
Editorial: A new season for biotechnology in Europe?

Is Europe being left behind in the biotechnology race? Europe's research system for life sciences is too fragmented, the regulatory approval system is cumbersome, intellectual property protection is shaky at best, with the EU Directive on protection of biotechnological inventions implemented in only 4 of the 15 member states, and the economic incentives, including venture capital, are not adapted to the needs of start-ups.

The European Commission itself has recognised that with respect to biotechnology, 'the time is ripe and we have no time to lose if we are to catch up with other regions of the world.'¹

This perception would appear to be backed up by the figures. A quick comparison between the US and EU biotechnology industries highlights the US lead. Revenues in 2000 totalled €23,750 million in the USA versus a 'meagre' €8,679 million for the EU. Similarly, the USA has 10 times more employees (162,000 versus only 61,000 employees for EU biotechnology firms). The number of biopharmaceuticals approved in the USA up to the year 2000 was double that of the EU, with a total of 95 products approved compared with 51 in the EU. Finally, critical for the research-based industry, the R&D expenditure of the USA more than doubles that of the EU (€4,977 million in the EU, €11,400 million in the USA).²

However, a closer look at the figures indicates a different story. While revenues in the EU may be lower, they have grown by 38 per cent relative to the previous year, while the USA grew by 10 per cent. R&D expenses grew by 48 per cent (with the USA staying stable at 1 per cent growth), and the number of European companies growing by an impressive 16 per cent in one year.

So what is the real situation – is Europe lagging without hope, or is it a latecomer

making up lost ground? Either way, Europe's biotechnology industry requires a significant boost before it competes on the same ground as the USA.

Change in EU policy

Over the past three years, the EU's policy towards biotechnology has undergone a slow but sustained revolution. The Lisbon Summit in March 2000 identified for the first time the key role of biotechnology as a high-technology sector in Europe. The Summit Conclusions established the principle of promoting high-technology sectors in order to make Europe become the 'most competitive and dynamic knowledge-based economy in the world'.³

The Lisbon call was followed up in March 2001 by a Resolution from the European Parliament which called for 'support for the development of biotechnology in the European Union to the benefit of its citizens'.⁴ This report, presented by Mr John Purvis, has served as the basis for a broader discussion within the European institutions, industry and the European public on the role of biotechnology in Europe.

Finally, in March 2001, European Heads of State reinforced their commitment to the sector at the Stockholm Summit, calling on the European Commission to 'examine measures required to utilize the full potential of biotechnology and strengthen the European Biotechnology sector's competitiveness'.

These three developments, coupled with a recommendation from the European Commission's 'G10 Group of Competitiveness of the Pharmaceutical Industry', which also calls on member states to support the biotechnology sector, have together marked an important turning point in Europe's political support for biotechnology.

In order to reverse the figures quoted at the start of this commentary, and to sustain the EU growth figures of recent years, it will be important to see the various local, national, regional and European political commitments implemented in full. These must be followed, or indeed paralleled, by support for all aspects of the industry, as outlined in the Commission's Strategy for Life Sciences, presented in January 2002, which will be discussed at the Barcelona Summit of the EU Heads of State in March.

In its Strategy, the European Commission has outlined four major concepts namely:

- harvesting the potential of biotechnology;
- networking Europe's biotechnology communities;
- responding to global challenges;
- coherence across policies, sectors and actors.

For the first time, an integrated policy on biotechnology has been developed and presented across the EU. It represents a Copernican revolution, bringing together all aspects of this exciting new technology. It recognises the ethical, cultural, social, legal, entrepreneurial, economic and financial elements that are needed to embrace this new technology with powerful potential benefits to humankind.

Member states and the European Commission have shown the political leadership required to ensure that Europe will not continue to fall behind and miss the opportunities represented by biotechnology.

Industry, consumers and other stakeholders should embrace this new

enthusiasm with open minds. As with all new beginnings, biotechnology has the potential for great new developments. We have already noted that more than 60 new drugs, in the short space of five years, have now been made available to European patients thanks to the breakthroughs of biotechnology. Many of these provide new therapies for previously untreatable diseases.

This opportunity should now be seized by all those involved in the policy development process, not just politicians or indeed industry. It is important that all stakeholders – consumers, patients, industry, politicians, representatives of the regions and others – are fully involved in this debate to ensure that the ethical, societal and economic needs are fully encompassed in the policy-making process.

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