Executive Summary

Innovation policies and sectoral innovation systems

Biotechnology has become the driving force of radical changes in innovation processes in various sectors. This is best illustrated by the pharmaceutical industry where the traditional chemical paradigm of drug discovery and development is being replaced by a new biotechnological paradigm. This has important consequences for the structure and functioning of the biopharmaceutical innovation system: biotechnology firms and public sector research organisations are becoming key actors generating new knowledge, tools and substances for the pharmaceutical industry. Regulations, standards and intellectual property rights (IPR) schemes have to deal with new types of components, and, on the demand side, new solutions are emerging for as yet unmet needs.

For this reason the biopharmaceutical sectoral innovation system was chosen as one of the pilot sectors of the OECD Case Studies in Innovation.[1] Building on previous work on national innovation systems (NIS), the OECD Case Studies in Innovation are aimed at improving the understanding of the idiosyncratic properties of particular areas of technology and sectoral innovation systems, so that a consistent and transparent policy mix can be designed that combines generic innovation policies with customised policies adapted to the characteristics of a specific area of technology or of a sectoral innovation system.

Aims of the case study

The general aim of the case study on pharmaceutical biotechnology was to provide a systematic comparison of biopharmaceutical innovation systems in a number of OECD countries. In particular, the characteristics of the national biopharmaceutical innovation systems that relate to the structure and dynamics of the systems, the role of demand factors and markets, and the openness of the systems were investigated, including an assessment of the performance in science as well as in innovation and industrial development and an assessment of the influence of incentives and other framework conditions shaped by government policies. In addition, systemic imperfections hampering the functioning of innovation systems were identified.

Based on this analysis, the study aimed at developing recommendations that enhance the effectiveness of policies to foster the economic competitiveness of national biopharmaceutical innovation systems. On the basis of a cross-country analysis and an identification of systemic imperfections which vary across countries, policy conclusions were drawn as to how to achieve a balance between horizontal innovation policies

1. The other two pilot sectors are energy technology and knowledge-intensive service activities (KISA).

applying across industries and fields of technology and measures that take into account the sectoral or technological characteristics of biopharmaceutical innovation systems.

A case study approach, combining quantitative and qualitative methods

Advancing the understanding of innovation systems requires a methodology which makes it possible to study these systems in depth as well as to make comparisons across innovation systems. The explorative and comparative nature of the study renders a case study approach most appropriate. A case study requires the description of the working, structure and dynamics of a sectoral innovation system in developing, producing and delivering products and services to satisfy demands of users and consumers, and of the way a sectoral system changes over time. However, a methodology which makes it possible to systematically compare innovation systems also requires quantitative information. In order to facilitate comparability across countries, a common methodology was developed for the national case studies combining both qualitative and quantitative methods. National reports – following a common structure – were prepared for Belgium, Finland, France, Germany, the Netherlands, Norway, Japan and Spain.

National performance in science and in innovation and industrial development

The analysis of the eight countries shows that in terms of overall performance in science as measured by a set of five indicators related to publications and citations, Belgium, Finland, the Netherlands – all smaller countries – take a leading position. Japan and Spain are ranked at the lower end of this scale, both with performance below the European average. For performance in innovation and industry development as measured by patent applications, the number of drugs in the pipeline, venture capital invested in biotechnology and the number of new biopharmaceutical firms (all per million population), Belgium and the Netherlands are among the leading countries. Spain, Japan and Norway, on the other hand, do not seem to perform very well.

Combining the rankings of each country for performance in "science" on the one hand and "innovation and industrial development" on the other reveals different clusters of countries. It turns out that Belgium scores highest in terms of "innovation and industrial development" and second in "science". Finland and the Netherlands are rather strong in "science" but have medium performance in "innovation and industrial development". Germany performs relatively well in "innovation and industrial development" but less so in "science". France and Norway do not excel in either "science" or "innovation and industrial development" but France still performs better in "innovation and industrial development" and Norway better in "science". Japan and Spain are performing poorly in both "science" and "innovation and industrial development".

Structure and dynamics of national biopharmaceurical innovation systems: openness

The openness of national biopharmaceutical innovation systems can be studied from different perspectives. International trade data seem to indicate that Finland, Japan and Norway tend to be more import-oriented while France, Germany and the Netherlands

tend to be more export-oriented. Activities of large multinational pharmaceutical companies help explain these patterns. It can be shown that the value added of pharmaceutical production was predominantly realised by foreign-owned firms in France, Norway and Spain, while domestic enterprises were more prominent in Finland and the Netherlands. However, very few of the small dedicated biotechnology firms were foreign-owned, reflecting the domestic origin of these firms as spin-offs from universities, public research organisations and other firms. The third and fourth indicators for openness focus on the international dimension of collaboration. The pharmaceutical industry is one of the most global industries in terms of alliances and collaborative activities. The surveys of dedicated biotechnology firms found that a majority of these firms that were involved in collaborative arrangements with other firms had foreign partners. The percentage of patent applications in biopharmaceuticals that involved international co-operation was high in Europe when compared to the United States and Japan. During the late 1990s there was a noticeable shift towards greater reliance on domestic knowledge sources. This could have been caused by the entry of many new dedicated biotechnology firms that were spun off from universities, firms, etc. Biotech firms that are active in the biopharmaceutical sector and which do not have alliances with large pharmaceutical firms tend to rely more heavily on domestic sources in their innovative activities, including universities and public research organisations.

Structure and dynamics of national biopharmaceutical innovation systems: demand-side factors

The analysis of the role of the demand side in national biopharmaceutical innovation systems, interpreting demand as "market pull" in a broad sense, shows that while market size may function as an attraction to industry, it is not necessarily conducive to innovation. This is because less innovative products may be sold in suitable volumes. In a more narrow sense corresponding to the "lead market" concept, a market may exert a pull effect if it is "demanding", *i.e.* if it requires sophisticated products. Such requirements may be articulated by customers themselves, or by their representatives, *i.e.* physicians, or they may be set by regulatory authorities. The necessity of cost containment measures, however, dictates a different strategy, leaving hardly any incentives to develop innovative products. Rather, incentives predominantly work towards the use of generic products. This may in turn have an adverse impact on industrial strategies. Another main finding is that the influence of "users" is extremely limited in all countries studied. This is perhaps not surprising given the complex nature of the products in question. In order to stimulate diversification and the diffusion of innovative products, decisions to reward product differentiation and products developed for specific niches may be warranted in the future.

Structural and dynamic characteristics and the performance of the systems

There is no single "optimal" configuration of the national innovation system leading to superior performance measured by indicators based on either science or innovation and industrial development. For this reason, the structural and dynamic characteristics of the biopharmaceutical innovation system of countries with similar performance in science as well as in innovation and industrial development may vary widely. Some features, however, appear to be conducive to performance in innovation and industrial development in a rather robust manner. With respect to framework conditions,

institutional set-up and policy, such factors appear to be, for example, the maturity of the national private equity markets, the existence of policies and instruments for the commercialisation of technology and the biotechnology-specific character of these commercialisation policies. Policies creating and sustaining an advanced knowledge base tend also to be crucial for commercialisation, but the reverse is not true. Countries adopting a comprehensive policy approach using a broad set of policies to promote biotechnology that address all functions of the innovation system tend to perform better than countries with patchy and fragmented policies.

Systemic imperfections

Systemic failures can raise barriers or lead to severe disadvantages in the innovation process. Systemic imperfections include the absence or inappropriate functioning of actors in the production, diffusion and application of new knowledge, the absence of linkages and interactions between parts of the system, etc. The national case studies have identified a large number and variety of systemic imperfections in all parts of the innovation system, but most are related to the exploitation and commercialisation of knowledge and to framework conditions. Examples are the lack of biotechnology expertise in technology transfer offices, inappropriate models for attributing the ownership of and returns from intellectual property between the researcher and the research organisation, insufficient valorisation and exploitation policies of public research organisations, inadequate public-private linkages, the shortage of risk capital, the availability of specific expertise in human resources. Most of the systemic imperfections do not seem to be caused by a single category (actors, functions, institutions and interaction) but rather are rooted in a combination of factors.

Policy recommendations

The role of governments in innovation policy making has changed considerably over the last decades. Based on the linear model of innovation, first generation innovation policies in the post-war period were focused on funding R&D, especially basic – *i.e.* generally applicable – research as its major policy instrument. This funding – "at a certain distance from the market" – was designed to compensate for market failures leading companies to underinvest in R&D. Since the mid-1990s the complexity of the innovation system requires governments to address "systemic failures". Recognition was given to the diffusion of innovation, the interactive character of the innovation process (with many feedback loops between the different stages of the process) and the regional and/or sectoral specificity of innovation processes. Policies are designed to address systemic failures which block the functioning of the innovation process. These failures provide a rationale for government involvement not only through the funding of basic research, but also – and here the second generation of innovation policies comes in – more widely in ensuring that the innovation system performs well as an entity.

A new role of government involvement in the coming years is to recognise the importance of innovation in the innovation policy governance system itself. The focus of first and second generation policies was on the research and education system, the business system, framework conditions, infrastructure and intermediaries. The focus of third generation policies will be on government itself. An important function is to close the "co-ordination gap" within the government between the separate departments that

each deal with specific aspects of the innovation chain, but also between national, international and regional governments.

Given the systemic failures that have been identified in the national biopharmaceutical innovation systems in the national case studies and the need for an integrated innovation policy approach that includes first, second and third generation policies, recommendations have been formulated that address:

- ***Coherent and consistent innovation policies*:** combine objectives such as improving international competitiveness through innovation policies towards pharmaceutical biotechnology on the one hand, and a high-quality and affordable public health care system on the other hand.
- ***Public governance*:** facilitate a more active role of patients and/or their organisations in innovation processes, clinical trials and market access; potentially important sources of innovation remain untapped.
- ***Promote co-operation and networking*:** create network linkages throughout the biopharmaceutical innovation system, especially between actors in science and the business system.
- ***Support for an innovative industry*:** develop instruments that provide incentives for private financers to invest in biopharmaceutical firms.
- ***Regulatory framework*:** develop transparent and stable regulations with short application procedures and good information on procedures and the development of an adequate system for protecting biopharmaceutical innovations.
- ***Technology transfer*:** stimulate the exploitation of public sector biopharmaceutical research, include IPR indicators in review and evaluation procedures, establish qualified supportive infrastructure for start-ups (legal, business, marketing expertise, incubator and technical facilities).
- ***Stimulate sound science systems*:** the persistence of market imperfections associated with basic research requires a role for government research policies and research funding.