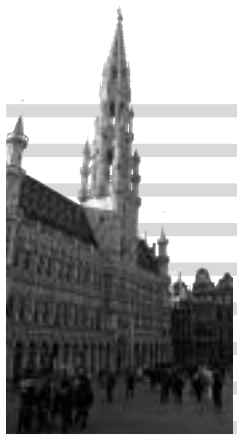


Annual Meetings 2005

Efpia

BRUSSELS | 31TH MAY 2005 | SPECIAL ISSUE

EMERGING BIOPHARMACEUTICAL ENTERPRISES

Almost five years in being

In the second half of the year 2000, a specialised group has been created under EFPIA's umbrella, to which research-based pharmaceutical companies using emerging biopharmaceutical technologies could apply for membership. Since then, quite a lot of research-based companies wishing to join the specialised group have sent their applications and supported their applications with a description of their activities in the particular segment of the pharmaceutical market related to bioscience technologies. After five years in being, EBE has grown its membership every year (for details see table of development between 2003 and 2005) to a total of 59 companies.

Many of EBE's general activities have become a routine, such as promoting a favourable business and regulatory climate for the successful and rapid application of the emerging biopharmaceutical technologies in the pharmaceutical sector in the EU. It also stands by to enhance the better understanding of the new opportunities expected from biopharmaceutical technologies in terms of their contribution to healthcare.

As a specialised group within EFPIA, the EBE group serves as a forum allowing companies to pool their expertise on topics of common interest and to present consolidated and therefore more powerful arguments; and to represent their needs and interests and fully exploit their potential at European level. EBE provides assistance to overcome the specific barriers faced by emerging biopharmaceutical enterprises, enabling them to address the distinctive requirements specifically raised by their involvement in bioscience technologies; finally, to benefit from the specific expertise available in EFPIA, and vice versa: EBE is available to support EFPIA work in particular fields when EFPIA's Board considers such support crucial to reinforce the pharmaceutical industry's messages.

Members of EBE come together at least once a year in a General Assembly meeting, such as today. The assembly can agree on additional subscriptions and their distribution among member companies with a view to funding specific actions. EBE Board consists of seven representatives. To maintain the representative balance, the Board is constituted in principle by European small and medium-sized enterprises. However, membership is open to company representatives from other regions that are eligible and willing to serve. One Board member serves as President and one as Vice-President for a term of two years, renewable. EBE's President is invited to EFPIA's Board meetings as an observer, with a view to promoting co-ordination between EFPIA and EBE activities.

Non-EFPIA member companies are allowed to join EBE without becoming an affiliate member of EFPIA, as long as their turnover in medicinal products does not exceed €50 million. In today's meeting, the following issues will deserve special attention:

The Commission has announced its intention to have a call especially dedicated to SMEs in the last part of the Sixth Framework Research Programme, due to end in 2006. To this end, EBE and Commission experts will organise a workshop for SMEs in Brussels on 28 June 2005. The SME call will mean some €170 million available for projects.

The European Medicines Evaluation Agency has asked EBE for input on the future of the system for orphan medicines in Europe in its capacity as official coordinator of the industry representation towards the working group of the Committee for orphan medicinal products (COMP) with interested parties.

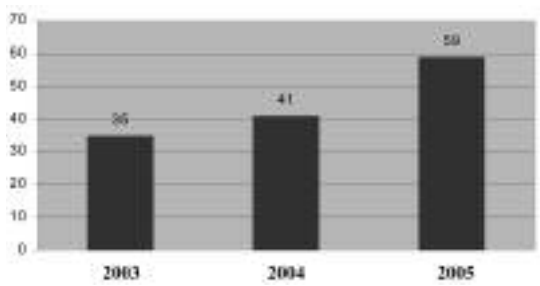
2000 - 2005

Brian Ager, Director General

Another actual policy issue of EBE deals with the legal requirements for the marketing authorization of copy products of biopharmaceuticals, or "biosimilars" as they are also known. The European regulatory authorities are breaking new ground in this regard. There are no precedents for them to follow, therefore it will be important to advance carefully, in a cooperative manner, allowing for increasing scientific knowledge and always with the patient's interests at heart.

On the occasion of its fifth year in being, EBE and its membership deserve particular credits for their thorough promotion of thoughts and arguments concerning the distinctive requirements of bioscience technologies in Europe. ◗

EBE Membership Development



EUROPEAN BIOPHARMACEUTICAL COMPANIES

A long term perspective to Stimulate Growth

The world is witnessing an explosion of knowledge in life sciences and the impact of biopharmaceutical achievements on our economies and societies are already will be more so substantial. Already today, biotechnology processes are playing a leading role in many areas of our daily life. They are affecting almost every field of human activity. i.) by transferring genetic material from one species to another, green biotech is aiming to make plants resistant to heat, salt, and parasites; ii.) white biotech will be allowing new production processes to reduce the world's resource consumption. It will enable mankind to reconcile our high standard of living with environmental concerns; and iii.) the most advanced sector, red biotech has been speeding up the medicine discovery processes, leading to innovative therapies.

While biotechnology was rather late and also slow to take off in Europe, it has to be mentioned that the general situation today has already improved. More than 1.800 European companies, among them many small and medium sized enterprises (SMEs), are employing around 77.000 people raising €12 bn per year. It is SMEs who create 50 per cent of new job in biotechnology. However, compared to the US Europe still has some way to go to establish a mature and consolidated industry. Only 16 per cent of EU companies have gone public, but they employ half of all employees in the sector and represent half of revenues and research expenditure. In the US, public companies represent 77 per cent of the total. Another disquieting tendency takes place in the pharmaceutical sector - one of the promising fields of biotechnology. Here, Europe is confronted with a move of research and production of innovative drugs outside the region.

If Europe should underestimate this widening gap it will lose further research and development activities, not only to the US but also to the upcoming centres of excellence in Asia, notably Japan, Taiwan, Singapore, China and India. If happening this loss will be going to have major social and economic consequences for Europe, leading to i.) a delayed access to innovative drugs for the population; ii.) an erosion of the general European research base; iii.) a continued "brain drain" of researchers; and, finally iv.) a loss of entrepreneurial talent.

One must not over-dramatise the situation, but it is clearly high time to reverse this trend and unlock Europe's potential. Undoubtedly, the biotechnology sector can play a significant role in the economic development of Europe to become the backbone of a knowledge-based economy and a significant driver of the economic recovery. Only a viable economy will generate the financial resources to sustain the standard of living of European citizens.

To achieve this, policy-makers will have to set the right conditions for making Europe the most attractive place to invest while at the same time industry is expected to deliver on economic growth and new jobs. Just recently, the EU Commission has announced to review its methods of preparing legislation. Among others, these principles include the carrying out of solid impact assessments, extensive consultations with stakeholders, cutting red tape, simplification, respecting the principle of proportionality and leaving room for alternative methods of regulation.

Peter Heinrich, EBE President

In 2002, the EU Commission's Biotechnology Strategy has laid the groundwork for the catch-up efforts. The plan covers all fields of biotechnology and addresses the major issue areas and policy fields, from research and development to the regulatory framework and access to capital for SMEs. The recent revision of the regulatory framework governing medicines has significantly contributed to a more competitive structure for industry. Several provisions encourage innovation, in particular in the field of intellectual property rights with appropriate data exclusivity. Particular points relevant to SMEs include: i.) waivers and deferrals for a number of fees; ii.) access to scientific advice from the EMEA; iii.) incentives to develop orphan drugs and finally, iv.) administrative support by establishing a special office for SMEs within the EMEA.

All in all it is mandatory to put the pharmaceutical and biotechnology industry back on top of the political agenda, in order to ensure that Europe develops into a major centre for investment in both sectors. ◗

EBE AND BIO

One Year of Transatlantic Cooperation

End of May 2004, the Emerging Biopharmaceutical Enterprises (EBE) announced at its General Assembly in Dublin that it had signed a formal agreement with the well-respected US counterpart organisation, BIO (Biotechnology Industry Organization). The agreement had been set up to see the two organisations working together to exchange information and intelligence on regulatory affairs as well as cooperation on events organisation.

While EBE represents biopharmaceutical companies operating in Europe, particularly small and medium-sized enterprises, and serves as a forum in Brussels, through which these companies can promote their interests and activities, BIO is based in Washington DC. It was established in 1993 and has more than 1,000 members. BIO focuses on advocacy on behalf of the biotech industry, informing the national and international media about the biotech industry, its progress and issues; and provision of business development services, including investor and partnering meetings. BIO is the best-known organisation in the global biotechnology scene. The annual convention and exhibition is the largest biotechnology event in the world. Next month, this year's event will take place in Philadelphia. EBE has organised a panel with investors and will be present with a stand. Further information about the convention can be obtained at www.bio.org

EBE was established in late 2000. Despite EBE's younger age, the BIO leadership and Board were of the firm opinion that EBE would be the organisation's appropriate European match. Despite being different in size and age, the objectives and principles of the two organisations were considered to be similar. The reasoning for both parties was that understanding and coordinating regulatory affairs is increasingly important for companies that seek to make their products available to patients in more than just one geographic region. The desire for regulatory cooperation was also reflected at agency level, in the agreement signed by the European Medicines Evaluation Agency (EMEA) and the US FDA.

With their step the European and US biopharmaceutical industry organisations were able to mirror this cooperation, providing information and support to their members in creating a stable and predictable science-based approval system. The cooperation has led to the provision of better support and regulatory intelligence to their members, as well as the coordination of advocacy activities where appropriate. Europe's regulatory environment, in particular is rather complex and will be undergoing fundamental change as the new medicines legislation will come into force in November 2005. There was also the Union's expansion to 25 Member States in May 2004. EBE, via its position at the heart of the EU and its network of legislators and other interested stakeholders, is the ideal partner for BIO to monitor the EU environment and to give expert advice and co-ordination to the biopharmaceutical companies.

Research by the pharmaceutical industry has led to many specialised treatments. However, further improvements are still urgently needed.

Meanwhile, EBE and BIO are cooperating on regulatory issues of mutual interest – such as biosimilars. During the last 12 months, EBE members were taking part in BIO's existing programme of business development events, such as the recent BioEquity in Zürich, where EBE was one of the organisers. The second event is Bio Europe, Europe's premier partnering event in the life sciences field. BIO-Europe 2004, the 10th anniversary edition, was the first concrete cooperative event between EBE and BIO. ◗

EUROPEAN RESEARCH COUNCIL

A Consequence of the European Research Area

Since the original proposal for an European Research Council (ERC) was advanced, as a natural consequence of the European Research Area, a lot of enthusiasm for the idea has developed amongst researchers. The concept of an agency, whose mission would be to fund basic or fundamental research, and whose activities would be complementary to the EU programme of targeted scientific research, has proved appealing.

So far, there exists no European granting agency for fundamental research. This creates a strangely European paradox. Whereas targeted research is by its nature more specific and local, and basic research is essentially universal and international, it is done the other way round. In Europe, the funding mechanisms support basic science at the local, or national level, and targeted research at the European, or international level. To catch up with the regions of the world, the EU needs an agency capable of operating on the same scale as agencies in North America or in Asia. Otherwise, the aims enshrined in the Lisbon declarations will remain rather unrealistic hopes.

Thus far, there is wide agreement. Matters become complex when the mode of delivery is discussed. To this, one can add the usual European habit of having many cooks and an infinite number of dishes to choose from. There have been not less than four international meetings since the Copenhagen Conference which was held under the Danish Presidency. EU scientists expect the ERC to come soon and its budget to be at least five per cent of the total EU expenditure on science, to match what the EU is already spending on targeted research. Otherwise, the flurry of excitement will be taken as another example of European sound and fury, followed by no effective action. ◗

Programme Wednesday, 1st June 2005

Parallel Sessions
09:00 – 14:00 European Vaccines Manufacturers (EVM): General Assembly & Board Meetings followed by lunch, EFPIA Office - Room "Trône"
09:00 – 12:00 MI PAT, GSK Offices - groundfloor
09:00 – 12:00 Trademarks ad hoc group, NOVARTIS Brussels Office
12:45 – 16:30 IPPC, NOVARTIS Brussels Office
09:00 – 12:00 ETPC, EFPIA Office – Room "Caprice"
12:00 – 14:00 Lunch for participants in ETPC, IPPC and Trademarks, EFPIA's Cafeteria

Open Forum
"Medicines Research – Driving Europe's Health" at Concert Noble
16:30 Registration of participants:
17:30 Welcoming of participants by Brian AGER
17:35 Keynote Speech by Günther VERHEUGEN
17:50 Q & A moderated by Giles MERRITT with participation of Günter VERHEUGEN, Dagmar ROTH-BEHRENDT, Thomas LÖNNGREN, Sir Tom McKILLOP, Jean GEORGES and Michel MARTY
19:15 Closing remarks by Franz B. HUMER
19:30 End of Conference
20.15 **Dinner** at Concert Noble

For more information, contact the hospitality desk at the Conrad Hotel.

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