Many actors interact at the different phases of drug discovery, development, production and marketing of medicines: European universities, pharmaceutical companies, small biotech companies, patients, healthcare professionals, regulators and government agencies. It is the overall success of this “innovation ecosystem” of different partners and agencies, which determines the ability of large and small operators to innovate. But clearly, all actors require an adequate innovation policy environment and access to capital. This is what I would like to talk about during the next 12 minutes, keeping in mind the theme of the conference: from research to market. This means that reaching the market is included in the plan and it should be an attractive outcome.

Much has been done in Europe already in terms of research funding and creating space for collaboration. This is especially true with the Innovative Medicines Initiative (IMI) launched by DG Research and EFPIA at the end of 2008. However, there are threats to a growing and successful ecosystem for biopharmaceutical innovation and these come from other policy directions and regulations. The threats come from some of the ways in which the clinical trials directive has been implemented to the various constraints on the commercialisation of medicinal products in member state markets. In short, there is real promise in many of the “supply side” research initiatives, but there are continuing problems with regulation and the “demand side” of innovation in Europe.

Our common goal is to identify and reduce remaining obstacles for the EU to unleash its full innovative potential, in particular through innovative SMEs. To achieve that, and to put it simply, we need improved framework conditions.

Successful outcomes from innovation policy require consistency in the broader political context. For instance, protection of innovation IP is vital for investor confidence. This is why industry supports the European Commission initiatives for the adoption of the Community Patent. Consistent respect for IP rights is a foundation of any future innovation policy, and stating the obvious, the medicines lifecycle is strongly reliant on the IP framework.

Biomedical research is one area where Europe is especially strong. But the biopharmaceutical industry is a sector where specific conditions and policies are needed to ensure its continued success.

Yes, innovation is the main driver of our industry. In fact, the Pharma & Biotech sector spends more in R&D than any other sector. As you know, the biopharmaceutical R&D process is complex, costly, risky and it takes time. On average, the process of developing a new medicine takes 10-12 years and today, costs over €1000 million. Why? Because the easy targets for medicine development have been identified and there has been a shift in R&D focus on medicines for complex, multi-symptomatic and multi-factorial chronic diseases.
Clinical R&D costs are also rising as regulators require more and bigger clinical trials to meet more stringent safety requirements.

As I said, the pharmaceutical sector is Europe’s biggest spender on R&D. How does this translate into numbers? The research-based pharmaceutical industry represents 19% of private R&D expenses and 3.5% of manufactured exports. Pharma & biopharma companies in Europe invested Euro 27 billion in R&D in 2008. These companies have together more than 630 medicines in development, including over 250 for various cancers.

Incidentally, E&Y reported earlier this month that for the first time in 30 years the biotech sector has become globally profitable. 30 years is a long journey, with commitment and risk taking by many entrepreneurs and investors.

Today, those who innovate in healthcare face unlimited opportunities...but also greater challenges. We know that medicines have helped reduce mortality and in some cases cut in half deaths from disease (e.g. HIV/AIDS, certain cancers, cardiovascular diseases). Medicines have led to significant progress in quality of life. But huge challenges remain (e.g. cancer, antimicrobial resistance). Aging societies also bring new challenges.

We know that new medicines and treatments will play an important role... but the science is harder, hurdles for new products are higher, and there is too much focus on health care costs as a burden rather than as an investment in the future. The healthcare sector actually requires a specific approach to innovation policy because in most EU countries, there is a growing conflict between willingness and ability by public payers to pay for innovation.

On a positive note, new European regulatory frameworks can effectively support innovation. As examples, I can speak of two European regulations, which have had a positive impact on biopharmaceutical innovation. These EU regulations have fostered growth, especially in profitable niche markets where small & medium-sized biotech companies can be strong.

First example: the Orphan Medicinal Products Regulation adopted in 2000 boosted R&D in rare diseases. It had led to 62 approved orphan drugs by now, 10 years after, and over 720 OD designations granted to products in development. (Initially 50 % developed by SMEs; now big pharma is picking up on OD designations).

Second example: the Advanced Therapies Regulation adopted in 2007 established a harmonised EU regulatory framework for the development, evaluation and marketing approval of cell-based therapies, gene-therapy products and tissue-engineering products. Many SMEs are developing advanced therapies and should hopefully benefit from this new framework.

What we need to maintain in Europe, even during the economic recession, is a Biopharmaceutical Innovation Platform, which rests on 4 pillars that together provide the incentives required for investing in R&D and innovating in healthcare: (1) Successful health care systems; (2) Efficient markets; (3) Effective use of IP; (4) Predictable and adequate regulatory requirements.
The innovation climate, which needs to be maintained, will rely on several factors but if I would name just one, I would say: fair reward for innovation, incl. incremental innovation. Yes, incremental innovation in pharmaceuticals can result in direct benefits for public health. The impact of innovation on patients does not just come from ‘breakthrough’ progress, but also from the refinement of existing products and services. In pharmaceuticals, outcomes such as simplified dosage and reduced side effects can make significant differences to patients’ lives.

The IMI is a major public-private partnership to remove bottlenecks and speed up drug development for the benefit of patients. Industry is a partner in IMI and industry is committed to improve its processes to bring innovative medicines to patients more quickly and efficiently while complying with the highest safety and quality standards. But industry could call on the EU institutions and national authorities to match the joint IMI undertaking with rationalising and simplifying the European regulatory and administrative processes.

For example, the Clinical Trials Directive has failed to achieve its goal of “simplifying and harmonising the administrative provisions governing clinical trials”. The main problem is that Member States have adopted different approaches in implementing the Directive, so the benefit of a single approach has been diluted. We are looking forward to the revision of the CT directive framework. I am sure that the sponsors of clinical trials present here will agree.

Back to the theme of this conference, yes, there have been great measures put in place to improve collaboration and excellence in research. But it is possible that the most critical obstacles to innovation in medicines are the markets for medicines themselves. These markets not only shape the future of large biopharmaceutical companies but also the community of biotech SMEs. I could say that the investment climate and support for biotech SMEs is directly linked to their own ability or the ability of the larger players who acquire their IP to commercialise new medicines. If new medicines are facing greater hurdles to reach patients, these market obstacles to innovation become more significant and detrimental to future innovation in Europe.

This brings me to my last point. The EU can and should help provide adequate access to finance to healthcare SMEs through the product development cycle. Europe has had long-standing structural problems in providing adequate access to public and private financing for biopharmaceutical SMEs and these problems have been exacerbated by the global financial crisis. Compared to the USA, there is a relative lack of private investors and venture capital for early-stage biopharmaceutical product development in Europe.

Tomorrow two sessions will review some of the structural issues in access to finance for product development faced by biopharmaceutical SMEs and their investors in Europe, i.e. venture capitalists. You will also learn about existing European mechanisms and national programmes to get government funding or co-investment.

Are investors losing faith? Well, VCs and the institutional investors in their VC funds need to see a demonstration of regulatory and commercial success. And the issue is not to create more companies…but companies with a future!
This biotech SME funding issue has an impact on the upstream R&D component of the overall medicines lifecycle in Europe. So, it is one source of innovation in the biopharmaceutical sector, which is partly at stake. A new European policy framework could be designed and implemented to ensure that both private and institutional investors remain confident in the biotechnology sector over the longer term. For example, new funding initiatives championed by the European Commission, which would share risks between private and government funds or increase public and private co-investment, could bring back investors’ confidence in the sector.

In short, we encourage the European Commission to engage into new types of actions to address the increasingly serious problem of access to finance for biopharmaceutical SMEs in Europe. If you want to hear the details and recommendations from CEOs and VCs, join our session tomorrow morning!

To conclude, at EBE we represent the very large, the large, the medium-sized and the small biopharmaceutical companies because together they form a continuum in research and innovation in healthcare. As I said at the beginning, all these players are part of an overall innovation ecosystem.

The continued health and success of all parts of this ecosystem are interdependent. All parts of the ecosystem need to be involved in planning and participating in actions designed to encourage innovation. This is why EBE and many of our members who are in this room are pleased to be attending this conference. This is a great initiative by the European Commission.

Thank you.

E. Chantelot / EBE / 20 May 2010