



# The future of the European biomedical healthcare sector: Four scenarios

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# Introduction

This report describes four scenarios for the European biomedical healthcare sector. These scenarios depict plausible hypotheses about the future and provide a tool for forecasting, analysing and formulating policy as well as for strategic planning in private companies and among social partners. In a rapidly changing and complex world where demand and supply opportunities change equally quickly, planning cannot rely on simple projections of past trends. Alternative views of the future can help to broaden our understanding of issues that need to be addressed today. Scenario methodology provides such alternative views by embracing the element of uncertainty inherent in the future.

A scenario is a coherent description of the possible outcomes of the drivers, trends and events that can influence and change the subject of analysis over a given period. Scenario analyses and exercises do not aim to predict the future, but rather to describe a possibility. Given the uncertainty of the future, it should be explicitly stated that any scenario is only a possibility, as likely or unlikely as many others.

Tensions between short-term considerations and long-term visions and strategies often affect policy-making. Scenarios are a way of developing more robust, innovative and future-oriented best practices for particular futures. Though often set in a 10 to 15-year perspective, scenarios can be a navigation tool and early warning system for current conditions. Scenario building can also point to ideas and methods for putting insights generated in case studies and market study into operation. Consequently, scenario analysis should be regarded as a tool for insight and futures literacy and as a catalyst for strategic conversations and discussions, but not as an end in itself.

The four scenarios presented here represent realistic, internally consistent and plausible pictures of alternative futures:

- Scenario 1: ‘Slow boat to China’
- Scenario 2: ‘Forever young’
- Scenario 3: ‘Simply the best’
- Scenario 4: ‘Should I stay or should I go’

## Objectives

The objective of this study is to present a scenario analysis that can be used as a vehicle to develop long-term visions (10-year lead time) of opportunities, barriers and requirements for the optimisation of the biomedical healthcare sector and the sustainable development of its workforce. This objective is pursued as a task split into the following two sub-goals:

- To develop exploratory scenarios for the macro drivers influencing the biomedical healthcare sector. Macro drivers are understood here as trends that, with very few exceptions, cannot be influenced by individual companies or political actors.
- To present plausible implications of each scenario for the biomedical labour market.

## Methodology

In order to be a forceful tool for policy analysis and strategic analysis to describe a possible future, a scenario should fulfil the following criteria:

- It should be *plausible*, but does not have to be the most probable.
- It should be *internally consistent* in order to be plausible and in order to enable a coherent discussion.

- It should *project backwards* from the posited future to the present so that participants can better understand how that future might arise.
- It should contain *sufficient information* so as to identify the role of the subject organisation.

Scenario building was designed as a two-stage process.

*Stage 1* was devoted to developing exploratory (not normative) scenarios. These are partly based on existing work, but in this case they are mainly based on desk research by the scenario team, without the direct involvement of external sector experts. At this stage, the main macro drivers and important dimensions of change are examined in order to determine the most important elements of the future. When these drivers and dimensions have been identified, they are fleshed out into plausible and concrete scenarios.

*Stage 2* examined the plausible implications that different configurations of the macro drivers might have on companies and on issues that companies must address. This examination was carried out partly by desk research and partly by drawing on strategic discussions that took place between scenario experts, sector experts and company managers when the case studies were produced.

# Construction of the scenarios

The construction of the scenarios employs a conceptual framework, designed to capture changes in the external environment of service provision, by means of five types of drivers and trends:

- socio-cultural;
- technical;
- economic;
- ecological;
- political/ regulatory.

The scenario team collated opinions on the major trends and drivers of these categories over the next 10 years in relation to factors that will have a significant impact on the biomedical sector. The team used assessments of around 50 trends and drivers to identify a range of dimensions on which the scenarios could be built. These were then consolidated and assessed within the team according to two criteria:

- importance (low, medium, high);
- uncertainty (low, medium, high).

Six main drivers were identified as being the most important:

1. Economic performance in Europe.
2. Access to (venture or public) capital.
3. Public values.
4. Public perception of biotechnology.
5. Regulation of the biotechnology industry.
6. Protection of IPR (intellectual property rights).

## Description of the drivers

### Development of the world economy

In any study of future conditions for an economic sector, the development of the economy is a key driver. The biomedical industry is characterised by a complex value chain, which is influenced heavily by public interventions in the form of public subsidies for medical products on one side and more or less strict regulation of development, marketing, distribution and sales on the other. Nonetheless, market conditions – particularly access to investment – play a crucial role for the development of the sector. Due to long lead times and the need to have cutting-edge technological equipment at its disposal, the investment requirements in the sector are comprehensive.

### Access to (venture or public) capital

Access to risk-bearing capital, be it public investment or private venture capital, is vital to the biomedical industry. The industry is very R&D intensive and technologies are often new and proprietary. In the bio-pharmaceutical part of the industry, time to market for new drugs is considerable.

### Public values

Public values, elusive as they may seem, play a crucial role in shaping the future. Our values influence the way we choose to live, work and consume. At present, Europeans have high regard for individuals' aspirations, desires and opportunities and, for many, consumerism is one of the prime paths to self-realisation. However, there are values that oppose stark individualism by claiming that our regard should be less for ourselves and more for the environment or for upholding communitarian views. Consequently, from a 10-year perspective, the direction in which our shared value systems will develop is not obvious.

### Public perception of biotechnology

Public perception will affect market opportunities and research in the field of biotechnology. Surveys indicate that the European public is becoming more positive towards biotechnology; however, scares and uncertainty about the effects of biotechnology could change public perception in a negative direction very quickly. Also, moral issues (stem cells, genetic testing, etc.) will not disappear from the public agenda.

### Public regulation

Public perception of biotechnology will have an impact on the regulation of the sector. A sceptical population will translate into stricter regulation. However, strict regulation of the biotechnology sector could, in time, inspire trust in the sector, leading to a more positive perception of biotechnology.

### Protection of intellectual property rights

Intellectual property rights play a crucial role in the biomedical sector, which relies heavily on cutting-edge know-how and technology. Patenting is the established way to protect IPR, but recent experiences of companies who have sourced activities to countries outside the EU – for instance, China – indicate that patents do not provide universal protection against theft of knowledge. Hence, while production costs are low in China and India, companies in the sector hesitate to move high-value manufacturing and R&D activities to places where IPR is not sufficiently protected.

Another – but closely related – issue in relation to IPR is the increasing competition that the pharmaceutical industry faces from biosimilars and generics. As soon as patents expire, cheap products are marketed, which – at least with regard to medical properties – are identical to branded products. The implication is that large companies have difficulties in achieving the sales volume that enables them to cover the costs of developing the drugs in the first place.

#### IPR in China

China is expected to become the fifth largest drug market in the world by 2010, with a growth rate of 20–25% per annum in the next three years.

However, the Chinese social environment for the protection of intellectual property rights is complex. Locally produced generics and copy products dominate the Chinese drug market. It is estimated that about 97% of the drugs produced by local companies are generics or counterfeits.

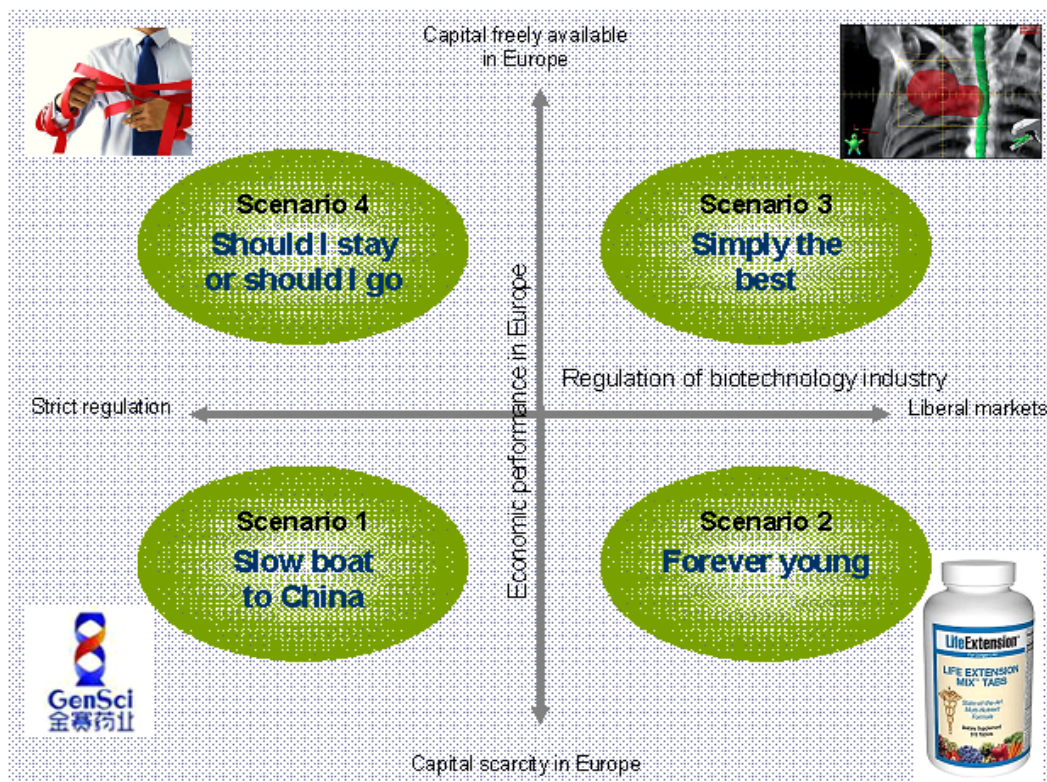
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### Scenario drivers

Combinations of the six drivers give rise (by way of combination) to  $2^6 = 64$  possible scenarios. However, some of these are very similar and some turn out to be implausible. We have compared the combinations and selected four, which differ considerably, yet can still be considered plausible. Ideally, the scenarios should be visualised in a six-dimensional space,

but as this is not technically possible, we have shown their position in a two-dimensional space, defined by two of the drivers (see Figure 1), namely the availability of capital for investment in the sector and the extent of public regulation.

Figure 1: Four scenarios for the biomedical industry in Europe 2017



Scenario 1 – ‘Slow boat to China’. This is a crisis scenario. Companies in the European biomedical sector are under a lot of pressure in Europe and hence look to Asia for growth opportunities.

Scenario 2 – ‘Forever young’. This scenario is characterised by growth. R&D is market driven and market strategies are focused on lifestyle products sold directly to individual consumers rather than on developing new, innovative medicines.

Scenario 3 – ‘Simply the best’. This scenario is also characterised by growth, but companies in the sector are focused on developing a wide range of products (new medicines, lifestyle products, etc.) for both consumers and the healthcare sector.

Scenario 4 – ‘Should I stay or should I go’. In this scenario the biomedical companies in Europe are faced with a difficult choice: either exploit opportunities for funding and operate in the face of regulatory and ethical barriers for development, or move to other regions that present companies with a better mix of opportunities and barriers.

The four scenarios are described in detail below. For each scenario, a table shows the state of each of the six drivers in the particular scenario compared to the other three scenarios. Of particular interest with these scenarios is whether the scenario is compatible with further development of biomedical healthcare industry operations in Europe or whether the incentives to move business abroad are greater. Green cells in each table indicate positive incentives for biomedical companies to develop their business within Europe, while red cells indicate that the incentives to move out or start business outside Europe outweigh the incentives to stay.

# Scenario 1: Slow boat to China

Uncertain drivers with high impact	Slow boat to China	Forever young	Simply the best	Should I stay or should I go
Economic growth in Europe	<b>Stagnating</b>	Stagnating	Positive	Positive
Access to investment capital	<b>Low level</b>	Low level	High level	High level
Public values	<b>Community/sustainability</b>	Individuality/health	Individuality/health	Community/sustainability
Public perception of biotechnology	<b>Sceptical</b>	Positive	Positive	Sceptical
Regulation of biotechnology industry	<b>Extensive</b>	Limited	Limited	Extensive
Protection of IPR	<b>Global protection</b>	Strong in EU – poor in emerging economies	Strong in EU – poor in emerging economies	Global protection

## Economy and market

After years of positive economic developments in Europe, rising oil prices, rising inflation and the burst of the housing bubble in 2008 resulted in a sharp economic decline in Europe. This has put pressure on public finances and limited public and private spending on healthcare, including products used in healthcare. Limited market opportunities and low growth have deterred investors from the biomedical sector and venture capital is turning to other sectors with higher returns.

Biotechnology-based products on the market are relatively expensive and very few governments can afford to reimburse medical products like medicine or aids for the disabled or elderly. The difficulties involved in getting biotechnological products approved for reimbursement has decreased the profitability of the most innovative biomedical companies.

Consumers are not in a position to buy relatively expensive biotechnology-based products themselves. Hence, the main market is the public health sector and private hospitals and clinics. Also, growing public concern about the use of biotechnology has contributed to reducing the consumer market for biotech products.

## Policy framework

For the biomedical sector, the economic downturn has resulted in limited availability of public funding for research into innovative medicines and medicines targeted at rare diseases. Funding is channelled away from research and into the operation of health services. Hence, industries that supply these services with consumables, such as medical instruments, surgical dressing materials, various types of fixtures, etc., experience higher growth than the biopharmaceutical industry.

There is a heavy regulatory burden on the biomedical industry. Substances and materials have to comply with very strict regulations and documentation requirements for quality systems are comprehensive. Liberalisation of the drugs market has not expanded; on the contrary, the requirements that chemist shops must fulfil in order to receive authorisation to sell drugs have actually increased.

Together with pronounced difficulties in securing investment, this has had a substantial negative impact, especially on small biomedical companies. There are very few start-ups in the sector, and many companies are struggling to find private investors in order to continue research. Many biomedical companies have gone bankrupt and medium-sized companies are under severe stress. The key to survival in the biomedical sector is to have a recognised product on the

market. Therefore, the large enterprises with a broad portfolio of non-biotechnology products are doing comparatively well in spite of the economic downturn, as their product development mainly takes the form of incremental changes to existing products. In general, the biomedical sector is characterised by a low degree of innovation.

Global protection of IPR has improved since the US and Europe put strong pressure on China and India following several breaches of patents and medicine scandals in China itself. China's own biomedical research base is now so strong that Chinese companies are able to undertake the necessary basic research and development.

In Japan, health robotics is booming, and some European producers are now acting as subcontractors for this industry.

### Society and culture

At the beginning of the new millennium, the popular perception of the prospects for biotechnology in Europe was becoming increasingly positive. However, this changed in 2009 after several scientists presented results indicating that biotechnology-based medicines could seriously damage human fetuses and stimulate the evolution of new, and very deadly, super-bacteria with no known treatment. In addition, a large explosion at a biotech facility in France (a possible terrorist attack), which caused contamination of a substantial area and the infection and death of several thousand inhabitants of a nearby city, generated fear of a 'Biotech Chernobyl' across Europe.

As a result, Europeans experienced a technology shock that changed their perception of biotechnology from positive to very sceptical. Several groups also now question the ethics of 'manipulating nature' – stem cells and genetic testing are issues that are still high on the public agenda. The concept of sustainability has been evoked to give impetus to a popular drive towards the 'natural'. This drive also means that using robots as aids in care for the sick and elderly has not taken off in Europe. On the contrary, alternative treatments and an increasing consumption of food designed to boost health and prevent illness are picking up.

### Company strategies

As a result of these developments, companies in the sector are increasingly turning their attention to Asia, where economies are booming, as is economic ability and the demand for healthcare in all forms, including innovative medicines and robotics. These markets are not so sceptical about (bio) technology and people there can afford to buy relatively expensive products.

However, alternative medicine is considered an opportunity in Europe – the documentation requirements for dietary supplements are still lax, and the general public associate products derived, more or less directly, from plants or animals with health and spirituality.

### Developments in the value chain

As the conditions for biomedical R&D have deteriorated, commercial biomedical R&D activities in Europe are disappearing. It is no longer commercially viable to build a business solely on expertise in the first phases of biomedical innovation, so R&D-based SMEs have either shut down, moved away or have been merged into multinational enterprises. Most SMEs remaining in Europe employ a business model whereby manufacturing does not take place in Europe. Typical examples are the parallel importers of brand name products, who import, re-package and market medicine in Europe; companies who produce (abroad), market and sell generic medicines; and suppliers to the public health service sector. Due to stagnating consumer power, strict regulation and an ageing population, direct sales to consumers is decreasing, while a growing part of the market for biomedical products is served either through authorised

chemists or via the public health sector. The most successful companies have established subsidiaries abroad and parts of the administration are often outsourced or relocated to these subsidiaries because of the lower labour costs.

### Location decisions

These companies have, in turn, outsourced large shares of R&D to China, India or Japan and manufacturing to Africa or Latin America. Corporate management, marketing and logistics are still in Europe, but in many companies, the survival of even these activities in Europe is only a question of time. Executive managers are recruited worldwide, and any historical reasons for keeping the corporate headquarters in Europe lose their validity with each passing day, even more so as markets are contracting in Europe and the US and expanding in Asia and Latin America. There are still a number of packaging facilities left in Europe to package imported generics and dietary supplements for local markets. Top scientists follow the money, and Europe is thus experiencing a ‘brain drain’, which is affecting all countries, reducing critical mass and thus future potential. A vicious circle is in operation as skilled employees leave Europe, while those that remain command wages way in excess of those commanded by their Asian counterparts.

### Product innovation

In terms of R&D, the niche strategies (e.g. rare diseases) previously adopted by small biomedical companies in particular have largely been abandoned in favour of research into major diseases using more ‘traditional’ technologies. These technologies include traditional biochemistry or – in the case of aids and devices – traditional manufacturing processes. Biotechnology-based products are rare and those on the market have been through long periods of testing before they were ‘accepted’ and considered safe. The growing scepticism towards biotechnology has, of course, contributed to this development. Some innovations are taking place in the public health service sector, mainly spurred by the need to provide products (bandages, rehabilitation aids, etc.) which are less time-consuming, as seen from the perspective of public health staff.

The biomedical sector in Asia has been leading in R&D for years, helped by extensive funding and very limited regulation. In 2015, the public was stunned by the first (at least the first official) birth of human clones. The two healthy and apparently very intelligent babies, Yin and Yang, were both created in China. In the Far East, neurosurgical techniques that enable people who have lost limbs or senses to regain their abilities through implants with direct connection to the relevant parts of the brain is a big growth area, but European industries are not at the centre of this development.

### Process innovation

Few manufacturing operations are left in Europe and in those that remain, manufacturing processes are fully automated. Packaging for local markets is largely done by means of robotics.

### Labour market, skills and competencies

Employment in the biomedical healthcare sector has decreased since 2007. The massive relocation of R&D and manufacturing to Asia has reduced the need for scientists and skilled workers in this sector. Management and administration, packaging, sales and distribution are the main activities left behind.

### Manufacturing process

As most manufacturing has moved to low-cost countries, there is little demand for process workers and process technicians. However, due to the strict regulations, companies need to provide detailed documentation of products and processes at their production sites, regardless of their location. Although quality documentation, to a large extent, relies on technological solutions (logging, traceability of batches and individual packages), the demand for staff with the technical skills and knowledge needed to work as quality inspectors has increased considerably. As packaging is generally automated, few workers are needed to inspect the processes.

### **Marketing and R&D**

As marketing is one of the main activities of European biomedical SMEs, there is some demand for people with skills in marketing and sales. The need for these people to have any skills in biomedical technologies is limited. However, as one of the major markets is the public health service sector, insight into the structure of this sector and the methods it employs is of utmost importance. In all biomedical companies, there is a large demand for administrative employees who possess, or are capable of achieving, insight into the regulatory framework and who can ensure compliance with quality requirements.

### **Management**

General management skills are also called for. As manufacturing is contracted out, usually to foreign countries, contract and finance management skills are vital to ensure efficient operation.

### **Main challenge for biomedical companies**

The main challenge facing the companies in the sector is staying in business, in view of the fierce competition, strict regulation and stagnating consumer demand. Going where markets are bigger and more liberal means having to adapt the whole company to match a new business environment. Some companies face this challenge by a gradual relocation, but this presents a challenge in itself, having to manage a company that is split between several locations.

# Scenario 2: Forever young

Uncertain drivers with high impact	Slow boat to China	Forever young	Simply the best	Should I stay or should I go
Economic growth in Europe	Stagnating	<b>Stagnating</b>	Positive	Positive
Access to investment capital	Low level	<b>Low level</b>	High level	High level
Public values	Community/sustainability	<b>Individuality/health</b>	Individuality/health	Community/sustainability
Public perception of biotechnology	Sceptical	<b>Positive</b>	Positive	Sceptical
Regulation of biotechnology industry	Extensive	<b>Limited</b>	Limited	Extensive
Protection of IPR	Global protection	<b>Strong in EU – poor in emerging economies</b>	Strong in EU – poor in emerging economies	Global protection

## Economy

The European economy has been stagnating for several years and this has put pressure on public finances and reduced private consumption of high-value products. Economic development has resulted in a polarisation of European consumers – the majority mainly consume low-value products, while a (large) minority of more wealthy households can still afford high-value products. Furthermore, the pressure on public finances has limited the public resources available to R&D, and private capital is flowing towards less risky sectors. Shortage of risk-bearing capital has slowed down the innovation rate in the biomedical healthcare sector, making it very hard, especially for SMEs, to stay in business.

## Policy framework

Although strict regulation of the sector offered some protection to consumers, it was found that the administrative burden on the industry was creating a massive barrier for the development of the sector. In addition, the protection did not even work out as intended, as a small number of ruthless firms found ways to bypass legislation and control procedures, which, in some cases, has led to substandard products being put onto the market. This has led politicians to relax regulation of the sector somewhat and instead to put their stakes into increasing consumer awareness and to support self-discipline within the sector. Consequently, the industry's costs, related to quality assurance and documentation, have been reduced. Biopharmaceuticals are still under strict monitoring, but other types of biomedical products (implants, devices, etc.) are not subject to the same administrative requirements as they used to be.

At the same time, European legislators have focused on establishing the best possible framework for the protection of IPR. Although the regulatory framework is not considered optimal by the companies in the sector, it is still considered risky to move operations with large knowledge content abroad.

## Society and culture

Public perception of biotechnology is very positive and consumers willingly buy products manufactured on the basis of biotechnology – this goes for food as well as medical products. The controlled lifestyle trend, which focuses on controlling one's own health and outward appearance, has gone on and gained momentum, and the demand for lifestyle-enhancing products is increasing – not only in Europe, but also in other regions of the world. However, economic stagnation in Europe has reduced the market potential for high-value products with high specificity. A large share of the population fulfils their demand for products that will support their control of life by consuming bulk lifestyle products

produced in Asia (fat reduction pills, anti-ageing lotion, standardised implants, etc.), while the more wealthy segments provide a small market for innovative products and services (DNA-adapted medication, sense aids, robotic strengtheners, etc).

One of the most successful European biotechnology companies is BIOBeauty, specialising in non-intrusive products for elderly people who want to feel and look young. In 2014, the company introduced a revolutionising gel on the healthcare market. The gel is injected directly into the limbs and instantly starts building up muscles, nerves and tissue, making it possible for people to stay active and look sharp right through their lives. While beauty clinics and sport centres are the company's main clients, some of the company's products are sold directly to clients via the internet. The company has established a hotline, which enables personal assistants to monitor and help the clients with using the company's products. The beauty-and-sports market is very competitive and requires companies to focus on targeted marketing of products and a high level of service to their clients.

### Company strategies

Due to the shortage of private and public funding for research, companies in the sector are focusing on less research-intensive products and services. The increasing demand for lifestyle products among private consumers is considered a huge opportunity for biomedical companies, since such products are less investment intensive and less highly regulated than biopharmaceuticals. Other biomedical companies (SMEs in particular) are entering the service sector, providing biotechnology-based services to companies in the chemical and pharmaceutical industries. Companies that have already launched successful biomedical products mostly focus on the re-use of existing products for other conditions and diagnoses.

### Development in the value chain

Large companies dominate the sector due to their capacity for attracting both investment and high-skilled employees. Small companies are struggling to stay in business due to lack of funding. Even SMEs that have managed to find funding for their research are often acquired by large pharmaceutical companies who are desperately looking for drug candidates to fill their pipelines. Many SMEs are pushed backwards in the value chain, operating solely as subcontractors for larger companies (performing tests, etc.).

### Location decisions

European companies retain R&D activities in Europe due to the strong protection of IPR here. However, bulk manufacturing of low- and high-value products are moving towards Asia, where demand for high-value lifestyle products is increasing among large groups of consumers. Remaining manufacturing operations in Europe only serve the European market.

### Product innovation

There is a very low level of product innovation in Europe. Most companies focus on beauty and endurance-enhancing products, rather than developing new, innovative medicines or appliances. Such products have a shorter time to market and are not subject to the same extensive control and approval requirements as biopharmaceuticals.

### Process innovation

Process innovation is focused on developing direct sales to costumers. Many companies work with a network of freelance salespeople who sell products at neighbourhood sales (like Tupperware parties). Other companies put a lot of effort into CRM, e-commerce and virtual communities.

One key initiative is the establishment of customer service departments, where personal health counsellors are assigned to clients, providing them with information on the use of the company's products as well as related health and wellness matters under the label of 'health coaching'.

### **Labour market, skills and competencies**

#### **Manufacturing process**

Most manufacturing activities are sourced in Asia or Latin America. Some companies have even tried sourcing to Africa due to rising costs in Asia, but have encountered problems with political and economic instability. In manufacturing operations, there is still a need for staff trained in carrying out clinical trials; however, the demand for qualifications has stagnated in Europe due to global sourcing.

#### **Marketing and R&D**

Marketing skills are vital for companies in the sector due to tough competition. Also, there is increasing demand for skilled personnel in customer relations departments. These employees are typically front office clerks or students at higher education institutions that are given a crash course in the company's product portfolio. At the high end, the cognitive sciences are contributing to the development of new products that could enhance people's mental capacity (the IQ pill). Finally, skills related to e-commerce and consumer services are in demand.

#### **Management**

Managers in the sector need to change their focus from research management to identifying market opportunities in the beauty and sports sector.

### **Main challenge for biomedical companies**

Companies in the sector are facing a radical transformation from being research intensive to focusing on providing services. In this scenario, most companies focus their efforts on the market for lifestyle products, implying that companies need to build up competences in communication, marketing and direct interaction with clients.

# Scenario 3: Simply the best

Uncertain drivers with high impact	Slow boat to China	Forever young	Simply the best	Should I stay or should I go
Economic growth in Europe	Stagnating	Stagnating	Positive	Positive
Access to investment capital	Low level	Low level	High level	High level
Public values	Community/sustainability	Individuality/health	Individuality/health	Community/sustainability
Public perception of biotechnology	Sceptical	Positive	Positive	Sceptical
Regulation of biotechnology industry	Extensive	Limited	Limited	Extensive
Protection of IPR	Global protection	Strong in EU – poor in emerging economies	Strong in EU – poor in emerging economies	Global protection

## Economy and market

The European economy is doing well and the welfare of European citizens is increasing. People can afford to buy expensive products and to take good care of themselves and their friends and family. In the European health sector, innovative and personalised medicines based on genetic profiling are in demand and so are health services provided by private companies.

Among the European success stories in the sector is BioGuard, a global health service company providing full personal scans for potential diseases, using implanted sensors to monitor individual health around the clock and providing clients with appropriate therapies and advice. The company has radically expanded the concept of ‘from cradle to grave’, so that potential parents are now able to get a full health and risk profile of their potential babies, even before conception, based on the genetic profiles of the parents. This facilitates the match of partners for parenthood; even if partners who are not a ‘perfect match’ decide to stay together and have children, BioGuard can provide therapies that reduce risks. This has sparked grave controversy in religious circles, and BioGuard and other companies in the sector and their employees have to deal with increasing threats from religious fanatics who want to put an end to this business. Also, groups of ethically concerned citizens are worried that this service will result in the breeding of ‘super-humans’ and reduce the diversity of the human species with possible negative consequences.

Other companies in the European biomedical sector are devoting many resources to the development of new products. Marketing efforts vis-à-vis general practitioners and clinics are being stepped up by offering not only participation in luxurious conferences, but also advanced personal services and equipment for GPs to ensure that they choose a specific product.

## Policy framework

Universities are thriving and producing the basic knowledge at the root of biomedical innovation. In addition, extensive public investment is channelled into the biomedical sector via R&D grants, and private investors are constantly looking for new opportunities in the sector. In order to ensure the competitiveness of the sector, European legislators have worked hard to reduce the regulatory burden on biomedical companies while upholding the protection of the safety and health of patients and healthcare personnel. Some patient organisations have voiced concerns that the regulatory set-up is too focused on competitiveness and does not provide patients with sufficient protection.

Joint European action in the field of IPR has resulted in a strong regulatory regime protecting biomedical products from counterfeiting in European markets. Conditions in Asia are still not satisfactory, leading to an inflow of foreign biomedical R&D-intensive companies to Europe. A dedicated European police force, BIOCOP, is monitoring the global markets and helping to establish the technical and legal capacity in countries that need assistance with IPR protection. Major countries, such as China and India, have declined such assistance, and carrying out R&D and high-value manufacturing in these countries is considered risky.

Some countries have introduced the citizen chip, which serves a multitude of purposes, including carrying the person's genetic profile and medical record. Policy makers are intensely debating the human rights implications of the citizen chip.

### Society and culture

Health and physical performance are among the primary concerns of European citizens, and consumers can afford to buy expensive healthcare products. European citizens are very positive about the use of biotechnology, although stem cell research and genetic profiling still provoke intense ethical debate. Much work on identifying and avoiding the side effects of nanotechnology has led to the widespread acceptance of cures using nanotechnology in combination with biotechnology.

### Company strategies

#### Developments in the value chain

Companies involved in healthcare are all working with biotechnology, and even 'traditional' pharmaceutical companies are now transformed into biopharmaceutical companies. SMEs are thriving due to good funding opportunities and are introducing new, innovative biomedical products onto the market.

#### Location decisions

Europe is an interesting market and provides a good business environment for biomedical companies. A key motivation for companies who choose to locate in Europe is access to highly qualified (albeit expensive) staff. Foreign companies seek to have a strong presence in the European market and locate R&D, sales, distribution and marketing activities within strong European clusters. European regional authorities are competing intensely to attract foreign companies. Manufacturing operations are split up so that those involving the least knowledge (and hence are least critical in terms of competition) move out or are outsourced, while high-value manufacturing is retained in Europe to protect IPR. Large investments in process technology have increased the innovation rate, making advanced manufacturing cost effective in Europe, even in the light of the higher wage levels for process technicians.

#### Product innovation

Biomedical companies are involved in a range of different areas. They develop new, innovative medicines but also exploit opportunities within lifestyle products and the reuse of existing products. Moreover, biomedical companies have used the available funding and positive regulatory environment to explore opportunities related to converging technologies, and several products and regimens have been introduced, based on different generic technologies (nano, ICT, cognitive sciences, etc.) and involving robotics, sensors, etc. Implants of self-dosing medicines and supplements has become commonplace.

### **Process innovation**

Innovation in process technologies has made the testing and manufacturing of complex biomedical products less demanding in terms of time and resources. The level of outsourcing of manufacturing and quality assurance is decreasing.

### **Labour market, skills and competencies**

#### **Manufacturing process**

The demand for low-skilled workers in the sector has fallen due to the widespread automation of manufacturing processes. The existing workforce needs to have their skills upgraded in order to be able to handle and monitor new manufacturing equipment. Technological convergence means that engineers and, to a certain extent, technicians need basic knowledge in more than one field, e.g. communication technology and biotechnology.

#### **Marketing and R&D**

Exploiting the opportunities related to converging technologies requires recruiting or cooperating with scientific experts from non-biotechnology fields, such as nanotechnology, ICT and cognitive sciences. Furthermore, experts in user interfaces and in the opportunities arising from the use of communication technology (personal communicators) are increasingly being used in marketing departments.

There is also a growing demand for experts in IPR law and people who can set up efficient monitoring systems.

#### **Management**

The convergence of technologies and expertise calls for managers who are able to facilitate synergy among very diverse groups of employees. General managers need not have deep scientific or technical insight into any part of the business, but do need to understand the basics in each component of the business. Being able to create innovative synergy is more important in this scenario than supply chain management.

### **Main challenge for biomedical companies**

Innovation is the key word for biomedical companies. This is a very competitive market and companies need to be on the cutting edge of technological developments – not only in biotechnology, but also in other technological areas.

# Scenario 4: Should I stay or should I go

Uncertain drivers with high impact	Slow boat to China	Forever young	Simply the best	Should I stay or should I go
Economic growth in Europe	Stagnating	Stagnating	Positive	Positive
Access to investment capital	Low level	Low level	High level	High level
Public values	Community/sustainability	Individuality/health	Individuality/health	Community/sustainability
Public perception of biotechnology	Sceptical	Positive	Positive	Sceptical
Regulation of biotechnology industry	Extensive	Limited	Limited	Extensive
Protection of IPR	Global protection	Strong in EU – poor in emerging economies	Strong in EU – poor in emerging economies	Global protection

## Economy and market

The European economy is developing positively. Growth rates across Europe have evened out somewhat, at the same time as the growth rates in China and India have slowed down slightly (they are still about twice that of Europe's). Oil prices have continued to rise and so have freight rates. Markets for all types of consumer goods have continued to expand; however, demand for ecologically sustainable, innovative products and services is expanding much more than demand for traditional consumer products. Investors recognise the innovative potential of European industry generally, while at the same time the 'quick buck' to be made in Asia has become less tempting.

## Policy framework

After the European Reform Treaty was finally adopted in 2009 and following attempts to arrive at a global climate treaty, European policy has focused on sustainable growth with some success. Following EU recommendations, most EU countries have decreased tax on labour and increased green taxes. European policies and funds are directed towards research and development, which supports sustainable technologies and methods of production.

A high level of public funding ensures basic research in the life sciences and hence there is scientific potential for developing innovative medicines. Yet along with the drive towards sustainability, there has been growing concern about the unwanted side effects of biotechnology since the mid-2000s. Policy makers at European and national level are aware of the public scepticism. In attempts to support innovation, while at the same time avoiding medical scandals and ethically problematic situations, the extent and complexity of legislation regulating the production and distribution of biomedical products has been steadily increasing.

Intellectual property rights are well protected after pressure was put on Asian, African and Latin American members of the WTO to enforce international patents.

## Society and culture

The European public is increasingly aware of sustainability issues. This is reflected in very different attitudes towards biotechnology. Some (typically well educated segments) see biotechnology as a 'smart alternative' to traditional manufacturing, being less energy intensive and producing less (and less dangerous) waste in the process. However, a large segment of the population is very sceptical towards biotechnology for different reasons. Members of the religious

majority (many of whom are elderly people) claim that biotechnology is tampering with God's nature or that man is 'playing God', while a large segment of eco-conscious intellectuals are doubtful about the side effects of biotechnological production (uncontrolled emissions of genetic material, social side effects of biological improvement of species, etc.).

More broadly speaking, sustainability issues influence the behaviour of consumers, who expect that products (including biomedical products) are produced with due regard for sustainability ground rules, i.e. using as few raw materials as possible, using renewable materials and energy, not being transported too far, etc.

The market for biomedical products designed to improve individual looks and physical performance dwindled after a hectic boom from 2005 to 2010, as human diversity and natural ageing is now considered of more value, and artificial improvement of natural potential is considered superficial and a waste of resources. On the other hand, there is strong potential for products to improve the quality of life of elderly citizens.

### Company strategies

Consumer behaviour presents the companies with a dilemma – should the company keep activities in Europe and benefit from the public funding and private capital available but having to comply with rather strict regulations, or should the company move to other regions with a better business environment in terms of regulation?

Both strategies are being pursued; some large companies even pursue both at the same time. The companies that tend to stay in Europe are those whose business set-up and products are best aligned with a sustainability strategy, while large, traditional manufacturing operations and R&D operations in technologies involving human cell material tend to move abroad.

### Developments in the value chain

Most companies pursue strategies that seek to minimise the transport of persons and goods, partly because of the high price of transport, partly as a component of 'sustainability branding'. Global sourcing of raw materials is still necessary, so reduction of transport costs is often sought by placing production facilities close to markets and by avoiding unnecessary transport of persons through decentralising management and support staff.

The public health sector is thriving, so much innovative and marketing power is directed towards Europe.

### Location decisions

Large companies are better at dealing with regulatory burdens than small ones. On the other hand, smaller companies have the advantage of being able to locate close to markets. Large-scale manufacturing is mainly located outside of Europe.

### Product innovation

Innovation in biotechnology is taking place at a slow rate. Innovation intensity is high for improving the sustainability parameters of existing products and in the development of products and services that can improve the quality of life of elderly people; however, innovation in biotechnology is taking place at a slow rate. Public health services' demand for innovative products with sustainable characteristics means that much effort goes into the development of materials that can be produced and consumed with minimal impact on the environment and, at the same time, minimal hassle for health service staff.

### Process innovation

The manufacturing companies that have chosen to remain in Europe put much energy into developing production processes that are, to the greatest possible extent, ecologically neutral. Hence, technologies for decreasing the consumption of materials and energy in the production of biomedical products receive much attention.

### Labour market, skills and competencies

Overall employment in the European biomedical industry is stagnant, as most of the value added in the industry comes from auxiliary technologies and sectors.

### Manufacturing process

The demand for skilled workers and process technicians in Europe has remained constant, in spite of the relocation of some of the big manufacturing operations. This is largely due to the creation of new, smaller production facilities close to the centres of population. The demand for production engineers is increasing due to the emphasis on process innovation.

### Marketing and R&D

The R&D that takes place in Europe is, to a large extent, directed towards minimising the environmental impact of production and distribution. Hence, biochemists and eco-biologists are in high demand in product development departments, as are professionals with legal expertise to ensure that products comply with legal and administrative requirements.

Top experts in stem cell technology are moving out of Europe, while the demand for experts in innovative materials is growing.

Marketing is focused on the public health sector, so marketing professionals need insight into this sector, but also a keen understanding of issues related to sustainability.

### Management

In SMEs that are located close to population centres, leaders with visible public profiles are called for. They must also be able and willing to discuss issues relating to ethics and sustainability in public.

### Main challenges

There is growing segmentation of the biomedical healthcare sector, with some businesses moving out of Europe, others staying and new businesses looking for the potential in an environmentally aware, highly regulated but otherwise affluent environment. Strategic focus and segmentation of markets is of utmost importance.

Companies that make one wrong step, for example, by attempting to market stem cell technologies to the mass market, may well find themselves out of (European) business. Complying with the strict regulations is costly and calls for a very strong focus on efficiency in quality assurance and documentation. The most innovative part of the sector is faced with a particularly strong management challenge, ensuring that expertise is used to create synergy, which can be transformed into a competitive advantage.

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