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Biotechnology's Contribution to an Innovative and Competitive Europe

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Ladies and Gentlemen,

The impact of life sciences on our economies and societies will be substantial.

We are witnessing an explosion of knowledge in biosciences. Already now biotechnology and life sciences play an ever-increasing leading role in many areas of our daily life. It will affect almost every field of human activity. Let me just name a few major examples:

- **White biotech** allowing for new production processes will reduce our resource consumption. It will enable us to reconcile our high standard of living with environmental concerns. Bio-plastics and biofuels creating energy from biomass are just two examples of the enormous potential this area provides.
- **Green biotech** aiming to make plants resistant to heat, salt, and parasites.
- **Red biotech** speeding up the drug discovery processes, leading to new advanced innovative therapies, e.g. tailor-made drugs and cell-mediated organ transplantations or new tissues.
- Finally, **security** measures to protect ourselves against bioweapons and bioterrorism.

These biotech-applications are not mere promises. They are either reality or are about to become so. In particular red biotechnology has already produced amazing new products in the field of drugs and therapies.

Ladies and Gentlemen,

While biotechnology was **late and slow** to take off in Europe, it has to be acknowledged that the situation today has already improved: more than 1800 companies in Europe, among them many small and medium sized enterprises, are employing around 77.000 people raising 12 billion euros per year.

However, compared to the situation in the USA we still have some way to go to establish a mature and consolidated industry. Only 16% of our companies have gone public, but they employ half of all employees in the sector and represent half of revenues and research expenditure in Europe. In the USA public companies represent 77% of the total. We have to strive to match this. To do so we look to develop the high potential of our research-intensive SMEs. It is they who create 50% of new jobs.

Another disquieting tendency taking place in the pharmaceutical sector, which is one of the most promising fields of biotechnology. Here, we are confronted with a move of research and production of innovative drugs outside Europe.

Let me just give you a few simple figures which may illustrate the state of play of our **pharmaceutical sector**, an industry which is strongly affected by the life science revolution.

While in the late 1980s only 41% of the top 50 innovative drugs were of American origin, in the late 1990s the U.S. percentage climbed to 62%. Europe has remained more or less static at 18% respectively 21%. In 1990, the pharmaceutical industry spent 50% more on research in Europe than in the U.S. In 2001, the situation was reversed with 40% spent more in the U.S. In 1992, 6 out of the 10 top medicines in worldwide sales were European, while in 2002 this figure had fallen to just 2.

Ladies and Gentlemen,

We must not underestimate this widening gap. Losing R&D in life sciences is going to have major social and economic consequences for Europe, e.g.:

- delayed access to innovative drugs for the European population,
- erosion of the general European research base and losses in employment,
- continued “brain drain” of researchers from Europe to the U.S. and elsewhere
- and a loss of entrepreneurial talent.

A further relocation of development centres of the pharmaceutical industry to the U.S. bioscience clusters will lead most certainly to a decline of the European biotechnology industry.

International competition in life sciences, including the pharmaceutical area, is largely confined to the U.S. or Japan. However, life sciences and/or biotech are also the focus of several policy initiatives in countries like Singapore, India and China.

I do not want to over-dramatise the situation, but it is clearly high time to reverse this trend and unlock Europe’s potential. I am convinced that the biotech sector can play a significant role in the economic development of Europe, and I do not want to see it falling further behind in global competitiveness. It can become the backbone of a knowledge-based economy and a significant driver of Europe’s economic recovery.

Growth and jobs are vital for Europe’s sustainable development and every sector has its specific contribution to make. Only a **viable economy** will generate the financial resources to sustain the European model, i.e. combining a market economy with social justice and high environmental standards.

Ladies and Gentlemen,

This is exactly the reason why the new Commission has put the **Lisbon strategy** at the heart of its five year programme and has called for a European-wide partnership for growth and jobs. Within this partnership, 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. For the different industry sectors this means that we have to find tailor-made solutions for each of them taking into account its specific situation and needs.

One important pillar of the Lisbon Strategy is **better regulation**. The Commission has come to the conclusion that we must review our methods of preparing legislation. We have agreed recently on several principles we intend to fully respect on each and every legislative proposal the Commission will submit to Council and Parliament. These principles include, mainly, the carrying out of solid impact assessments, extensive consultations with stakeholders, cutting red tape, simplification, respecting the principle of proportionality, leaving room for alternative methods of regulation and of course ensuring a uniform application by Member States of common rules.

Legislation is a powerful tool to promote competitiveness and this link has to be preserved.

Ladies and Gentlemen,

What does this general framework mean in concrete terms for biotechnology?

First of all, an overall strategy is needed, and we are in the comfortable situation that it already exists. The European Commission's Biotechnology Strategy has laid the groundwork for our catch-up efforts in 2002 and was welcomed by Member States and the European Parliament.

It is a comprehensive plan that covers all fields of biotechnology, green, white and red, and addresses all major issue areas and policy fields, from R&D to the regulatory framework and access to capital for SMEs.

The strategy acknowledges that we have to look at the promotion of biotechnology as well as at the societal concerns linked to it.

Only this will ensure policy coherence and success. In close collaboration with Member States and Industry we have to further fine-tune and up-date this strategy and set clear and precise priorities.

Secondly, in accordance with the above-mentioned principles of better regulation we have to provide industry with a predictable and stable regulatory framework to operate and plan investment.

In the area of green biotechnology, notably **GMOs**, regulations have been difficult to achieve. I am confident that we now have a relatively stable legislative environment in the European Union. In this area our focus must therefore be to closely monitor its proper implementation.

In the field of **innovative pharmaceuticals**, we are in the process of completing our legislation with the long awaited regulation on advanced therapies and **tissue engineered products.**

The recent **revision of the regulatory framework governing pharmaceuticals** has significantly contributed to a more competitive structure for industry. Several provisions encourage innovation, in particular in the field of intellectual property rights with long **data exclusivity.** Other measures, which are particularly relevant to SMEs, include:

- waivers and deferrals for a number of fees;
- easier access to scientific advice from the Medicines Agency, EMEA;
- special incentives for companies developing orphan drugs and finally
- administrative support by establishing a special "SME Office" within the EMEA.

Thirdly, we need to promote innovation and ensure adequate financing of research at EU level.

Last week the Commission adopted two very important proposals for the future of our industry:

- the 7th Research framework programme and
- the Competitiveness and Innovation Programme.

These programmes will run from 2007 to 2013. The funds available for all sectors will be substantial and represent nearly 10 % of public spending in the Union. They include a doubling of the Research and Development budget to 70 billion euros and financial support of over 4 billion for innovation. It is expected that it will have a significant leverage effect on private and public research spending:

Access to finance for SMEs and start-ups is included in the Innovation Programme that will cover several entrepreneurship issues. A key feature of the 7th Research Programme will be a significant simplification of its operation to make the funds accessible to potential participants. It will be more focused on the needs of the European Industry.

The **Technology Platforms**, on which work has already started, will foster public-private partnerships at the European level and bring together Academia, Industry, Member States and the Commission in order to pool our limited resources to create added value. Industry's leading role will be crucial as it will ensure that our efforts are focussed on potential future markets and help us to reap the economic benefits of this cutting-edge technology.

Last but not least we need to preserve a strong industrial base in Europe by means of modern industrial policy. A policy that will not hinder structural change or cover up management errors, but one that will seek a long term perspective for individual sectors to stimulate growth potential. My main initiative in this field will be to launch a **structured dialogue** with stakeholders in order to promote the competitiveness of our pharmaceutical industry. This initiative will bring together biotechnology and pharmaceuticals and will build upon the solid foundations created by the G-10 exercise.

All in all I intend 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.

Ladies and Gentlemen,

Having said this, we of course have to acknowledge that policy makers and industry are not alone in deciding the future of this specific industry.

We must recognise that there are serious health and safety concerns as well as prejudices among the public at large. Biotechnology, in particular in agriculture and food, has raised some fundamental concerns, particularly with regard to ethics and the environment. Hotly debated issues like "GENETICALLY PRODUCED SUPER HUMANS", "GENETICALLY MODIFIED ORGANISMS" and "DESIGNERFOOD" seem to dominate the headlines in newspapers.

We should not underestimate the fact that this highly controversial public debate between proponents and opponents deals with some very fundamental questions: **What are the limits to genetic research? Is life patentable? What is the use of embryos and stem cells in research? Are animal transplants safe? Should we sacrifice animal lives at all to save humans? What are the limits and the social and moral consequences of genetic testing?**

There is no doubt that this debate creates uncertainty for business and adversely affects its image. But in an open society such as ours, it is necessary and unavoidable, and we can only expect that it will even increase as science progresses. We have, therefore, to actively participate in this debate and take the best possible decisions taking account of it.

I am convinced that on such fundamental issues, the European regulator has to take the different ethical and religious approaches to such questions in Member States seriously. Public opinion needs the assurance that perceived problems, even if only potential, are taken into consideration and that there will be no trade-offs between profitability of the industry and the safety of life and nature.

At the same time, however, an open and steady exchange of views combined with thorough information also provides a big chance: it allows us to separate the real ethically controversial areas from the perceived. Clarity and knowledge will help to decrease emotional prejudices and lead to more matter-of-fact conclusions. The fact that Europeans widely accept medical uses of biosciences shows that they are not against biotech per se.

Thus comprehensive communication to the public and with the public is essential. We, i.e. industry, academia, governments and the European Institutions are called upon to lead a matter-of-fact debate and to provide sufficient and convincing information about **the risks as well as benefits** of this technology.

To establish a climate of trust and de-emotionalise the debate, legitimate concerns have to be addressed in a transparent way, not the least from industry. Hiding behind partial findings after a scandal will not create a more favourable climate.

I am confident that, at the end of the day, European societies will, across different national perceptions, find a common denominator for the acceptance of biotech and the benefits it can bring while preserving their fundamental ethical principles.

As far as I am concerned, I intend to use all means at the Commission's disposal to support a change in the climate of public debates and to ensure that European companies are at the forefront of the development and application of biotechnology.

I count on your support in making Europe the natural home for biotechnology in the 21st Century.