

The Pharmaceutical Industry in Figures







Europe has a great deal to gain in health and economic terms from a strong and competitive indigenous researchbased pharmaceutical sector. The researchbased pharmaceutical industry is one of the few remaining leading high technology industries in Europe, amounting to 17% of EU business R&D investments and about 3.5% of the total EU manufacturing value added.

Like other industrial sectors, researchbased pharmaceutical companies have felt the effects of the recent economic downturn. The combination of fixed prices, currency exchange rate volatility, and additional cost containment measures increase pressures on companies' bottom lines, and hence cash flows needed to feed into the R&D engine. In the difficult economic environment the researchbased pharmaceutical industry operating in Europe faces a number of challenges:

Pharmaceuticals & biotechnology 16.5% Software & computer services 9,6% Technology hardware & equipment 8,6% Health care equipment & services 6.1% Leisure goods 6,1% Automobiles & parts 4,4% Electronic & electrical equipment 4.2% Aerospace & defence 4.1% All sectors 3,3% Chemicals 2,9% Industrial engineering 2,7% General industrials 2.3% Household goods 2.2% Fixed line telecommunications 1.7% Food producers 1,5% Oil & gas producers 0,3% 10

The costs of pharmaceutical R&D have soa-

red due to a variety of factors including the increasingly complex nature of science and the size of clinical trials, which require more participants than ever before. The latest study released in 2007 estimated the average cost of researching and developing a new chemical or biological entity at \in 1,059 million.

- There is rapid growth in the market and research environment in emerging economies such as Brazil, China and India, resulting in further migration of economic and research activities outside of Europe to these fast-growing markets. According to the March 2010 IMS Health forecasts, emerging economies' pharmaceutical markets are expected to grow at a 14-17% percent rate through 2014.
- Innovation uptake remains slow on most European markets. According to data from IMS Health, 61% of sales of new medicines launched during the period 2005-2009 were on the US market, compared with 29% on the European market. In 2009, North America accounted for 39.8% of world pharmaceutical sales compared with 30.6% for Europe.
- The fragmentation of the EU pharmaceutical market has resulted in lucrative parallel trade. This benefits neither social security nor patients and deprives the industry of additional resources to fund R&D. Parallel trade was estimated to amount to € 4,400 million (value at ex-factory prices) in 2008.

The pharmaceutical research-based sector is an important engine of economic recovery. Continued support for innovation and R&D will help Europe to regain its global leadership in pharmaceutical R&D.

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RANKING OF INDUSTRIAL SECTORS BY R&D/SALES RATIO (2008)

- Note: Data relate to the top 1,350 companies with registered offices in the EU, Japan, the USA and the Rest of the World, ranked by total worldwide R&D investment Source: The 2009 EU Industrial R&D
 - Investment Scoreboard, European Commission, JRC/DG Research

MAIN TRENDS

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN (€ MILLION, CURRENT EXCHANGE RATES), 1990-2009



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

(e): estimate

Source: EFPIA member associations, PhRMA, JPMA

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE (€ MILLION)



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

CHALLENGING POLICY AND REGULATORY ENVIRONMENT

The pharmaceutical industry is not immune to the impact of the economic crisis. Like other industrial sectors, research-based biopharmaceutical companies have felt the effects of the recent economic downturn. Pressures on market growth in most industrialized countries' markets have increased companies' need to reduce costs at all levels (including downsizing) and to reconsider R&D projects in which to invest.

Governments in Europe have been trying to balance a series of competing general policy and health care policy goals, particularly overall budgetary control and coverage of the complex health care needs of the population. The mission proves all the more difficult in the current environment of unprecedented economic and financial crisis. While the task that governments face is undeniably difficult, effort is required to avoid falling into the usual trap of introducing short-term cost-containment measures that undermine the stability and predictability required for the pharmaceutical industry to undertake its activity successfully.

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN (MILLION OF NATIONAL CURRENCY UNITS*), 1990-2009



* Note: Europe: € million; USA: \$ million; Japan: ¥ million x 100 (e): estimate

Source: EFPIA member associations, PhRMA, JPMA

CHANGING GLOBAL MARKET DYNAMICS

Over the period 1995-2005, 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 saw a significant shift of economic and pharmaceutical research activity towards the US over the period.

Today there is rapid growth in the market and research environment in emerging economies such as Brazil, China and India, resulting in further migration of economic and research activities outside Europe to these fast-growing markets. The geographical balance of the pharmaceutical market will continue to shift towards emerging economies, whose pharmaceutical markets are expected to grow at a 14-17% percent rate through to 2014 (compared with a 3-6 percent growth for major developed markets) according to IMS Health.

GEOGRAPHICAL BREAKDOWN (BY MAIN MARKETS) OF SALES OF NEW MEDICINES LAUNCHED DURING THE PERIOD 2005-2009



Note: New medicines cover all new active ingredients marketed for the first time on the world market during the period 2005-2009

Europe includes non-EU members and CIS markets Source: IMS Health MIDAS MAT December 2009

The implications of the economic downturn, that will continue to deepen over the coming months, have different dimensions for the research-based pharmaceutical industry in Europe. The combination of fixed prices, currency exchange rate volatility and additional cost containment measures increases the pressure on companies' bottom lines, and hence cash flows needed to feed into the R&D engine. Furthermore, innovation uptake remains slow on most European markets.

According to data from IMS Health, 61% of sales of new medicines launched during the period 2005-2009 were on the US market, compared with 29% on the European market.

Furthermore, the fragmentation of the EU pharmaceutical market results in lucrative parallel trade. This benefits neither social security nor patients and deprives the industry of additional resources to fund R&D. Parallel trade was estimated to amount to \notin 4,400 million (value at ex-factory prices) in 2008.

GLOBAL PHARMACEUTICAL MARKET BY REGION AVERAGE GROWTH RATE FOR THE PERIOD 2004-2009 (%)



Source: IMS Health Market Prognosis, March 2010 Note: IMS audited and unaudited markets, constant average growth rates (constant US \$)

SHARE OF PARALLEL IMPORTS IN PHARMACY MARKET SALES (%) - 2008



Source: EFPIA member associations

LIFE EXPECTANCY (YEARS) TOTAL POPULATION AT BIRTH, EUROPE



Source: OECD Health Data 2009, Statistics and Indicators for 30 countries, November 2009 – EFPIA calculations (non-weighted average for 23 European countries)

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

Science today offers greater promise for finding new treatments than ever Sbefore, thanks to new knowledge and new technologies. Today, European citizens can expect to live up to 30 years longer than they did a century ago. Huge reductions in mortality (e.g. in HIV/AIDS, many cancers or cardiovascular disease) and significant progress in the quality of life are the results of some large and many small steps in biopharmaceutical research.

European citizens can expect not only to live longer, but to live longer and be healthier. High blood pressure and cardiovascular disease can be controlled with antihypertensive medicines and cholesterol-lowering medicines, knee or hip replacements prevent patients from immobility, and some cancers can be controlled or even cured thanks to newer targeted medicines. Yet, there remain huge challenges in many disease areas such as Alzheimer, multiple sclerosis, many cancers and orphan diseases.

The key contribution of the research-based pharmaceutical industry to medical progress is turning fundamental research into innovative treatments that are widely available and accessible to patients. Since aspirin was invented more than a century ago, scientific and technological breakthroughs in the pharmaceutical industry have enabled researchers to target increasingly complex diseases, firstly by exploring the biochemistry of tissues, and subsequently 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.

Five-year Relative Survival (%)* during Three Time Periods By Cancer Site					
 All sites 	50	53	66		
 Breast (female) 	75	79	(89)		
 Colon 	51	59	65		
 Leukemia 	35	42	49		
 Lung and bronchus 	13	13	(16)		
 Melanoma 	82	86	92		
Non-Hodgkin lymphoma	a 48	53	63		
 Ovary 	37	40	45**		
 Pancreas 	2	3	$\overline{5}$		
 Prostate 	69	76	100		
 Rectum 	49	57	66		
 Urinary bladder 	73	78	82		

*5-year relative survival rates based on follow up of patients through 2003.

**Recent changes in classification of ovarian cancer have affected 1996-2002 survival rates. Source: Surveillance, Epidemiology, and End Results Program, 1975-2003, Division of Cancer Control and Population Sciences, National Cancer Institute, 2006.



THE PHARMACEUTICAL INDUSTRY: A KEY ASSET TO THE EUROPEAN ECONOMY

As well as driving medical progress and improving health within Europe and worldwide, the research-based pharmaceutical industry is a key asset of the European economy. It is one of Europe's top performing high-technology sectors.

INDUSTRY (EFPIA total) (1)	1990	1995	2000	2005	2008	2009
Production	63,010	88,912	123,282	172,099	196,283	195,000 (e)
Exports ⁽²⁾	23,180	44,188	90,935	181,575	230,770	240,000 (e)
Imports ⁽²⁾	16,113	31,018	68,841	145,823	178,576	185,000 (e)
Trade balance	7,067	13,170	22,094	35,752	52,194	55,000 (e)
R&D expenditure	7,766	11,484	17,849	21,949	26,545	26,000 (e)
Employment (units)	500,879	506,894	536,733	635,937	633,056	630,000 (e)
R&D employment (units)	76,126	82,618	88,397	100,337	113,378	110,000 (e)
Pharmaceutical market	40,281	58,790	86,727	128,797	146,455	150,000 (e)
value at ex-factory prices	40,201	50,770	00,727	120,171	140,400	100,000 (0)
Pharmaceutical market	64,626	93,032	136,627	188,109	209,513	215,000 (e)
value at retail prices	04,020	75,052	130,027	100,107	207,313	213,000 (0)
Payment for pharmaceuticals by	40.007	F0 100	7/ 000	100 (04	110 407	120,000 (a)
statutory health insurance systems ⁽³⁾	40,807	58,128	76,909	108,604	118,497	120,000 (e)

Values in \in million unless otherwise stated

- Data relate to EU-27, Croatia, Iceland, Norway and Switzerland since 2005 (EU-15, Norway and Switzerland 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 1995-2009)

The research-based pharmaceutical industry accounts for approximately 3.5% of total EU manufacturing value added and for 17% of total EU business R&D investments. The pharmaceutical industry performs well on most standard indicators, such as:

- employment: about 633,100 jobs in Europe, including 113,400 in R&D facilities;
- R&D investment: € 26,500 million in 2008 (up from € 7,800 in 1990);
- trade surplus: € 52,200 million in 2008 (up from € 7,100 in 1990).



PHARMACEUTICAL INDUSTRY RESEARCH & DEVELOPMENT IN EUROPE

EFPIA 2008	€ million	
LIFIA 2000		
Austria	433	
Belgium	1,884	
Bulgaria	n.a.	
Croatia	n.a.	
Cyprus	14	
Czech Republic	n.a.	
Denmark	1,052	
Estonia	n.a.	
Finland	228	
France	5,120	
Germany	4,840	
Greece	4,040	
Hungary	n.a.	
Iceland	n.a.	
Ireland	250	
Italy	1,200	
Latvia	n.a.	
Lithuania	n.a.	
Malta	n.a.	
Netherlands	471	
Norway	117	
Poland	n.a.	
Portugal	71	
Romania	30	
Slovakia	n.a.	
Slovenia	100	
Spain	914	
Sweden	811	
Switzerland	3,500	
United Kingdom	5,426	
entreu ninguoni	0,120	
Total	26,545	

Note: The figures relate to the R&D carried out in each country. Austria, Cyprus, Denmark, France, Netherlands, Romania, Slovenia: 2007 data Belgium, Denmark, France, Greece, Ireland, Italy, Netherlands, Norway, Romania, Sweden (LIF members), Switzerland (Interpharma members): estimate

Source : EFPIA member associations (official figures)

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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 \in 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 ever larger 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 to 2 in 10,000. The financing of such R&D expenditure 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.

PHASES OF THE RESEARCH AND DEVELOPMENT PROCESS



ESTIMATED FULL COST OF BRINGING A NEW CHEMICAL OR BIOLOGICAL ENTITY TO MARKET (\$ MILLION - YEAR 2005 \$)



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

2 to 3 years of administrative procedures SPC (supplementary protection certificate) max.+ 5 years

¹⁰ years of R&D

R&D AS PERCENTAGE OF SALES, 1985-2009 (%)



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

IMPORTANCE OF PHARMACEUTICAL R&D

n 2008 the pharmaceutical industry invested about € 26,500 million in R&D in Europe. After a decade of strong US market dominance, which led to a significant shift of economic and pharmaceutical research activity towards the US during the period 1995-2005, Europe is now also facing increasing competition from emerging economies. Today there is rapid growth in the market and research environment in emerging economics such as Brazil, China and India, resulting in further migration of economic and research activities outside of Europe to these fast-growing markets. The geographical balance of the pharmaceutical market – and ultimately the R&D base – is likely to shift gradually towards emerging economies.

CLINICAL TRIAL PHASES

Stage	Typical number and type of patients	Typical duration	Purpose
Phase I	20-100 healthy volunteers	Up to 1 year	To ensure the medicine is safe and find the most suitable dose
Phase II	Up to several hundred patients	1-2 years	To assess effectiveness and look for side effects
Phase III	Several hundred to several thousand patients	2-4 years	To confirm effectiveness and monitor any side effects from long-term use
Phase IV	Variable: commonly several thousand	Variable	To develop new treatment uses, compare with other treatments, determine the clinical effectiveness and long-term safety of the medicine in a wide variety of patient types and/or to satisfy conditions of authorisation

Source: EFPIA, Intellectual Property and Pharmaceuticals, June 2008

ALLOCATION OF R&D INVESTMENTS BY FUNCTION (%)



As a whole, the research-based pharmaceutical industry invests about 18% of its sales into R&D in Europe. In terms of allocation of R&D investment, companies spend on average 27.0% 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 53.6% of R&D budgets while an additional 14.4% of R&D is spent on additional trials (pharmacovigilance) once the medicine has been approved by the regulatory authorities. In addition, 4.7% of R&D is allocated to the approval process.

Source: PhRMA, Annual Membership Survey 2010 (percentages calculated from 2008 data)

PHARMACEUTICAL R&D EXPENDITURE VALUE & ANNUAL GROWTH RATE (%)



Annual percentage change USA (%)

2009: estimate Source: EFPIA, PhRMA

USA (\$ million)

NUMBER OF NEW ACTIVE SUB-STANCES LAUNCHED ON THE WORLD MARKET OVER THE LAST FIVE YEARS (2005-2009)



Source: SCRIP

ORIGIN OF THE 25 NEW MOLECULAR (CHEMICAL AND BIOLOGICAL) ENTITIES LAUNCHED ON THE WORLD MARKET IN 2009



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

DEVELOPING NEW CHEMICAL OR BIOLOGICAL ENTITIES (NCEs/NBEs)

he European pharmaceutical industry has for many years been the world's leading inventor of new medicines. However, since the mid-90's, the United States has become the dominant player in the pharmaceutical sector, including in research fields such as biotechnology where Europe needs to catch up.

The latest data available (period 2005-2009) show the predominance of the United States, which has now become the leading discoverer of new molecules in the world. Since the mid-90's, US research-based companies account for a significantly increased share of the world's top selling medicines. They launched 45.2% of the new chemical and biological entities over the period 2005-2009 compared with 35.6% for European companies.

Twenty-five new molecular (chemical and biological) entities reached the world market for the first time in 2009. According to Adis R&D Insight Database, the total number of compounds in clinical trials or awaiting approval amounted to about 2,950 in 2009.

NUMBER OF NEW CHEMICAL OR BIOLOGICAL ENTITIES (1990-2009)



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 Arepresented 1.90% of the European Union's Gross Domestic Product (GDP) in 2008 against 1.86% in 2000. The gap with regard to R&D expenditure in the United States and Japan remains significant since these countries spent respectively 2.76% and 3.44% 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 3.75% and 3.73%, made the greatest research effort.





 Note: Switzerland: 2004 data; China: 2005 data; Greece, Japan, Turkey: 2007 data
 Belgium, Bulgaria, Cyprus, Estonia, France, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, U.K., USA: provisional data Austria, Denmark, Germany, Greece, Sweden, EU-27: estimate
 Source: Eurostat, 12 March 2010, 'Science, technology and innovation in Europe', 2009 edition **BIOPHARMACEUTICALS**

SHARE OF GLOBAL BIOTECHNOLOGY REVENUES, PUBLIC COMPANIES (2008)



Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2009' (data relate only to publicly traded companies)

SHARE OF GLOBAL BIOTECHNOLOGY R&D EXPENSES, PUBLIC COMPANIES (2008)



Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2009' (data relate only to publicly traded companies) 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.

BIOPHARMACEUTICALS (2008)

Value in € million	Global	USA	Europe	Canada	Asia-Pacific
Revenues	60,952	44,960	11,228	1,388	3,376
R&D expenditure	21,583	17,181	3,516	478	408
Net income (loss)	(980)	284	(477)	(777)	(10)
Number of employees (units)	200,760	128,200	49,060	7,970	15,530
Number of public companies (units)	776	371	178	72	155

Source: Ernst & Young, 'Beyond Borders, Global Biotechnology Report 2009' (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 provides a wide range of value-added services to its 63 member companies. Further details about EBE and its activities are available on www.ebe-biopharma.org



Europe is the main manufacturing and research location for human-use vaccines. About 90.2% of the total production of the worldwide vaccine manufacturers originated from Europe in 2008. 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 \in 13,662 million in 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 122 as of 31 December 2008. Of the 144 R&D projects ongoing in 2008 (including 22 in Phase IV development), nearly 60% were based in Europe (Europe: 84 projects; North America: 53 projects; Asia (including Japan): 2 projects, Others: 5 projects). Major international vaccine manufacturers altogether had 20 manufacturing sites and 22 R&D sites based in Europe in 2008.

TOTAL NUMBER OF R&D PROJECTS BY INTERNATIONAL VACCINE MANUFACTURERS

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Pre-clinical Phase I Phase II Phase III Source: European Vaccine Manufacturers (EVM), 2010

NUMBER AND LOCATION OF MANUFACTURING AND R&D SITES BY INTERNATIONAL VACCINE MANUFACTURERS IN EUROPE (2008)

	Manufacturing	R&D
Austria	2	2
Belgium	3	4
Czech Republic	1	
France	2	4
Germany	2	3
Hungary	1	1
Ireland	1	
Italy	1	1
Netherlands	1	3
Spain	1	
Sweden	1	
Switzerland	3	1
U.K.	1	3
Total	20	22

Source: European Vaccine Manufacturers (EVM), 2010

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 for a whole range of diseases including HIV, malaria and cancers. Further details about EVM and its activities are available on www.evm-vaccines.org

GEOGRAPHICAL BREAKDOWN OF WORLDWIDE MAJOR VACCINE MANUFACTURERS MARKET VALUE (2008)



Source: European Vaccine Manufacturers (EVM), 2010



EMPLOYMENT IN THE PHARMACEUTICAL INDUSTRY

EFPIA 2008	Units
Austria	10,534
Belgium	29,600
Bulgaria	n.a.
Croatia	n.a.
Cyprus	1,140
Czech Republic	2,200
Denmark	17,019
Estonia	n.a.
Finland	6,002
France	103,384
Germany	105,843
Greece	13,500
Hungary	n.a.
Iceland	n.a.
Ireland	24,500
Italy	69,500
Latvia	n.a.
Lithuania	n.a.
Malta	445
Netherlands	16,000
Norway	4,630
Poland	23,905
Portugal	10,244
Romania	22,000
Slovakia	2,000
Slovenia	7,100
Spain	40,385
Sweden	15,725
Switzerland	35,400
United Kingdom	72,000
Total	633,056

Note: Austria, Poland, Romania: 2007 data; Malta: 2004 data

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

Source: EFPIA member associations (official figures)



The research-based pharmaceutical industry is one of Europe's major hightechnology 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 633,100 people, of which 113,400 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 - 2009)

EMPLOYMENT IN THE PHARMACEUTICAL INDUSTRY (1985-2009)



Note: Data include Czech Republic (since 2008), Cyprus (since 2007), Romania & Slovakia (since 2005), Malta, Poland and Slovenia (since 2004) Source: EFPIA member associations (official figures) (e): EFPIA estimate

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



PHARMACEUTICAL PRODUCTION

EFPIA 2008	€ million
Austria	2,082
Belgium	5,518
Bulgaria	n.a.
Croatia	n.a.
Cyprus	135
Czech Republic	n.a.
Denmark	5,551
Estonia	n.a.
Finland	987
France	34,600
Germany	27,105
Greece	825
Hungary	n.a.
Iceland	n.a.
Ireland	17,540
Italy	22,984
Latvia	123
Lithuania	32
Malta	34
Netherlands	5,664
Norway	679
Poland	2,501
Portugal	2,054
Romania	280
Slovakia	n.a.
Slovenia	1,411
Spain	14,108
Sweden	6,372
Switzerland	22,841
United Kingdom	22,857
Total	196,283

Note: All data based on SITC 54

Belgium: 2008 provisional data; Norway, U.K.: 2007 data; Netherlands: 2005 data; Malta: 2004 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 IPIROIDUCTIION

With an estimated share of 38.1% of the world pharmaceutical production, the USA 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 82%) of the world pharmaceutical production. In 2008, EFPIA countries' pharmaceutical production was worth an estimated total of \in 196,300 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 total EU manufacturing value added and for 17.0% of the EU business R&D expenditure. The dominant sectors by R&D significantly differ in the three main world regions, with a higher concentration of biopharmaceutical R&D in the USA. On average the pharmaceutical industry account for 19% of the worldwide business R&D expenditure.

SHARE OF INDUSTRIAL SECTORS IN R&D INVESTMENT IN THE THREE MAIN WORLD REGIONS - 2008



Note: EU relates to EU-27 countries (excluding Norway and Switzerland)

Source: The 2009 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG Research

BREAKDOWN OF THE WORLD PHARMACEUTICAL PRODUCTION (AT EX-FACTORY PRICES), 2007



Source: EFPIA member associations, PhRMA, JPMA, OECD, IMS Health – Estimate (EFPIA calculations)

EUROPEAN PHARMACEUTICAL PRODUCTION, 1990-2009 (€ MILLION)



ted 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 2008	€ million	
Austria	2,921	
Belgium	4,189	
Bulgaria	617	
Croatia	682	
Cyprus	188	
Czech Republic	1,832	
Denmark	2,006	
Estonia	141	
Finland	1,978	
France	26,196	
Germany	26,523	
Greece	5,573	
Hungary	2,091	
Iceland	101	
Ireland	1,760	
Italy	17,824	
Latvia	291	
Lithuania	436	
Malta	77	
Netherlands	4,680	
Norway	1,345	
Poland	5,014	
Portugal	3,660	
Romania	1,914	
Slovakia	1,057	
Slovenia	493	
Spain	13,949	
Sweden	3,172	
Switzerland	2,919	
United Kingdom	12,826	
Total	146,455	

 Note: Medicinal products as defined by Directive 2001/83/EEC Denmark, Finland, Iceland, Latvia, Norway, Slovenia, Sweden: pharmaceutical market value at pharmacy purchasing prices Malta: 2007 data; Estonia, Malta: pharmacy sales only; Greece: including parallel exports Belgium (2008 provisional), France, Germany, Ireland, Italy, Norway, Spain: estimate

Source: EFPIA member associations (official figures) - Bulgaria, Estonia, Lithuania, Malta, Romania: 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 \in 579,510 million (\$ 808,300 million) at ex-factory prices in 2009. The North American market (USA & Canada) remained the world's largest market with a 39.8% share, well ahead of Europe and Japan. In 2009 the Asian region was by far the fastest growing market with an estimated growth of 15.9%, whilst the growth of the North American and European markets was estimated at 5.5% and 4.8% respectively.

BREAKDOWN OF THE TOTAL PHARMACEUTICAL MARKET VALUE (AT EX-FACTORY PRICES) BY MAIN DISTRIBUTION CHANNELS (IN € MILLION), 2008

	Total	Pharmacy	Hospital	Other channels
Austria	2,921	2,012	909	0
Belgium	4,189	3,702	487	0
Bulgaria	617	530	87	0
Croatia	682	541	141	0
Cyprus	188	90	98	0
Czech Republic	1,832	1,380	452	0
Denmark	2,006	1,185	797	24
Estonia	141	n.a.	n.a.	n.a.
Finland	1,978	1,469	488	21
France	26,196	20,955	5,241	0
Germany	26,523	22,528	3,805	190
Greece	5,573	4,107	1,466	0
Hungary	2,091	1,709	382	0
Iceland	101	81	20	0
Ireland	1,760	1,449	290	21
Italy	17,824	11,719	6,027	78
Latvia	291	239	52	0
Lithuania	436	376	60	0
Malta	77	n.a.	n.a.	n.a.
Netherlands	4,680	3,570	933	177
Norway	1,345	1,024	299	22
Poland	5,014	4,356	658	n.a.
Portugal	3,660	2,577	1,070	13
Romania	1,914	1,709	205	0
Slovakia	1,057	957	100	0
Slovenia	493	397	93	3
Spain	13,949	10,459	3,490	0
Sweden	3,172	2,605	552	15
Switzerland	2,919	1,577	595	747
United Kingdom	12,826	8,100	4,155	571
EFPIA total*	146,237	111,403	32,952	1,882

BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET – 2009 SALES



- North America (USA, Canada)
- Europe
- Africa, Asia (excluding Japan) & Australia
- 🔲 Japan

🔲 Latin America

- Note: Europe includes non-EU members and CIS markets
- Source: IMS Health Market Prognosis, March 2010 (data relate to the total 2009 unaudited and audited market at ex-factory prices)

*Total excluding Estonia and Malta (breakdown not available)

Note: Other channels include dispensing doctors, supermarkets, drugstores and other retail outlets Denmark, Finland, Iceland, Latvia, Norway, Slovenia, Sweden: pharmaceutical market value at pharmacy purchasing prices Belgium (2008 provisional). France Germany, Ireland, Italy, Norway, Spain; estimate

Belgium (2008 provisional), France, Germany, Ireland, Italy, Norway, Spain: estimate Greece: including parallel exports

Source: EFPIA member associations (official figures) – Bulgaria, Estonia, Lithuania, Malta, Romania: IMS Health



TOTAL EXPORTS, IMPORTS AND TRADE BALANCE (2008 - € MILLION)

	Exports	Imports	Trade balance
Austria	4,970	4,266	704
Belgium	33,552	29,743	3,809
Bulgaria	260	553	-293
Cyprus	156	210	-54
Czech Republic	958	2,577	-1,619
Denmark	5,472	2,316	3,156
Estonia	37	243	-206
Finland	798	1,668	-870
France	22,637	17,540	5,097
Germany	46,723	32,524	14,199
Greece	863	3,653	-2,790
Hungary	2,272	2,193	79
Ireland	16,917	2,867	14,050
Italy	11,311	13,626	-2,315
Latvia	212	419	-207
Lithuania	139	512	-373
Luxembourg	65	308	-243
Malta	166	88	78
Netherlands	8,792	9,569	-777
Norway	476	1,247	-771
Poland	1,153	4,408	-3,255
Portugal	406	1,997	-1,591
Romania	161	1,815	-1,654
Slovakia	264	1,216	-952
Slovenia	1,568	649	919
Spain	7,734	10,371	-2,637
Sweden	6,220	2,879	3,341
Switzerland	34,829	14,965	19,864
United Kingdom	21,659	14,154	7,505
EFPIA total	230,770	178,576	52,194

Note: All data based on SITC 54

Norway, Switzerland: veterinary products excluded

Source: Eurostat (COMEXT database – December 2009)

Norway: Statistics Norway; Switzerland: Swiss Federal Trade Office

PHARMACEUTICAL TRADE

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 2008 EFPIA countries' pharmaceutical exports totalled \in 203,800 million. This amount also includes the trade flows between the EFPIA countries, which were estimated to \in 124,300 million in 2008. Exports to non-EFPIA countries amounted to \in 86,400 million, i.e. 37.4% of total exports. Pharmaceuticals represented 5.6% of total EU manufacturing exports in 2008 against 2.1% in 1990.

Europe is a net exporter of medicines. The European pharmaceutical industry generates a substantial trade surplus, which amounted to \in 52,200 million in 2008. 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. The European Union's main trading partners are the USA and Switzerland.

THE EUROPEAN UNION'S TOP 5 PHARMACEUTICAL TRADING PARTNERS - 2008



Source: Eurostat, SITC 54, External and intra-European Union trade, Monthly statistics, Issue number 4/2010

EU-27 TRADE BALANCE - HIGH TECHNOLOGY SECTORS (€ MILLION) - 2009



______ STIC 87 Professional, scientific, controlling material 7,23

Source: Eurostat, External and intra-European Union trade, Monthly statistics, Issue number 4/2010



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

	1960	1970	1980	1990	2000	2007
Austria	4.3	5.2	7.4	8.3	9.9	10.1
Belgium	-	3.9	6.3	7.2	8.6	10.2*
Czech Republic	-	-	-	4.7	6.5	6.8
Denmark	-	-	8.9	8.3	8.3	9.8
Finland	3.8	5.5	6.3	7.7	7.2	8.2
France	3.8	5.4	7.0	8.4	10.1	11.0
Germany	-	6.0	8.4	8.3	10.3	10.4
Greece	-	5.4	5.9	6.6	7.9	9.6
Hungary	-	-	-	-	6.9	7.4
Iceland	3.0	4.7	6.3	7.8	9.5	9.3
Ireland	3.7	5.1	8.3	6.1	6.3	7.6
Italy	-	-	-	7.7	8.1	8.7
Luxembourg	-	3.1	5.2	5.4	5.8	7.3
Netherlands	-	-	7.4	8.0	8.0	9.8*
Norway	2.9	4.4	7.0	7.6	8.4	8.9
Poland	-	-	-	4.8	5.5	6.4
Portugal	-	2.5	5.3	5.9	8.8	9.9
Slovakia	-	-	-	-	5.5	7.7
Spain	1.5	3.5	5.3	6.5	7.2	8.5
Sweden	-	6.8	8.9	8.2	8.2	9.1
Switzerland	4.9	5.4	7.3	8.2	10.2	10.8*
Turkey	-	-	2.4	2.7	4.9	5.7
United Kingdom	3.9	4.5	5.6	5.9	7.0	8.4
Europe	3.5	4.8	6.9	7.1	7.9	8.9
USA	5.2	7.1	9.0	12.2	13.6	16.0*
Japan	3.0	4.6	6.5	6.0	7.7	8.1

* estimate

Note: Japan, Luxembourg, Portugal: 2006 data; Turkey: 2005 data

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

Source: OECD Health Data 2009, Statistics and Indicators for 30 Countries, November 2009

BREAKDOWN OF TOTAL HEALTH EXPENDITURE IN EUROPE – 2007



 Out-patient care & others
 Pharmaceuticals & other medical non-durables



Medicines only constitute a small part of disease costs with, on average, 17.0% Mof total health expenditure in Europe being spent on pharmaceuticals and other medical non durables. In costly diseases such as cancer and rheumatoid arthritis, medicines account for even less than 10% of the total disease costs. Medicines can also generate additional savings, for example by substantially reducing costs in other branches of healthcare (hospital stays, invalidity, etc).

Even though medicines make a major contribution to improvements in health whilst adding relatively little to the health care bill, they have been and continue to be a prime target of Member States' health care cost-containment policies. With the recent economic crisis, cost-containment policies targeting mainly or exclusively medicines have been proliferating. These have sought to make short-term cost savings whilst taking little or no account of the added value of innovative medicines to healthcare.

Most of these policies ignore 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 structural factors which drive the growth in healthcare and pharmaceutical spending, i.e.:

- population ageing and population increase;

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- increasing living standards and increasing patients expectations to get access to newest treatments;
- widening range of treatments available and technological progress;
- widening social security cover, which is now available to almost the entire population in European countries.



DISTRIBUTION OF CANCER COSTS IN SWEDEN



RHEUMATOID ARTHRITIS - DISTRIBUTION OF COSTS IN EUROPE

Source: Comparator Report on Patient Access to Cancer Drugs in Europe, N. Wilking, B. Jönsson, D. Högberg, N. Justo, November 2009

Source: Kobelt et al, JBS 2008



PAYMENT FOR PHARMACEUTICALS BY COMPULSORY HEALTH INSURANCE SYSTEMS AND NATIONAL HEALTH SERVICES (AMBULATORY CARE ONLY)

EFPIA 2008	€ million	
Austria	2,148	
Belgium	3,241	
Bulgaria	n.a.	
Croatia	349	
Cyprus	98	
Czech Republic	1,252	
Denmark	967	
Estonia	62	
Finland	1,243	
France	22,611	
Germany	29,225	
Greece	4,527	
Hungary	1,295	
Iceland	65	
Ireland	1,872	
Italy	11,383	
Latvia	110	
Lithuania	n.a.	
Malta	91	
Netherlands	5,206	
Norway	1,019	
Poland	2,007	
Portugal	1,467	
Romania	574	
Slovakia	990	
Slovenia	294	
Spain	11,453	
Sweden	2,115	
Switzerland	2,923	
United Kingdom	9,910	
Total	118,497	

Note: France, Greece, Ireland, Netherlands, Norway, Sweden, United Kingdom: estimate Croatia, Malta, Romania: 2007 data; Estonia: 2006 data

Source: EFPIA member associations (official figures)



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 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 %) – 2008

 $\hfill\square$ Costs paid by compulsory health insurance systems (%)

Costs paid by the patient (%)

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. Croatia, Romania: 2007 data; Estonia: 2006 data EFPIA calculations – Estimate

Source: EFPIA member associations

GENERICS

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), 2008

Note: Denmark, Finland, Greece, Poland, 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

- Iceland, 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 MIEDICINES

Distribution margins, which are generally fixed by governments, and VAT rates differ significantly from country to country in Europe. On average, approximately 36.4% of the retail price of a medicine does not revert to the manufacturer but rather to distributors (pharmacists and wholesalers) and the State.

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 Bulgaria, Denmark and Germany. The table below shows the VAT rates applied to medicines in European countries on 1 January 2010.

Country	Standard VAT rate (%)	VAT rates applied to medicines		
Country		Prescription (%)	OTC (%)	
Austria (1)	20.0	10.0	10.0	
Belgium	21.0	6.0	6.0	
Bulgaria	20.0	20.0	20.0	
Croatia	22.0	0.0	22.0	
Cyprus	15.0	0.0	0.0	
Czech Republic	20.0	10.0	10.0	
Denmark	25.0	25.0	25.0	
Estonia	20.0	9.0	9.0	
Finland	22.0	8.0	8.0	
France (2)	19.6	2.1	5.5	
Germany	19.0	19.0	19.0	
Greece	19.0	9.0	9.0	
Hungary	25.0	5.0	5.0	
Iceland	24.5	24.5	24.5	
Ireland (3)	21.0	0.0 - 21.0	0.0 - 21.0	
Italy	20.0	10.0	10.0	
Latvia (4)	21.0	10.0	10.0	
Lithuania	21.0	5.0	5.0	
Luxembourg	15.0	3.0	3.0	
Malta	18.0	0.0	0.0	
Netherlands	19.0	6.0	6.0	
Norway	25.0	25.0	25.0	
Poland	22.0	7.0	7.0	
Portugal	20.0	5.0	5.0	
Romania	19.0	9.0	9.0	
Slovakia	19.0	10.0	10.0	
Slovenia	20.0	8.5	8.5	
Spain	16.0	4.0	4.0	
Sweden	25.0	0.0	25.0	
Switzerland	7.6	2.4	2.4	
UK (5)	17.5	0.0	17.5	

PRICE STRUCTURE - BREAKDOWN OF THE RETAIL PRICE OF A MEDICINE, 2008 (%)



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

- (1) Austria: VAT decrease from 20% to 10% for all medicines on 01/01/2009
- (2) France: reimbursable medicines 2.1%; non-reimbursable medicines 5.5%
- (3) Ireland: oral medication 0%; other medication 21%

(4) Latvia: VAT increase from 5% to 10% for all medicines on 01/01/2009

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



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

Country	1960	1980	1990	2000	2010	2020	2030
Austria	12.0	15.4	14.9	15.5	17.6	19.9	24.8
Belgium	12.0	14.4	14.9	16.9	17.4	20.3	24.1
Bulgaria	7.5	11.9	13.1	16.6	17.6	20.5	23.1
Cyprus	5.9	10.3	10.9	11.3	13.2	15.8	19.0
Czech Republic	9.3	13.4	12.5	13.8	15.3	19.5	21.4
Denmark	10.6	14.4	15.6	14.8	16.7	20.1	22.7
Estonia	10.5	12.5	11.4	15.0	17.0	18.6	20.7
Finland	7.2	12.0	13.4	14.9	17.2	22.3	25.1
France	11.6	14.0	14.0	16.3	17.0	20.9	24.3
Germany	11.5	15.6	15.0	16.4	20.5	23.0	28.2
Greece	8.3	13.1	13.7	16.7	18.3	20.7	24.0
Hungary	9.0	13.4	13.3	14.7	16.4	19.3	20.4
Iceland	8.0	10.1	10.6	11.7	11.9	14.6	19.4
Ireland	11.2	10.7	11.4	11.2	11.4	13.8	16.7
Italy	9.3	13.1	15.3	18.2	20.4	23.0	26.8
Latvia	10.5	13.0	11.6	15.3	17.5	18.3	21.1
Lithuania	7.7	11.3	10.9	13.9	16.4	18.0	21.8
Luxembourg	10.8	13.7	13.5	14.2	14.0	15.1	18.0
Malta	7.4	9.9	10.6	12.3	14.9	20.1	23.7
Netherlands	9.0	11.5	12.8	13.6	15.4	19.7	23.8
Norway	11.1	14.8	16.3	15.2	15.0	18.0	20.8
Poland	5.8	10.1	10.1	12.2	13.5	18.3	22.4
Portugal	8.0	10.5	13.4	16.1	17.9	20.6	24.5
Romania	6.7	10.3	10.4	13.5	14.9	17.4	19.2
Slovakia	6.7	10.4	10.3	11.4	12.3	16.1	20.0
Slovenia	7.8	11.4	11.1	14.1	16.4	20.4	24.5
Spain	8.2	11.2	13.5	16.8	17.2	18.7	22.7
Sweden	12.0	16.3	17.8	17.2	18.3	21.0	22.6
Switzerland	10.1	13.8	14.4	14.6	17.2	20.2	24.1
Turkey	3.4	4.6	4.0	5.2	6.0	7.5	10.4
United Kingdom		15.1	15.9	15.8	16.6	18.5	20.9
EU-27	9.9	13.3	13.9	15.7	17.5	20.3	23.8
USA	9.2	11.2	12.2	12.3	13.0	16.1	19.8
Japan	5.7	9.0	12.0	17.2	22.6	28.5	30.8
World	5.3	5.9	6.1	6.9	7.6	9.3	11.7

Note:Figures for the years 2010, 2020 and 2030 are United Nations projections.Source:World Population Prospects (United Nations), OHE



 $S_{ive} = S_{ive} = S_{i$

Part of this growing burden of chronic disease can be prevented or reduced. Medicines can 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.

PERCENTAGE OF ELDERLY PEOPLE (65 AND OVER) IN TOTAL POPU-LATION IN EUROPE



Note: Figures for the year 2030 are United Nations projections. Source: World Population Prospects (United Nations), OHE

10



AVERAGE LENGTH OF STAY FOR ACUTE CARE (DAYS), 2007

Note: Denmark, Greece: 2005 data; Belgium, Ireland, Italy, Spain: 2006 data Europe: non-weighted average (23 countries) – EFPIA calculations

Source: OECD Health Data 2009, Statistics and Indicators for 30 Countries, November 2009



CAUSES OF DEATH BY MAJOR DISEASE AREAS IN EUROPE (IN % OF ALL DEATHS)



DISABILITY AND MORTALITY CONTRIBUTION TO THE TOTAL DISEASE BURDEN FOR SELECTED DISEASES IN EUROPE (WHO SUB-REGION EUR A)



Source: Access to Innovative Treatments in Rheumatoid Arthritis in Europe, G. Kobelt and F. Kasteng, October 2009



Medicine has played a central role in health care and therapeutic practice since the earliest times. Medicines have and continue to greatly contribute to the increase in life expectancy, to the improvement of quality of life and to the eradication of diseases which were previously life threatening. The example of cancer shows that screening programmes and improvements in treatments have greatly improved the chances of survival. In 2006, over 2.4 million new cases of cancer were diagnosed in Europe (30 countries), about 10% more than 2002. Over the same period, mortality only increased by 0.4%.

With the increase in life expectancy, more and more European citizens are affected by chronic diseases which, whilst having less of an impact on mortality, greatly affect patients' quality of life. Rheumatoid arthritis (RA) is one such example where the disease burden – the symptoms – has an overwhelming impact on the patient's quality of life. Patients are particularly affected by their inability to work and difficulties in conducting daily activities. This makes patients dependent on family and friends. However, treatment is available and studies show that the quality of life of RA patients increases by between 20% (for mild cases) and 85% (for severe cases) following on treatment.



NUMBER OF NEW CANCER CASES AND DEATHS IN SELECTED CANCERS 2002-2006

Source: Comparator Report on Patient Access to Cancer Drugs in Europe, N. Wilking, B. Jönsson, D. Högberg, N. Justo, November 2009 (www.comparatorreports.se)

PATIENTS W.A.I.T. INDICATOR

"Patients W.A.I.T." stands for patients waiting to access innovative therapies. The indicator provides a benchmarking analysis of the waiting times recorded in 15 European countries. The latest edition shows that, depending on the patients' country of residence, doctors are only able to prescribe between 47% and 90% of the new medicines with a valid EU marketing authorisation granted between 1 January 2006 and 31 December 2008. For those new medicines that doctors can prescribe under national health care provisions, the average time elapsing between the date of EU market authorisation and the effective "accessibility" date (i.e. date of completion of pricing/ reimbursement procedures in some countries; date of market launch with no direct implication for reimbursement in others) in 15 European countries will vary from 101 to 403 days.

AVERAGE TIME INTERVALS BETWEEN MARKETING AUTHORIZATION AND PATIENT ACCESS FOR EMEA MEDICINES



Average time interval between MA and "accessibility date"

Percentage of medicines "available" for the period 2006-2008

- Note: Medicines with EU marketing authorisation (MA) from 1 January 2006 to 31 December 2008 (the complete database includes 88 new medicines of which 65 are considered in the study period 2006-2008)
- Source: EFPIA, Patients W.A.I.T. Indicator, 2009 report (see www.efpia.eu for detailed information)

ECONOMIC INDICATORS

Country	GDP 2008 € million	Population 01/01/2009 (1,000)	Inflation 2008	€ rate 2008
Austria	281,868	8,355	3.2	13,760
Belgium	344,676	10,750	4.5	40,340
Bulgaria	34,118	7,607	12.0	1,956
Croatia	47,365	4,435	5.8	7,224
Cyprus	17,248	797	4.4	0,585
Czech Republic	147,879	10,468	6.3	24,946
Denmark	233,027	5,511	3.6	7,456
Estonia	16,073	1,340	10.6	15,647
Finland	184,179	5,326	3.9	5,946
France	1,950,085	64,351	3.2	6,560
Germany	2,495,800	82,002	2.8	1,956
Greece	239,141	11,260	4.2	340,750
Hungary	105,536	10,031	6.0	251,51
Iceland	10,274	319	12.8	143,83
Ireland	181,815	4,450	3.1	0,788
Italy	1,567,851	60,045	3.5	1,936.270
Latvia	23,160	2,261	15.3	0,703
Lithuania	32,203	3,350	11.1	3,453
Luxembourg	39,348	494	4.1	40,340
Malta	5,697	414	4.7	0,429
Netherlands	595,883	16,486	2.2	2,204
Norway	309,251	4,799	3.4	8,224
Poland	362,415	38,136	4.2	3,512
Portugal	166,462	10,627	2.7	200,482
Romania	139,753	21,499	7.9	3,683
Slovakia	64,778	5,412	3.9	33,775
Slovenia	37,135	2,032	5.5	239,64
Spain	1,088,502	45,828	4.1	166,386
Sweden	328,088	9,256	3.3	9,615
Switzerland	341,330	7,702	2.3	1,587
Turkey	498,602	71,517	10.4	1,906
UK	1,818,948	61,635	3.6	0,796
EU-27	12,501,668*	499,724*	3.7	
USA	9,818,738	304,060	3.8	1,471
Japan	3,313,309	127,692	1.4	152,5

*Totals do not add due to rounding

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

GDP: Gross Domestic Product at market prices

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

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



NUMBER OF COMPANIES REPRESENTED BY EFPIA MEMBER ASSOCIATIONS

EFPIA 2009	Units	
Austria	121	
Belgium	146	
Bulgaria	21	
Croatia	22	
Cyprus	8	
Czech Republic	32	
Denmark	37	
Estonia	26	
Finland	64	
France	270	
Germany	47	
Greece	66	
Hungary	27	
Iceland	17	
Ireland	56	
Italy	202	
Latvia	21	
Lithuania	21	
Malta	n.a.	
Netherlands	39	
Norway	44	
Poland	31	
Portugal	136	
Romania	26	
Slovakia	22	
Slovenia	21	
Spain	211	
Sweden	65	
Switzerland	61	
Turkey	40	
United Kingdom	64	
Total	1,964	

Note: Number of members as of 1 January 2009 Austria: Pharmig members Source: EFPIA member associations

STRUCTURE OF THE PHARMACEUTICAL INDUSTRY

About 2,000 companies (separate legal entities) are represented by EFPIA and Aits 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. On average a leading pharmaceutical company spends more than \notin 14.7 million on R&D per day.

Since the mid-90's, US research-based companies account for a significantly increased share of the world's top selling medicines. They launched 45.2% of the new chemical and biological entities over the period 2005-2009 against 35.6% for European companies.

ORIGIN OF THE TOP 25 BIOPHARMACEUTICAL COMPANIES BY WORLDWIDE R&D INVESTMENT, 2008 (€ MILLION)

Roche (Switzerland)

Pfizer (USA)

0

1000

ORIGIN OF THE TOP 15 COMPANIES BY WORLDWIDE SALES, 2009



Note: American companies (Pfizer; Merck & Co; Johnson & Johnson; Lilly & Co; Abbott; Amgen); European companies (Novartis; Sanofi Aventis; GlaxoSmithKline; AstraZeneca; Roche; Bayer; Boehringer Ingelheim); Japanese companies (Takeda); Others (Teva) Source: IMS Health, MIDAS, December 2009 (total audited markets, sales at manufacturer prices)

5,883.4

5 715 9

NEW CHEMICAL AND BIOLOGICAL ENTITIES LAUNCHED DURING THE PERIOD 2005-2009





Johnson & Johnson (USA) 5,451.1 Novartis (Swizerland) 5.194.3 Sanofi Aventis (France) 4.608.0 GlaxoSmithKline (UK) 3,835.6 AstraZeneca (UK) 3.622.3 3,457.1 Merck & Co (USA) Lilly & Co (USA) 2,763.3 2,725.0 Bayer (Germany) 2,579.2 Bristol Myers Squibb (USA) 2,538.9 Schering-Plough (USA) Wveth (USA) 2 426 8 2.188.8 Takeda (Japan) Amgen (USA) 2.179.9 Boehringer Ingelheim (Germany) 2.109.0 Abbott Laboratories (USA) 1,934.4 1,297.4 Daiichi Sankyo (Japan) 1,234.4 Merck Serono (Germany) 1,095.5 Eisai (Japan) Astellas Pharma (Japan) 1.067.2 994.9 Novo Nordisk (Denmark) 911.0 Genzyme (USA) 771.3 Biogen Idec (USA) UCB (Belgium) 767.0

Note: Bayer classified under 'Pharmaceuticals & Biotechnology' instead of 'Chemicals'; acquisition of Wyeth by Pfizer in 2009; merger between Merck & Co and Schering-Plough in 2009 Source: The 2009 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG Research

3000

4000

5000

6000

2000

IEIFIPITAL MIEMIBIEIRSIHIIP

EFPIA represents the pharmaceutical industry operating in Europe. EFPIA brings together 32 European national pharmaceutical industry associations as well as 40 leading companies undertaking research, development and manufacturing of medicinal products in Europe for human use.

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 IIac Firmalari Dernegi (AIFD) 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

Albania: Albanian Society of Multinational Pharmaceutical Industry (SHPF) Bulgaria: Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM) Croatia: Croatian Association of Research-based Pharmaceutical Companies (CARPC) Cyprus: Association of Pharmaceutical Companies (CAPC) Czech Republic: Association of Innovative Pharmaceutical Industry (AIFP) Estonia: Association of International Pharmaceutical Manufacturers in Estonia (AIPME) Hungary: Association of Innovative Pharmaceutical Manufacturers (AIPM) Latvia: Association of International Research-based Pharmaceutical Manufacturers (AFA) Lithuania: Association of Representative Offices of Ethical Pharmaceutical Manufacturers (EFA) Malta: Maltese Pharmaceutical Association (PRIMA) Romania: Association of International Medicines Manufacturers (ARPIM) Serbia: Innovative Drug Manufacturers' Fund (INOVIA) Slovakia: Slovak Association of Research-based Pharmaceutical Companies (SAFS) Slovenia: Forum of International Research and Development Pharmaceutical Industries (EIG)

MEMBER COMPANIES

FULL MEMBERS

Abbott Almirall Amgen Astellas Pharma Europe AstraZeneca Baxter Bayer HealthCare Biogen Idec Boehringer Ingelheim Bristol Myers Squibb Chiesi Farmaceutici Daiichi-Sankyo Europe Eisai Eli Lilly & Co Laboratorios Dr Esteve Genzyme GlaxoSmithKline Grünenthal lpsen Johnson & Johnson H. Lundbeck Menarini Merck Serono Merck & Co Novartis Novo Nordisk Orion Pharma Pfizer Roche Sanofi-aventis Servier Sigma-Tau Takeda UCB Vifor Pharma Warner Chilcott

AFFILIATE MEMBERS

Bial	Portugal
Bracco	Italy
Otsuka Pharmaceuticals	Japan
Recordati	Italy

USA Spain USA United Kingdom United Kingdom / Sweden USA Germany USĂ Germany USA Italy Germany Japan **ÚSA** Spain USA United Kingdom Germany France USA Denmark Italy Germany USĂ Switzerland Denmark Finland USA Switzerland France France Italy Japan Belgium Switzerland USA



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). Croatia and Iceland are included since 2007.

COMPOSITION OF OECD SITC HEADING 54

 $\mathsf{OECD}\ \mathsf{SITC}\ \mathsf{heading}\ \mathsf{54}\ \mathsf{covers}\ \mathsf{Chapter}\ \mathsf{30}\ \mathsf{and}\ \mathsf{several}\ \mathsf{sections}\ \mathsf{of}\ \mathsf{Chapter}\ \mathsf{29}\ \mathsf{of}\ \mathsf{the}\ \mathsf{Combined}\ \mathsf{Nomenclature}:$

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.



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 40 leading pharmaceutical companies undertaking 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 2,000 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:

EFPIA

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