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Healthcare
Manifesto
2011 - 2012
INTRODUCING YOU TO HEALTHCARE BIOTECHNOLOGY

Healthcare biotechnology refers to a medicinal or diagnostic product or a vaccine that consists of, or has been produced by the use of, living organisms. Often recombinant DNA (a form of DNA that does not exist naturally and which combines DNA sequences that would not normally occur together in order to establish new functions) forms the basis for such biotechnologically manufactured products.

Healthcare biotechnology has a tremendous impact on meeting the needs of patients and their families – it not only encompasses medicines and diagnostics that are manufactured using a biotechnological process, but also gene and cell therapies and tissue engineered products.

Today, the majority of innovative medicines, whether manufactured using biotechnology or via a chemical synthesis like a traditional small molecule medicine, and many diagnostic products, are made available by applying modern biotechnology in their development and/or manufacturing processes.
More than 350 million patients have already benefited from approved medicines manufactured through biotechnology to treat or prevent cancers, heart attacks, stroke, multiple sclerosis, leukaemia, diabetes, rare and other diseases.

650 new biotech medicines and vaccines are currently being developed for more than 100 diseases.

In Europe, there are more than 60 approved orphan medicinal products, most of them biotech medicines, for the prevention or treatment of rare, life-threatening or serious conditions.

Whilst the individual number of patients suffering from rare diseases might be low, all together, more than 30 million Europeans are affected.

With the completion of the human genome mapping and the resulting improved understanding of inter-individual variability, current medical science is evolving towards a “personalised” approach in which we are better able to develop and subsequently target medicines to patients who are more likely to benefit.

The pharmaceutical industry is increasingly shifting towards biotechnology. Projections estimate that in 2014, 50% of the top 100 drugs will be biotech medicines.

By 2015, the OECD estimates that healthcare biotechnological knowledge will be used in the development process for all new pharmaceuticals.

More than 70% of biotech and pharmaceutical companies in the EU-27 have less than 50 employees. Although small, biotech SMEs provide the high value-added jobs that will help the EU achieve its goal of becoming the foremost knowledge-based economy in the world.

Recently, larger biopharmaceutical companies have tended to place greater reliance on outsourced R&D, mostly coming from emerging biotech SMEs. These programmes now represent as much as 30% to 50% of the pipeline for many major companies.
Investment in healthcare innovation will be essential in securing the economic future of Europe. This will be achieved firstly by helping to ensure a fit population with a lower burden of disease, secondly by providing a valuable, leading high-tech industry sector in Europe and thirdly by pushing the boundaries of science to increase our understanding of the disease mechanisms and to address unmet medical needs. Researchers today are increasingly able to understand the pathways and molecular mechanisms of a given disease and of clinical response. Creating more predictable outcomes based on diagnostic-therapeutic combinations is the essence of greater capabilities for personalised medicine.

Over the last two years, the financial crisis has had a dramatic and negative impact on the healthcare biotechnology industry, not only by limiting access to finance for smaller companies, but also by pressing national governments into implementing measures to contain costs in their healthcare systems and on their science and research budgets. Often the first affected area by these cost containment measures is the spending on research into, and uptake of, innovative biotech medicines. Often short-term by nature, these measures, including narrow Health Technology Assessments (HTAs) and pricing and reimbursement processes, should ensure that patients benefit in the long-term from these healthcare innovations while ensuring health systems get value for money.

The European Commission (EC) has launched its Strategy to achieve a more competitive and socially inclusive European Union by 2020, as well as the first European Innovation Partnership in the field of active and healthy ageing. Furthermore, Commission Vice-President Antonio Tajani is leading a new initiative to improve access to innovative medicine in the European Union (EU) - the so-called “Process on Corporate Responsibility in the Field of Pharmaceuticals”. Nevertheless, there is growing concern among the healthcare biotech industry that an irreversible disconnect is emerging between the long-term access policies promoted at EU level and the short-term actions taken at EU Member States level.

EuropaBio welcomes the EU institutions’ impetus to revitalise the competitiveness of the sector. However, the EU must also recognise that there is a need for a more coherent approach for setting policies. This would ultimately ensure that positive and constructive initiatives implemented at one level are not undermined at another. The European Commission, in close collaboration with Member States, has a unique strategic position to address this issue. This Manifesto intends to provide some suggestions on how the EC can fulfil this role.

Healthcare biotechnology provides patients with new and targeted solutions for a wide range of major diseases such as cancer, diabetes or stroke. However, while healthcare biotechnology can support governments in their efforts to enhance the sustainability of their healthcare systems, cost containment measures can also have the contradictory effect of hampering innovation and access for patients by delaying or limiting entry into market of new technologies.

EuropaBio Healthcare Council members are committed to developing new products that help society live better, longer and healthier. This Manifesto, the EuropaBio Healthcare Council Policy Roadmap for 2011-2012, sets out how EuropaBio will contribute, through a transparent and open dialogue with all relevant stakeholders, to the development and implementation of sound policies that will lead to innovative solutions to unmet medical needs.

Thomas Bols,
Vice President Health Policy & Market Access, Merck Serono, and Chair of the EuropaBio Healthcare Council (2009 – 2011)
EuropaBio is committed to the socially responsible use of biotechnology to improve the quality of lives, to treat and cure diseases, to improve the quality and quantity of food, to produce chemicals and to sanitise and to prevent release of hazardous wastes. EuropaBio recognises its responsibility to address societal ethical concerns and to encourage, through constructive dialogue between stakeholders, a better mutual understanding of such concerns. These concerns encompass cultural or religious aspects, possible environmental impact and the adequacy of regulations. The association and its members have therefore developed a set of Core Ethical Values.

These Core Ethical Values are addressed to consumers, patients, the industrial and agricultural communities, politicians, legislators, the media and others who wish to know about the key ethical values that underpin our work. All members of EuropaBio commit to these Core Ethical Values and adhere to them as an integral part of the bylaws of the association.

They can be viewed at: http://www.europabio.org/positions/general/CoreEthicalValues2009.pdf
ACHIEVING BETTER POLICY-MAKING THROUGH SCIENCE

Science is a fast driver of innovation, providing patients with cutting-edge healthcare solutions to address unmet medical needs.

EuropaBio’s role is to foster open discussion and exchange between all relevant stakeholders in order to improve the understanding of the latest developments in science. Ultimately, EuropaBio believes that a better understanding of science leads to the setting of better policies.

“Personalised medicine combines predictive diagnostic and therapeutic tools to create predictable outcomes and tailor medical treatment to the individual characteristics of each patient.”

Personalised medicine

With the completion of the human genome mapping, it became clear that biology is much more complex than expected. Research into understanding inter-individual variability at several molecular levels has continued world-wide. Private and public scientific developments are strongly driving the medical paradigm towards an approach that ensures the right treatment, to the right patient at the right time. This personalised medicine approach combines predictive diagnostic and therapeutic tools to create predictable outcomes and tailor medical treatment to the individual characteristics of each patient. This change is not only driven by scientific advances but also by society’s demand for novel solutions to old problems and more efficient therapies.

Modern healthcare biotechnology methods and tools such as gene and cell therapies have the potential to answer this demand, providing personalised, innovative, safe, and effective healthcare biotech products for patients. There are now a growing number of biomarkers, genetic and proteomic tests being developed and validated to identify patients who will most likely respond to associated treatments.

Applications of personalised medicine go beyond therapeutic usage and are also increasingly used in drug development from pre-clinical to clinical development. A variety of tools help identify respondents, non-respondents and patients who are likely to suffer from adverse reactions. As a result, pre-clinical and clinical trials are likely to become smaller, safer, more focused, faster and less expensive.
From a public health perspective, tailoring treatments to patients who are most likely to derive benefits from them will contribute to a re-distribution of financial resources in healthcare systems in a more rational way. The personalised medicine approach has the potential to bring more effective and safer treatments on the market as well as reducing the use of ineffective treatments and the number of adverse reactions – thereby reducing unnecessary hospitalisations.

**Rare Diseases & Orphan Medicines**

Ten years after the adoption of the European Regulation (EC/141/2000) on orphan medicinal products (OMPs), more than 60 new treatments for rare, chronically debilitating and life-threatening diseases have received a positive opinion from the European Medicines Agency (EMA) recommending the granting of a marketing authorisation. More than 720 applications for orphan designation have been granted for products in development to treat more than 200 different rare diseases. The approved treatments resulting from the OMP Regulation make a significant difference for patients, bringing hope to some 30 million Europeans and their relatives, affected by one of the 5,000 to 7,000 rare diseases. However, much still needs to be done since many patients still face delays in access to treatment: access to OMPs in Europe remains slow and variable, despite the high unmet medical need, the lack of alternative treatments in most cases and/or the added significant clinical benefit that these therapies must demonstrate before being granted a marketing authorisation.

**Achieving better policy-making through science by:**

- Fostering a multi-expert platform for discussion and experience sharing through the EuropaBio Task Force on Personalised Medicine.

- Contributing to the development of an innovative and coherent EU policy and regulatory framework that is responsive to the scientific evolution in personalised medicine and healthcare delivery.

- Continuing the dialogue with all relevant policy and regulatory stakeholders to communicate the potential role and impact of personalised medicine on the healthcare biotech industry, from drug discovery to market access.

- Advocating for a complete implementation of the initiatives put forward in the European Commission (EC) Communication on Rare Diseases and agreed by the EU Member States in the Council Recommendation on Rare Diseases, which will greatly increase access to treatment for rare disease patients in the EU.

- Working at EU level with the EU Committee of Experts on Rare Diseases (EUCERD) and at national level through the EUROPLAN initiative to develop and implement coordinated national plans for rare diseases ensuring effective diagnosis, treatment and care for rare diseases.

- Communicating the medical, economic and social value of OMPs to policy-makers, regulators and other relevant stakeholders, particularly by contributing to the discussion on the implementation of the Clinical Added-Value of Orphan Drugs (CAVOD).
ACHIEVING REGULATIONS THAT SUPPORT INNOVATION

A sound EU regulatory framework encourages and stimulates responsible innovation to help people live longer and healthier lives. EuropaBio brings its expertise and experience into all key regulatory discussions to help in the development of a predictable and workable framework.

EuropaBio’s involvement in and commitment to such an approach will ultimately improve timely access to new medicines and the competitiveness and attractiveness to investors of the healthcare biotech sector in Europe.

“Better regulation is required now if we want to maintain an innovative and viable European bioscience industry that can compete globally.”

Clinical Trials

A harmonised, transparent and evenly implemented regulatory framework for clinical trials throughout the EU is vital for the European bioscience industry to thrive. The adoption of the Clinical Trials Directive 2001/20/EC was an important first step towards harmonising the requirements and processes in EU Member States and should have created synergies and time savings. However, the uneven and inconsistent implementation of the Directive by EU Member States has resulted in cumbersome, lengthy and costly processes for clinical trial sponsors.

For EuropaBio, patient safety is of paramount importance. However, there is no supporting evidence that multiple layers of regulatory approvals enhance the safety, rights or well-being of patients – the very objective of the Clinical Trials Directive. Thus, the additional administrative requirements appear redundant. What we do know, however, is that there has been a dramatic drop in the number of drug development companies formed in Europe in recent years. Not only is this a major concern for the biopharmaceutical industry, but also, the societal aspects need to be highlighted. Ultimately, patients will be denied access to innovative medicines.

Better regulation is required now if we want to maintain an innovative and viable European bioscience industry that can compete globally. EuropaBio welcomed and contributed to the EC’s impact assessment concerning the application of the Directive and believes the European Institutions should use this opportunity to thoroughly review the legal framework and its implementation and, if necessary, to propose new legislation. Only in this way can we achieve real harmonisation and consistency in the approval and conduct of clinical trials in the EU in accordance with Good Clinical Practice principles.

Incentives for the development of new indications for authorised medicinal products

Restoring the EU as a world leader for biotech innovation and avoiding delays for patient access to innovative treatments are essential and obvious policy objectives. Healthcare biotechnology gives rise to new possibilities for treatments, therefore addressing unmet
medical needs much more than in the past. The medical research model is evolving with researchers departing from the old model of “one disease – one medicine” and focusing instead on understanding the pathways and molecular mechanisms of a given disease.

This mechanistic understanding has shown that many diseases that were considered as unrelated actually share common molecular features. These features could be targeted by a medicine specifically for this pathway. As a result, research and drug development does not stop with the creation of a product for one specific condition, but will continue throughout and beyond its lifecycle.

A new consensus is now needed on how important new medicines or new applications for existing medicines can be brought to patients in a sustainable way. A fair and appropriate reward system supporting innovation would encourage more investment into R&D of new uses for authorised medicines.

Biosimilars

Biological medicines are far more complex than chemical pharmaceuticals. This means that they are harder to precisely characterise, manufacture and copy than chemical medicines, whose ingredients are easily identifiable and can be exactly reproduced. Small variations in the structure of all biological medicines may lead to differences in safety, efficacy and/or quality.

Biological medicinal products similar to a reference medicinal product (i.e. biosimilars) do not usually meet all the conditions to be considered as a generic medicinal product, mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action.

The concept of a biosimilar medicine was introduced in the Community Code relating to medicinal products in 2004. The EC has subsequently developed an abridged approval pathway for such medicines and the EMA has developed a number of guidelines concerning the required data needed for marketing approval. Despite the fact that progress has been made with the introduction of a legislative specific regulatory-framework for biosimilars, EuropaBio believes that there are still some issues which remain to be addressed, such as the naming and labelling requirements for biosimilars, pharmacovigilance tracking, interchangeability (i.e. where products can be exchanged one with another without a significant risk of adverse health outcome) and automatic substitution (i.e. the practice by which a different product to the one specified on the prescription is dispensed to the patient without the prior consent of the treating physician). EuropaBio believes that automatic substitution should not be allowed in the case of biological medicines and that the physician should always be involved in the decision to initiate or change treatment with a biological medicine.

Achieving regulations that support innovation by:

- Actively engaging with regulators and policy makers and contributing to the revision of the Clinical Trials Directive.
- Continuing the dialogue with key stakeholders to communicate the detrimental impacts on the European bioscience industry if a harmonised, transparent and evenly implemented regulatory framework for clinical trials in the EU is not implemented as quickly as possible.
- Raising awareness about the gradual R&D paradigm shift within which disease mechanisms are increasingly understood and more new indications for already approved products are developed.
- Continuing the ongoing dialogue with all relevant stakeholders about the appropriateness of the current EU incentive schemes to reward R&D efforts, within the context of this R&D paradigm shift.
- Working to ensure that certain fundamental issues, which still remain unclear, such as the naming and labelling requirements for biosimilars as well as their pharmacovigilance tracking, are adequately addressed.
- Working at EU Member State level, in close collaboration with the EuropaBio’s National Associations Council, to address legal and regulatory implementation issues such as national rules on interchangeability and automatic substitution.
ACHIEVING BETTER ACCESS TO MARKET THROUGHOUT THE EU

Regardless of their country of residence, all patients deserve timely access to innovative therapies.

However, as EU Member States increasingly resort to cost-rationing measures to contain their healthcare expenses, promoting the value and uniqueness of biotech medicines has become essential to ensure that tools such as HTA or tenders are used appropriately and do not reduce patients’ access to life-saving therapies.

Value of Innovation in Health Policy

The healthcare biotechnology industry is a critical source of innovation and, as such, is a key player within the EC reflection “Vision for European Union in 2020”. Today, the sector is seven times larger than it was ten years ago and has a 20% annual growth rate. However, due to the complexity of the sector (i.e. products, policies and regulatory environment), healthcare biotech’s contribution to society is at best underestimated.

The value of an innovation tends to be split into at least two categories: breakthrough innovation and incremental innovation. Breakthrough innovation can either be established by a landmark discontinuity or be the result of discrete incremental improvements. Such minor increments may ultimately be just as important to patients. An example from within the healthcare biotech area could be an improved mode of administration of a medicine rather than a new medicine as such. Failing to also acknowledge and reward all categories of innovation – including incremental innovation – will undermine a vital part of the innovation process.

EuropaBio’s role is two-fold: i) promote the medical, economic and societal benefits of biotech innovation and ii) engage with all relevant stakeholders in constructive interactions to explore ways to maintain and to strengthen the industry’s innovative efforts.

Health Technology Assessment (HTA)

Many EU Member States have established Health Technology Assessment (HTA) processes to systematically determine the relative “value for money” provided by new technologies – including biotech medicines – to, ultimately, support decision-makers in their pricing and reimbursement decisions.

However, HTA evaluations have a potentially critical impact on patient access to treatment and on the rate of innovation availability when used instead as a tool of cost-containment policies in healthcare. Rewards to innovation should be

“Rewards to innovation should be appropriately and fairly granted based on holistic assessments of new and of existing technologies.”
appropriately and fairly granted based on holistic assessments of new and of existing technologies. Such assessment should acknowledge key elements such as value to society as well as to the economy, ethical views of disease management, impact on productivity and quality of life, and value to both the patients and to the community (i.e. patients’ relatives, caregivers and employers). Current EU efforts to provide a common methodological framework to HTA systems such as the Joint Actions on HTA should be given the right consideration and be further integrated into a wider EU innovation policy to ensure consistency of approaches.

EuropaBio calls for a robust and participative framework governed by transparency and in which relative effectiveness and HTA would be a tool to encourage the development of new and innovative therapies for the benefit of patients, whilst allowing health care planners to appropriately fund and manage resources effectively in these financially uncertain times.

Access to Innovative Medicines

In some EU Member States, purchasers (i.e. governments, hospitals, institutions and insurers) increasingly resort to procurement procedures in order to award contracts for the supply of biotech medicines. Due to the complex nature of biotech medicines, biopharmaceutical procurement is a particularly complex process which involves many steps, authorities and suppliers/manufacturers.

EuropaBio acknowledges that all biotech products approved by the EC, FDA or a similar regulatory authority qualify for the current Good Manufacturing Practice (GMP) standards and have been approved to safely and effectively address a given indication. However, by nature, healthcare biotech products are different from each other, and are much more complex than small-molecule medicine. Therefore, it is important that their unique features be borne in mind when discussing the viability of tendering for biotech medicines.

Patient safety is of course paramount and within biotech products, which in most instances address debilitating or life-threatening diseases, small variations in a “similar” but not “identical” product can be crucial. Therefore, whilst EuropaBio acknowledges that tendering might be an appropriate tool for purchasing biotech products within some specific fields; overall, EuropaBio does not believe that tendering with a sole focus on price is an appropriate way forward for medicines in general, including biotech products.

Achieving better access to market throughout the EU by:

- Continuing to bring specific healthcare biotech expertise to all the forums on HTA, in particular the Joint Action on HTA, the Swedish EU Presidency Assessing Drug Effectiveness project (SPADE) and the discussions on the role of the EMA in assessing the relative efficacy of products.

- Increasing the understanding of the impact of HTA processes and their use on Small and Medium Enterprises (SMEs) through the whole product life-cycle, and developing recommendations for EU and national authorities to address SME-specific HTA hurdles.

- Continuing to communicate on the specific clinical, social and economic value of healthcare biotech products and increase the understanding among all stakeholders.

- Organising a series of workshops, in partnership with other industry associations, on the specific policy, regulatory and access hurdles for the most innovative healthcare biotech technologies.

- Contributing to the revision of the Transparency directive; to ensure that the future framework takes into consideration the pricing and reimbursement issues associated with emerging technologies; in close collaboration with other industry associations.
Small is the new big

In the EU, SMEs comprise approximately 99% of all firms and provide two out of three of the private sector jobs. Globally, SMEs account for 40% to 50% of GDP. Biotech SMEs are knowledge-based enterprises and provide the high value-added jobs that will help the EU achieve its goal of becoming the foremost knowledge-based economy in the world. Furthermore, SMEs are a major contributor to innovation and these companies form what is described as a symbiotic relationship with large, multi-national companies across the healthcare, energy and agricultural sectors, paving the road for improved healthcare for Europe’s citizens.

Within the healthcare sector, larger pharmaceutical companies are increasingly looking to small biotech companies to improve their pipeline and provide the innovation needed to remain competitive. These same large companies have also become increasingly reliant on external R&D, mostly performed by SMEs. These programmes now represent as much as 30% to 50% of the pipeline of many major pharmaceutical companies. Therefore it is critical that the EU is able to ensure that there is adequate funding for these SMEs. Too many potentially great innovations go to waste because of a lack of funding. It has been recognised by several member states (e.g. France and the UK) that there is a market failure due to the long R&D timelines, the increasing costs and the high risks associated with biotech medicine developments. Potentially lifesaving treatments are often either put on hold, are significantly delayed or terminated altogether. In the end, this results in fewer innovative treatments reaching patients in dire need.

The EuropaBio SME Platform works together with stakeholders to provide policy makers with recommendations on how to best support biotech SMEs, which often have specific issues when compared to SMEs from other industry sectors. The Platform brings together SMEs, national biotech industry associations, venture capitalists and financing bodies, amongst other stakeholders. It is dedicated to highlighting issues and solutions of particularly high relevance for SMEs on topics, such as financial constraints, the optimisation of EU funding instruments and patents.

One example is the Seventh EU Framework Programme for Research (FP7), where the target is to increase the number of participating SMEs. So far, despite making SMEs a priority, within health proposals, only 10.8% of the budget is currently directed to SMEs (the target being 15%). The need for funding for translational research should also be acknowledged: contrary to basic research, which is more speculative and takes more time to be implemented, applied research is characterised by

Creating optimal conditions for Europe’s healthcare biotech SMEs by:

- Continuing to work to ensure a bigger proportion of SMEs in FP7 and FP8 by suggesting concrete changes that lower the administrative burden for SMEs and make the topic proposals more suited for SME applications.
- Being a “one-stop shop” for information on developments and opportunities for biotech SMEs, at European and national levels, through our “SME Centre” portal on the EuropaBio website.
- Supporting the realisation of a common EU patent. This would be a landmark improvement for SMEs to protect their inventions at an affordable cost, and without the need to validate patents at a national level as they currently must do.
- Continuing our support of the EMA SME Office through active involvement in workshops and meetings.
- Contributing to the work of the Innovation Union provisions to avoid internal market fragmentation, eliminate restrictive interpretation of State Aid for SMEs and to improve more general access to finance for those SMEs.
being capable of having an impact in practice within a relatively short time-frame, and by often representing an incremental improvement to current processes rather than delivering radical breakthroughs.

Ensuring coherence from European to national level

EuropaBio represents over 20 National Associations which together form the National Associations Council (NAC); a platform which helps to ensure the coordination of EuropaBio actions throughout Europe at Member State level, giving a focus to developing Europe’s biotech sector and strengthening its scope both in Europe and internationally. National Associations in particular support over 1,800 SMEs and play a significant role in our vision of a bio-based economy for Europe. Since healthcare is a national competence amongst Member States, the NAC provides a fundamental bottom-up approach to the regulatory framework, as well as an insight into the national landscape of biotechnology and how this understanding can inform policy markers at the European level.

Agenda 2020 is characterised by the need for a smart, sustainable, inclusive and greener economy. In order for this vision to become reality for the healthcare sector, it is essential that we consider how decisions at the European level shape national policy in order to produce a truly patient-centered healthcare system for Europe. This approach is increasingly important in light of unprecedented financial, economic and social strains under which national healthcare budgets operate.

From one Member State to another, the lack of harmonisation in the implementation of EU legislation can greatly hamper innovation by creating a variety of divergent, and sometimes conflicting, legal environments limiting the development and access to new biotech medicines. EuropaBio will continue to work with National Associations in order to adopt a holistic approach to policy-making and implementation at the European level and in turn ensure effective and innovative European healthcare systems for patients’ benefit.

Ensuring coherence from European to national level by:

- Working together to ensure consistent and workable implementation of EU policies at Member State level, particularly on issues related to biosimilars.
- Being actively involved in the review of the Clinical Trials Directive (and other legislation, for example the Transparency Directive) process in order to have a harmonised, transparent and evenly implemented regulatory framework across the EU, ensuring Europe’s healthcare biotech sector remains competitive globally.
- Ensuring EuropaBio is the EU’s ambassador for biotechnology companies, disseminating information in a familiar context and language.
EuropaBio is the voice of the European biotech Industry. It represents the interests of the industry towards the European institutions so that legislation encourages and enables biotechnology companies in Europe to innovate and provide for our society’s unmet needs.

The European Association for BioIndustries was created in 1996 and represents 66 corporate and 7 associate members operating worldwide, 4 Bioregions and 22 national biotechnology associations representing some 1800 small and medium sized enterprises.

Our corporate members are involved in a wide range of activities: human and animal healthcare, diagnostics, bio-informatics, chemicals, biofuels, crop production, agriculture, food and environmental products and services.

EuropaBio also welcomes associate members such as international commercial, financial asset management and other service providing companies, regional biotechnology development organisations and scientific institutes. The common denominator among all our members is the use of biotechnology at any stage of research, development or manufacturing.

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