



Business and Industry Advisory Committee to the **OECD**

Comité Consultatif Economique et Industriel Auprès de l' **OCDE**

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BIAC suggestions for future priorities of the OECD Working Group on Human Health-Related Biotechnology

Thank you for the opportunity to submit comments on the future work program of the OECD Working Group on Human Health-Related Biotechnology (WG HHRB). We strongly recommend that particular projects be put within the overall framework of innovation and economic growth and development, which is a common platform of OECD and BIAC. In addition, the approach should focus on the new terms of reference for science and technology and networks for innovation. These include identification of new agents of innovation with different distinctions drawn with respect to what is the “private” and what is the “public” domain.

The framework of work should rest on a set of enabling conditions for innovation that could be elaborated further by BIAC members in various policy groups. These could include the following:

- Access to medical innovation (including dissemination of innovation);
- Strong intellectual property protection including good enforcement;
- Competition on the supply side and choice on the demand side;
- Efficient regulatory approaches that acknowledge new configuration of public and private agents and new collaborations in science and technology networks;
- Open trade and investment;
- Investment in basic research and education;
- Ethics and the rule of law.

Some examples of work projects are discussed below.

How new technologies are changing the cycle of innovation and how to improve the policies and regulations impacting the key factors of success in the health sector?

It is important to have a good understanding of the cycle of innovation and the related success factors for the application of biotechnology and other technologies to health. Governments should assess the factors stimulating innovation in the health care sector, which will enable them to improve their regulatory approaches with respect to innovative companies, to increase the efficiency of incentives and to avoid harmful or irrelevant regulation or legislation.

The policies supporting such developments are specific to each country, and the knowledge of their impacts should be explored. The OECD would be ideally suited to carry out such a study, which could address the following questions:

- 1/ What are the characteristics of the life cycle of the various kinds of innovative biotechnological health products and how do they evolve?
- 2/ What are the key success factors of innovations at each stage of their life cycle?
- 3/ What are the impacts of the various success factors?
- 4/ How do policies and regulations influence the key success factors?
- 5/ What are the impacts of the various national arrangements of incentives and disincentives on innovation?

6/ How could policies and regulations in the health sector be improved with enhanced knowledge of leveraging effects of key success factors?

New and emerging sectors in biotechnology and the trend of convergence between technologies

New domains of research appear in the biotechnology sector, for example, genomic, nano-technologies, genetic testing, stem cell research, (including tissue/cell engineering and cloning). Each field of research is quite specific and creates a sector that can be defined by its activity, its products and its market. The stakes, the organization of the sectors, the key factors of success and the opportunities are not the same among the sectors.

At the same time, we can notice a growing convergence between biotechnologies and other technologies leading to the creation of new domains of research combining biotechnology, telecommunications, medical devices and services.

Knowledge of new emerging sectors in biotechnology and awareness of the trend of convergence will assist governments to develop policies that may support growth in these sectors.

Questions to be addressed:

- 1/ What are the main emerging research fields and emerging sectors in biotechnology and in converging sectors?
- 2/ How are they structured?
- 3/ What are their main stakes?
- 4/ What are their specific characteristics?
- 5/ How do governments address their needs?
- 6/ How might their policies and regulatory aspects be improved?

The ways to articulate the demand for biotechnological products

The health related industry is heavily regulated. At the same time, it has a specific market in terms of demand that is expressed by various means and various actors; its impacts need to be explored. Classical market functioning does not apply to the market of the health-related innovative industry. The supply side has often been studied and analyzed, but the expression of the demand can be largely improved. By developing tools to better understand the demand side, one can expect to improve the functioning of the health system.

Issues and questions to be addressed:

- 1/ Who are the stakeholders that articulate the demand for innovative products and what is their rationale?
- 2/ How the stakeholders articulate their demands?
- 3/ The introduction of the innovative products;
- 4/ What are the leverages for improving the meaning and the relevance of the demand?
- 5/ How can diseases lacking a viable commercial market, such as rare diseases and diseases in developing countries best be addressed?

Interactions between the biotechnology sector and the health system

The biotechnology sector is of a somewhat paradoxical nature. On the one hand, researchers and producers try hard to raise funds to find, develop and sell new products. On the other hand, most of the buyers claim that they struggle with cost pressure and management of expenses. However, investors still step up their funding of biotechnology-related research. This kind of situation is typical for industrial sectors confronted with revolutionary technologies.

Without innovation by industry, there will be no new molecule. Without new molecules, there will be no new drugs. New drugs are needed to fight diseases, plagues and address the challenge of ageing populations. This will undoubtedly be expensive. That is the major dilemma for the health

authorities. The OECD would be well placed to analyze this situation and describe the interaction between the three partners of the “health biotechnological system”: health authorities as regulators and buyers of the biotechnological products; investors as funders of biotechnology companies; companies as researchers, developers and producers of biotechnology products.

The following questions should be addressed to get a better idea of the “health biotechnological system” and the relationships among its components.

- 1/ What can governments do to stimulate innovation and address market failure without disrupting the market?
- 2/ How can governments enhance support for innovation in the field of biotechnology and address market failure without disrupting the market?
- 3/ What is the attitude of the various governments toward biotechnology companies?
- 4/ What is the perspective of biotechnology companies toward innovation science and cost containment?
- 5/ What is the rationale of investors in innovation by biotechnology companies?
- 6/ What are the interactions among the stakeholders of the “health biotechnological system”?
- 7/ How can the interactions among stakeholders of the “health biotechnological system” be made more efficient?

Ensuring sustainable development of information technologies and innovative services

In the past decade we witnessed a period of vital innovation in the health services as a result of the combination of process reengineering techniques, rise of new needs, and development of the Internet. The provision of innovative services to patients has been based upon the creation of a network of social and health workers, who have used the IT development wave. The role of IT in the improvement of the quality of service has been vital. The stock market directly and indirectly fueled this wave.

Yet these developments have not met the success expected by their promoters. One effective exercise might be to analyze how to organize the health system coupled with appropriate aspects of the economic environment to achieve sustainable development of both new technologies and the innovative services they offer.

Specific issues to be addressed could include:

- 1/ Description of the IT wave and the new services generated
- 2/ Results that have been achieved
- 3/ Lessons learned and costs associated with those lessons
- 4/ Main challenges including funding constraints
- 5/ Suggested improvements

Research and development programs: how to improve their performance?

Global programs on health related research and development have played a crucial role in the development of new drugs, procedures or technologies. These programs will play an ever-increasing role due to the continual emergence of new challenges. Examples of such emerging challenges include: SARS, AIDS, genetic research, etc. It is important to look at how to improve program performance and efficiency, and how to increase the quality of results. A comparative study of the way a selection of these programs are designed and managed would be useful to achieve improvements and make specific recommendations for future health related research and development programs.

Preliminary research could address the following questions:

- What are the main reasons for organizing global research and development programs in health related technologies?
- What are the international dimensions of these programs?

- What is the current typology of research and development programs in health related technologies?

Including a focus on:

- 1/ Definition of the programs
- 2/ Stakeholders
- 3/ Funding of the programs
- 4/ Organization of the programs
- 5/ Outcomes of the programs

The role of the health related industry in OECD economies

The companies in the health sectors are diverse. Some are public, others are privately owned. They produce mainly medical devices, hospital equipment, pharmaceutical drugs, biotechnological products, and information technology devices. These companies are essential for innovation and improvement of the health systems. At the same time, the biotechnological and pharmaceutical products are often associated with the increase of health expenditure.

Enhanced dialogue between Governments and the health-related industry, especially its innovative component, will improve industry's potential both with regard to health and the economy as well as the government's understanding of the various roles of such enterprises. A study of the health sector should focus on the possible evolution of the sector, the opportunities it offers and the challenges it faces. This approach is aimed to give a firmer background to the regulatory and economic policies concerning this sector.

In addition, we would like to offer the following specific examples of work projects, which are directly related to the "enabling conditions for health-related innovation":

- Measuring dissemination of medical technologies in OECD countries: market demand side and, on the supply side, measuring generation of new health related technologies and their contribution in total innovative effort in the OECD countries.
- Work on the importance of IPR to economies at different levels of development and different human resources and capital
- Looking at the conditions of industrial competitiveness including licensing agreements.
- Looking at the conditions on the demand side such as relative pricing freedoms, access to markets, etc.
- Harmonization of quality controls and their harmonization such as in the current project on the quality of genetic testing.
- Project on privacy concerns in sharing genomic databases. Potential projects on eliminating barriers in insurance to patients receiving care in different countries and/or doctors and hospitals offering services in different countries (export/import of medical services)

We hope that the above-mentioned recommendations are helpful and stand ready to give you any further details you might require. Thank you again for the opportunity to submit these comments.