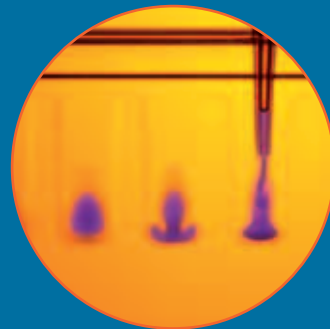


european biopharmaceutical enterprises

The Voice of Biopharmaceuticals in Europe

ebe



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The mission of “European Biopharmaceutical Enterprises” (EBE) is to:

- Represent biopharmaceutical companies of all sizes operating in Europe in the formulation of policies at global and European levels.
- Support innovation initiatives and new opportunities for biopharmaceutical technologies in the European knowledge-based economy.
- Contribute industry expertise to the development of new regulatory frameworks, guidelines and standards of relevance to biopharmaceuticals.
- Promote the exchange of good practices to foster the development of safe, efficacious and high-quality medicines.
- Increase awareness of the sector, its products and the tangible benefits that biopharmaceuticals bring to patients and society worldwide.
- Support the business development of member companies, especially SMEs, through advice, networking, training and educational opportunities.
- Facilitate information exchange and communications between all stakeholders in the biopharmaceuticals field through EBE acting as resource centre.

Biotechnology Brings New Solutions to Healthcare

Biotechnology is delivering significant advances in human healthcare. Entirely new medicines are being created, notably for rare or previously untreated diseases. Biotech production methods provide safer versions of existing treatments in unlimited quantities. Biotechnology has revolutionised the research and development of new medicines and allows better product-targeting for specific diseases and patient groups. A greater understanding of the genetic causes of disease allows early detection and treatment, and the new field of gene therapy may even herald the possibility to cure diseases, not simply treat them.



New Solutions Now...

Biotech medicines already account for around 10 - 15% of the current pharmaceutical market and the sector is outperforming the market as a whole. Significantly, more than one-fifth of new medicines launched on the world market each year are now biotechnology-derived. This will likely grow with the scientific advances currently underway; and the application of biotechnology in healthcare is leading to an increasing number of innovative products.

Biotechnology has already provided a wide variety of products for chronic and rare diseases, such as some cancers, hepatitis C, chronic renal failure, haemophilia, diabetes, Fabry's disease, growth deficiency, multiple sclerosis and Crohn's disease.

...and in the Future

Biotechnology will continue to provide new breakthroughs in medical research in the years to come, leading to treatments in fields which have previously eluded us (including AIDS, cancer, asthma, Parkinson's disease, Alzheimer's disease), as well as continuing to provide alternatives to existing conventional treatments.

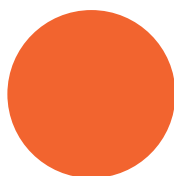
In short, biotechnology is "delivering the goods" for the development of new pharmaceutical products.



New Medicines Thanks to Innovative Technologies

The use of biotechnology to develop novel medicines has several specific advantages:

1. Biotechnology allows the development and production of new substances that were previously beyond the capacity of traditional technologies. This includes the design and production of new drugs with greater potency and specificity and, consequently, fewer side effects. One example of this is the treatment for multiple sclerosis.
2. Concerns about product safety in developed countries have largely been removed thanks to the development of biopharmaceuticals. Biotechnology offers a greater control over the manufacturing process, allowing significant reduction in risks of contamination through infectious pathogens. A prime example is the blood products used to treat haemophilia.
3. Biotechnology offers better product-targeting for specific diseases and patient groups, through the use of innovative technologies, in particular, genetics. Examples include, amongst others, treatments for rare diseases and cancers.
4. Some products are not naturally created in sufficient quantities for therapeutic purposes. Biotechnology makes large-scale production of existing substances possible, for example, insulin in the field of diabetes treatment.



Innovation is the Key Driver of the Biopharmaceutical Industry

The development of a large number of new technologies in the past decade has provided an excellent basis for breakthrough innovation in many better and safer medicines. However, there has been widespread concern about Europe's ability to maximise on its potential.

Recognising that Europe will stand little chance of becoming an attractive place for biopharmaceutical research unless there is a major change in attitude towards the environment in which companies operate, the European Commission has initiated and supports several actions for a more fertile research climate and infrastructure. The biopharmaceutical industry has responded enthusiastically to these initiatives which foster research and innovation in the biomedical field in Europe.

However, it is vital to continuously highlight the importance of research and ensure that the biopharmaceutical industry's perspectives are included in the debate and involved in initiatives to boost Europe's competitiveness.



Examples of Advanced Therapeutic Areas

- Pharmacogenetics and pharmacogenomics offer the possibility of treatments tailored to the specific genetic makeup of individual patients, allowing better targeted treatments, increasing treatment efficiency and reducing the risk of side effects.
- Gene therapy is a technique providing a novel approach in treating, curing, or ultimately preventing diseases by changing the expression of a person's genes. It can be targeted to somatic (body) or germ (egg and sperm) cells, but currently research is focusing on somatic gene therapy. With this, the recipient's genome is changed, but the change is not transferred to the next generation.
- Tissue engineering allows the replacement of diseased or damaged living tissue with living tissue that is designed and constructed to meet the needs of each individual patient.

Scientific Advances & Ethical Values

Clearly, new technologies giving rise to new treatments need to be appropriately regulated. Existing legislation often does not fully address the issues raised by biotechnological solutions. It is important for all concerned that the new rules are developed in parallel with technological progress. In order to ensure that patients can benefit from the advances in treatment, an ongoing dialogue is important and the legislative framework must be made sufficiently flexible to adapt to the fast pace of change.

Dialogue between all stakeholders involved in developing, commercialising, using and monitoring biotechnology products is crucial in order to secure opportunities for participation and influence in the direction of scientific development. The changes brought about in the healthcare field are considered a positive opportunity. But opportunities also bring certain responsibilities, which must be treated in harmony with the basic values of society.

Advances such as cell therapy and pre-and post-natal genetic testing, while providing hope for patients, also need careful monitoring to ensure not only that safety and efficacy are assured, but also that the individual's human dignity and fundamental rights are respected.

Smaller Biopharmaceutical Companies Have Specific Requirements

The majority of companies active in the biopharmaceutical sector are Small and Medium-sized Enterprises (SMEs) and these merit particular attention. If patients and society are to benefit from the advances being made by these companies, the business climate also needs to ensure that they can be successful. If there is a failure of the business environment to foster a healthy biopharmaceutical SME sector, there is a risk that the full potential of the biopharmaceutical revolution will not be realised.

Biotechnology companies are reinvesting more than half of their revenues straight back into finding more healthcare solutions. Thus, when revenues increase, so does investment in research and development for new treatments. To guarantee that patients continue to benefit from this reinvestment, it is important to create and support the right environment for biotech companies.

The Way Forward for the Biopharmaceutical Sector in Europe

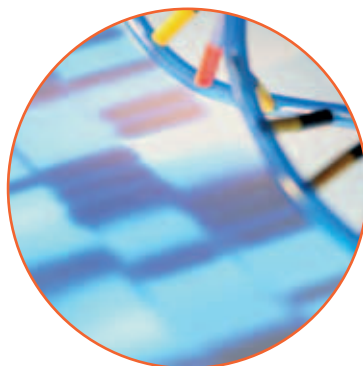
Biotechnology offers a wealth of possibilities but to obtain results from biopharmaceutical research requires considerable investment. Developing any medicinal treatment is an extremely long and costly undertaking (around 12 years and approximately 800 million Euros). However, in the case of biopharmaceutical products, on top of the standard R&D costs, the complexity of the scale-up and manufacturing process must be added.

Europe has an excellent research base and, therefore, great potential in the biopharmaceutical field. However, companies will only be able to develop this research into concrete treatments and medical products if the environment encourages this investigation and allows them to flourish. Moving from discovery to marketable product requires investment in, and fostering of, both individual companies and the European biopharmaceutical industry as a whole.



Adequate nurturing of innovation and subsequent protection for new ideas is a pre-requisite for promoting financing in this sector. Emerging from this is a strong link between the legislative framework for protecting intellectual property and the long-term viability of the biopharmaceutical sector in Europe. A clear understanding of the nature of the sector is vital in raising confidence and encouraging private finance. Moreover, there should be appropriate incentives from Member States to encourage innovation and – as a result – increase patient access to the benefits of biopharmaceutical research.

All stakeholders should stand to benefit from the advances in healthcare that biopharmaceutical technology offers and they all have a role to play. This is why EBE has become a key focal point for information exchange between the research-based biopharmaceutical industry operating in Europe and all major stakeholders engaged in this process.



The 5 Strategic Goals of EBE

Goal A – Public Affairs

To represent the research-based biopharmaceutical industry operating in Europe in the promotion and formulation of policies creating a favourable scientific, business and regulatory environment, thanks to building and communicating common industry positions through direct representation to key stakeholders at European and global levels.

Goal B – Regulatory & Technical Affairs

To contribute industry expertise to the development of new regulatory frameworks, guidelines and standards of relevance to biopharmaceutical companies operating in Europe and to promote the exchange of good practices fostering the development of safe, efficacious and high-quality medicines.

Goal C – Business Development Support Services

To support the business development of member companies, especially small & medium-sized enterprises, through the provision of quality membership services including advice, networking, training and educational opportunities.

Goal D – Information and Communication

To increase awareness of the industry sector, its products and the tangible benefits that biopharmaceuticals bring to patients and society worldwide. Facilitate information exchange and communications between all stakeholders in the biopharmaceuticals field through EBE acting as resource centre.

Goal E – Membership Growth

To continuously develop a strong membership base composed of large pharmaceutical corporations, biotechnology companies and SMEs that will strengthen the sector's representation and the association's expertise & influence in Europe and further afield.

EBE supports the business of its members and helps raise the competitiveness of the biopharmaceutical sector in Europe, with an eye towards profitability, economic growth, and ultimately to saving lives.

A Few Words about the Structure and Activities of EBE

European Biopharmaceutical Enterprises (EBE) is the European trade association that represents biopharmaceutical companies of all sizes operating in Europe. It was established in 2000 as a specialised group of EFPIA and is headquartered in Brussels. Membership in EBE is open to all companies using biotechnology to discover, develop and bring new medicinal products to market.

EBE's focus on the biopharmaceutical sector provides targeted and results-oriented support for its members. It has developed a wide range of activities and services for members, embracing policy advocacy, regulatory intelligence, strategic communications, business development, networking, education and training.

EBE coordinates specialised committees and task forces composed of member company representatives to provide industry input to the European legislative and regulatory process. Through EBE, policy makers can meet with the sector to understand the business implications of existing or proposed legislation regulating healthcare biotech product development and distribution. The number and complexity of regulations affecting the biopharmaceutical sector is also increasing and regulators need a forum for industry consultation.

EBE has also developed specific programmes to address technical matters (e.g. biotech manufacturing standards and good practices) and cover growing niche markets (e.g. orphan medicinal products).

Focus on Orphan Medicinal Products, a Priority Activity at EBE

Orphan Medicinal Products (OMPs) are designed to diagnose or treat rare diseases that are serious, life-threatening or chronically debilitating and that affect five or fewer people in every 10,000 in the EU. Because of such small patient populations, companies have little opportunity to develop, register, and place an orphan product on the market at normal prices while reaping an adequate return on their investment.

In response, governments in the U.S., Japan, Singapore, Australia and the EU have designed regulatory instruments to encourage the development of OMPs. As a result, biopharmaceutical companies are increasingly active in the OMP sector and, in many cases, are forerunners in the field.

The COMP Working Group for Interested Parties is a multi-stakeholder group at the European Medicines Agency (EMA) that enables all interested parties - the EMA, patients, academia and industry - to address issues around the approval and availability of orphan medicinal products. By continuing to contribute to the work of the group, as well as the work of the individual companies developing therapies, the biopharmaceutical industry in Europe will continue to lead the field in bringing more therapies that will save lives and/or enhance the quality of life for those suffering from rare conditions.

www.ebe-biopharma.org

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