

## **Can Europe compete in biomedical research?**

**Summary of the second Annual Forum Lecture given by Sir Tom McKillop  
FMedSci, Chief Executive of AstraZeneca, on 31 March 2004.**

### **Introduction**

The deliberately provocative title of this lecture: ‘Can Europe compete in biomedical research?’ was chosen to convey a genuine concern about the serious decline of biomedical research in Europe and a worrying lack of direction in European policy-making to tackle it.

Europe, and the UK in particular, has an outstanding record of success in biomedical research. It has made innumerable contributions to every branch of medicine and the related sciences. This scientific largesse is mirrored by an equal success in pharmaceuticals. Europe was the cradle of the pharmaceutical industry, which it dominated for decades.

Today the scene is very different. Europe is being outspent and outperformed. By almost any measure the US is leaving Europe behind. Formidable new competitors are also emerging in China and India.

Despite the enthusiasm for biotechnology professed by its politicians, Europe is a long way behind. Over 90 per cent of the top-rated biotechnology clusters in the world can be found in North America. It is estimated that half a million of Europe’s leading scientists are working in North America, while much of the European pharmaceutical industry seems to be in transit to the US or elsewhere. The position in Europe has become so difficult that many individuals, institutions and companies are losing heart.

This begs the questions: is European biomedical research a lost cause? And does it matter?

### **Does biomedical research in Europe matter?**

Biomedical research does matter. It improves health. We should all aspire to the improved quantity and quality of life resulting from a better understanding of diseases and their diagnosis and treatment. But investment in biomedical research does not only lead to better health, it also creates real wealth. There are clear correlations between the health status of populations and their economic productivity. Generally speaking, good health leads to far more productive societies.

The pharmaceutical and other health-related industries are huge net economic contributors in Europe, the US and elsewhere. Often little account is taken of the value these industries add. Every year the pharmaceutical industry benefits the EU by contributing over €25 billion in net balance of payments. In contrast, office machines and computers, another high-tech sector, conveys a massive net €33 billion deficit. In fact, the pharmaceutical industry is by far the most successful high-tech industry Europe has ever had. It is the fifth largest employer in the industrial sector, generating 582,500 highly qualified jobs, invests €19.8 billion every year in research and developments (R&D) and produces an annual €40 billion trade surplus.

Today, biomedical research is on the threshold of a revolution. Technological advances such as the understanding of the human genome could lead to huge new developments. But there is an enormous amount still to do. The scale of opportunity for biomedical research in Europe

and overseas is immense: from improving treatment for the 300 million people who suffer from atherosclerosis, to confronting the epidemic of obesity, to treating multi-drug resistant infection.

### **In the shadow of North America**

Compared to the US, innovation in European biomedical research is declining. US spending on biomedical R&D increased from 2.4 per cent to 2.8 per cent of gross domestic product (GDP) over the last two decades. Over the same period in Europe it has fallen from 2.4 per cent to 1.9 per cent. This led European governments to set the Lisbon agenda - with wonderful words about making Europe a high-technology innovation-based economy. The target is three per cent of European GDP invested in research by 2010. The problem is that Europe is going in the opposite direction.

US government spending as a percentage of GDP on health R&D in the US is more than twice that of any European country. The scale of the US National Institutes of Health investment in research dwarfs that of Europe – which spends less than one fifth the amount. Indeed, despite hundreds of millions being invested by the MRC, BBSRC, Wellcome Trust, and others the UK is still being outspent by the US both in absolute terms and as a proportion of GDP.

A gaping deficit is opening up between European and US investment in R&D by the pharmaceutical industry. The US is roaring ahead, its share of world pharmaceutical R&D spending increasing from around 30 per cent in 1990 to over 50 per cent by 2002. Meanwhile Europe is in the doldrums: UK spending since 1990 is levelling off, whilst that of Germany and France is in decline. Since 1990 there has been a progressive switch in where European companies perform their R&D. More and more it is moving to the US and the early signs are to India and China as well.

Of course this leads to a significant impact on innovation. Historically Europe dominated in terms of both the number and value of new drug molecules it produced. In 1980 eight out of the top ten drugs were discovered in Europe. Today, eight out of the top ten drugs were discovered in the US.

### **The innovation gap**

Why is Europe giving up its position of enormous strength in biomedical R&D? One factor is underinvestment in healthcare and specifically pharmaceutical products, much of which is due to a fundamental difference in attitude to innovation in the US and Europe. Innovation is rewarded more in the US than in Europe - the US is hungry for it, while Europe has become cautious.

It is often thought a large fraction of GDP is spent on pharmaceuticals. This is not true. In the US this stands at less than 2 per cent of GDP, in the UK the figure is below 1 per cent. The innovative pharmaceutical products, those launched in the last five years, make up 35 per cent of the US national pharmaceutical market but in the UK these products represent closer to 15 per cent of the market. So, less than 0.2 per cent of UK GDP is being spent on innovative products. A similar pattern can be seen across the rest of Europe.

The UK also has the slowest take-up of new products in the developed world. Even five years after a product launch the median take-up in the UK for 41 medicines studied was just under half of that of the rest of developed world.

It can take up to two years for pharmaceuticals to go through the bureaucratic clearance processes required before sale, delaying the reimbursement of its parent company. This delay represents the loss of an enormous block of value.

No surprise therefore that by 2002 the North American pharmaceutical market was significantly bigger than that of Europe, a reverse of the situation a decade previously. Given that 70 per cent of the worldwide total sales of innovative pharmaceutical products are in the US, can any pharmaceutical company be blamed for focusing on that market?

### **Structural problems**

Europe is not functioning well. We are awash with laws and regulations: the European Clinical Trials Directive, the Chemicals Directive, the Freedom of Information Act. A Biotechnology Directive was passed years ago and is still to be implemented in some countries. For over 15 years there has been talk of a European patent but it still has not been achieved. National governments are obviously responsible for health matters but so much of its regulation is derived from Brussels. There is no integrated strategy for biomedical R&D across Europe. No priorities are set. There seems to be no way of getting cohesion across Europe.

Despite strong support from government and elsewhere the worrying problem of animal activists has not been solved. Across Europe there is very little facilitation of academic-industrial collaboration that was achieved in the US a decade ago. Furthermore, there is also under investment in education and training.

### **Market distortions**

In Europe there is a very serious set of market distortions. Individual European countries have all introduced different mechanisms to control supply and demand of pharmaceutical products including arbitrary price setting and there is a pre-occupation with mechanisms to control the introduction of new products. On top of this, every bit of bad practice in one country seems to be picked up by many others.

If that is not bad enough, many of the problems that derive from differences in the economies of the 15 member states will be exacerbated by the incorporation of the accession states in May 2004, where economic differences are even more marked. Thus the problems, unless dealt with, will increase.

This steady deterioration in the quality of the European market is made much worse by parallel trade. The free movement of goods and services across Europe enshrined in the Treaty of Rome means that what ever country sets the lowest price for a product becomes the major source of that medicine across Europe.

Something like 15 per cent of all the pharmaceutical products in the UK, representing over €2 billion, are being parallel traded. Its prevalence can be seen across the board and it is growing in Germany and the UK in particular. This is very serious for pharmaceutical companies as this loss of sales value drops right through to the bottom line because there are no offsetting cost savings for the company. Much of this lost profit could be reinvested in R&D in Europe.

It has been argued that this lost profit is in fact a saving for health services. This is not true. A number of studies show very clearly that very little of those lost sales come through to governments. What is happening instead is that the parallel traders are becoming some of the richest people in Europe.

In the last year the German government has cut its prices by 16 per cent across the board. We had arbitrary cuts imposed in Italy. Hungary, which joins the EU in May 2004, also announced a cut recently. A constant downward spiral of the value of the European market can be seen. This is caused by a clash of dogma between the European Commission and the governments of the member states, with the European pharmaceutical and biomedical research squeezed in the middle - seriously suffering.

### **G10**

G10 provides an opportunity to address some of these problems. The G10 group was formed to balance industry and healthcare policy interests by addressing the loss of competitiveness of the European-based pharmaceutical industry. The Group consists of Health and Industry Ministers from five Member States, representatives from different sectors of the industry, mutual health funds and a specialist in patient issues. G10 has come forward with a balanced set of recommendations, not all favourable to the R&D based pharmaceutical industry, which need to be implemented. These recommendations concern improving access and availability of medicines, while resolving some of the market distortions. They aim to improve the regulatory process, and to stimulate innovation. They also propose a virtual institute of health to incentivise research in Europe, and consider patients' right to objective information. They will benefit European citizens and can provide a substantial contribution to the Lisbon agenda by reversing the decline in European biomedical R&D.

### **Conclusion**

The pharmaceutical industry and biomedical research around Europe is at a very important crossroads. Nobody can refute their decline. What is at stake is Europe as a site for life science research. G10 will not solve all the problems by any stretch of the imagination. Many more changes have to happen. However, G10 is an important part of the process of reversing Europe's decline in biomedical R&D.

Now there are some positives. It is very positive that European governments and the Commission have recognised the importance of biomedical R&D in setting out the Lisbon agenda. The goals in the Lisbon agenda may not be reached but at least recognising the challenge is a step in the right direction.

Another positive is G10, but will governments implement its recommendations?

A very important step taken by the UK government was the setting up of the Pharmaceutical Industry Competitiveness Task Force (PICTF) that led to a healthier dialogue with industry. They understood each other's problems much better. There was a very frank exchange of views that is now being picked up in a number of other European countries that might emulate the idea. Indeed, G10 activity derived in some measure from PICTF.

The UK government is also increasing spending on health and education, vital components of a biomedical R&D base, and recently there has been a long-term commitment to a national science plan.

Fora like the Academy of Medical Sciences are another important step forward. Settings are needed where these issues can be discussed. The outcome of reports such as 'Strengthening Clinical Research' need to be heard, the ideas generated picked up and pursued with some vigour.

Some questions remain. Are these initiatives enough? Do our leaders have the courage to take action to back their words? Can we get real cooperation across Europe and between

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academia, the health systems and industry? Individual European countries will struggle to compete with the US but together we can compete.

Do not be worried about the pharmaceutical industry. It will survive and prosper because there is a fundamental need for its products. The issue is not whether there is a future for biomedical research or the pharmaceutical industry. The issue is whether Europe wants to be part of it.

Please note that the presentation slides that accompany this lecture are available at [http://www.acmedsci.ac.uk/f\\_pubs.htm](http://www.acmedsci.ac.uk/f_pubs.htm).

Laurie Smith, April 2004

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Notes:

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