 3.0        | 4.6        | 6.5        | 6.0        | 7.7        | 8.0        |

\* estimate

Note: Iceland, Italy, Luxembourg, Norway, Switzerland: 2006 data

Hungary, Netherlands, Japan: 2004 data

Europe: non-weighted average (22 countries) – EFPIA calculations

Source: OECD Health Data 2007 Statistics and Indicators for 30 Countries, October 2007

## **HEALTH CARE EXPENDITURE**

Over the last 40 years the growth in health care spending has outstripped that of gross domestic product in all industrialised countries. After accelerating sharply in the 1960s and 1970s, the rate of growth in health spending declined substantially at the end of the 1980s. Public health spending grew faster than total health spending until the end of the 1970s. By the beginning of the 1980s, health cost containment policies had begun to stabilize the share of public spending in total health spending.

The latest available OECD data show that European countries spent on average 8.9% of their gross domestic product on health care in 2005. The US continues to top the OECD ranking for overall healthcare spending at \$ 6,401 (€ 5,145) per capita in 2005, more than twice the European average. Although more than half of this spending is financed through private spending, public spending per capita in the US is quite high and amounts to levels equivalent to those of most European countries.

### ***Chart***

|      | Total expenditure (public and private)<br>on health per capita<br>(\$ PPP) |       |        | Public expenditure on health per<br>capita<br>(\$ PPP) |       |        |
|------|--|-------|--------|--|-------|--------|
|      | Europe   | USA   | Japan  | Europe   | USA   | Japan  |
| 1970 | 181  | 347   | 150    | 128  | 127   | 105    |
| 1980 | 671  | 1,055 | 583    | 524  | 439   | 416    |
| 1990 | 1,241  | 2,738 | 1,121  | 908  | 1,080 | 870    |
| 2000 | 2,031  | 4,539 | 1,967  | 1,529  | 1,995 | 1,599  |
| 2005 | 2,857  | 6,401 | 2,358* | 2,157  | 2,884 | 1,927* |

\* 2004 data

Note: Europe: non-weighted average – EFPIA calculations

Source: OECD Health Data 2007, Statistics and Indicators for 30 Countries, October 2007

In any industrialized country, the share of income spent on health care generally rises with income itself. However, increased incomes and living standards do not by themselves explain the growth in health care spending. This growth is in fact due to several factors, including:

- population ageing;
- population increase;
- growing proportion of health care dispensed in hospitals and psychiatric institutions;
- widening range of treatments available and technological progress;
- widening social security cover, which is now available to almost the entire population in European countries.

**CAUSES OF MORTALITY**  
**NUMBER OF DEATHS (per 100,000 population), 2004**

|                   | All causes<br>of death | Malignant<br>neoplasms | Cerebro-<br>vascular<br>diseases | Diseases<br>respiratory<br>systems | Diabetes<br>Mellitus | Infectuous,<br>parasitic<br>diseases |
|-------------------|------------------------|------------------------|----------------------------------|------------------------------------|----------------------|--------------------------------------|
| <b>Europe</b>     | <b>693.1</b>           | <b>187.3</b>           | <b>66.7</b>                      | <b>50.5</b>                        | <b>14.3</b>          | <b>8.0</b>                           |
| Austria           | 571.5                  | 157.0                  | 38.3                             | 33.3                               | 27.1                 | 5.5                                  |
| Belgium           | n.a.                   | n.a.                   | n.a.                             | n.a.                               | n.a.                 | n.a.                                 |
| Czech Republic    | 806.0                  | 218.0                  | 106.5                            | 35.4                               | 10.0                 | 2.6                                  |
| Denmark           | 713.0                  | 209.3                  | 56.9                             | 65.1                               | 17.1                 | 5.1                                  |
| Finland           | 598.8                  | 137.8                  | 53.7                             | 34.7                               | 7.0                  | 4.3                                  |
| France            | 572.0                  | 170.2                  | 34.5                             | 32.9                               | 11.9                 | 11.5                                 |
| Germany           | 592.6                  | 161.2                  | 45.4                             | 36.1                               | 16.2                 | 8.3                                  |
| Greece            | 621.0                  | 153.7                  | 98.5                             | 43.5                               | 5.8                  | 4.0                                  |
| Hungary           | 982.3                  | 244.8                  | 129.5                            | 39.3                               | 18.4                 | 3.7                                  |
| Iceland           | 510.8                  | 154.8                  | 41.1                             | 36.4                               | 6.0                  | 4.1                                  |
| Ireland           | 588.9                  | 173.8                  | 40.9                             | 79.4                               | 10.0                 | 3.6                                  |
| Italy             | 541.4                  | 167.3                  | 55.4                             | 31.3                               | 16.4                 | 4.6                                  |
| Luxembourg        | 578.0                  | 156.8                  | 53.4                             | 45.6                               | 7.1                  | 11.9                                 |
| Netherlands       | 598.2                  | 182.2                  | 45.2                             | 52.7                               | 16.3                 | 8.3                                  |
| Norway            | 553.0                  | 161.2                  | 45.4                             | 42.6                               | 8.1                  | 7.1                                  |
| Poland            | 819.6                  | 201.4                  | 88.1                             | 37.8                               | 11.3                 | 5.2                                  |
| Portugal          | 686.8                  | 151.3                  | 111.2                            | 55.9                               | 27.8                 | 17.4                                 |
| Slovakia          | 915.6                  | 200.0                  | 84.9                             | 52.2                               | 12.8                 | 3.6                                  |
| Spain             | 533.4                  | 155.3                  | 44.0                             | 50.5                               | 13.2                 | 11.3                                 |
| Sweden            | 566.2                  | 148.8                  | 53.1                             | 36.2                               | 11.6                 | 7.1                                  |
| Switzerland       | 489.5                  | 142.3                  | 29.2                             | 28.8                               | 12.0                 | 5.3                                  |
| United<br>Kingdom | 610.4                  | 175.6                  | 55.9                             | 74.1                               | 7.1                  | 6.3                                  |
| Japan             | 439.0                  | 145.1                  | 50.7                             | 55.0                               | 5.5                  | 9.5                                  |
| USA               | 666.7                  | 166.3                  | 39.9                             | 61.5                               | 20.9                 | 18.0                                 |

Note: Europe: non-weighted average – EFPIA calculations  
Austria, Ireland: 2005 data; France, Hungary, Portugal: 2003 data; Italy, Slovakia, Sweden,  
USA: 2002 data; Denmark: 2001 data

Source: OECD Health Data 2007, Statistics and Indicators for 30 Countries, October 2007



## **HEALTH STATUS & VALUE OF MEDICINES**

Medicine has played a central role in health care and therapeutic practice since the earliest times. Medicines have greatly contributed to the increase in life expectancy, to the improvement of quality of life and to the eradication of diseases which were previously life threatening. In the debate on the future of the health care system in various European countries, and the funding pressures health systems face in meeting the needs and expectations of the population, medicines have a key role to play. There is strong evidence in health outcomes research literature of the added value of medicines in the health care context, not only in terms of global cost savings but also in terms of contribution to the quality of care.

Major advances in scientific knowledge and, particularly, in modern medicines offer entirely new opportunities to treat diseases and ill health. Spending on medicines actually reduces the overall cost of disease treatment by cutting or eliminating the burden in other sectors of state expenditure and speeding up the delivery of health care. On the eve of major health care reform discussions in Europe, governments must look beyond the short term and invest in medicines for the future. The rewards – and savings – by increased spending on medicines might not be immediate but will be far higher than short-term cost cutting.

### **Average length of stay for acute care (days), 2005**

### ***Graph***

|                |     |
|----------------|-----|
| Austria        | 5.9 |
| Belgium        | 7.1 |
| Czech Republic | 8.0 |
| Denmark        | 3.5 |
| Finland        | 4.8 |
| France         | 5.4 |
| Germany        | 8.6 |
| Greece         | 6.2 |
| Hungary        | 6.3 |
| Iceland        | 5.4 |
| Ireland        | 6.6 |
| Italy          | 6.8 |
| Luxembourg     | 7.3 |
| Netherlands    | 6.8 |
| Norway         | 5.2 |
| Poland         | 6.5 |
| Portugal       | 7.1 |
| Slovakia       | 7.3 |
| Spain          | 6.7 |
| Sweden         | 4.6 |
| Switzerland    | 8.5 |

|                |            |
|----------------|------------|
| United Kingdom | 6.1        |
| <b>Europe</b>  | <b>6.4</b> |
| United States  | 5.6        |

Note: Belgium, Italy, Spain: 2004 data

Europe: non-weighted average – EFPIA calculations

Source: OECD Health Data 2007, Statistics and Indicators for 30 Countries, October 2007

*(pie chart)*

### **Rheumatoid Arthritis – Distribution of costs on different resources in Europe**

|                     |     |
|---------------------|-----|
| Medical costs       | 21% |
| Drug                | 14% |
| Non-medical costs   | 14% |
| Informal care costs | 19% |
| Indirect costs      | 32% |

Source: The Burden of Rheumatoid Arthritis and Patient Access to Treatment, J. Lundkvist, F. Kastäng & G. Kobelt, The European Journal of Health Economics, Volume 8, Supplement 2, January 2008

## BURDEN OF RHEUMATOID ARTHRITIS (RA) - ANNUAL COST

|                       | Number<br>of RA<br>patients<br>Thousands | Total cost<br>Million euros | Medical cost<br>excluding drugs<br>Million euros | Drugs<br>Million<br>euros | Non-medical<br>costs<br>Million euros | Informal care<br>Million euros | Indirect cost<br>Million euros |
|-----------------------|--|-----------------------------|--|---------------------------|---------------------------------------|--------------------------------|--------------------------------|
| Australia             | 136                                      | 2,164                       | 409  | 288                       | 257                                   | 744                            | 143                            |
| Austria               | 55                                       | 862                         | 136  | 167                       | 67                                    | 189                            | 303                            |
| Belgium               | 69                                       | 1,208                       | 154  | 94                        | 103                                   | 415                            | 442                            |
| Bulgaria              | 51                                       | 144                         | 49   | 34                        | 31                                    | 19                             | 17                             |
| Canada                | 215                                      | 2,249                       | 701  | 562                       | 155                                   | 209                            | 119                            |
| Cyprus                | 3  | 42                          | 11   | 7                         | 6                                     | 7                              | 11                             |
| Czech<br>Republic     | 68                                       | 401                         | 88   | 62                        | 81                                    | 65                             | 105                            |
| Denmark               | 36                                       | 619                         | 115  | 0                         | 102                                   | 155                            | 248                            |
| Estonia               | 9  | 49                          | 13   | 9                         | 11                                    | 6                              | 10                             |
| Finland               | 35                                       | 662                         | 147  | 104                       | 85                                    | 126                            | 201                            |
| France                | 283                                      | 6,200                       | 2,101  | 1,259                     | 420                                   | 968                            | 1,451                          |
| Germany               | 544                                      | 12,219                      | 1,649  | 1,051                     | 1,213                                 | 2,090                          | 6,216                          |
| Greece                | 50                                       | 585                         | 128  | 90                        | 88                                    | 107                            | 172                            |
| Hungary               | 67                                       | 379                         | 102  | 72                        | 85                                    | 47                             | 75                             |
| Iceland               | 2  | 49                          | 10   | 7                         | 6                                     | 10                             | 15                             |
| Ireland               | 28                                       | 544                         | 110  | 77                        | 70                                    | 110                            | 176                            |
| Italy                 | 264                                      | 4,347                       | 526  | 301                       | 307                                   | 1,616                          | 1,597                          |
| Latvia                | 15                                       | 64                          | 18   | 13                        | 16                                    | 7                              | 11                             |
| Lithuania             | 22                                       | 101                         | 26   | 19                        | 24                                    | 13                             | 20                             |
| Luxembourg            | 3  | 63                          | 12   | 8                         | 7                                     | 14                             | 22                             |
| Malta                 | 2  | 16                          | 4  | 3                         | 3                                     | 3                              | 4                              |
| Netherlands           | 108                                      | 1,354                       | 265  | 64                        | 288                                   | 177                            | 560                            |
| Norway                | 31                                       | 705                         | 148  | 104                       | 84                                    | 142                            | 226                            |
| Poland                | 252                                      | 1,419                       | 343  | 241                       | 292                                   | 209                            | 334                            |
| Portugal              | 70                                       | 745                         | 196  | 138                       | 124                                   | 110                            | 176                            |
| Romania               | 143                                      | 619                         | 207  | 146                       | 130                                   | 83                             | 72                             |
| Russian<br>Federation | 950                                      | 5,941                       | 735  | 517                       | 462                                   | 2,600                          | 257                            |
| Slovakia              | 36                                       | 179                         | 43   | 30                        | 40                                    | 25                             | 40                             |
| Slovenia              | 13                                       | 126                         | 29   | 21                        | 20                                    | 22                             | 34                             |
| Spain                 | 197                                      | 3,036                       | 493  | 159                       | 1,275                                 | 427                            | 682                            |
| Sweden                | 60                                       | 770                         | 125  | 137                       | 88                                    | 18                             | 402                            |
| Switzerland           | 49                                       | 1,181                       | 228  | 160                       | 137                                   | 252                            | 403                            |
| Turkey                | 482                                      | 2,665                       | 722  | 507                       | 454                                   | 604                            | 252                            |
| UK                    | 399                                      | 6,577                       | 1,953  | 140                       | 280                                   | 1,646                          | 2,558                          |
| USA                   | 1,976                                    | 41,631                      | 8,755  | 14,275                    | 4,009                                 | 5,876                          | 8,716                          |

|                |       |        |       |       |       |       |        |
|----------------|-------|--------|-------|-------|-------|-------|--------|
| Europe         | 2,962 | 45,263 | 9,429 | 4,717 | 5,481 | 9,078 | 16,584 |
| Western Europe | 2,302 | 41,846 | 8,529 | 4,084 | 4,768 | 8,589 | 15,875 |
| Eastern Europe | 660   | 3,417  | 900   | 633   | 713   | 489   | 708    |

Source: The Burden of Rheumatoid Arthritis and Patient Access to Treatment, J. Lundkvist, F. Kastäng & G. Kobelt, The European Journal of Health Economics, Volume 8, Supplement 2, January 2008

## **HEALTH CARE SYSTEMS & BURDEN OF DISEASE**

Since the early 1950s, Europe's social history has been marked by the progressive establishment of social security systems which cover more and more people and offer an ever-wider range of services. Health care systems have achieved extraordinary results in terms of longer-living, healthier people, a reduction in disability, and a more productive workforce. However, health care systems, as a whole, are facing serious challenges. In particular, the ageing of our population is about to create a large burden of chronic disease for individuals and society.

Much of this growing burden of chronic disease can be prevented. Medicines can also help reduce morbidity, mortality and disability, and improve patients' quality of life by controlling disease when it does arise, allowing patients to be healthier for a longer time. Medicines also help control costs by reducing the need for expensive care, such as hospitalization, nursing home admission, and surgery.

### **Overview of health care systems**

| Characteristic properties         | Tax-financed system (Beveridge type)*                      | Premium financed system (Bismarck type)**             | Private insurance system                        |
|-----------------------------------|--|---|---|
| Type                              | National Health Service                                    | Social insurance                                      | Pluralistic (Medicare /Medicaid - Managed Care) |
| General definition                | Government-regulated care with health services             | Health care as guaranteed basic right                 | Health goods are largely consumer goods         |
| Finances                          | Taxes. Every tax-payer contributes                         | Contributions from employees/employers                | Largely private finance                         |
| Service organisation              | Public   | Private/public  | Largely private                                 |
| Service package                   | More supply-oriented                                       | More demand-oriented                                  | Demand-oriented                                 |
| State intervention                | Strong/direct  | Mostly direct   | Weak/indirect                                   |
| Payment transfer                  | Indirect   | Largely indirect                                      | Direct and indirect                             |
| Role of professional associations | Not very strong  | Strong  | Very strong                                     |
| Opinion-forming                   | Top-down   | Bottom-up   | Bottom-up                                       |
| Examples                          | Scandinavian countries, U.K., Italy, Spain, Greece, Canada | Japan, Germany, France, Belgium, Netherlands, Austria | USA, Switzerland                                |

\* Sir William Henry Beveridge (1879-1963), founder of British National Health Service (NHS) in 1948.

\*\* Fürst Otto Eduard Leopold von Bismarck (1815-1898) established the first national health insurance system in Germany in the 1880s.

Source: F. Schmidt, M. Egler & R. Geursen, Aventis Pharma AG, Drugs made in Germany 44, n°3 (2001)

## GDP, POPULATION, INFLATION AND EURO RATE

| Country        | GDP 2006<br>€ million | Population<br>01/01/2007<br>(1,000) | Inflation 2006 | € rate 2006 |
|----------------|-----------------------|-------------------------------------|----------------|-------------|
| Austria        | 257,897               | 8,265                               | 1.7            | 13.760      |
| Belgium        | 316,622               | 10,511                              | 2.3            | 40.340      |
| Bulgaria       | 25,238                | 7,718                               | 7.4            | 1.956       |
| Cyprus         | 14,631                | 749                                 | 2.2            | 0.576       |
| Czech Republic | 114,021               | 10,251                              | 2.1            | 28.342      |
| Denmark        | 220,069               | 5,427                               | 1.9            | 7.459       |
| Estonia        | 13,234                | 1,344                               | 4.4            | 15.647      |
| Finland        | 167,041               | 5,255                               | 1.3            | 5.946       |
| France         | 1,791,953             | 62,998                              | 1.9            | 6.560       |
| Germany        | 2,322,200             | 82,437                              | 1.8            | 1.956       |
| Greece         | 213,984               | 11,125                              | 3.3            | 340.750     |
| Hungary        | 89,901                | 10,076                              | 4.0            | 264.26      |
| Iceland        | 13,305                | 299                                 | 4.6            | 87.76       |
| Ireland        | 174,705               | 4,209                               | 2.7            | 0.788       |
| Italy          | 1,479,981             | 58,751                              | 2.2            | 1,936.270   |
| Latvia         | 16,180                | 2,294                               | 6.6            | 0.696       |
| Lithuania      | 23,721                | 3,403                               | 3.8            | 3.453       |
| Luxembourg     | 33,852                | 469                                 | 3.0            | 40.340      |
| Malta          | 5,066                 | 405                                 | 2.6            | 0.429       |
| Netherlands    | 534,324               | 16,334                              | 1.7            | 2.204       |
| Norway         | 267,892               | 4,640                               | 2.5            | 8.047       |
| Poland         | 272,131               | 38,125                              | 1.3            | 3.896       |
| Portugal       | 155,277               | 10,569                              | 3.0            | 200.482     |
| Romania        | 97,718                | 21,610                              | 6.6            | 3.526       |
| Slovakia       | 44,571                | 5,389                               | 4.3            | 37.234      |
| Slovenia       | 30,454                | 2,003                               | 2.5            | 239.60      |
| Spain          | 980,954               | 43,758                              | 3.6            | 166.386     |
| Sweden         | 313,327               | 9,047                               | 1.5            | 9.254       |
| Switzerland    | 309,096               | 7,459                               | 1.0            | 1.573       |
| Turkey         | 419,232               | 72,519                              | 9.3            | 1.809       |
| UK             | 1,912,656             | 60,393                              | 2.3            | 0.682       |
| <b>EU-27</b>   | <b>11,621,708</b>     | <b>492,915</b>                      | <b>2.2</b>     |             |
| USA            | 10,508,681            | 299,399                             | 3.3            | 1.256       |
| Japan          | 3,485,310             | 127,770                             | 0.3            | 146.0       |

Note: € rate: yearly average value in national currency units

Eurozone: Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Portugal, Slovenia, Spain

GDP: Gross Domestic Product at market prices

Source: Eurostat (GDP, population, inflation); European Central Bank (€ rate); OECD (Population: USA, Japan)

## **NOTES**

This booklet provides some general statistical data on the pharmaceutical industry's activities and on the context in which it operates. The statistics have been compiled mainly on the basis of information supplied by EFPIA's member associations, supplemented with data from various other sources, such as the OECD and Eurostat.

Every effort has been made to compile these statistics on a common basis. For several years, EFPIA has based its work in this area on the OECD Standard International Trade Classification (SITC) heading 54, which covers the entire chapter on medicinal products and some sections on specific active substances produced by the pharmaceutical industry.

It should also be noted that:

- Differences between these statistics and those published by EFPIA's member associations are almost certainly due to the choice of classification (SITC 54) and the need to establish common definitions for all countries represented by EFPIA. As it does not include certain basic substances, SITC 54 may in some cases be too restrictive to provide an accurate picture of pharmaceutical industry activity in some countries;
- Some data have been updated and revised, and concepts clarified. As a result, the data in this edition may not be strictly comparable with those in preceding ones;
- All data have been converted into a single currency, the EURO (€). Any proper analysis should therefore take the impact of exchange rate movements on the figures in this booklet into account;
- Since 2005 EFPIA aggregate figures include Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia (although data are not always available in several of these countries).

### **Composition of OECD SITC heading 54**

OECD SITC heading 54 covers Chapter 30 and several sections of Chapter 29 of the Combined Nomenclature:

| Composition of SITC heading 54 | Combined Nomenclature (CN) |
|--------------------------------|----------------------------|
| Provitamins                    | 29.36                      |
| Hormones                       | 29.37                      |
| Heterosides                    | 29.38                      |
| Alkaloids                      | 29.39                      |



|                         |             |
|-------------------------|-------------|
| Antibiotics             | 29.41       |
| Pharmaceutical products | 30.01-30.06 |

Since the 1988 revision of SITC, heading 54 no longer covers sulphonamides; these are now included in heading 51.

## **Definition of a medicinal product**

Any survey of the pharmaceutical sector requires a definition of what is meant by medicinal products. Within the European Union, Article 1 of Directive 2001/83/EEC defines medicinal products as follows:

1. Proprietary medicinal product:

Any ready-prepared medicinal product placed on the market under a special name and in a special pack.

2. Medicinal Product:

Any substance or combination of substances presented for treating or preventing diseases in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

3. Substance:

Any matter, irrespective of origin, which may be:

- human, e.g. human blood and human blood products;
- animal, e.g. micro-organisms, whole animals, parts or organs, animal secretions, toxins, extracts, blood products;
- vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;
- chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.