

## Editorial

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### Stop losing ground in pharmaceutical innovation in the EU

#### 1. Introduction

Today Europe is faced with major health, economic and scientific challenges. The EU has been losing ground in pharmaceutical innovation. It is important to slow down or even reverse this trend.

The pharmaceutical sector makes an important contribution to European and global wellbeing through the availability of medicines, economic growth and sustainable employment. It has been and remains a strategic sector for Europe. It employs more than 634,000 people and accounts for more than 18.5% of the total EU business R&D expenditure and 5.5% of the total EU manufacturing added value.

Most importantly, innovation in human medicines has enabled patients to benefit from treatments considered unimaginable a few decades ago. However, at the beginning of the 21st century Europe has been losing ground in pharmaceutical innovation.

The centre of gravity for research has moved to the U.S. and Asia. New international competitors emerge. In the 1990s pharmaceutical research and development expenditures in Europe were higher than in the U.S. (EUR 7.766 billion compared with EUR 5.342 billion). However, the picture had changed by 2006 (EUR 22.500 billion in the EU while EUR 27.053 billion in the U.S.). Between 1990 and 2006, R&D investment in the United States grew 5 times while in Europe it only grew 2.9 times.

While in general the number of new pharmaceutical substances has decreased worldwide, the decrease has been significantly sharper in the EU than in the US and other parts of the world. Research and Development is a key to pharmaceutical innovation. However, Research investment has gradually been relocating from Europe to the United States and Asia. While certain factors are sector-specific others also relate to broader factors such as fiscal policy, cost of labour or education and training.

The crisis is part of the lack of political will of EU Member States in advancing towards deeper processes of integrating their policies. The clearest example is provided by the so-called Lisbon Strategy for growth and development. Its aims were laudable and necessary but the governments were unable to commit to a precise timetable and quantified targets. Everything was left to the goodwill of States and simple procedures for cooperation. Cooperation between States is necessary but

not sufficient. The process of European construction has demonstrated that only integration procedures ensure significant progress. But many national governments appear to have not yet learned the lesson. Hence, after ten years of experience with the Lisbon strategy the results are rather disappointing, despite sustained reorientation.

The original Lisbon Strategy was launched in 2000 as a response to the challenges of globalisation and ageing. The European Council defined the objective of the strategy for the EU “to become the most dynamic and competitive knowledge-based economy in the world by 2010 capable of sustainable economic growth with more and better jobs and greater social cohesion and respect for the environment”.

However, the original strategy gradually with multiple goals and actions and an unclear division of responsibilities and tasks, particularly between the EU and national levels, was re-launched in 2005 focused on growth and jobs. Its main targets, 70% employment rate, and 3% of GDP spent on R&D have not been reached. There are one 10% of unemployment and the EU has failed to close the productivity growth gap with leading industrialised countries. Total R&D expenditure in the EU expressed as a percentage of GDP only improved marginally (from 1.82% in 2000 to 1.9% in 2008).

In the Strategic Report on the renewed Lisbon strategy for growth and jobs, the Commission identified investing in knowledge and innovation as one of four priority areas for focused actions in the 2008–2010 cycle. Protection of intellectual property is a key framework condition for innovation, stimulating R&D investment and transfer of knowledge from the laboratory to the marketplace.

In this context, on December 10th, 2008, the European Commission adopted a Communication and three legislative proposals with the overarching objective of ensuring that European citizens are increasingly able to benefit from a competitive industry that generates safe, innovative and accessible medicines.

The Communication sets out different measures on various topics to tackle the growing issues of counterfeiting and illegal distribution of medicines; to better protect patients by strengthening the EU system for safety monitoring (‘pharmacovigilance’) on medicines. Once approved and placed on the market, medicines are monitored throughout their lifespan to ensure that any product which presents an unacceptable level of risk can be rapidly withdrawn from the market; and finally to enable citizens to get high-quality information on prescription-only medicines.

In addition, it suggests several non-legislative initiatives such as: to discuss with Member States ways to improve market access by making pricing/reimbursement decisions more transparent; to develop initiatives to boost EU pharmaceutical research; to intensify cooperation with major partners (USA, Japan, Canada) and to improve medicines safety worldwide.

The Commission Communication on the Pharmaceutical Sector outlines the vision to ensure that European citizens will benefit from a competitive industry that generates safe, innovative and accessible medicines. A more competitive and innovative industry will generate more growth and sustainable jobs for European workers and also foster the development of new medicines for unmet medical needs. To make

further progress towards a single and sustainable market in pharmaceuticals; to take on the opportunities and challenges of globalisation; and to make science deliver for European patients and restore the EU's role as the natural home for pharmaceutical innovation.

Given the importance of the pharmaceutical industry for economic growth and employment, as well as its role for public health, the Commission need to pursuing policies that create an environment conducive to creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry.

The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines.

From 2000–2007 innovative companies spent on average 17% of their turnover from prescription medicines on R&D worldwide.

Government and EU Institution need to assume that Innovation is of key importance for the pharmaceutical sector. Industry requires continuous innovative efforts in order to find new medicines. Without the very significant R&D efforts of innovative companies and other stakeholders, as universities, these benefits would not be possible.

Intellectual property rights are a key element in the promotion of innovation. The protection of intellectual property rights is important for all sectors of economic life and is paramount to Europe's competitiveness.

Given the presence of certain indications that competition in the pharmaceutical market in the European Union might not be working well, the Commission launched a sector inquiry into pharmaceuticals on 15 January 2008. The inquiry sought to examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline in innovation as measured by the number of new medicines coming to the market.

The sector inquiry has provided the Commission with reliable data on how competition functions in the pharmaceutical sector as regards the competitive relationship between originator and generic companies and amongst originator companies, quantifying industry practices and pointing to certain areas of concern.

## **2. Pharmaceutical global harmonization will be the permanent objective**

Tackling worldwide health threats is in itself a sufficient reason to strengthen international cooperation. The global burden of disease is increasing, including poverty-related and neglected diseases which disproportionately affect developing countries.

Establishing and enforcing international public health standards is essential to minimise the risk that unsafe products enter the EU market. The work carried out with the US and Japan at the International Conference on Harmonisation (ICH) is essential in this context and must be expanded. ICH standards should be promoted

so that they can become worldwide standards. International harmonisation at ICH and the promotion of the use of international standards by third countries beyond the US and Japan should be further developed.

The EU-US Transatlantic Economic Council (TEC), in particular, provides a unique chance to bring closer the two biggest pharmaceutical markets in the world, lowering costs by reducing unjustified regulatory divergences.

Using the TEC areas for simplification and convergence of rules between the US and the EU and engaging in upstream regulatory dialogue for major legislative proposals should be pursued.

New technologies and therapies and innovative information and communication technology tools for healthcare offers a huge potential. The new EU Regulation on Advanced Therapies should speed-up the development of these products and foster industry's competitiveness. But new Community instruments are needed to support their development. Europe needs a dynamic and competitive pharmaceutical sector.

In the view of the European pharmaceuticals organization EFPIA, property rights are at the core of a modern market based economy. Intellectual property (IP) rights are merely a particular form of these rights. Moreover, the infringement of the IP rights is not the right solution to the critical problem of health in the less developed country. Intellectual property rights have come into the firing line in many international instances. The Commission should send a clear signal of its committed support to the maintenance of high standards for intellectual property protection within the EU and worldwide.

The conditions for enforcing the EU legislation on data protection need to be improved.

### **3. Research and development and patents is a key to pharmaceutical innovation**

On 16 July 2008, the Commission adopted a Communication on an industrial property rights strategy for Europe which outlines actions to ensure Europe has a high quality industrial property rights system in the years to come. It complements the 2007 Communication on the patent system, which set out a way forward towards the adoption of a Community patent and an integrated EU-wide jurisdiction for patents.

Intellectual property law establishes protection over intangible property. Are two main categories: industrial property and copyright. Patents and trade marks are the best-known industrial property rights. Patents are a limited term exclusive right granted to an inventor in return for the disclosure of technical information from the invention. Industrial property rights are diverse and include rights such as industrial designs, geographical indications and plant variety rights. What all these rights have in common is that they enable holders to prevent unauthorised use of an intangible asset of potential commercial value. Europe requires strong industrial property rights

to protect its innovations and remain competitive in the global knowledge-based economy.

Patents are a driving force for promoting innovation, growth and competitiveness, but the single market for patents remains incomplete. The current fragmentation of the patent system, the costs and complexity, as well as the legal insecurities are all harmful to the competitiveness of European companies. It should be cost-effective, legally secure and reduce complexity for companies. It should also allow for more efficient enforcement of rights in the European Union and its external borders. The wilful infringement of patents and the copying of patent protected products have equally serious consequences.

Europe is lacking an industrial strategy. The lack of support on vital matters to the industry such as intellectual property rights, the lack of understanding of how pharmaceutical research works and who conducts this research are examples of a lack of integrated industrial strategy. Europe does not sufficiently reward innovation. In Europe, the focus has been on cost not on the value of medicines to patients and society. More and more medicines prices are arbitrarily based on the sole objective of containing healthcare costs and without tracking outcomes. With such a policy the real value of new medicines is not appropriately rewarded.

Protection of new innovations by intellectual property must be accompanied by effective enforcement mechanisms. Counterfeiting and piracy are reaching alarming levels with significant implications for innovation, economic growth and job creation in the EU and risks for health and safety of European citizens. Strong protection of industrial property rights should be accompanied by rigorous application of competition rules.

#### **4. Keep public budgets under control**

It is generally acknowledged that public budgets, including those dedicated to cover health expenditure, are under significant constraints. Competition, in particular competition provided by generic medicines, is essential to keep public budgets under control and to maintain widespread access to medicines to the benefit of consumers/patients.

Pricing and reimbursement policies need to ensure a control of pharmaceutical expenditure for Member States. Nevertheless stakeholders continue to raise concerns with regard to the market fragmentation linked to disparities in national pricing and reimbursement schemes, unnecessary regulatory burdens caused by divergences in the implementation of Community legislation. The exchange of data between Member States on relative effectiveness should be fostered in order to avoid delays in the market access of innovative treatments.

National Government and EU institution not arrives to assume the reality of our society. The percentage of elderly people – 65 and over – in the total population of

Europe is expected to increase from 16.8% in 2005 to some 20.6% in 2020. Over-regulation and rationing are certainly not the way that they will cope with the growing demand for pharmaceuticals, resulting notably from longevity and morbidity, and the financing of this demand.

On average approximately € 430 was spent on medicines in 2007 for each European and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over €138 billion ex-factory and €214 billion at retail prices.

## **5. Medicinal products as an investment in health**

In 2009 it was said that the cost of medicinal products per person per year in the EU countries was 500 euros. This amount does not in itself tell us much. A first economic approach is obtained by taking into account the average expenditure per person per year in the homes in EU countries. Everyone can do this particular calculation according to their income and family members. Moreover, this cost should be contrasted with other expenses such as the consumption of tobacco and alcohol, the amount spent on gambling or on telephone communications, to mention only those expenses that approximate to the annual cost of medicinal products consumed.

In the EU countries, one way or another, the cost of medicinal products used is mostly covered by organizations of Social Security, so that they do not figure in the family's economy, while at the same time, governments, directly or indirectly, control and manage the procurement of these products. It also means that governments exercise an important control over the operation of a sensitive sector of the economy. Governments do not always use this power to improve citizens' health, life expectancy and welfare, but rather they use it in a threatening manner, constantly warning to cut back these benefits, within the dynamics of limited public resources and these limitations are imposed, when there are no genuine measures of rationing, which is not the same as measures of rationality in public spending.

But seeing things as they really are, beyond the functioning of government and related services, an individual, from whom the state does not take away taxes for this purpose, may not consider it foolish to spend 500 euros to finance the consumption of medication throughout the year, given that spending on the telephone and Internet costs the same amount. A smoker spends more money buying tobacco than medicinal products, and always with the bad conscience of knowing that, besides being annoying to family, friends and co-workers, he is also harming his own health. Similar reasoning can be applied to gambling and alcohol consumption.

Bearing in mind that the cost per person per year in medicinal products cannot be considered as an acceptable lump sum without more by society as a whole and by each citizen in particular, then it has to be understood that the medicinal product is a commodity, albeit a very special commodity.

From the conception of the medicinal product until it is used by each of us as potential patients, multiple actors intervene in the economic, social and scientific dimension of these products, and they are therefore subject to diverse contingencies and dysfunctions.

Making the chain of links in the production and marketing of medicines effective is the first responsibility of governments and other actors involved. This should guide many government policies, if it is thought that the expenditure on medicinal products per person per year is very high and governments should do what is possible to reduce it to an acceptable figure. The problem is that governments devote little attention to these many and varied responsibilities. They seem only to care about the final price. This is serious and unacceptable to the public.

Without seeking to be comprehensive, the following summary of the main factors affecting the price and final consumption of medicines has to be remembered. Governments must have policies to promote research, innovation and development; an effective policy of industrial property protection; an effective education system; training of health professionals to enable them to make effective use of medicines; an efficient health services to allow time for medical professionals to implement an accurate diagnosis that can lead to prescribing the appropriate medicinal product; an efficient industrial policy and evaluation, control and distribution structures of medicinal products in efficient conditions to ensure that all medicines available to patients are safe and effective. And finally, citizens need to be educated with adequate training and information to share responsibility for their own health and medicinal product use following the guidelines set by health professionals and information on the medicinal product. These are all complex responsibilities that governments neglect, since they are medium and long term actions. However, they have most of the facilities to decide on what are called budget cuts affecting the price of medicines and conditioning and rationing their use. Citizens should not accept this. The responsibilities are for the entire circuit of medicinal products.

If there are failures in the chain of life of the medicinal product, it is for governments to confront, and to lower the cost of medications. In turn it must ensure a policy of research and innovation to guarantee that innovative medicines continue to appear on the market to alleviate or address the many dysfunctions and diseases that people suffer.

Whether medicinal product use per person per year is right or not, adjusting ourselves to the harsh daily reality that we the citizens who endure governments suffer, that five hundred euros per person per year is not an exorbitant amount but rather modest, and even more so when we take other parameters into account. The cost of medicinal products can not be treated as expenditure but rather as an investment in human capital of health and wellbeing. If the cost of consuming a medicinal product per person per year avoids just a one-day stay in hospital, society would be saving that cost, and businesses would not lose a day of work.

And from the personal and individual point of view, all society is aware that medicinal products are a basic tool to increase quality of life and life expectancy

for all citizens, including the oldest. As it affects us all in our own lives, citizens must be very critical and vigilant with governments to prevent their irresponsibility from seriously undermining the right to health and access to better medicines that science can make available to humanity. Each actor in the chain of responsibility of the medicinal product has different responsibilities.

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