European Foundation for the Improvement of Living and Working Conditions

Sector Futures

The biomedical healthcare sector – what future?

european Monitoring Centre on Change

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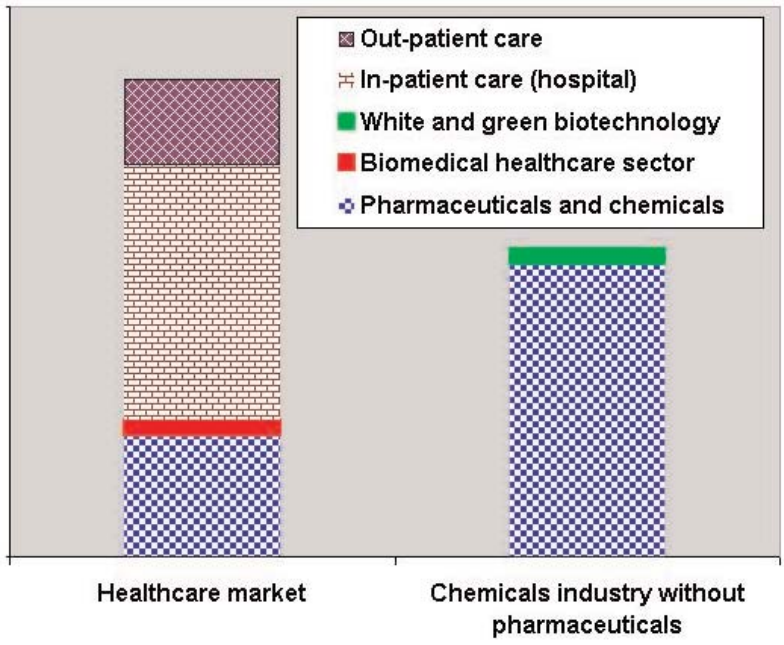
Biomedical healthcare industry – what future?

The biomedical healthcare sector comprises biotechnologies dedicated to the treatment of human beings. The first of three articles in the Sector Futures series on biomedical healthcare looks at key features of the sector, including the size and structure of its market, the nature of employment, the main trends and drivers shaping the present and future of the industry and the principal issues and uncertainties at stake in the industry.

Defining the biomedical healthcare industry

The biomedical healthcare sector comprises biotechnologies dedicated to the treatment of human beings. This sector is related to the pharmaceuticals industry in so far as pharmaceuticals is also dedicated to the treatment of human beings. A wider linkage is to other products and services of the healthcare market, such as the supply of hospitals and ambulant health services. Moreover, biomedical healthcare is related to biotechnologies, which to a certain extent are based on similar technologies, but are dedicated to applications outside the healthcare market. Green biotechnology, for example, provides products for agriculture and white biotechnology has a wide range of applications in different industries. Both of these sectors are linked to the chemicals industry. Figure 1 depicts the relationship between the sectors of biotechnology and the mature industries.

Figure 1: *Biotechnology and related mature industries in the EU15 plus Norway and Switzerland*



Source: **EuropaBio**[1], *2005, p. 5;* **European Federation of Pharmaceutical Industries and Associations (EFPIA)**[2], *2005, pp. 11 and 25.*

[1] **http://www.europabio.org/events/BioVision/CriticalI%20studyBiotech-Europ.pdf**

[2] **http://www.efpia.org/6_publ/infigures2005.pdf**

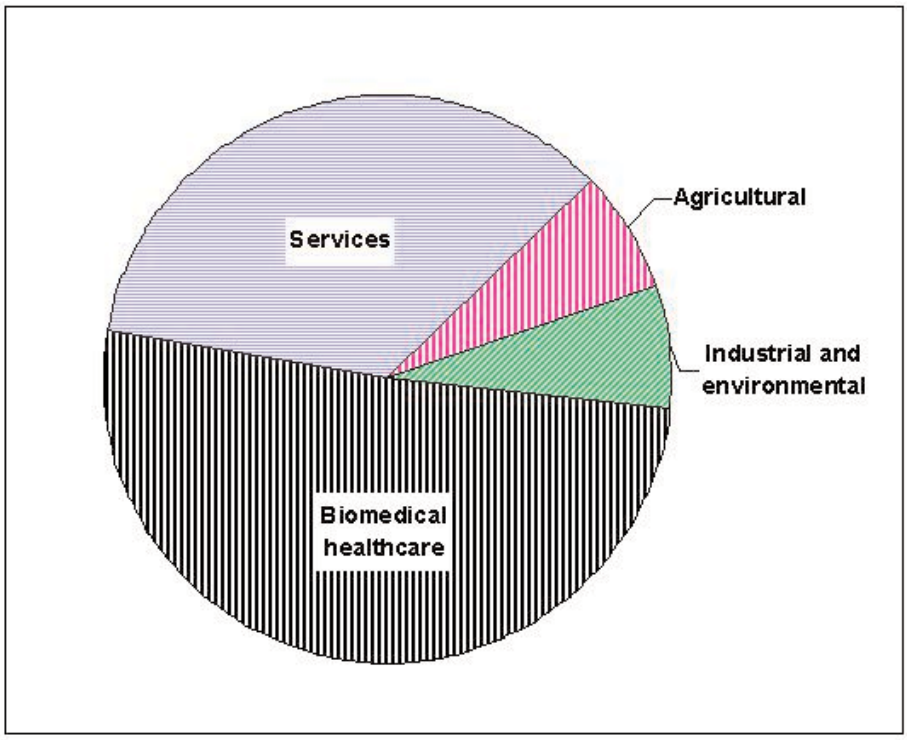
The biotechnology industry is divided into the following activities:

- **red biotechnology**, which belongs under life sciences;
- **white biotechnology**: industrial and environmental products and processes, such as biocleaning, bioremediation, environmental and industrial diagnostics, water and effluent treatment as well as recycling;
- **green biotechnology**: veterinary healthcare, biopesticides, plant agriculture, food technology and processing;
- **services**, such as contract research, contract manufacturing, bioinformatics and functional genomics.

As an industry, biotechnology is a young, dynamic and research-intensive sector of great interest to policymakers. Nevertheless, official quantitative data for the assessment of its importance are not available; surveys and other information supplied by stakeholders in the sector are the main sources of hard data about this industry.

In April 2005, the European Association for Bioindustries (EuropaBio) published a survey of the biotechnology industry in Europe, i.e. the EU15 plus Norway and Switzerland (EU15plus). According to this study there were 1,976 biotechnology companies in the EU15plus in 1993, with around 94,000 employees and revenues of €19 billion. Some 51% of the turnover was attributable to the biomedical healthcare industry (see Figure 2).

Figure 2: *Structure of the biotechnology industry by revenues in the EU15 plus Norway and Switzerland, 2003*



Source: *EuropaBio, 2005, p. 5.*

The biomedical healthcare industry is concerned with human health, specifically with the diagnosis of health risks, and the prevention and treatment of illnesses. Biomedical healthcare products and processes are part of the human medicine market served by the pharmaceuticals industry. The products provide treatments for illnesses that could not be treated until recently; they are more efficient than traditional cures and many of them are on the verge of replacing traditional

pharmaceuticals. This means that the demand for biomedical healthcare is driven by roughly the same factors as the demand for the products and services of life sciences as a whole.

The principal activities and products of the biomedical healthcare industry may be grouped as follows.

- **Cell and tissue therapies** provide healthcare solutions ranging from prosthetic and restorative to therapeutic applications. Active research involving human cell- and tissue-based products is currently conducted in the regeneration and repair of bones, tendons, nerves and ligaments.
- **Research on stem cells** provides cell-based therapies to treat serious diseases, including Parkinson's and Alzheimer's. The research is also relevant to the treatment of spinal cord injuries, diabetes, strokes, heart diseases and other ailments.
- **Gene therapy** is dedicated to some of the most debilitating diseases that do not yet have a cure. The molecular basis of many inherited disorders, such as haemophilia, cystic fibrosis and muscular dystrophy, has been revealed by the discovery of affected genes. Many types of genetic predisposition play an important role in some forms of cancer. Identifying the genes for such diseases and redirecting their course is one of the most promising means of cure.
- There are many (some 5,000) **rare diseases** (affecting around 20 to 30 million Europeans), for which biotechnology can provide powerful tools to develop diagnostics and treatments.
- **Proteomics** is concerned with the analysis of the physiological functions of proteins and their effects on diseases. Some diseases occur if genes do not produce sufficient proteins, or if they produce incorrectly folded proteins. Biotechnology uses recombinant (artificially created) deoxyribonucleic acid (DNA) and cell cultures to produce missing or defective proteins. Replacement protein therapies include Factor VII, a protein essential for the blood-clotting process, or insulin, a protein hormone that regulates the level of glucose in the blood.
- **Pharmacogenetics** studies the effect genes may have on an individual's response to a drug. It is based on the application of biotechnologies, not only to improve diagnosis, but also to provide new ways to match doses and treatment to individual patients. Pharmacogenetics can offer better-selected drugs to treat elusive variations of common as well as rare diseases. It can also limit the occurrence of adverse drug reactions in patients.
- In diagnostics, **biotechnology** has provided new tools to detect many diseases and medical conditions more quickly and with greater accuracy than before. For instance, the Polymerase Chain Reaction (PCR) is a technology that imitates a cell's ability to replicate DNA by generating multiple copies of specific sequences of DNA through amplification. In clinical diagnostics, a small amount of genetic material can be copied by PCR, which will provide sufficient material to detect the presence or absence of a virus as well as to quantify its level in the blood. Important applications are the diagnosis of HIV and of prostate and ovarian cancer.

Genetic testing is based on the information made available by the Human Genome Project. There are currently more than 1,000 hereditary diseases that can be identified in this way. The majority of the tests detect the presence of a mutation or mutations in a single gene, which lead to monogenic disorders, most of which are relatively rare diseases. Many diseases are caused by a combination of environmental factors and one or more hereditary factors. There are complex interactions between the environment and a number of alternative genes, called 'susceptibility' genes. These interactions can be disclosed by genetic testing, and the resultant information highlights individual risk factors, and thus gives the patient the opportunity of avoiding environmental triggers for diseases.

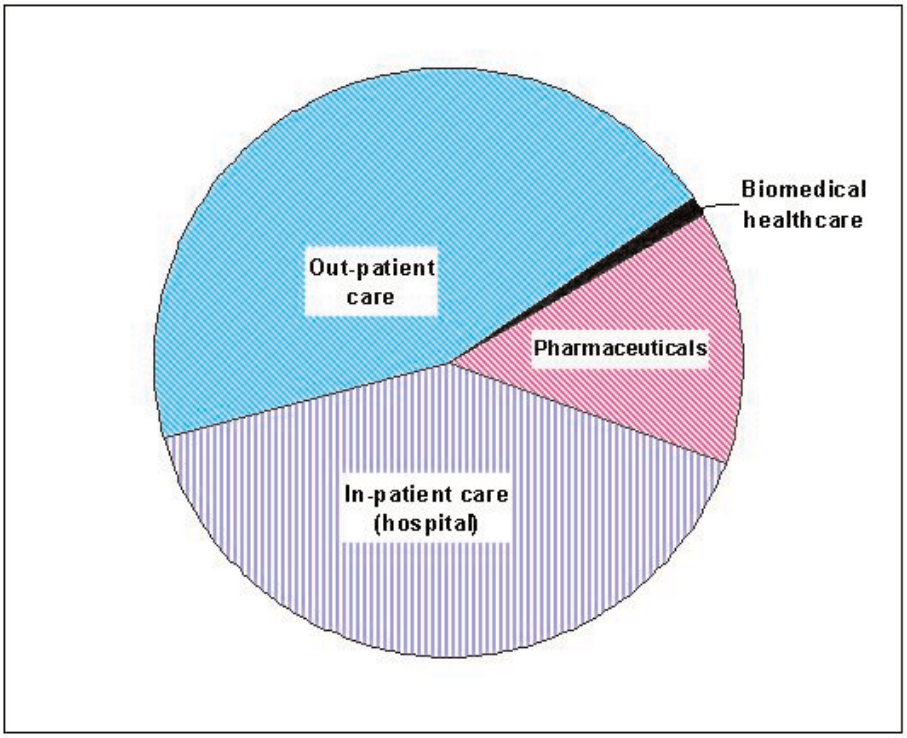
The foregoing summary makes it clear that the biomedical healthcare industry is a 'sunrise' industry with a strong focus on research and development (R&D) and dedicated to supplying innovative products with a broad range of applications. At present there are a small number of products in the market, but this number is growing rapidly. The prospects for the future importance of this industry are good in all parts of the life sciences market.

Market size, market structure and employment

Market size

The biomedical healthcare industry serves the healthcare market, which comprises the broad subsectors of in-patient care (hospital), out-patient care and pharmaceutical products. The European Federation of the Pharmaceutical Industries and Associations (EFPIA) has calculated the contributions of these subsectors to the total European healthcare market. In 2003, the total market amounted to €730 billion for the EU15plus and only €110 billion euro of which was spent on pharmaceutical products (see Figure 3).

Figure 3: *The life science market in the EU15 plus Norway and Switzerland, 2003*



Source: **EFPIA**[3], *2005.*

Although the €10 billion revenues of the biomedical healthcare industry in 2003 amounted to only between 1% and 1.5% of the total European healthcare market, its importance lies in the fact that innovations in healthcare supply increasingly originate from the biomedical healthcare industry.

Market structure

The healthcare industries mostly supply services for patients, but pharmaceuticals as well as the biomedical healthcare industry have a stronger focus on the supply of manufactured products and related technologies. A comparison of these two industries reveals structural differences that can be attributed to the pace of innovation in biotechnologies and a rate of growth stimulated by an ever-increasing number of new products and applications.

[3] **http://www.efpia.org/6_publ/infigures2005.pdf**

Table 1: *Key figures for the pharmaceuticals and biomedical healthcare industry in the EU15 plus Norway and Switzerland, 2003*

Indicator	Units	Pharmaceuticals industry	Biomedical healthcare	
				as % of pharmaceuticals
Companies	Numbers	3,538	1,008	28.5%
Employees	Numbers	550,899	47,940	8.7%
	per company	156	48	30.6%
Employees in R&D	Numbers	58,844	17,850	30.3%
	as a % of total employees	10.7%	37.2%	-
Revenues	Billions €	160	10	6.1%
	per employee 1,000 €	290	202	69.6%

Source: *EuropaBio, 2005, p. 5, calculations by the Institute for Economic Research (Ifo), Munich, 2005.*

The majority of biomedical healthcare companies are young; more than half the businesses have been founded since 2000. As a consequence, the companies are small, with an average of around 50 employees. Regarding the number of companies, and even more so in the number of employees, biomedical healthcare is a small industry compared to the pharmaceuticals industry. Its revenues of €10 billion only amount to 6% of those of the pharmaceuticals industry. On the other hand, the high level of innovation in biomedical healthcare becomes comprehensible if one compares the share of employees in R&D. Pharmaceuticals, a mature research-intensive industry, employs around one-tenth of its workforce in R&D; the biomedical healthcare industry more than one-third (see Table 1).

Despite large structural differences between the two industries, there are also strong linkages. Pharmaceuticals companies founded a considerable number of biomedical companies. They are owned or partly owned by large pharmaceuticals groups and are often staffed by experts from the pharmaceuticals industry. Such companies can be understood as externalised units, which carry out research in areas remote from the markets. A similar development took place in the engineering industries more than 10 years ago. In the era of newly available technologies for the control of manufacturing processes, engineering companies created small firms for the development of advanced hardware and software. The rationale for this was that there was no internal know-how for these new technologies available, and R&D could be carried out more or less independently of the parent company.

Other biomedical companies are taken over by pharmaceuticals companies to obtain access to new technologies that are likely to yield new opportunities in their traditional business areas. For instance, the Belgian pharmaceuticals group UCB acquired the Celltech Group, a leading British biotech company, in 2004. Consequently, analysis of the biomedical healthcare market also must take developments in the pharmaceuticals market into account.

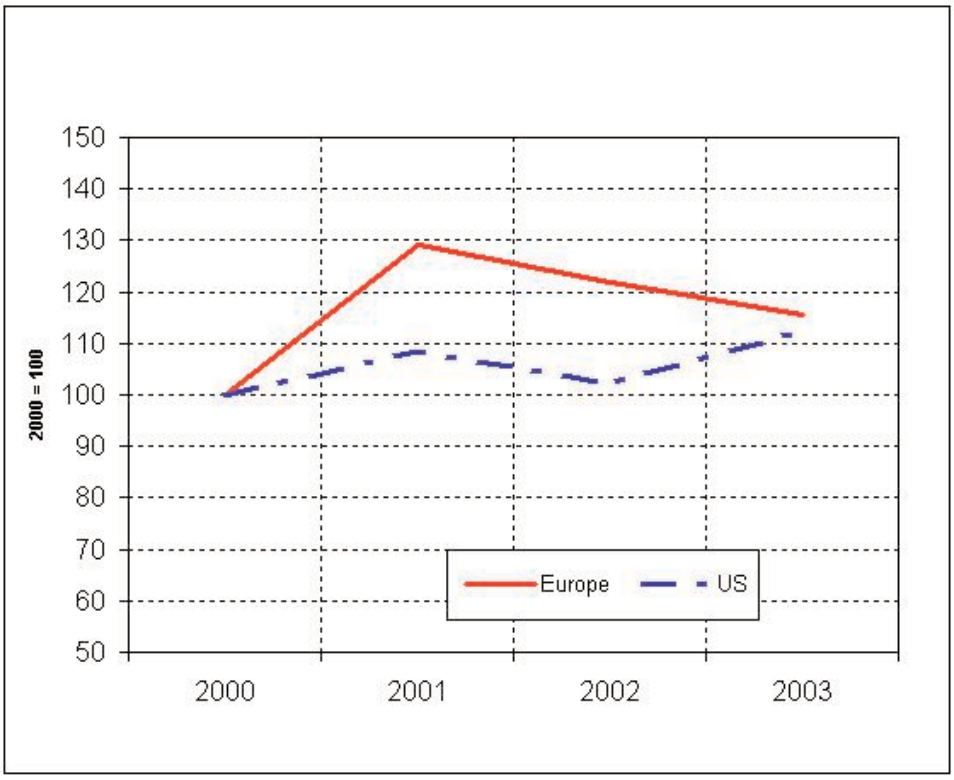
Employment

Employment in the European biotechnology industry had been growing strongly from 1995 onwards, but it reached a peak in 2001, after which the bursting of the dotcom bubble precipitated a decline. In the United States, employment increased more slowly than in Europe, but resumed its upward growth in 2003 after suffering a fall in 2002. In Europe, however, there was no resumption of employment growth in 2003 (see Figure 4).

Despite the bursting of the dotcom bubble, employment in biotechnology in Europe was still 15.5% higher in 2003 than it had been in 2000. The overall pattern of employment growth since 1995 suggests that biotechnology, as a young and growing industry, will provide good job opportunities, especially for highly qualified personnel, as soon as the consolidation of the recent past has been completed. That is one reason why European governments are taking initiatives

to stimulate innovation and competitiveness in this industry. It must not be forgotten, however, that biotechnology is still a relatively small industry, unable to make much of a contribution to reducing unemployment in Europe on its own until it generates 'spill-over' effects on other industries, above all on pharmaceuticals and downstream industries.

Figure 4: *Employment in the biotech industry in the EU15 plus Norway and Switzerland and the US, 2000–2003*



Source: **EuropaBio**[4], *2003*.

Trends and drivers

Sociological

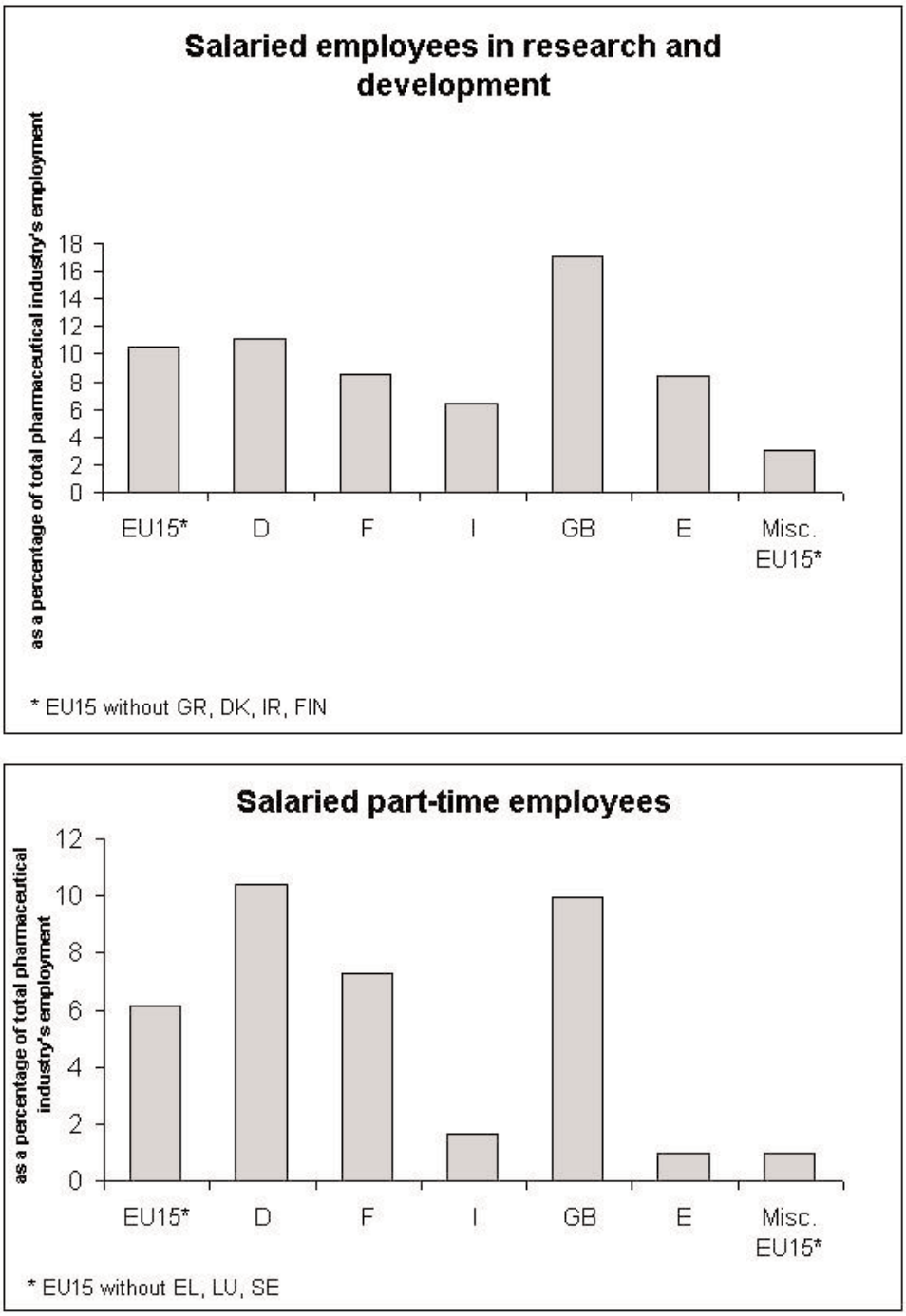
Several considerations suggest that working conditions in the biomedical healthcare industry are more flexible and less bound by traditional rules than in long-established businesses. The industry is knowledge-driven, its work settings, particularly in natural sciences, are attractive, and the majority of companies are young and thus have the opportunities to design their own patterns of work. However, it must be stressed that no hard data on working practices in biomedical healthcare are available, either from official statistics or from stakeholders in the industry. Nonetheless, the close links between biomedical healthcare and the pharmaceuticals industry allow data about working practices and creative working-time schemes in pharmaceuticals to be used as an indication of conditions in biomedical healthcare. Working practices in biomedical healthcare are likely to be more innovative, and certainly no less innovative, than in pharmaceuticals.

The pharmaceuticals industry is knowledge-intensive and the proportion of R&D personnel (up to 10% in the United Kingdom and Germany) is even higher than in the chemicals industry, but well below the figure of roughly 60% in

[4] **http://www.europabio.org/documents/EY2003report.pdf**

biomedical healthcare. Data on part-time employment give some indication of the propensity of pharmaceuticals to introduce new patterns of work. The high incidence of part-time work in pharmaceuticals indicates a more flexible approach to the design of working conditions (see Figure 5).

Figure 5: *Employment structure in the EU15 pharmaceuticals industry, 2002*



Source: Based on **Eurostat data**[5], *calculations by Ifo, 2005*.

[5] **http://epp.eurostat.cec.eu.int/portal/page?_pageid=0,1136195,0_45572097&_dad=portal&_schema=PORTAL**

Technological

Biomedical healthcare technology is the most recent of the technologies that are changing our world. The development of this technology rests on two major achievements of modern science. At the end of 2000, the Human Genome Project completed the sequencing of the human DNA macromolecule. This achievement was the result of a cooperative enterprise between a vast international public consortium and the private US company Celera, headed by Craig Venter. The more than 3 billion nucleotide letters of the DNA molecule provide the most important database for biomedical healthcare technology. In Europe, the core of biomedical healthcare technology is located in the **European Molecular Biology Laboratory**[6] (EMBL), whose head office is in Heidelberg, with laboratories in France and Italy, and the European Bioinformatics Institute at Hinxton in the UK. Exploiting the information in the human genome for the identification of genes, and the proteins that these genes code for the complete functioning of the human body, is the province of the new science of bio-informatics. The complexity of the task and the large amount of data involved require specifically designed software.

The work being done to make full use of the database created by the sequencing of the human DNA macromolecule is called post-genomics. Although there are only 30,000 genes, rather than the anticipated several hundred million, their alignment, three-dimensional deployment and the innumerable alignments of the nucleotide letters, whose significance is unknown, provide an infinite field for research, compared to which the sequencing of the genome was only the tip of the iceberg.

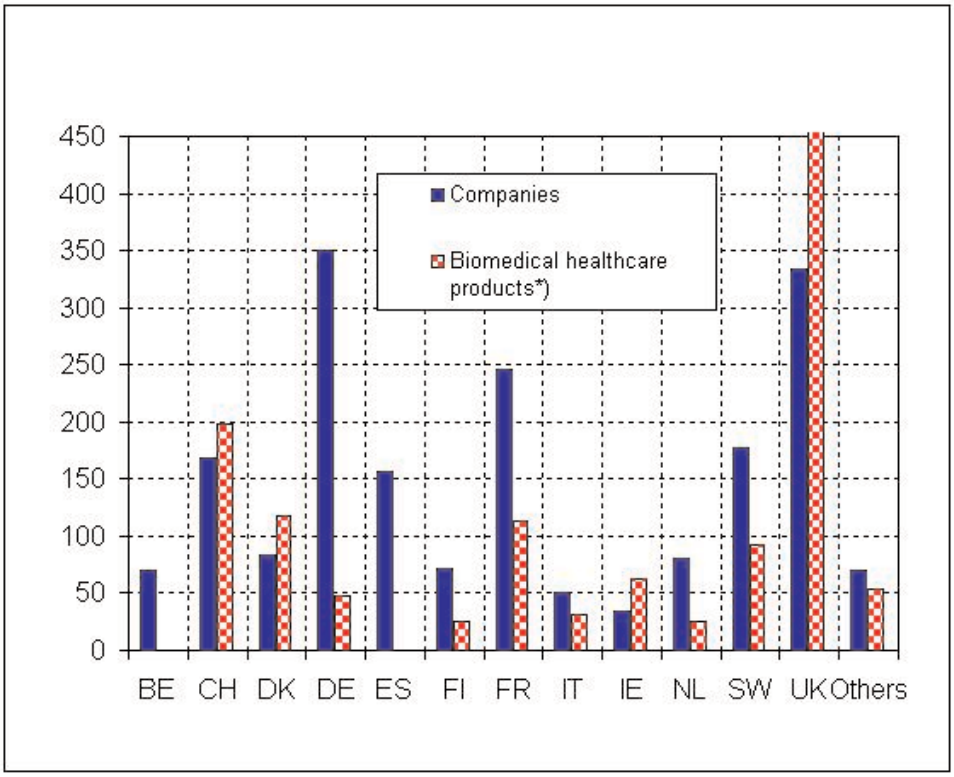
The other development was the identification, particularly from the late 1990s onwards, of new types of embryonic stem cells. These originally undifferentiated cells develop in the human egg. Their ability to reproduce exceptionally quickly and their extreme mutability have given rise to the hope that stem cells can be used for therapeutic purposes. However, this raises ethical problems because the research involves the use of human embryos, which is why research is now being conducted into identifying stem cells in adults.

The biomedical healthcare industry can be seen as the pharmaceutical industry's external R&D centre and source of product innovation. The share of biotechnology products in clinical trials as a share of total new pharmaceutical products has grown from 19.2% in 2000 to 27.1% in 2003.

The strength of the biomedical healthcare industry differs widely between European countries. The UK is ahead, with a total of 636 new biotech healthcare products in clinical tests, even though there are no more biomedical companies in the UK than in Germany. The UK industry, however, is more mature and its companies are larger. There are 43 quoted companies among its 334 biomedical healthcare companies, while the corresponding figures for Germany are 350 and 11, respectively (see Figure 6).

[6] **http://www.embl.org/**

Figure 6: *Regional distribution of the biomedical healthcare industry by the number of companies and new products*



* New biomedical healthcare products in the pipeline, 2000–2003.
Source: **EuropaBio**[7], *2003, calculations by Ifo, 2005.*

Environmental drivers

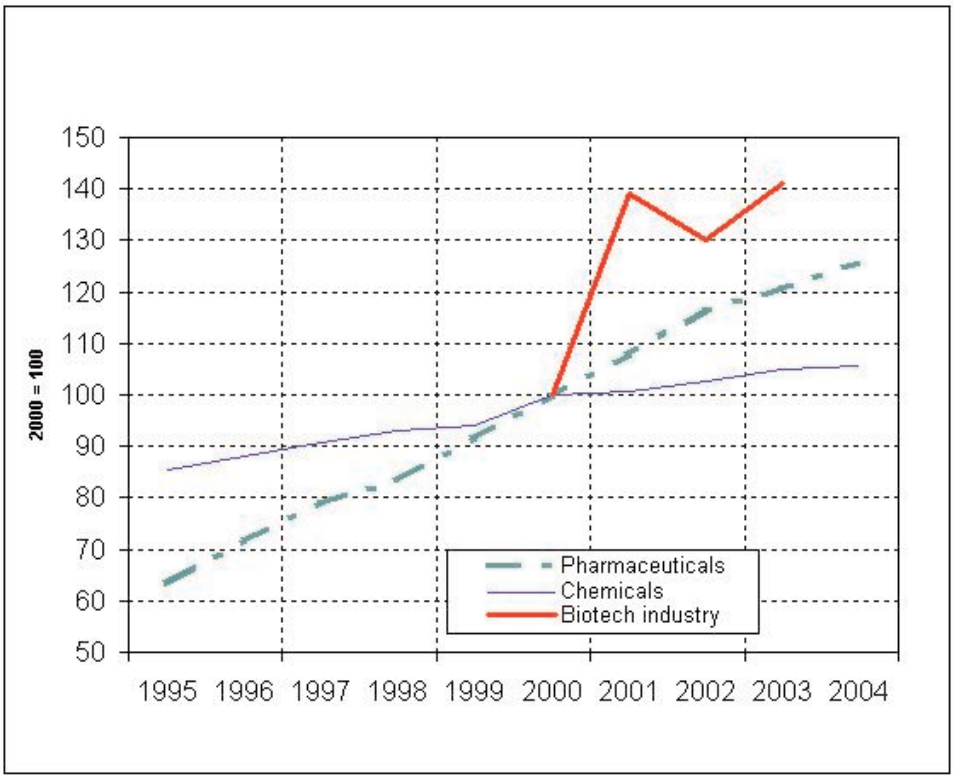
There is no specific information on environmental drivers available. It can be assumed that energy efficiency, waste and recycling play a far smaller role than they do in the production of traditional pharmaceuticals. This could provide an additional motive for the development of biomedical healthcare. In contrast to green biotechnology, genetically modified organisms are not seen to be a threat to the environment.

Economic drivers

There are no official time series data for the analysis of the biomedical healthcare industry. Data for the pharmaceuticals industry are used in Figure 7 as a lower baseline to plot the development of the biomedical healthcare industry. For some years, data for the biotechnology industry have been available from EuropaBio, the umbrella body for the European industry. These data support the inference drawn from the pharmaceuticals data that output growth of biomedical healthcare was much higher than output growth of chemicals over the period 1995 to 2004, although growth slowed markedly after the bursting of the dotcom bubble. Pharmaceuticals output grew much more rapidly than chemicals output, achieving double-digit growth rates over 1995 to 2000 and an average of 5% per year from 2001 to 2004.

[7] **http://www.europabio.org/documents/EY2003report.pdf**

Figure 7: *Development of the chemical and pharmaceuticals market*



Source: *Eurostat; EuropaBio, 2003; calculations by Ifo, 2005.*

US companies dominate the global biotechnology markets. The US industry is on the leading edge of this technology and it consistently achieves strong output growth. Therefore, the US biotechnology sector is a benchmark for the assessment of the state and competitiveness of this industry in other countries. The following paragraphs outline the economic conditions, the opportunities and the failings of the European biotechnology industry compared to its US counterpart. The comparison is based on the **2005 comparative study on biotechnology in Europe**[8] commissioned by EuropaBio. Although this study deals with the whole biotechnology industry and provides very few figures specifically about biomedical healthcare, it is safe to treat the findings and conclusions of the study as applicable to biomedical healthcare, since this is the most prominent subsector of the biotechnology industry. In Europe the revenues of the biomedical healthcare industry account for about 50% of the total revenues of the biotechnology industry, whereas in the US the share is 60%.

The numbers of biotechnology companies are roughly the same in the US and in Europe, but the European companies are younger and much smaller, having on average only half the number of employees of the US companies. The most striking difference, however, lies in the higher innovation intensity of US companies compared to European ones. When companies are launching new products on the market, the proportion of revenues they devote to R&D tends to be lower than the proportion devoted by companies that are still developing new products. US companies, however, are not only bringing more new products onto the market than European companies, but they also devote a higher share of revenues (almost 40%) to R&D than European companies (31.6%). This suggests that even though European companies are younger than US companies, Europe is not catching up on the US lead in innovation in biotechnology (see Table 2).

[8] **http://www.europabio.org/events/BioVision/CriticalI%20studyBiotech-Europ.pdf**

Table 2: *Key figures for the European and the US biotech industries, 2003*

Indicator	Units	Europe (EU15 plus Norway and Switzerland)	US	Europe biotech as a % of US
Companies	Numbers	1,976	1,830	108.0%
Employees	Numbers	94,000	172,400	54.5%
	per company	48	94	50.5%
R&D expenditure	Billions	6	16	36.6%
	as a % of revenues	31.6%	39.0%	
Revenues	Billions	19	42	45.2%
	per employee 1,000 €	202	244	83.0%

Source: *EuropaBio, 2005, p. 5, calculations by Ifo, 2005.*

The pharmaceuticals industry is knowledge driven and capital intensive. These characteristics, along with the regulation of national healthcare systems, are often seen as barriers preventing developing countries from entering this market. Yet in the era of globalisation, market access barriers have shrunk and competitors from developing countries are also entering pharmaceuticals markets. As in the case of computer software, India has a pharmaceuticals industry with an indigenous knowledge base. In addition, Indian companies are particularly successful in the development of active agents, i.e. substances that produce chemical reactions, as intermediate products for the manufacture of generics, i.e. medicines marketed without a brand name, and most of these products are delivered to European or US pharmaceuticals companies. For example, Biocon (headquartered in Bangalore) produces active agents for Western manufacturers by fermentation methods based on its own patents. Furthermore, Indian companies are poised to enter the US market with generics, and are also entering knowledge-driven market segments with innovative products based on their own expertise.

Indian companies have also become interested in the acquisition of smaller European pharmaceuticals firms in order to get access to their distribution channels. The importance of distribution channels was highlighted by the interest of the German pharmaceuticals manufacturer, Bayer, and the UK pharmaceuticals company, Glaxo-SmithKline, in buying the over-the-counter pharmaceuticals division of the UK retailer, Boots. Their interest, however, was thwarted by the merger between Boots and Alliance Unichem announced at the beginning of October 2005.

Not only do companies from India and other emerging countries enjoy decisive cost advantages in production, but they also have access to a highly qualified labour force at the labour-intensive stages of pre-clinical development and clinical trials. Consequently, competition from developing countries can be expected to grow not only in the area of traditional pharmaceuticals, but also in biomedical healthcare products. This is a challenge above all for the European players in the market, which are lagging behind their US counterparts and are thus exposed to tough competition from two sides, on the leading edge of technology from US firms and from emerging biomedical companies in India.

A comparison of the age patterns of the biotechnology industry in the US and Europe reveals that Europe is not lacking in entrepreneurial spirit. The establishment of new firms is dynamic. Around 60% of the industry's businesses have been created within the past five years, which exceeds the corresponding US figure of 43%. The explanation for the rapid creation of new companies in Europe lies not only in the delayed take-off of this industry in Europe and a process of catching up with the US, but also in the availability of finance for start-ups.

Public authorities have launched schemes for the establishment of innovative companies. Among other examples, in the Netherlands the **BioPartner**[9] programme has helped to create around 80 new companies, while in France the initiative **Jeunes Entreprises Innovantes**[10] (JEI) is dedicated to support independent, research-oriented companies. It provides tax breaks, particularly for the reduction of labour costs. These programmes concentrate above all on seed and start-up finance.

Financial markets are of outstanding importance for young industries. The liberalisation involved in the creation of the Single European Market has improved the financial environment for biotechnology companies in Europe, but compared to the US, the supply of funds is not sufficient, especially for companies beyond their early stages. Finance for funding growth is harder to secure in Europe than in the US and market volumes are much smaller, even when the respective sizes of the biotechnology industries is taken into account.

Table 3: *Funding of European and US biotech industries, 2004*

Indicator	Units	US	Europe (EU15 plus Norway and Switzerland)	
			Absolute figures	as a % of US
Venture capital	Millions €	940	2,850	33%
Initial public offering	Millions €	414	1,270	33%
Follow-on offering	Millions €	250	2,250	11%
Debt financing	Millions €	1,150	5,054	23%

Source: *EuropaBio, 2005, pp. 13–18, calculations by Ifo, 2005.*

Two drivers are of paramount importance to demand for biomedical healthcare products: financial restrictions in public healthcare systems and the ageing population. The public healthcare system is the most important determinant of demand. Its share of the total healthcare market is as high as 80% in some Member States and about 65% in others. There are striking differences between the health and social security systems in different Member States, and these systems are likely to remain subject to national control for the foreseeable future. Within the EU, and sometimes within the same country, government-run systems exist alongside self-administered systems subject to national regulation. However, the funding of all types of public healthcare systems has become ever more difficult over the past 10 years or so. Governments have had to introduce austerity measures to contain the rapid rise in costs that have become an increasing burden on the systems.

Public healthcare systems are to a large extent financed by wage-based insurance contributions, which cover healthcare services as well as social welfare. The share of wages spent on healthcare services has grown over the past 10 years and the subsequent rise in labour costs has impaired the competitiveness of European companies. Tackling these problems is a daunting task because so many political objectives are related to the issue of allocating resources to welfare services and the broader issues of allocating scarce resources. Unless funding problems are solved, there will not be sufficient resources to cater for the growing needs of an ageing and more health-conscious society.

[9] **http://www.hollandbiotechnology.nl/starters/home.html**

[10] **http://www.france-biotech.org/TEMPLATES/TemplateGenerique.asp?ID_DOC=528&ID_RUBRIQUE=93**

Demographic changes in European societies are leading to a growing share of pensioners in the total population. For instance, in Germany pensioners represented 9.7% of the population in 1950, but 16.3% in 2000. On present trends, pensioners will account for around 30% of the German population in 2050, and the share of people aged between 20 and 65 will fall from 62% to 55%. This demographic development produces a growing need for healthcare services while narrowing the financial base of the German public health system.

Political drivers

In many areas of importance for the biomedical healthcare industry, the institutional setting is provided by the Member States. Not only is this true of the different national systems for healthcare, but the conditions under which biomedical companies operate vary considerably between Member States, especially as regards restrictions on entrepreneurial activity in this field and acceptance and regulation of the relevant technologies. The results of such differences are seen in the different levels of development of the biomedical healthcare industry between different countries. While the UK's biomedical healthcare industry is ahead, the German industry is in an early state of development with a large number of small research companies, but a comparatively small output of products.

The current position is not satisfying at EU level. The European Commission's Sixth Framework Programme has provided very little support specifically for stem cell research. The Commission envisages incorporating this field in the Seventh Framework Programme, and proposals are to be assessed by ethics committees. However, the European Parliament has voted against spending money for research on stem cells. Although this decision is not binding on the European Commission, the Parliament's decision reveals the difficulties this field faces in Europe.

European initiatives on R&D contribute to progress in the biomedical healthcare industry. Under an initiative of DG Research, the European Federation for the Pharmaceutical Industry (EFPIA) and the Association of **European Biopharmaceutical Enterprises**[11] (EBE) created a multi-stakeholder platform, one aim of which is to help formulate and provide input to the Commission's programme for funding. Within this programme, efforts are being made to give special support to small and medium-sized enterprises in the biomedical healthcare industry. This type of support can contribute to a more balanced development of this young industry. At present it finds supportive conditions in some countries and, at best, neutral conditions in others. Although the European Commission cannot change national legislation, it can provide a more supportive environment for R&D by offering funds for research projects in certain areas.

One of the difficulties faced by small and medium-sized pharmaceuticals and biopharmaceuticals companies is the elaborate procedure of applying for product authorisation. Since 1995 the **European Medicines Agency**[12] (EMEA) has been engaged in streamlining the process to authorise medicinal products in the Single Market and removing the need to make multiple applications on behalf of the same product. There is now a European system with a centralised procedure of mutual recognition. The certification of medicines is to be carried out in conformity with the arrangements laid down by the World Health Organisation (WHO). EMEA and the national authorisation bodies form a network which is responsible for the approval and supervision (pharmacovigilance) of medicinal products in the market.

The authorisation of biopharmaceutical products is subject to specific requirements. Both EBE and EFPIA are involved in drawing up adequate requirements. Cooperation between the European Commission, EMEA and EBE has resulted in a proposal to implement fee reductions and administrative support to SMEs which are taking their products to the EMEA. This is of vital importance for biomedical healthcare companies since the high costs of their product dossiers are a heavy burden on them.

[11] **http://www.ebe-biopharma.org/**

[12] **http://www.emea.eu.int/**

Uncertainties and issues

The varying conditions and stages of development of the national institutions relevant to the biomedical healthcare industry are factors which hamper the kinds of joint European initiatives that are essential if European companies are to catch up with their US competitors. The dynamic development of the industry in some Member States shows that Europe has the potential to catch up, but isolated national efforts will not be sufficient for European companies to compete at the same technological level as their US counterparts. Moreover, initiatives to bring controversial areas of technology into EU research programmes have encountered resistance from the European Parliament, which has led the Commission to take a more cautious stance, but one that is not adequate to meet the US challenge.

Public healthcare systems are of outstanding importance in shaping demand for healthcare products and services in Europe. These systems are under stress because of misallocation of resources and financial restrictions. The result is that there are only very limited financial resources for financing new cures and medicines developed by the biomedical healthcare industry. Among these new cures are treatments for very rare ('orphan') and hereditary diseases for which therapies hitherto have not been available. Reform of national social insurance systems and health markets will be necessary if there is to be a more efficient use of resources, as well as access to new sources of finance, for example from private health insurance.

The single currency has contributed much to the creation of a European financial market by making it easier to secure finance for companies and to make use of such financial instruments as private equity investment. This development is decisive for a young industry that has to invest in research before it earns enough from products to pay for the research. More risk-oriented financiers than commercial banks are necessary for such an industry, particularly because investment is not in tangible but rather in intangible assets.

Although the position has improved in recent years, funding in Europe for this industry is far less supportive than it is in the US. There are sufficient public funds available for seed and start-up financing, but there is not enough 'mezzanine' funding available for biomedical healthcare companies that are no longer in the start-up phase, as public funds can only be made available for research and start-up activities but not for activities that are directly market oriented. Further improvements in sources of finance for this young industry are necessary.

Methodological note

The statistics used in the article are based on Eurostat, as far as the pharmaceuticals industry is concerned, which has been defined in line with the NACE nomenclature and comprises all products as mentioned in NACE 24.4. Furthermore, supplementary information is based on Cambridge Econometrics E3ME database in order to complete the time series. Additionally, surveys and statistics from the entrepreneurial associations of the industry were taken into consideration, and most references are from EuropaBio.

Biomedical healthcare industry – visions of the future

This second article in the Sector Futures series on the biomedical healthcare sector focuses on the main factors shaping the present and future of the industry. It assesses the major trends and drivers, and evaluates different scenarios for the biomedical healthcare industry. The article also examines why the European biomedical healthcare industry is lagging behind the US, and is facing increasing competition from companies in developing markets.

Biomedical healthcare is a young industry, engaged in the most advanced biological research and aiming to create innovative products. It is relatively free from traditional employment patterns and it seeks, through new flexible forms of employment and the nature of its work, to attract a highly-qualified workforce.

As the European industry is younger than the US biotechnology industry, Europe lags the US at the leading edge of research. At the same time European biotechnology companies face increasing competition from companies in developing markets, particularly India, which are also engaged in original research. In addition, the European biomedical healthcare industry also faces challenges from the scarcity of funding to support companies after the start-up phase and from concerns about the ethical issues involved in stem cell research. These concerns give rise to regulations of different degrees of strictness in different EU Member States.

The biomedical healthcare industry has an important role to play in coping with the medical and financial consequences of the ageing of the European population. However, unless a more uniform approach is adopted across Europe, the European biomedical healthcare industry will not live up to its potential as a source of products to help in the prevention and treatment of illnesses.

STEEP analysis

The following table summarises the sociological, technological, economic, environmental and political (STEEP) factors affecting, or expected to affect, the biomedical healthcare industry.

Table 1: *STEEP analysis of factors affecting the biomedical healthcare industry*

Trends and drivers	Summary
Sociological drivers	People are attracted to scientific research due to a highly congenial work setting and the fact that it is knowledge driven and innovative.
	Part-time employment, sabbaticals and other forms of flexible working attract highly qualified people and make the sector attractive to women.
Technological drivers	Biomedical healthcare technology is the most recent of the technologies that are changing our world.
	The industry is about to reach a critical mass for economic take-off and for the convergence of different research strands.
Economic drivers	The European biomedical healthcare industry is highly dynamic and is catching up with the US after a later start.
	There is a considerable amount of start-up and seed finance available for the biomedical healthcare industry in Europe.
	The lower availability of mezzanine finance and private equity reflects the industry's short track record compared to the US.
	US companies devote a higher share of revenues to research and development (R&D), which will ensure their lead over European counterparts in the foreseeable future.
	Globalisation is breaking down barriers to entry in biomedical healthcare, challenging European companies in knowledge-intensive segments of the market.
	Despite the challenges facing the European biomedical healthcare sector, the long-term prospects are good because an ageing population has greater needs for medical treatment.

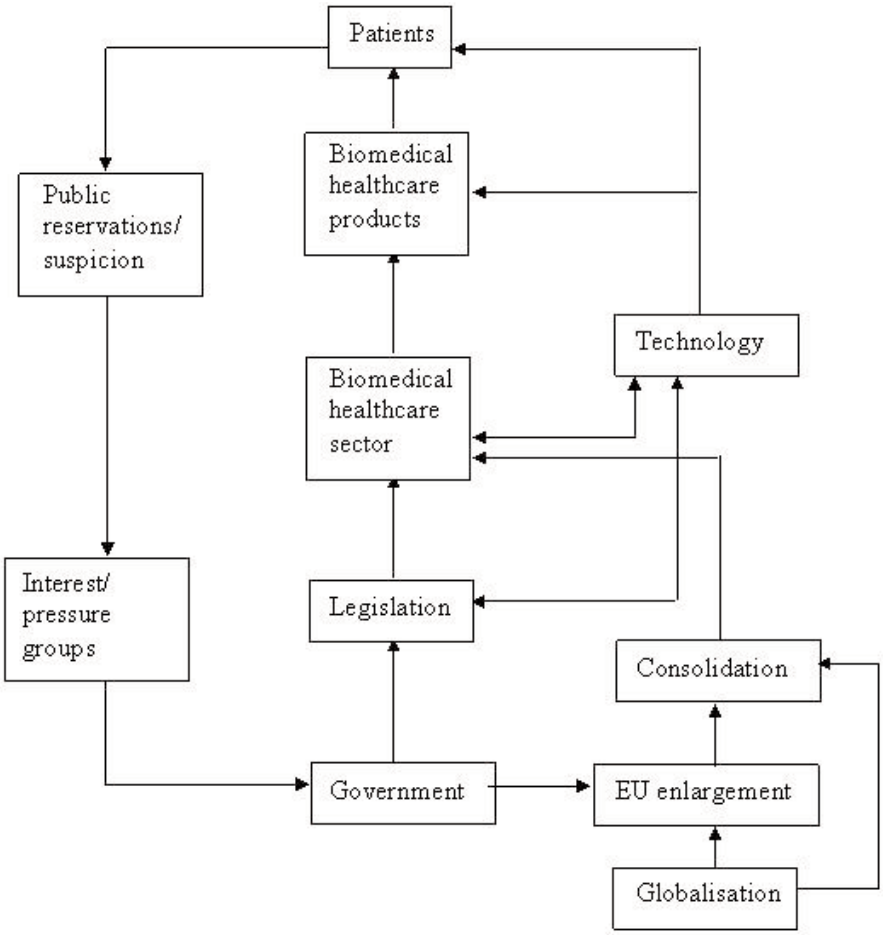
Table 1: *STEEP analysis of factors affecting the biomedical healthcare industry (cont'd)*

Trends and drivers	Summary
Environmental drivers	Energy efficiency, waste and recycling are far less important issues in the biomedical healthcare industry than they are in the production of traditional pharmaceuticals.
Political drivers	The conditions u nder which biomedical companies operate vary considerably between Member States, both with regard to restrictions on entrepreneurial activity and the acceptance and regulation of the relevant technologies.
	A more unified approach is needed in relation to the ethical issues, particularly in the area of stem cell research and therapy, if the biomedical healthcare industry is to live up to its potential for growth in Europe.
	The European Commission can play an important role promoting a better understanding of the opportunities provided by biomedical technologies.
	The current position is not satisfactory at EU level, with very little support specifically for stem cell research.
	The European Medicines Agency (EMEA) needs to streamline the process for authorising medicinal products in the Single Market.

Trends and drivers of change

Trend and driver linkage

Figure 1: *Trend and driver linkage*



Assessment of major trends and drivers

The biomedical healthcare industry is unusual because of the controversy it is capable of creating and the strict regulations it is subject to. This is particularly true of stem cell research and therapy, which raise ethical concerns. Public opinion is therefore very important to the industry, as it feeds through to the political environment responsible for the level of regulation, which is already holding back the industry, more in some countries than others.

Technological progress can ignite social reaction, thus managing technological advances is crucial to how society will use and perceive biotechnology. Not only can operational management help improve the public acceptance of the industry, but it can help to bring about changes to the legislation that is holding back research.

Globalisation also affects the industry. On the cutting edge of research, US companies are likely to continue to lead. Not only is the industry more mature in the US and biomedical healthcare companies are more developed and larger, the internal market is also larger. Because the average European firm size is much smaller, consolidation is likely to follow the start-up stage for most firms. To a certain extent, EU enlargement is addressing the problem of serving a small market. This should also make European businesses stronger to fend off competition from companies emerging in developing countries, which have the advantage of lower costs combined with high levels of scientific knowledge, expertise and innovation.

Scenarios for the biomedical healthcare industry

Scenario summary

In the international journal, *Technological Forecasting & Social Change*, Sager (2001, pp. 109–29) developed four scenarios for biotechnology, which depend on two key drivers (one technological, one social) that will shape the future of the industry.

The technological driver arises from the integration of technologies from the various sectors of biotechnology, combining with nanotechnology and information technology. This technological integration is expected to lead to new levels of progress and expansion in the industry. More specifically in terms of biomedical healthcare, this could speed up the development of molecular breeding, pharmacogenomics and embryonic stem cell technology, all of which will have a profound impact on the public's perception of health and ageing.

The speed and extent of technological integration is, however, closely linked to the social driver, which is public acceptance of biotechnology. All the emerging sectors of biotechnology have the potential to ignite social reaction, thus managing technological integration is crucial to how society will use and perceive biotechnology. The biotechnology industry needs to gain the public's trust to be successful. Public acceptance will not only shape market demand, as the public is ultimately the client of the industry's products, but also the political environment and, to a certain extent, regulation as the public vote for the politicians who shape policy.

Mixing the two drivers creates the following four scenarios for the future of biotechnology:

1. *Present day* (low public acceptance and low technology integration);
2. *Police state* (low public acceptance and high technology integration);
3. *Techno-utopia* (high public acceptance and high technology integration);
4. *Grass roots* (high public acceptance and low technology integration).

The assumptions made in each of the scenarios are based on the current views of technological integration and public acceptance of biotechnology.

The *Present day* scenario is based on the assumption that the current low public acceptance and low technology integration will continue. Together these will contribute to confusion about biotechnology among the public and lead to low market penetration. As a result, the full potential of biotechnology will not be realised.

The *Police state* scenario is based on the assumption that even when there is high technology integration and significant market penetration, the public still does not accept biotechnology. As a consequence, biotechnology products and processes have low market value and are poorly understood by the public.

The *Techno-utopia* scenario is based on the assumption that there is high public acceptance and high technology integration, so that society fully embraces biotechnology. There is a near-seamless integration of biotechnology into agricultural, medical, engineering and industrial products and services. The industry is encouraged to be transparent about its products and processes to facilitate further market penetration.

The *Grass roots* scenario is based on the assumption that society embraces biotechnology even in the absence of significant industry integration. This leads to high value being placed on the relatively rare biotechnology goods and services, and the public supports continued expansion of biotechnology.

Evaluation of the scenarios

Of the four scenarios, the *Present day* and *Police state* scenarios are the most plausible while the *Grass roots* scenario is the least plausible. It is very unlikely that the public would accept biotechnology and create demand for biotechnology products, but that the industry would not react and develop to satisfy demand. This would go against the current views of technological integration and public acceptance of biotechnology, as well as plain business interests.

The *Techno-utopia* scenario also seems unlikely because it requires a dramatic shift in attitudes towards biotechnology from both the general public and politicians, especially in Europe, where people remain suspicious of biotechnology. Thus, it seems unlikely that there would be a near-seamless integration of biotechnology into agricultural, medical, engineering and industrial products and services.

The *Present day* scenario is highly likely. The current low public acceptance is likely to persist even though technology integration continues. Although educating the public and careful actions by operational management can shape public acceptance, the public is likely to remain relatively ignorant of the biomedical healthcare sector, along with much of the other areas of biotechnology. As a result, biotechnology products and processes have low market value and are poorly understood by the public.

The *Police state* scenario is also likely. The main difference with the *Present day* scenario is that technology integration continues at a faster rate, despite low public acceptance. The consequences are the same, with low market value and poor public understanding of biotechnology products and processes.

Implications

It is expected that the biomedical healthcare sector will be shaped by five related pressures:

1. Ethical concerns, in particular in the area of stem cell research and therapy. Strict regulation of the research and use of embryonic stem cells is holding back the development of biomedical healthcare research and products in some countries.
2. Public acceptance of biotechnology. This will shape both market demand and public policy.
3. Competition on the leading edge of technology from US firms.
4. Competition from emerging biomedical healthcare companies in developing countries, most notably India.
5. Shift of R&D to non-European locations.

Countries that are more open to new technologies are going to benefit more from developments in biotechnology than countries that have reservations and anxieties about it. In terms of the ethical concerns, in particular in the area of stem cell research and therapy, European countries such as the UK fall in the category of countries open to new technology, whereas Austria, Germany, Latvia and Poland are far less open. Unless the differences in regulation are reduced, some countries in Europe are going to be in a more advantageous position than others to enhance the biomedical healthcare sector.

There are two threats from outside Europe to the development of biomedical healthcare in Europe. First, US companies are likely to hold their position on the leading edge of biotechnology. Second, companies in emerging markets such as India are particularly successful in developing and patenting innovative biotechnology products. They can thus combine lower costs with high levels of scientific knowledge, expertise and innovation. If Europe cannot overcome the forces that restrict the development of biomedical healthcare, biomedical companies in developing countries could well overtake European companies in innovation and product development.

The biomedical healthcare industry – policy issues and major challenges

The third and final article in the series about biomedical healthcare discusses policies that could enhance the international competitiveness of the European biomedical healthcare industry. In particular, it looks at issues related to bioethics, globalisation, economic growth and employment as well as demographics and welfare.

This last article in the series on biodmedical healthcare builds on the discussion of the first two articles in the series. **Article 1**[13] outlined the significant features of the sector: the size and structure of its market, the nature of employment, the main trends and drivers shaping the present and future of the sector and the principal issues and uncertainties that it faces. **Article 2**[14] investigated the future of the biomedical healthcare sector under four alternative scenarios. Under the *Present day* scenario, which is based on the assumption that the fundamental conditions do not change, the sector has only poor prospects. The *Police state* scenario, which was judged to be the most likely of the four, anticipates better prospects for the sector because of improvements in the supply side. The sector has the best prospects under either of the other two scenarios (*Techno-utopia* and *Grass roots*), because of stimuli from the demand side, but neither is very likely to come about.

Major policy issues and challenges

Bioethics: the pros and cons of biomedical healthcare

In modern democratic societies, it is difficult to make full use of new technologies unless they command widespread public acceptance. This means that public discussion of their advantages and disadvantages is essential. However, such discussion is often hampered because expert knowledge is not widely available and the opponents of new technologies generally believe that expert advocates have a personal interest in the adoption of the technology. One side tends to accuse the other of ignorance, while the opponents of the new technology distrust the motives of its supporters.

Such features characterised the debates about atomic energy and are found today in debates about biotechnology. This is true not just of the most publicised issue, stem cell research, but of other areas as well. Genetically modified (GM) crops, for example, arouse strong opposition not only from consumers in general, but also from farmers who fear for their livelihood. In particular, alternative agronomists fear that their business will suffer if there are no controls on the spread of GM crops.

Consequently, it will not be easy to hold open-minded discussions about biotechnology and stem cell research in particular. Nevertheless, it is essential to invite all groups in society to debate these subjects. Ethical questions are the most difficult issues to be addressed. Not only are there considerable differences between different groups within countries, but there are also different values and institutions between European countries. In this respect, communication and debate between national ethics committees is of outstanding importance as a prerequisite for the formulation of a consistent European research programme for the biotechnology industries. Only then will an efficient use of resources become possible.

[13] http://www.emcc.eurofound.eu.int/content/source/eu06002a.html?p1=sectorfutures&p2=eu06001a&p3=Biomedical_healthcare

[14] http://www.emcc.eurofound.eu.int/content/source/eu06003a.html?p1=sectorfutures&p2=eu06001a&p3=Biomedical_healthcare

A discussion of ethical questions needs to take into account all the effects of biotechnological research and the opportunities provided by the results of research. For instance, in the area of stem cell research, this means balancing ethical concerns related to the use of embryos against the opportunities for the treatment of illnesses for which there is either no cure today or for which the treatment has harmful side effects.

There should also be more initiatives taken in the near future to encourage debate among the groups involved in decision making. Greater understanding of different perspectives, values and traditions should take some of the heat out of the discussion of ethical problems and make it easier to reach decisions that command wide support. An arena such as the **US National Health Policy Forum**[15] could act as a catalyst in the debate on healthcare that is urgently needed within the EU to achieve a better understanding of the opportunities provided by biomedical technologies, along with their perils and the ethical problems. The European Commission's Health and Consumer Protection DG (DG SANCO) should push such European initiatives forward.

In future, it is also crucial for political leaders to communicate their understanding of the issues to the wider public. This will help to moderate the public discussion. Such steps may well reduce the emotional pressures in the current debate and allow for the creation of more adequate institutional conditions for biotechnology.

If such an approach is successful, the prospects for biomedical healthcare become brighter than described in the *Present day* scenario (one of the four scenarios described in the **second article of this series**[16]) and the *Police state* scenario becomes realistic. In this scenario, the institutional framework for biotechnology in Europe improves and technological progress is not constrained by an exodus of scientists. However, these changes alone will not be sufficient. Economic conditions for biomedical technology will need to be improved through publicly funded schemes and research programmes. Such a supply-side push is necessary to compensate for the weakness of demand.

Domestic demand often plays a decisive role for the competitiveness of an industry, but demand for biomedical products and services in Europe will remain weak until there is a better public acceptance of the related technologies and a greater interest in biomedical products. An indispensable prerequisite for such a change is a better knowledge of biotechnology to overcome the resistance and anxieties it provokes.

Improvements in natural sciences education will benefit European biomedical healthcare in two ways. A better understanding of what biotechnology really is will lead to a more balanced discussion of the complex issues involved in research into and application of this technology. This will contribute to better supply-side conditions. Second, there will be a more open-minded attitude to biomedical healthcare products and a greater willingness to use innovative products.

If the supply and demand sides could both be improved, biomedical healthcare would become an integral part of European society and economy and would have a good chance of becoming a global leader able to compete on equal terms with its US counterpart. This is the outlook of the Techno-utopia scenario described in Article 2. However, it is not a very likely outcome because of the difficulties of overcoming public resistance and scepticism.

[15] **http://www.nhpf.org/index.htm**

[16] **http://www.emcc.eurofound.eu.int/content/source/eu06003a.html?p1=sectorfutures&p2=eu06001a&p3=Biomedical_healthcare**

Globalisation

Traditional trade theories speak of the creation of wealth by an international division of labour based on the comparative advantages and factor endowments of different regions. The advantages of trade arise from the fact that at least some of the tangible and intangible input factors necessary for production cannot (easily) be moved. Yet the era of globalisation is characterised by the wide dissemination of know-how and capital. Consequently, it is no longer true that the manufacture of capital-intensive and knowledge-driven products can be carried out more advantageously in mature industrialised countries, whereas low-tech and labour-intensive products are more suited to less developed countries.

Countries in the process of industrialisation, such as India and Korea, have become important players in new technologies, among them biotechnology. These countries have created appropriate institutions for R&D and hence have become attractive to scientists who want to carry out research in the leading edge of technology. That is why Korea has launched an ambitious stem cell project and has invited biotech researchers to participate. This project will provide researchers with opportunities that they cannot find in the EU because of ethical objections.

There is a threat that the European biotech industry, which is about to leave its stage of infancy, will suffer from a brain drain if no adequate institutions are installed. Different institutional frameworks in the Member States hamper the design of European research initiatives in the area of biotechnologies. The major challenge is to create a consistent multinational framework in order to prevent the waste of resources by a number of diversified, poorly coordinated research efforts. There is a need to design pan-European research activities aimed at catching up with the US biotech industry.

If such initiatives are not taken, the EU will lose even its current medium position in international competition. The prospects might then be even worse than under the conditions of no change, as described in the *Present day* scenario, where it is assumed that misunderstanding and fear about biotechnology among the public prevent the improvement of the institutional framework and also keep demand weak. The present cautious optimism about the future of biomedical healthcare in Europe would fade away.

In the medium term, supportive conditions for the growth of biomedical healthcare companies must be created. Comparison of the European and the US biomedical healthcare industries shows that venture capital to support the creation of new companies is available in Europe, but the funding of growth is more difficult than in the US. Remedying this deficiency goes far beyond policy support for this sector. There is also a need for an adequate financial market to provide sufficient venture capital. 'Business angels' – until now not that common in Europe – can support such a development. More use should be made of the experience of older managers to help small research-oriented businesses become market-oriented companies.

Economic growth and employment

The EU25 is the world's largest economy, when measured by output and the number of inhabitants. The creation of the Single Market has given a stimulus to economic development, but growth has slowed down in most Member States since 2000 and there were virtually no signs of improvement before 2005. Although some improvements are expected in the near future, growth will remain weaker than in the US and Asia. The creation of new jobs was not sufficient to make up for job losses, and medium-term prospects are not encouraging.

In 2000, European leaders committed the EU to the Lisbon Agenda, with its objectives to make Europe the most dynamic economy in the world by 2010 and to reduce unemployment. After five years, the mid-term assessment of the goals reached so far is disappointing. Growth has been well below the rates envisaged and no substantial improvement is expected in the near future. One major obstacle to injecting more dynamism into the European economy is believed to lie in the many different and conflicting objectives advocated by the political groups. The European Commission plans to reactivate the Lisbon process, under the leadership of the Commissioner for Enterprise and Industry. The process will

involve an evaluation of the institutional settings of the EU in order to identify barriers to growth and entrepreneurial freedom, with proposed measures for overcoming these barriers.

The several branches of biotechnology are all characterised by dynamic technological development. Although biotechnology companies are mainly small and have not so far generated a large number of jobs, their pace of output and employment growth is rapid and accelerating. Total biotechnology output in Europe grew by more than 40% and employment by more than 15% between 2000 and 2003. Biomedical healthcare is the most important industry within biotechnology, accounting for about half of biotechnology output. There is a sharp contrast between biotechnology and such related industries as pharmaceuticals and chemicals. Their output has not grown appreciably since 2000 and they have generated hardly any increase in employment.

Policies to support economic growth ought to pay particular attention to new and fast-growing industries like biotechnology. A better institutional framework would facilitate the development of such industries and improve their chances of success in the global race. It is also important to remember that biotechnology has spill-over effects, which will become even more important in the future. Just as technological advances in micro-electronics prompted developments in information and communication technologies (ICT), so will biotechnology stimulate growth, above all in chemicals and pharmaceuticals, but also in agriculture and nutrition.

The importance of biomedical healthcare to the whole pharmaceuticals sector should be emphasised. In a wide range of applications, biomedical healthcare has become the R&D laboratory for the development of new pharmaceuticals products. More than one quarter of all pharmaceuticals used in clinical trials of medicines are biomedical products. This represents an increase of more than 50% between 2000 and 2003. These figures illustrate the importance of the biomedical healthcare sector to the future of the European pharmaceuticals industry.

Because of the spill-over effects of biomedical healthcare on pharmaceuticals and other high-technology industries, policies that promote biomedical healthcare will contribute to the Lisbon objectives. Such policies will also be supporting an industry that is well suited to achieve other social objectives. Work in this industry requires high levels of skill and qualifications. Furthermore, working conditions are flexible and innovative and thus offer equal opportunities to both sexes.

Demographics and welfare

The European healthcare market is highly regulated: public institutions control more than half of the market. To a large extent, social insurance is funded by contributions from employers and employees. For many years, contributions have been rising faster than wages, but the income of public health systems has still not kept pace with demands on their resources. A solution is urgently needed, for at least two reasons. First, international competition has been exerting downward pressure on labour costs, and as a result, employees' net real income has been shrinking. Second, demographic changes will worsen the situation. The share of pensioners in the total population will continue to rise, which will lead to increasing demand for healthcare services, while the labour force as a share of total employment will decline further.

This demographic development cannot be avoided even if there were to be an immediate rise in the birth rate. For the next 20 years the gap between the growing need for healthcare services and a shrinking base of contributing employees will not be narrowed.

It is the responsibility of national governments to take adequate measures to keep the public healthcare systems running. Measures will have to be taken to stabilise the balance between receipts and expenditures. It will be necessary to find new sources of finance to reduce the burden of levies borne by employers and employees alone. Moreover, individuals

will have to take more responsibility for insuring themselves against the costs of medical treatment. Conversely, long-term solutions will have to be found in order to make healthcare systems better able to meet rising demand. DG Health and Consumer Protection (DG SANCO) has a role to play in this. It can use best-practice analyses to create a better understanding of the deficiencies that lead to a misallocation of resources.

Until now, decision makers have tended to react only to acute crises. Until the problems of healthcare systems are tackled from both directions, funding will be inadequate and the systems will not be able to cope with growing demand. This will further impair the prospects for biomedical healthcare, since there will not be adequate finance both to meet current needs and to pay for new medicines and cures made possible by progress in biotechnology.

In the pessimistic *Present day* scenario and the more realistic *Police state* scenario, healthcare systems unresponsive to demographic changes will restrict the market for biomedical healthcare products. Biotechnology will be poorly understood and individuals will be reluctant to pay for advanced cures and medicines. Furthermore the public healthcare systems will not have the means to pay for new therapies. Thus, illnesses will remain untreated although medicines are available.

Conclusion

Biomedical healthcare is a young industry with considerable potential for growth in output and employment. It provides good working conditions for qualified personnel. Its flexible working practices and recruitment strategies provide good opportunities for female employment. However, the current institutional framework does not support a dynamic evolution of this industry. Furthermore, the biomedical healthcare industry in Europe is being challenged from two sides. In this industry, the US sector is the technological leader and US products dominate the market. At the same time, competitors from emerging countries enjoy a more adequate institutional environment and are catching up with the leading industrialised countries.

The institutional framework of the biomedical healthcare sector is far from being the same in all European countries, and this has led to considerable differences between the industry in several countries within Europe. One task for the European Commission is to take initiatives to create a more homogenous supply side, in particular by intensifying the discussion of ethical issues. If the supply side could be improved, biomedical healthcare would become a European industry able to enhance its international competitiveness through the exploitation of synergies and economies of scale.

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