



**DRAFT REPORT**

**EU biotechnology policy reports and news  
from the Member States**

**by**

**EuropaBio's National Biotech Associations**

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# National Reports from National Biotech Associations

24 July 2006

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## **Regulation - Healthcare Biotech**

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**Switzerland - The Swiss Biotech Association (SBA)** The presentation of the Swiss Biotech Report (E&Y et al.) showed that the industry is still going in the right direction. 223 companies (core Biotech and Suppliers) produced again a solid foundation for the sector. The successful sale of Glycart to Roche in 2005 still shows some encouraging later benefits for finance seeking companies. In conjunction with the other associations, the SBA is monitoring the lawmaking situation such as the consultation and implementation of the HumanResearchLaw for the country.

- *Contributed by SBA*

### **Sweden - VAT on clinical trials abolished in Sweden**

Sweden has been the sole country to extract VAT on Clinical trials from foreign companies that have hired Swedish CROs. This unfortunate situation was a result of a communication from the Swedish Tax Authorities in December 2004 where they stated that CRO services should not be considered as "Consultancy services" with regard to the VAT-legislation, and therefore forced Swedish CROs to add VAT on invoices to foreign companies. SwedenBIO has been active in communicating the misapprehensions in this decision and the Swedish Tax Court recently ruled in favor of the industry.

- *Contributed by SwedenBIO*

### **Belgium - New working groups started at Bio.be**

° Working group Red Biotech (general)

° Working group Biosimilars

- *Contributed by BIO.be*

### **UK - TGN1412 Clinical Trial Adverse Events: Industry Taskforce To Provide Expert Input**

A joint taskforce has been set up by the BIA and the Association of the British Pharmaceutical Industry (ABPI) to provide industry input to the expert working group set up to learn from the TGN1412 clinical trial adverse events at Northwick Park. The BIA/ABPI industry taskforce is co-chaired by Dr David Chiswell and Sir Colin Dollery, with its membership consisting of bioscience and pharmaceutical industry experts in fields such as immunology, biopharmaceutical development and clinical trials.

The taskforce will offer input in the areas to be considered by Professor Gordon Duff's expert group which is reviewing early stage clinical trial design with specific reference to:

- biological molecules with novel mechanisms of action
- new agents with a highly species-specific action
- new drugs directed towards immune system targets

On July 25, the Joint Taskforce proposed recommendations to enhance and clarify the existing guidelines governing the testing of new medicines in humans following the TGN1412 clinical trial at Northwick Park. The taskforce recommendations, which are

based on existing best practice within industry, have been submitted to the scientific expert group chaired by Professor Gordon Duff reviewing early stage clinical trials. Specific recommendations include:

- Use of an alternative initial dose-setting assessment for certain novel agents.
  - Giving only one subject the active medicine on the first day.
  - Following this with 'staggered dosing' as doses are increased.
  - Conducting such studies at a hospital with intensive care facilities.
  - Providing all investigators with appropriate training in such studies.
  - Giving particular emphasis to manufacturing controls to ensure safety, quality and efficacy of the finished product.

The taskforce's report can be viewed at [HERE](#): Professor Gordon Duff's scientific expert group also released on July 25 its interim report. The BIA welcomes the recommendations included in the interim report: UK Department of Health Press Release [HERE](#)

- *Contributed by BIA*

#### **UK - Proposed Advanced Therapies Regulation: European Parliament Hearing and Rapporteur's Draft Report**

The BIA attended, with the Chair of its Regulatory Affairs Advisory Committee and EuropaBio, the Hearing on Advanced Therapies on 11 May at the European Parliament. The BIA is working with EuropaBio to put across its members views. This legislative proposal is currently a key priority for the BIA.

- *Contributed by BIA*

#### **UK - Commission Regulation on Conditional Marketing Authorisations**

The BIA welcomes the Regulation (EC) 507/2006 on the conditional marketing authorisation for medicinal products. The BIA responded to the Commission's consultation on the draft Regulation. Our comments and suggestions were taken into consideration by the Commission when finalising the Regulation.

- *Contributed by BIA*

#### **UK - EMEA Consultation on Compassionate Use Guideline**

The EMEA issued for public consultation a draft guideline on compassionate use of medicinal products. The BIA Regulatory Affairs Advisory Committee agreed that the BIA would contribute to procedural guidelines developed by the EMEA as part of the implementation of the new EU medicines legislation. The BIA has submitted a response.

- *Contributed by BIA*

## **UK - BIA Response to Consultations**

The BIA has also recently responded to these UK consultations:

- COREC Consultation on NHS Research Ethics Committee Services. The National Patient Safety Agency through COREC consulted on its plan for implementation of the recommendations of the Ad Hoc Advisory Group on the operation of NHS Research Ethics Committees.
- MHRA Consultation on Implementation of European Commission GCP Directive. The Commission Directive sets out principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use as well as the requirements for authorisation of the manufacturing or importation of such products.
- Davidson Review concerning Implementation of EU Legislation. The Cabinet Office's review focuses on the issue of over-implementation examining areas where the UK has regulations that is stricter or more burdensome than required by EU legislation.

- *Contributed by BIA*

## **Hungary - Life sciences have strong traditions in Hungary**

In 2005 the Hungarian Government declared five strategic sectors in terms of economic development, and life sciences/biotechnology has become one of these priority areas. Wisely the state turned to the industry to identify the needs to foster a dynamic growth in the field. The Hungarian Biotechnology Association (HBA), with the help of internationally renowned consultants, examined the practices of 17 countries, combined its findings with feedback of local managers, and developed a **national biotechnology strategy** to overcome all bottlenecks hindering the development of high-tech SMEs in the field of life sciences. The strategy addresses all challenges from legislative issues to infrastructure (such as biotech incubators and tech-transfer offices), work force; besides it explicitly defines Hungary's aim as catching up with the top 10 EU states in the area of biotechnology by 2010.

- *Contributed by Hungarian Biotechnology Association*

## **Regulation - Green Biotech**

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### **Switzerland – national research programme initiated**

The moratorium took immediate force after the vote in November 27, 2005. For five years no agricultural commercial applications will be possible. The moratorium is absolutely useless, since the current regulation is so tight that field tests take a lot of time to get approvals. A **national research program (NFP 59)** has been initiated as a first measure towards the moratorium.

- *Contributed by SBA*

### **Italy – the constitutional court ruling**

The Constitutional Court's sentence of March 17<sup>th</sup> 2006 (n. 116), has declared as illegitimate part of the decree dated November 22<sup>nd</sup> 2004 (n. 279), transposed with modifications into the law of January 28<sup>th</sup> 2005, n. 5.

The sentence:

- has confirmed the legitimacy of using GMOs authorized at European level in agriculture;
- it has determined to put an end to the prohibitions and limitations on GMO cultivation contained in a few regional laws on the grounds of incompatibility;
- it has sanctioned that the legislative power in regional coexistence matters in the various territories is of exclusive competence of the areas.

Furthermore, the sentence indirectly ends the moratorium which was in force in Italy on the introduction of the biotechnology in agriculture.

- *Contributed by Assobiotec*

### **Hungary – Association calls for right to grow GM crops**

After the meeting of the EU Agriculture Council on 22 May 2006 that brought clarity to the confused situation of GMOs in Europe, the Hungarian Biotechnology Association decided to publish a press release on the rights to grow GM crops with the aim of urging the Hungarian decision makers to follow the European Union's conclusions (and the already existing practice of South and North America as well as Asia) and liberalize GMO production.

- *Contributed by Hungarian Biotechnology Association*

## **Regulation - White Biotech**

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### **Switzerland – New industrial biotech initiative**

The Swiss Biotech Association (SBA) has presented a one-page paper with regard to the industrial biotechnology. On June 2, a well visited workshop showed that the sector needs to push the federation to re-develop this traditional strength from the viewpoint of education and research. A working group is preparing the next strategy steps in this regard.

- *Contributed by SBA*

### **Sweden – “Commission against the dependence on oil”**

In December 2005 the Swedish Government appointed a group called “The Commission against the Dependence on Oil”. The group has worked during the spring of 2006 under the chairmanship of the Prime Minister. It has now delivered a report called “On the track to an oil-free Sweden” which presents strategies and objectives and a number of measures in order to diminish significantly the Swedish dependence on oil by 2020. The report (in Swedish) is available at

<http://www.regeringen.se/content/1/c6/06/62/80/bf5c673c.pdf>

One of the recommendations in the report is to support the development of biorefineries. The same recommendation is found in a recent survey of Swedish industrial biotechnology carried out by BioteknikForum as an assignment from VINNOVA (the Swedish Governmental Agency for Innovation Systems) and Mistra (The Foundation for Strategic Environmental Research).

- *Contributed by BioteknikForum*

### **Belgium - BIO.be - Working group White Biotech will start in September**

- *Contributed by Bio.be*

### **UK - BIA launches industrial biotechnology working group**

The BIA has joined forces with the Department of Trade and Industry to identify the opportunities and challenges of industrial biotechnology in the UK. The BIA has established a working group of companies operating in this field to focus on regulation and standards, procurement and communications. The activities of this group will complement the work of the recently established Bioscience For Business Knowledge Transfer Network.

- *Contributed by BIA*

### **Hungary – New board and new white biotech committee**

Following the General Assembly of the Hungarian Biotechnology Association in June 2006, the newly elected executive board and the re-elected president, Erno Duda Jr. decided to reinforce the activities and collaboration in white biotechnology and set up a white biotech committee within the organization.

- *Contributed by Hungarian Biotechnology Association*

## **Financial Environment**

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### **Switzerland - Revised patent law and seed money**

The Swiss Biotech Association (SBA) is involved in the consultation process for a revised *Patent law* in Switzerland with regard to the Life Science and Biotechnology sector. The consultation process has revealed a series of challenges with this law proposal. The law modification process is in continuation. In another process the SBA is actively promoting to the federal administration and parliament the various deficits still unsolved to date. a) Pre-seed and seed money, b) costs of clinical trials etc.

The environment is still difficult, due to absent pre-seed and seed money. However there is an uplifted discussion going on with all stakeholders to address the situation for the immediate future.

- *Contributed by SBA*

### **Sweden - Government dialogue with Swedish industry concluded**

In Q1-2 SwedenBIO has been very active in the recently concluded “Industrial Sector Dialogue / Branschsamtal” a series of stakeholder meetings where the Swedish government has invited six selected industries to give input to the growth agenda for Sweden. This has resulted in a life science strategy program including the launch of a national post-doc program as well as a program for industry-academia collaboration. SwedenBIO view the implementation of the talks very positively, however it is also important that the financial environment is developed by a Swedish YIC-model to stimulate investments in R&D

- *Contributed by SwedenBio*

### **Sweden - Proposal for a Swedish YIC-model – Government meetings scheduled**

SwedenBIO will focus on realizing a Swedish YIC-model for R&D intensive companies in Q3 and Q4. Election to the parliament will take place mid-September and some parties have already included YIC-like models in their position papers. Argumentation will be mostly based on the report “Promoting Innovation by Tax Incentives”. Meetings are already scheduled with senior government representatives and other key stakeholders to explain the rationale of a Swedish YIC model and find a way forward.

- *Contributed by SwedenBio*

### **Sweden - SwedenBIO view EC proposal on state aid support positively**

SwedenBIO has been invited by the Swedish Government to provide input to the EC proposal for state aid. The new regulations have effect on the YIC-dialogue in Sweden and SwedenBIO view the EC proposal very positively and it is a chance for Sweden to catalyze its innovation policy and environment. Innovation is increasingly a European issue – not a national one.

- *Contributed by SwedenBio*

### **Sweden – New benchmark study on tax incentives**

The EU-supported project “Realisation of Young Innovative Company Status for Biotech Companies” has now delivered a benchmark study entitled “Promoting innovation by tax incentives”. It can be found at [www.sik.se/yicstatus](http://www.sik.se/yicstatus) under Public reports.

- *Contributed by BioteknikForum*

### **UK - BIA Heralds three year campaign resulting in publication of pre-emption group statement of principles**

The BIA in May 2006 applauded the Pre-Emption Group’s publication of a Statement of Principles that provides guidance to companies and investors on the factors to be taken into account when considering the case for disapplying pre-emption rights. This Statement of Principles is intended to inform the way all parties participate in the disapplication process. The Statement of Principles replaces the Pre-emption Guidelines, which had been in place since 1987.

The BIA has been lobbying for more than three years to effect a change in investors’ attitudes towards pre-emption rights. Strict enforcement of the previous, widely accepted, five per cent limit had hindered high growth companies in accessing capital swiftly and cost effectively.

The BIA is represented on the Pre-Emption Group by John Aston, Chair of the BIA’s Finance and Taxation Advisory Committee, and Chief Financial Officer of Cambridge Antibody Technology.

- *Contributed by BIA*

### **Hungary - The high tech seed fund**

The year of 2005 in Hungary has brought impressive advances that have surprised even the most optimistic: in less than six months after the Government accepted the national biotechnology strategy, a high-tech seed fund started operation, and by today about 40 million euros have been made available by the Government in the form of grants for applied research, cluster development, supporting patent costs for SMEs, and in addition, two incubators received funding as well. In all probability the most significant step in this process was the passing of the Bayh-Dole-like Innovation Act (December 2004), which among many significant changes, allowed universities to start spin-off companies and academic scientists to work for them while keeping their positions. Some estimate that this has led to the formation of nearly 200 high-tech start-ups since the beginning of last year. To make the Hungarian biotechnology companies more attractive and competitive, the adoption of the Young Innovative Company status is still awaited.

- *Contributed by Hungarian Biotechnology Association*

### **Spain – National Association calls for YIC at Annual Meeting**

Asebio at the general meeting officially proposed the creation of the Young Innovative Company status. Press release in [Spanish](#)

## ***Issues and other news***

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### **Switzerland – Biotech portal and new Eurobiojobs portal**

The Swiss Biotech Association (SBA) is monitoring emerging issues through the Biotech-Forum where other associations such as the SGCI and involved companies meet on a regular basis. The association's website [www.swissbiotech.org](http://www.swissbiotech.org) is becoming the one-stop-portal for interested people in Biotech.

The Job Portal [www.eurobiojobs.org](http://www.eurobiojobs.org) has been launched in April 2006. The presentation to the NAC's took place on June 20. The strategy is to bring on board all NAC's and EuropaBio, thus creating a real European Job Portal for the industry.

The USP of the portal is the 'matching engine' which facilitates the match-up between job offerer and job seeker. The SBA is already active to develop the matching tool. Potentially this could become a European project.

- *Contributed by SBA*

### **Sweden - New SwedenBIO board and chairman elected**

Professor Hans Sievertsson has been elected new Chairman of SwedenBIO. Hans Sievertsson has a strong industrial background from former Pharmacia and as board member of several Swedish companies. He is also one of the founders of SwedenBIO. Hans Sievertsson succeeds Björn Nilsson who has completed his three-year mandate.

The Newly SwedenBio elected board members:

Hans Sievertsson, Chairman

Hans Hultberg, Director Discovery Alliances, Astra Zeneca

Svein Mathisen, CEO BioInvent International

Akbar Seddigh, Board chairman Elekta and Ortivus

Reelected members:

Lars Adlersson, CEO Medivir

Peter Ehrenheim, CEO GE Healthcare Life Sciences

Annika Espander, Managing Director, Catella Healthcare

Magnus Lundberg, CEO Phadia

Mats Pettersson, CEO Biovitrum vice Chairman

P-O Wallström, CEO Karo Bio

- *Contributed by SwedenBio*

### **Belgium - New organisation : Bio.be (fusion between BBA and Belgobiotech).**

Fully operational from June 2006.

- *Contributed by Bio.be*

### **Italy - BioItaly and Assobiotec's Annual Meeting (Rome, June 14<sup>th</sup> - 15<sup>th</sup>, 2006).**

The Assobiotec's Annual Meeting was held in Rome last June 15<sup>th</sup>, 2006: during the closed session Assobiotec has confirmed Dr Roberto Gradnik as Chairman and elected its 25 board members for the period 2006-2008; Emma Bonino, Minister of International Trade and European Affairs, was the main guest speaker of the following public session. The previous day (June 14<sup>th</sup>, 2006) was held BioItaly, the first networking event organized by Assobiotec involving the Italian biotech companies, in order to foster knowledge and business collaborations.

- *Contributed by Assobiotec*

### **UK - Chairman and Deputy Chairman Awarded Honours**

Dr David Chiswell, Chairman of the BIA from January 2003 to December 2005, has been awarded an Order of the British Empire (OBE) for his services to the bioscience industry.

Glyn Edwards, Deputy Chairman of the BIA since 2000, has also been awarded a Member of the British Empire (MBE) for his services to the bioscience industry.

- *Contributed by BIA*

### **Hungary - Hungarian Biotechnology Association (HBA)**

Established by Hungary's 10 leading human biotechnology companies in 2003, the Hungarian Biotechnology Association (HBA) was created to promote the development of the Hungarian biotechnology sector. The Association – presently having almost 70 members - managed to obtain support for the continued development of national life sciences and the commercialization of scientific achievements. HBA's most important activity is the representation of Hungary's biotechnology, and the organization carries out harmonized lobby activities. The Association also represents its members at major international conferences and exhibitions where it displays company posters, brochures and flyers. HBA is also a member of various international biotechnological organizations, such as EuropaBio ([www.europabio.org](http://www.europabio.org)), the Biotechnology Industry Organization ([www.bio.org](http://www.bio.org)) and the European Federation of Biotechnology ([www.efbweb.org](http://www.efbweb.org)). HBA regularly forwards information and enquiries about international conferences, grants and events to its members and acts as a coordinator in emerging collaborations.

In June 2006 the Hungarian Biotechnology Association has launched a **biotech manager training program** with the aim of educating young, talented scientists on issues such as entrepreneurship, intellectual property and technology transfer, as well as financing and other areas where multifold expertise is lacking. With the support of the National Office for Research and Technology (NKTH), the course is held mainly by professionals invited from around the globe to share their experiences.

Furthermore, the Association is also starting programs which address the younger generations so that more students choose to pursue a career in science, particularly in biotechnology.

- *Contributed by Hungarian Biotechnology Association*

### **Spain – Asebio publishes annual report of activities**

Text reproduced in annex

**Greece – Life sciences business event – Greece October 5-7, 2005**

Bionova – EuropaBio's Greek national association is developing a major life sciences event in October 5-7, 2006. [www.igbf.gr](http://www.igbf.gr)

IGBF aims at becoming a scientific landmark for the development and transfer of Biotechnology (White, Green and Red) to and from Greece, Southeastern Europe and Middle East, as well as the Balkans and Russia.

Enjoying the auspices of the Greek Ministries of Development and of Health and Social Solidarity, and the National Organization for Medicines, while supported by EuropaBio (the European Association for Bioindustries counting more than 1.500 members), the IGBF's role in the Biotechnology field is obviously internationally acknowledged.

Every year the organization welcomes almost a thousand visitors (the number of this year's IGBF visitors is expected to surpass all previous records) and attracts significant media coverage. Visit the web site [www.igbf.gr](http://www.igbf.gr) or request full speakers programme and event agenda from Mr. Evangelos Bonoris, Managing Director Hellenic Biotech Association Phone: +30 210 800 49 10 Fax: +30 210 800 49 13 Mobile: +30 Email: [v.bonoris@bionova.gr](mailto:v.bonoris@bionova.gr)

# **Asebio Annual Report 2005**

## *Executive Summary*

The ASEBIO 2005 report aims to continue being a “thermometer” for evolution in the sector and consolidated as the Biotechnology reference guide in Spain. The report is directed at those readers who, through their profession or their personal interest, wish to get a clear view of the situation of the biotechnology sector in Spain.

ASEBIO wishes to thank both the Ministry of Education and Science and its sponsors and collaborators for their kind support, without which this report could not have been undertaken. The main ideas underpinning each of the chapters comprising the report have been summarised below.

### **Background**

#### **Twenty five years of biotechnology in Spain reviewed by Professor Emilio Muñoz**

Professor Emilio Muñoz, President of ASEBIO’s Scientific Council and a pioneer of the Spanish scientific policies, analyses progress made in the 25 years since the first Biotechnology Mobilisation Program, including changes implemented during his tenure as Director General of Scientific Policies for the Ministry of Education and Science.

From his positions as Director-General, Secretary General of the National Plan for R&D, President of the Spanish National Research Council (CSIC) and, in the late nineties, President of the Biotechnology Office in the CEFI Foundation – forum where ASEBIO was gestated, Professor Emilio Muñoz’ participation has been crucial in bringing together the academic and business worlds, the two mainstay of our field of activity.

This interview makes part of the historical memory of Professor Emilio Muñoz, and is, therefore, a very valuable part of the birth and development of the biotechnology in Spain.

### **Temperature of the Sector**

#### **The companies’ optimism and drive help to counterbalance the difficulties of the environment**

The ASEBIO Index (a tool that annually measures the opinions of the main players on the Spanish biotechnology stage) has reached in 2005 its best level ever and, for the

first time since 2000, it marked a positive value. This reflects an optimistic perception about the possibilities for the development of the sector.

Forty four organisations (biotechnological companies, supplier enterprises, user companies, enterprises from the R&D environment, foundations and financial entities/support services) took part in the elaboration of the ASEBIO Index 2005. Those questioned underlined, above all else, the ease of access to the sources of financing, key factor in enabling growth of the sector. However, there has been a noticeable lack of buyouts and mergers. Difficulties in gaining access to the international markets are another major barrier for Spanish companies.

## **Business Environment**

### **Cooperation is growing, but it is not yet sufficient to compete overseas**

- In 2005, five hundred and thirty-eight companies were doing biotechnological research in Spain. Of them, only one hundred and twenty have biotechnology as their only field of activity. Those are the companies that make the core of the sector and are the main motor in terms of producing knowledge. They have more than 370 MEUROs in total sales revenues, they invest almost 320 MEUROs in R&D (86% of their sales revenues) and devote more than 25% of their expenses to a highly qualified staff that exceeds 2.000 people.
- By sectors, the red, sanitarian biotechnology, with its two sides, therapy and diagnosis, counts for more than the 50% of the sector, followed by the agro-feeding applications or green biotechnology (around 20%). The rest is divided between the white, industrial biotechnology, with a 5,7%, and a large number of companies that offer technological platforms with applications in several fields (23,6%), like genomics and proteomics.
- In regard to the distribution of the companies solely dedicated to biotechnology, a shift has been noticed in the distribution of companies solely dedicated to biotechnology away from the regions historically more active in the field, like Madrid and Valencia, in favour of other emerging areas, like Asturias, Canarias and Baleares, which have joined the Spanish biotechnology map. Cataluña and Andalucía have seen their ratios improve slightly.
- With regards to human health some companies stand out. There have been several advances in the clinical development of molecules proceeding from Spanish biotechnology companies (Advancell, Digna Biotech, Genetrix, Neuropharma, OED...) and the creation of important researching consortiums under the shelter of the CENIT Programme. All these initiatives collide with a sanitary policy obsessively aimed at cutting sanitarian expenses, without any sensitivity to innovation
- The lack of a transparent, harmonized legal frame for the molecular diagnosis in Europe worries the companies in the sector, which, in spite of these difficulties, kept a good growing rate during 2005.
- The foodstuff biotechnological companies increased their partnership activities with traditional companies in order to reactivate ripe markets through innovative products lines.

- The foodstuff diagnosis based in biotechnology knows an important boom under the auspices of rules that acknowledge the potential of these new methods for guaranteeing the quality, the traceability and the food security.
- Agrarian biotechnology and, more specifically the development of new GMO agricultural varieties, is facing difficult situation that puts in risk the good position of the Spanish companies in the sector. The regulation frame work approved in Europe (which includes a strict system of rules for experimentation, authorisation, culture, traceability and labelling), is not being implemented at the suitable speed. This lack of leadership threatens our agriculture's competitiveness and increases its technological dependence.
- Industrial biotechnology is undergoing an important boom in our country, it covers various activities like bioenergy, bioremediation, biomaterials and bioprocesses, amongst others. The importance of the white biotechnology for a more sustainable industry has been repeatedly pointed out by entities like the European Commission, the OECD or the European Technology Platform for Sustainable Chemistry, the institution where ASEBIO participate in a newly constituted work-group.
- Enterprising activity in our country, understood as the percentage of the adult population that undertake an enterprising initiative, reached in 2005 a 5,5%. Of these enterprisers, only 1,9% developed any activity related to biotechnology. ASEBIO has identified 25 new companies in the last 18 months exclusively dedicated to biotechnology.
- A poll of veteran companies in the sector showed that most alliances had been made with other biotechnological companies and, in one third of all cases, with foreign companies.
- Asked about the most common barriers encountered in closing agreements, the companies stressed the lack of resources to identify the right partner, a difficulty that could have caused 50% of alliances to fail. Incompatibility between corporation' cultures (45%), differences between the economical terms and the lack of size (in the polled company) to fulfil the compromise, are other common reasons for the failure of these processes.

### **Institutional Environment**

#### **There is an urgent need for a state strategy that sums efforts, searches for synergies and eliminates redundancies**

ASEBIO values, from a business point of view, the conclusions of the report "Spanish biotechnology: economical impact, evolution and perspectives" published by Genoma España at the end of 2005, in the section dedicated to "Innovation policies and the support to biotechnology". The Association brings information through commentary and compares and contrasts the various tools, programs and performances identified by the state foundation.

### **Chapter 2**

#### *Executive Summary*

## **Social Environment**

### **Biotechnology industry, a paradigm of Corporate Social Responsibility**

Corporate Social Responsibility (CSR) is a voluntary attitude that tries to conciliate growth and competitiveness with social and environmental worries. This approach is very consistent with the mission of the biotechnology company, aimed at obtaining a profit (economical value) for the shareholders, by means of activities that generate useful knowledge (social value) and that are based in the sustainable utilization of living organisms (environmental responsibility).

## **Financial Environment**

### **More funds, more specialised**

2005 witnessed a recovery of confidence in the international financial market. Stock Exchange and venture capital investment indexes confirm the positive tendency shown in 2004 and bury definitively the consequences of 2000's "technological crisis". Both tendencies, optimism and consolidation, are reproduced to scale in Spanish case, although with a very different departure point. Biotechnology and venture capital are two activities trying to overcome an historical disadvantage in Spain, in an unfavourable political and economic environment. The described stage could change in the middle term if some of the initiatives announced during 2005 thrive. NEOTEC, the mixed fund promoted by the Centre for the Development of Industrial Technology to ease creation of innovative companies, stands out. Other initiatives have the investment in biotechnology as their exclusive activity (Biofocus FCR) or as their main activity (Unifondo). From the operations undertaken in 2005 those made by two of the three Spanish companies listed on the Stock Exchange stand out: The capital increase of Zeltia (65MEUROs), subscribed to by thirty specialised investors from the USA and the UK, is one of the four main accomplishment in the biotechnology sector in Europe during the last four years.

On the other hand, Natraceutical reinforced its international presence with the purchase of Braes Group, resulting from the merger of Overseal, from the UK, and Obipektin, from Switzerland. The purchase, worth 79,5 MEUROs , fifty percent of which has been financed by means of a capital increase and a syndicated loan.

## **Conclusions**

### **The sector demands State aids tailored to the biotechnology companies, and a stable regulating framework sensitive to innovation for the user companies**

The productive context and society in general acknowledge, increasingly, the possibilities of biotechnology as a business competitive vector and the opportunities offered by its products and services for the improvement in the quality of life and in the environment.

ASEBIO, which integrates more than eighty companies able to bring technological solutions to sectors that account for 30% of the GDP, has the compromise of incorporating biotechnology into the strategic agenda of our public authorities. With the support of the OECD, EuropaBio and a large part of the public system of R&D (represented by some well established partners such as the CSIC, the Carlos III Health Institute or the Spanish National Cancer Research Centre) we are ready to cooperate actively with the authorities in order to reinforce a promising tissue of biotechnology companies specialised in R&D, and to bring biotechnology to several user sectors.

Most companies totally dedicated to biotechnology have their origin in the public system of R&D (spin-offs), and are proving to be most active agents in transferring technology to our sector. Their mission is to convert the results of public investigation into products and services that improve citizen' quality of life. By so doing, they carry out one of the noblest ends of scientific activity, as legitimate as the generation of knowledge "per se".

Their work would be very difficult without the trust of the leading companies in their user sectors that already benefit from biotechnology, moreover they would be able to accomplish much more if the social and political environments were more engaged with innovation. This dynamic potential gets different dimensions according to the characteristics of each user industry:

- In markets with a high added value, exposed to a short life cycle of their products, like those related to health, biotechnology has become an indispensable means of the innovation in products and services.
- In other sectors, like agriculture and foodstuff, more influenced by price, biotechnology has been consolidated as a tool for the reactivating of ripe markets, allowing the development of new range of products (functional foods), reassessment of by-products or optimization of expenses in various processes.
- Last, biotechnology is postulating to become a profitable and sustainable alternative in various industrial processes (textile, paper, chemical), open new lines of business in the energy sector (biofuels) and environmental (bioremediation).

Besides, the promotion of biotechnology in user sectors could have a large impact by means of the creation of companies specialised in R&D&I from consolidated industrial groups (spin out). This phenomenon has been essential for the grown of the Spanish sector and is the origin of a large number of the more veteran biotechnological companies (Pharmamar, Natraceutical, Puleva Biotech). In the last year, it has stimulated the beginning of several projects (Indas Biotech, Biobide -belonging to Corporación Mondragón- and Suan Biotech, amongst others). Independent of its origin, the biotechnology company has a major role in Spain's current and future economy. From our point of view, innovation is not just another strategy for European industry, but the only alternative in the global context in which we will never again be competitive due to our prices.

The Spanish Government, although apparently engaged with the R&D&I strategy as an increase in the corresponding budget items shows, have not yet concreated any specific measures for the sector. These measures, which we hope to soon see incorporated into a Spanish Biotechnology Strategic Agenda, should take account of the total difference between supporting innovation in traditional sectors and supporting companies devoted entirely to R&D. Both approaches are needed and effective, but the tools are different, as are the results.

From ASEBIO we invite the concerned authorities to study, for instance, the implementation in Spain of a Statute for Young Innovative Companies, resembling the French one. It consists of a specific package of incentives for companies with less than fifteen years of life and more than 15% of expense devoted to R&D (criteria just at the reach of sectors like biotechnology, microelectronics and robotics). This Statute, which

many European States are about to adapt, has had a direct and very positive impact on the French biotechnology companies which benefited from, also among others, the following aids:

- Zero rate of taxation.
- Total exemption from social security contributions for staff
- Total exemption from the need of a guarantee in the request for loans and subsidies.
- Ease in the transfer of fiscal credits to shareholders' partners or allies who could benefit from the deductions for R&D&I until such time as the biotechnology companies make any profits.

We need specific measures with a direct impact in the sector, but these should go together with a stable socio-political and regulation environment, favourable to innovation. A State pact which would include, among other aspects, the keeping and improving of the current fiscal incentives and the rectification of some policies that affect in a negative way the resources that our user sectors could be dedicating to innovation. Actually, it is very inconsistent to promote innovation on one hand, whilst hindering its possibility of developing useful products and services on the other, through a restrictive legal and economic environment.

For instance, we can see the difficulties of the biotechnological agriculture or the non recognising by the authorities of the development of highly innovative drugs. ASEBIO has acted since 1999 as a platform for the promotion of the Spanish biotechnology sector and, with the sixth publication of this report, repeats its offer to cooperate with local, national and European authorities, as well as with any social organisation interested in the use of the biotechnology for the improvement of the quality of life, the environment and the creation of qualified jobs.

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