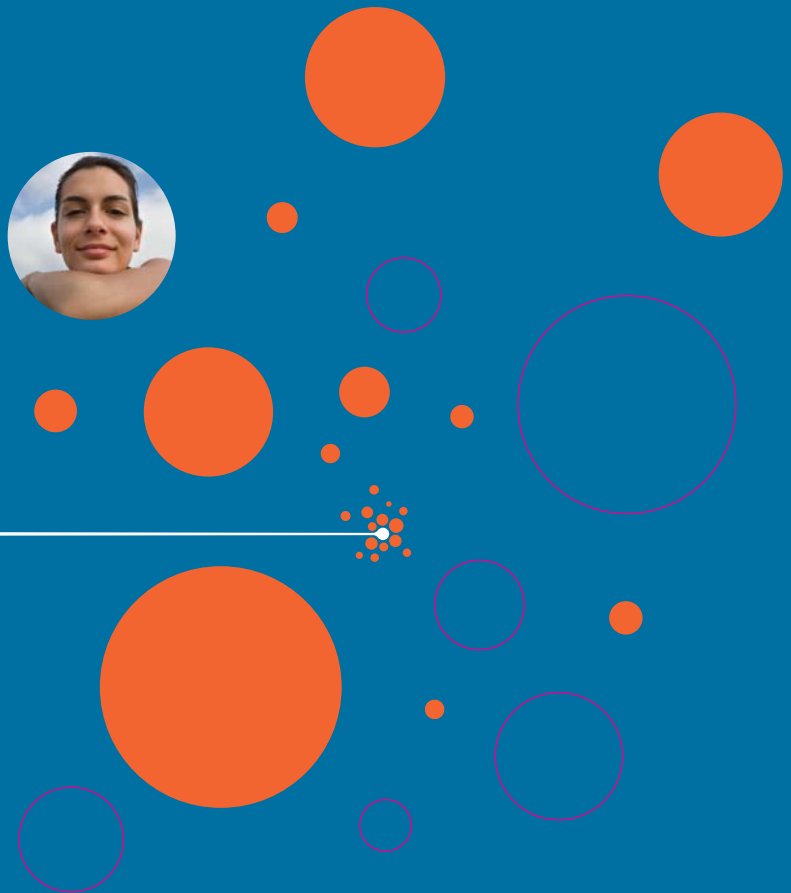


european biopharmaceutical enterprises

# Annual Report 2006 - 2007

ebe

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# The Expanding World of Biopharmaceuticals

## Biotechnology

Biotechnology has revolutionised the research and development of new medicines and allows better product – targeting for specific diseases and patient groups. Biotechnology has already provided a wide variety of biopharmaceuticals for chronic and rare diseases, such as cancers, diabetes, chronic renal failure, haemophilia, growth deficiency and multiple sclerosis. Biotechnology will continue to provide new breakthroughs in medical research, leading to innovative treatments for diseases such as AIDS, cancers, Parkinson's disease and Alzheimer's disease. New medicines are also being created for rare or previously untreated diseases.

## Biopharmaceuticals

The first biopharmaceutical to reach the market was recombinant human insulin in 1982. This was 25 years ago. Since then, about 150 biopharmaceutical products have been launched worldwide. As confirmed by the new European Commission study on Biotechnology for Europe (2007), the biopharmaceutical market in the EU is more dynamic than the pharmaceutical market as a whole, with average annual growth rates (23%) twice that of pharmaceuticals (11%). Hence, the market share of biopharmaceuticals in the total pharmaceutical market is increasing.

The majority of biopharmaceutical companies are SMEs and these deserve particular attention. If patients and society are to benefit from the advances being made by these companies, the scientific, economic and business environment need to be favourable.

## Opportunities

Europe has an excellent research base and provides great potential for biopharmaceuticals. However, research will only develop into concrete treatments and medical products if the environment encourages this investigation and allows companies 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.

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



## One Year of Transformation for EBE: Message from the President

**One of the major objectives for the European Union is to build in Europe the most competitive and dynamic knowledge-based economy in the world by 2010. The European biopharmaceutical industry supports this ambition and has responded enthusiastically to new initiatives aimed at fostering research and innovation in the healthcare field in Europe. It is essential that all the key stakeholders work together to raise the competitiveness of the biopharmaceutical sector in Europe.**

Established in 2000 as a specialised group of EFPIA in Brussels, European Biopharmaceutical Enterprises (EBE) has grown into a dynamic association, which currently serves and represents 62 biopharmaceutical companies of all sizes operating in Europe. One year ago, following the Extraordinary General Assembly of April 2006, our new Board of Directors and a new staff in Brussels initiated an upgrade of EBE. We planned and started implementing a new ambitious strategy. After one year of exciting transformation, I trust members and external stakeholders will agree that this has been successful and that we have been delivering value to our members.

This Annual Report 2006-2007 highlights recent activities and results as we are already looking ahead to our next action steps to meet each of our objectives.

We focus on the biopharmaceutical sector and provide targeted and results-oriented support for our members. Additionally, EBE acts in the capacity of the biotech arm of EFPIA and as such we have been leading on a range of biopharmaceutical-related topics in the policy and regulatory arena. EBE actions on biosimilars, advanced therapies, orphan drugs and bio-manufacturing are just key examples of where EBE made a real difference this year. Our dedicated range of activities and services embrace policy advocacy, regulatory intelligence, technical services, strategic communications, business development support, networking, education and training.

I wish to warmly thank all our member company representatives sitting on EBE committees and task forces who build our collective response on key issues and provide high-quality industry input to the European legislative and regulatory process. Through EBE, policy makers can meet with our industry experts to understand the scientific and business implications of existing or proposed legislation regulating biopharmaceutical product development

and commercialisation. As the number and complexity of regulations affecting the biopharmaceutical sector is increasing, this forum for industry consultation with regulators is proving more and more essential.

Finally, I wish to express my sincere appreciation to my fellow Board members and to the EBE staff led by Emmanuel Chantelot. They are the ones who make it happen through their uncommon drive and personal responsibility and help us deliver on our promises.

Let's go further on our successful collective endeavour!

Brussels, 10 May 2007.



*Dr. Carlo Incerti*  
*President of European Biopharmaceutical Enterprises*



# EBE: a Clear Strategy and a Strong Commitment from Members

## 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 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 a 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 and influence in Europe and further afield.



## Action Highlights 1: A Few Current Priorities

### Addressing Biosimilars

The introduction of similar biological medicinal products (biosimilars) into clinical practice presents challenges that are not presented by small-molecule generic medicines. This is because a biosimilar can only be proven to be similar and not identical to its reference product. EBE has coordinated actions on three key aspects for biosimilars: naming, substitution and labelling.

The naming of biotech-derived therapeutic proteins and biosimilars is the responsibility of the WHO INN Committee. The WHO initiated a review of the naming policies for biologicals and biotech products following consultations with regulators and industry in 2006. EBE played a leading role in the coordination of 6 innovator industry associations, providing input to WHO on adaptation of the naming system for biotech proteins. EBE also issued recommendations on the inapplicability of automatic substitution rules for biotech products and its recent proposal on biosimilars labelling was well received by the EMEA and the European Commission. This EBE work in Europe is also influencing policy in the USA, which is less advanced on these topics.

### Accelerating Access to Advanced Therapies

Gene Therapy, somatic cell therapy and tissue-engineered products are expected to have a major impact on public health and a regulatory framework, taking into account the characteristics of these innovative products, is needed. Pursuing this objective of consistent and harmonised evaluation, the proposed Regulation on Advanced Therapy Medicinal Products has been under review at the European Parliament and Council since November 2005. EBE has been actively engaged during this legislative procedure, communicating to MEPs on the biopharmaceutical industry support for this Regulation.

On 25 April 2007, the European Parliament adopted a compromise on the Advanced Therapies Regulation, which was welcomed by EBE as a very positive development and good news for Europe's patients, industry and research base. It is now the Council's responsibility to finalise this regulation and adopt it as rapidly as possible. This will create harmonised European safety standards for these innovative treatments and strengthen the biopharmaceutical sector.

### Supporting Orphan Medicinal Products in Europe

Orphan Medicinal Products (OMPs) are designed to diagnose or treat rare diseases that are serious, life-threatening or chronically debilitating and that affect 5 or fewer people in every 10,000 in the EU. Because of such small patient populations, companies have little incentive to develop, register and place an orphan product on the market at normal prices while reaping an adequate return on investment. In response, the EU adopted Regulation (EC) 141/2000 to encourage the development of OMPs in Europe.

EBE, through the OMP task force, has continued to intervene on orphan drug policy and regulatory topics and to evaluate the positive impact of OMPs on the European economy and society. EBE also coordinates the industry representation on the COMP Working Group for Interested Parties, 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.

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## Action Highlights 2: Contributing Expertise

### **EBE, the Industry Platform on Biopharmaceuticals Regulatory Affairs**

The EU's medicines marketing authorisation system ensures that medicines approved for use in the EU meet stringent criteria of safety, efficacy and quality. Whilst ensuring that these criteria are safeguarded, it is important to have a process which is as streamlined and easy-to-use as possible. Under the new EU pharmaceutical legislation, all biotechnology derived medicines and all orphan drugs are obliged to use the Centralised approval procedure (EMA).

The EBE Regulatory & Technical Affairs Committee contributes to the development of new EU regulatory frameworks, guidelines and standards for biopharmaceuticals and promotes the exchange of good practices for the development of safe, efficacious and high-quality medicines. The regulatory process is a particularly significant hurdle for smaller companies, and many biopharmaceutical companies in Europe are SMEs. Therefore, EBE works together with the European Commission and the EMA to ensure that the system is as easy to use and supportive of SMEs as possible.

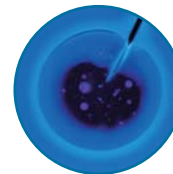
Information exchange on regulatory affairs is most important during the drug development process. Members have found it extremely useful to use EBE as their European industry platform to facilitate such exchange regarding biopharmaceuticals. Interacting with peers at specific EBE regulatory workshops and committee meetings has again provided added value this year for representatives of any company using the centralised procedure. Furthermore, a database on experience with the clinical trials directive is being compiled.

EBE has contributed expertise to the development of new regulatory guidelines. We recently commented the draft EMA guidelines on virus safety evaluation of biotechnological investigational medicinal products, conditional marketing authorisation, comparability of biotech-derived products, immunogenicity assessment and SME user guide. We provided input to the Commission for the review of the Variations regulation. EBE had members-only workshops on biosimilars and the new Paediatric Regulation and is planning more workshops in 2007. We also helped moderate special sessions for SMEs set up by EMA and DIA.

### **Promoting Best Practices in Bio-Manufacturing**

To meet the needs of members, a new EBE Working Group on bio-manufacturing was launched in September 2006 to address specific challenges associated with biopharmaceuticals development and manufacturing in the European technical, quality and regulatory environments. With the enthusiastic participation of experts from the main biopharmaceutical companies and SMEs, EBE has started to implement an action plan to tackle those issues.

EBE acts to raise the awareness about biotech manufacturing in the technical and quality area and protect the interest of the patients. In this context, EBE will be hosting jointly with PDA a European technical conference on Biopharmaceutical Development and Manufacturing on 20-21 June 2007 in Berlin. The EBE bio-manufacturing group also aims to promote consistent application of requirements by industry and competent authorities and provide a forum for information exchange between companies to develop common technical positions.



## Action Highlights 3:

# Grow the Biopharmaceuticals Business in Europe

### Promoting Policies which Foster Innovation and Market Development

Innovation is the key driver of the biopharmaceutical industry. Therefore, it is vital to continuously highlight the importance of research and innovation.

EBE ensures that the biopharmaceutical industry perspectives are voiced in the European debate and that our sector is involved in initiatives aimed at boosting its competitiveness.

The EBE Public Affairs Committee has coordinated representation of the industry interests in relation to key stakeholders at EU level. The goal is to build and communicate common positions to promote policies that foster the favourable scientific, business and regulatory environment needed by the research-based biopharmaceutical industry operating in Europe. We also produced new information tools to educate target audiences about the contribution of the biopharmaceutical sector.



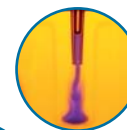
Examples of policy areas in which EBE has delivered results this year are the legislative process of the proposed Advanced Therapies Regulation and the policy issues raised by biosimilars and orphan drugs. EBE also collaborated with the European Commission / JRC over the past 12 months on the major "Biotechnology for Europe" study which has now been published.

In its Communication of April 2007 resulting from the mid-term review of the EU Strategy on Life Sciences and Biotechnology 2002 – 2010, the Commission proposed a refocus of actions to promote the European "knowledge based bio-economy". Biotechnology is viewed as an important means to promote growth, jobs and competitiveness in the EU and the latter should be enabled by research, market development and innovation programmes. To assist in the implementation of such refocused strategy on life sciences and biotechnology, EBE will aim to extend its cooperation with the Commission on behalf of its members regarding specific action points in the plan, which are relevant for biopharmaceuticals and biotech SMEs.

### Business Development Support Services

The EBE value proposition incorporates the provision of business development support services to member companies. These included new training sessions on legal and business development topics and the facilitation of networking for business development executives of biotech companies and larger pharmaceutical corporations. In this respect, the exclusive 2-day business development conference, which EBE organised in Berlin in December 2006 together with Bio-Deutschland was a resounding success according to all 90 participants.

EBE members are entitled to attend the EFPIA Annual Meetings as well. The Annual EBE Meetings 2007 in Brussels will include free members access to a high-level EBE programme, including business development workshops, and to all EFPIA events where executives can meet the key decision-makers from the large pharmaceutical companies in one location.



## Action Highlights 4:

# EBE, a Central Resource Centre



### Generate and Communicate Information on Biopharmaceuticals

A key EBE objective is to raise awareness of the products and special features of the biopharmaceutical industry and how these benefit patients and society. Our external target audiences include government decision-makers, patient organisations, the academic community, the media and other opinion-formers. We also make every effort to provide timely information to our member companies. Their representatives, from the CEO to the experts, can rely on EBE as a reliable source of information.

The transformation of EBE into a central resource centre on biopharmaceuticals is one of the core objectives in the new EBE strategy. We develop and maintain a wide range of information resources for members to use. These include publications, EBE reports, analysis, directories, presentations and statistics, most of which are stored on the EBE extranet only available to members. Thanks to the operational relationship with EFPIA, EBE members have also enjoyed access to the sector-specific experts at EFPIA for advice in areas such as regulatory, legal, communications, external trade and economic affairs.

In order to communicate professionally, EBE required a new image and new communication tools in line with its organisational upgrade. A new visual identity with new logo and design concepts were unveiled in October 2006. The creation of a new institutional brochure and presentation leaflets were followed by the revamping of the EBE internet and extranet websites [www.ebe-biopharma.org](http://www.ebe-biopharma.org) at the end of 2006.

### Developing Relationships and Building New Partnerships

In addition to its close relationship with EFPIA, EBE has continued to develop working relationships with other organisations active in the biotechnology and pharmaceutical sectors in Europe and around the world. These include BIO, IFPMA, PhRMA, EuropaBio and the European Federation of Biotechnology (EFB) among others. EBE is also an active member of EPPOSI, the European Platform for Patients' Organisations, Science and Industry.

EBE participates in a number of international biotechnology events during the year, often delivering keynote speeches. Recent events which EBE supported as partner or co-sponsor included BIO-Europe 2006 (Dusseldorf), BIO-Europe Spring 2007 (Milan) and EuroBio 2006 (Paris). We participated in BioVision 2007 and the BIO 2007 Convention. As partners, we are also preparing for EuroBio 2007 (Lille) and EFB's European Biotechnology Congress 2007 (Barcelona).

These international collaborations contribute to raise the profile of EBE as the voice of biopharmaceuticals in Europe and reach out to new potential member companies. Finally, members benefit from such partnerships thanks to the discounts on registration fees granted to EBE members at international events which we support.

# The Voice of Biopharmaceuticals in Europe

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.



# Our Members, Our Leadership, Our Team

As of April 2007

## EBE Membership (62 member companies)

Abbott	Genethon	Shire
Actelion	Genmab	Speedel
Alexion Europe	Génopoiétic	Swedish Orphan
Amgen	Genzyme	Symphogen
Aphton	HGS Europe	Tibotec
Ardana Bioscience	HRA Pharma	UCB
Ark Therapeutics	Hybrigenics	Wyeth
Austrianova	IDEA	Zymenex
Barrier Therapeutics	Ingenium	
Basilea	Intercell	
Baxter	Ipsen	
Bayer	Jerini	
Bioalliance Pharma	Maxygen	
Biogen Idec	MediGene	
Biovertis	Neurochem	
Boehringer Ingelheim	Newron	
Celgene	Novartis	
Cellerix	Novo Nordisk	
Centocor	OPI	
Cephalon Europe	Orphan Europe	
Chiesi Farmaceutici	OSI Pharmaceuticals	
Diatos	Paion	
Eli Lilly	Pharma Mar	
Ferring	Pfizer	
Fibrex Medical	PowderMed	
Fresenius Biotech	Rheoscience	
Genesis Pharma	Roche	

## EBE Board of Directors

President	Dr. Carlo Incerti	Genzyme
Vice-President & Treasurer	Marc de Garidel	Amgen
Past-President	Dr. Peter Heinrich	MediGene
Board Member	Prof. Klaus Strein	Roche
Board Member	Dr. William Gunnarsson	Orphan Europe
Board Member	Didier J. Malherbe	UCB
Chair, Public Affairs Committee	Silvia Matile-Steiner	Roche
Chair, Regulatory & Technical Affairs Committee	Anita Osborne	Rheoscience
Chair, Orphan Medicinal Products Task Force	Dr. Erik Tambuyzer	Genzyme

## EBE Staff

Emmanuel Chantelot	Executive Manager
Piers Allin	Deputy Manager
Roberta Mugnai	Assistant Manager
Joëlle Baruti	Assistant, Communications
Katy Somia	Administrative Assistant

[www.ebe-biopharma.org](http://www.ebe-biopharma.org)

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