

CAPÍTULO 47

STUDY OF THE NATIONAL POLICIES AND PROGRAMMES THAT SUPPORT THE INNOVATION SYSTEM IN BIOPHARMACEUTICAL SECTOR

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GOAL

The concept of National Innovation Systems has been gaining support as an explanatory variable of the size, role and performance of innovation within the economy of each country or region. This concept counts on the interplay between a series of actors whose actions and interactions are influenced by a set of factors: The financial subsystem, the business subsystem, the legal frame, the regulations, the skills of human resources, their mobility, the social relations and the negotiations practices.

The idea of National Innovation Systems relies in a view based on the complexity of the socio-economic activities.

The main goal of this study will be to determine if Spain do really possess the adequate national policies and programmes to support the Innovation System in Biopharmaceutical Sector and the identification of the critical factors that can contribute to improve the overall efficiency of the system.

INTRODUCTION

It can be said that the dynamics of technology production and its uses is one of the critical aspects in determining the strategic position of the countries as well as the competitiveness of their businesses. At the core of this problem, it is the capacity to produce technological innovations. At this respect, businesses and governments from industrialized countries recognize as a fundamental element of

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the policy and the strategy of a country, to be able to develop the conditions strengthening that capacity to innovate. In view of the inability of the public sector to generate from itself working in isolation, enough innovation and even to finance it, the need for the intervention of other actors: agents and institutions from private origin is deemed essential. These private actors may cover the deficit and help to sustain the process.

In this multointervention of actors relies the concept of National Innovation System (NIS). When we are talking of NIS we are not referring to any specific institution nor to particular activities but to a way to articulate diverse institutions and activities. We talk of system because there are an ensemble of elements or partners (the different agents and institutions that participate in the same) which are internally differentiated but whose joint intervention in harmonic and integrated way represents the “raison d’être” of a NIS. From this, it follows that the general goal of a NIS will be the establishment of a broad frame which improve the concerted action of all the elements (their connection and fluidity) and help to structure, drive and foster the science, technology and innovation activities with the aim to contribute the increase of the cultural, social and economic patrimony of the country.

NIS is composed by several agents and institutions, each one of them playing and which show differences at various levels: public-private; profit-non profit; political-corporate.

The effectiveness of a NIS demands the existence of three key factors in a national context: a culture of coordination, an interactive learning and entrepreneurial culture. The relevance and impact of a NIS will depends on two factors, from the characteristics of its economic actors (demand side) and from the own capacity of the system to generate innovations (supply side).

A NIS to be well established asks for a very significant number of informal relationships. This type of relationships is vital for building the real bases of consensus which may lead to a normative and legal frame. The dynamics of this process must be driven by the same outcomes of the innovation and so the normative and legal frame should be in agreement with this dynamics.

Any system is composed of different subsystems possessing similar characteristics that the whole system. Within an industrial system it is likely to find sector subsystems that are organized and whose functioning with similar characteristics.

The analysis of the Biopharmaceutical Innovation System can be approached by establishing and defining four subsystems:

1. Business Subsystems:

It is composed by the set of biopharmaceutical companies (PC) that are using the biotechnology as a tool for their products or in their processes as well as by the whole of small companies based on biotechnology (NBF).

2. Research Subsystem:

It comprises the ensemble of the public and semi-public institutions devoted to the scientific research and the technological development. The excellence

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is a quality of critical relevance for the intervention of the research centres in the system.

3. Financing Subsystem:

It is composed by the set of actors and institutions which support by financial instruments this type of projects and activities: capital firms, business angels, public institutions which promote financing.

4. Governmental Subsystem:

It is composed by the Government and its agencies, responsible for maintaining the cohesion of the whole system through the normative and legal frame. It also supports basic and essential funding to any of the other three subsystems.

However, a series of actors can be identify which to a greater or minor extent, are users of the health system and are indirectly involved in their processes of innovation. Among them: the patients association, medical or professional societies, foundations/non-profit organizations, etc.

POLICIES FOR R+D+I+T

As we said before, the main objectives of this work will be to determine if Spain do really possess the adequate national policies and programmes to support the Innovation System in Biopharmaceutical Sector and the identification of the critical factors that can contribute to improve the overall efficiency of the system.

The main public actors involved in the Spanish R&D&I&T is the MCYT¹ and the MSYC².

Special mention deserve some public institutions deeply involved in the development of the scientific research and technological development of this country. Among these institutions it should be emphasized at first glance the Consejo Superior de Investigaciones Científicas, CSIC, belonging to the Ministry of Science and Technology. It can be considered as the main representative of the public organisms of research in Spain and a basic element of the public research system as CSIC fosters many linkages with Administrations (state, regional and local), with other research institutions from public and private dependencies (universities, research centres, businesses) to collaborate in joint projects. Several of CSIC institutes and centres, in addition to perform research activities in “stricta sense”, devote part of the time of the researches and of their budget to promote the dissemination of Science through Conferences, Seminars, Workshops and to communicate basic knowledge to the society.

1. Ministry of Science and Technology.

2. Ministry of Health and Consumption.

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The scientific activity of CSIC develops within the frame established by the National Plan of R+D+I (plus technology), the distinct R & D Plans of the Autonomous Regions, and the Framework Programme of the EU³.

An Office for Technology Transfer (OTT) aims to make the bridge between the knowledge produced in CSIC centres⁴ and institutes and the eventual technological assets to all socio-economic sectors both at national and international levels. Its main goal is the transformation of the capacities and skills of CSIC human resources into economic, social and cultural wealth.

The Institute of Health Carlos III⁵ (ISCIII), with the statute of autonomous public organism belonging to the Ministry of Health and Consumption is another important organism that plays an important role in this process. This organism hold the mission to develop and offer scientific and technical services of the best quality to the National Health System (SNS of its name in Spanish, Sistema Nacional de Salud) and to the society in general.

Other public organisms of particular interest to this report are :

CIEMAT⁶- Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas –.

3. That activity is programmed and channelled by the researchers grouped in the following scientific and technical areas:

- a. Humanities and Social Sciences.
- b. Biology and Biomedicine.
- c. Natural Resources.
- d. Agronomical Sciences.
- e. Physical science and technologies.
- f. Materials science and technology.
- g. Food science and technology.
- h. Chemical science and technologies

4. In specific terms, the OTT-CSIC addresses the following objectives:

1. To spread and promote the living image of CSIC as well as its capacities among the socio-economic environments.
2. To easy and promote the relationships between its personnel and the actors from the production "milien".
3. To faster the creation of technology based firms

5. Among its functions it must be emphasized:

- The applied research of the National System of Health.
- The basic research on health problems.
- The advice and collaboration to the organisms acting in the field of innovation and technological development.
- The specialized training for the personnel involved in the health services and management of the health system.
- The promotion and coordination of the biomedical research activities.

6. CIEMAT is an autonomous public organism ascribed to the Ministry of Science and Technology, whose objectives are the promotion and development of basic and applied research activities as well as actions of technological development with particular emphasis on the areas of energy and environment.

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- IMIM⁷ - Instituto Municipal de Investigaciones Médicas –
 CNIO⁸ - Centro Nacional de Investigaciones Oncológicas –
 INIA⁹ - Instituto Nacional de Investigación y Tecnología Agraria y
 Alimentaria –
 IRTA¹⁰ - Instituto de Investigación y Tecnología Agroalimentaria –

MAIN POLICIES AND PROGRAMMES IN RELATION TO BIOTECHNOLOGY

Science and technology policies are becoming critical elements for the development in modern societies, as it has now been clearly stated that there is a direct relationship between the innovation capacity of a country and its competitive. Those policies are also horizontal policies that may influence many sector policies (education, health, environment), this contributing to the improvement of the wealth and the quality of life of the citizen, the essential goal of all public policies.

Under the context of European integration represented by the Economic and Monetary Union and the current setting of sustainable growth of the Spanish economy, Spain should keep the strategy of increasing the investment in R+D+I activities. Moreover, Spain must spare no effort in attempts to converge to improve its position in the European landscape of science and technology. For attaining this aim it is necessary to look for synergism with the activities of the European Framework Programme and the initiatives associated to the Structural Funds of the European Union.

7. IMIM is a public organism, located in Barcelona and associated to the local administration (it is managed through the local institution of health services – IMAS). The mission of this organism is the management, promotion, coordination and putting with force off the scientific research activities in biomedicine and health sciences, complemented with training actions and programmes for the human resources involved in these areas.

8. CNIO one of the new incorporations to the public health system and the most brilliant piece of the ISCIII. It is a public organism, organized as non-profit institution with the statute of Foundation but strongly linked to the direction of the ISCIII and the Ministry of Health its main sponsors. The funding of the activities takes place through the Agreement of the Industry for Stability and Innovation dealt in depth before. The mission of CNIO is to foster the research on oncology by means of the promotion, support and improvement of the scientific and medical advances in the field of cancer research.

9. INIA is public organism ascribed to the Ministry of Science and Technology whose mission is the management and implementation of all governmental competences related to scientific research and technological innovation in the areas of agriculture and food, the fostering of the cooperation both at national and international levels on those areas as well as the elaboration, coordination and management of the strategic actions on the agro food domain included in the National Plan of R+D+I+T.

10. IRTA is a public organism under the dependence of a regional government, Cataluña in this case. Its mission is to promote research and technological development in the agrofood sector, to assess the scientific progress and facilitate its application, as well as to coordinate the efforts made by public and private sectors in the most efficient way.

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The Law 13/1986, (Ley de Fomento y Coordinación General de la Investigación Científica y Técnica) established the National Plan for Scientific Research and Technological Development as the instrument to accomplish the task, corresponding to the State, of the promotion and general coordination of the scientific and technical research and created the Interministerial Commission for Science and Technology (CICYT, from its name in Spanish, Comisión Interministerial de Ciencia y Tecnología) as the organ for the planning, coordination and monitoring of the National Plan.

The efforts made from the approval of the First National Plan in 1988 to the present time has led to strengthen the Spanish System of Science-Technology-Business by increasing the capacity of the public component of the system and its opening to the productive sectors.

The main areas of interest in the National Plan for R+D+I for the present work are:

- 1.- Area of Biomedicine
- 2.- Biotechnology Area
- 3.- Sociosanitary Area

The instruments to put into force the attainment of objectives are a series of national programmes like the National Programme for Biotechnology and the National Programme on Health.

There are evident difficulties in Spain to distinguish between policies and special plans and strategies to foster the commercialisation of biopharmaceutical products and to promote knowledge. The border between both types of strategies are diffuse. By this reason, it is possible to find policies and programmes covering both aims.

Policies for the promotion of knowledge production

As mentioned before, there are specific National Programmes for Biotechnology and Health. These programmes aim, among other objectives, to promote knowledge.

The National Programme for Biotechnology (N.P.B.) addresses the four following subsectors:

1. Agrofood¹¹
2. Human and Animal Health¹²

11. The N.P.B. proposes the use of technologies supported by molecular and cellular biology advances. The targets are the agronomical and forest species with socioeconomic interest for Spain as well as the agrofood projects holding the greater relevance for the firms operating in Spain.

12. Priority is given to the projects addressed to solve the problems related to pathological problems for human and animals which hold the greater socio economic relevance. The N.P.B. focuses on technologies and instruments like vaccination, diagnostics, design of experimental models as well as the identification and characterization of genes of potential interest for the pharmaceutical industry, paying particular attention to the use of molecular and cellular biology based techniques.

3. Engineering of Biotechnological Processes¹³4. Environment¹⁴

The National Programme on Health (N.P.H.) addresses the following main objectives:

1. The development and application of new technologies in biomedicine
2. Cancer research
3. Research on infectious diseases
4. Research on neurosciences
5. Research on cardiovascular diseases
6. Research on chronic ailments
7. Pharmaceutical research

In this sector of activity, the collaboration between the industry and the public has been stepping up. In 2001, the pharmaceutical industry signed with the Ministry of Health an Agreement for the Collaboration for the Promotion and Development of Scientific and Technical Research in the Sanitary Field. The agreement represented the endowment of 33.06 millions of euro to foster and develop plans, programmes and activities of scientific research through the Institute of Health Carlos III (ISCIII).

The most significant event, as mentioned earlier, of this collaboration between industry (through the Employers Association, *Farmaindustria*) and the Ministry of Health, was the signature in 2001, the 31st of October, of an Agreement for the Elaboration and Performance of an Integral Plan on Control Measures of Pharmaceutical Spending and Rational Use of Drugs for the period 2002-2004. This Agreement shapes a pact for the stability and the innovation to benefit the citizens. The pact states the compromise of the pharmaceutical industry to increase the investments in R+D+I by a percentage higher than the GAP growth. The endowment agreed for the period reached a value of 1,352 millions of euro; which should be supplemented with 300 millions of euro to fund projects performed by the public institutions on subjects of sanitary research on topics of general interest.

The ISCIII promotes biomedical research through grants in aid. The grants fund two types of projects.

- a. Extramural Projects: support projects of biomedical research and health technologies under the frame of the National System of Health (SNS, from its name in Spanish, *Sistema Nacional de Salud*). The agency in charge of this programme is the "Fondo de Investigaciones Sanitarias", FIS (Fund for Health Research).

13. Particular attention will be devoted to the study of the processes on which there are foreseen entrepreneurial possibilities in Spain for any of the sectors: chemical, pharmaceutical, food, etc. The development of new experimental or therapeutic tools emerges as a critical element for the success of this topic as it will be driving, to great extent, the capacity to compete of the different sectors with biotechnological applications.

14. The aim is to use biotechnological instruments to solve environmental problems of specific relevance for Spain with particular emphasis in the processes of bioremediation and utilization of wastes of chemical and biological origin.

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- b. **Intramural Projects:** support research projects carried out by personnel from centres, institutes and units of the ISCIII. The management of this programme is carried out from the General Secretary of ISCIII, by the area responsible for search.

Concerning the regional realm, some Autonomous Regions have launched programmes to promote biotechnology, such as for example, the Basque Country with its programme “Biobask-10”, the Region of Valencia with its programme “Biosoluciones” or the Madrid and Cataluña Regions which have declared the biotechnology as a strategic priority for its Research and Innovation Plans.

In spite of these initiatives, it can be said that the regional support to life sciences and technologies remains insufficient and suffers from lack of strategy and coordination. This situation hampers the development of biotechnology, leading to the loss of opportunities for cluster generation, for the development of scientific parks and bioincubators.

Policies for commercialisation support

The most General Measures known programme of public support to the pharmaceutical research is the “Plan Profarma”, a programme to promote R & D activities in this sector.

In 1986, the Spanish Government launched the Plan de Fomento de Investigación en la Industria Farmacéutica (“Promotion Plan for Research in the Pharmaceutical Industry” called PLAN PROFARMA) to be held for a five years period with the following objectives:

1. To promote the R & D by the national industry to faster the development of new products to open new markets and to empower the development of technology.
2. To promote the collaboration between firms with the aim of introducing rationality in R & D activities, to facilitate the technological exchange and to make the best use of the existing infrastructure.
3. To promote the unification of the small R & D centres.
4. To promote the training of personnel in specialized techniques.
5. To increase the level of requirements for the selection of projects according to the research proposed.
6. To increase the level of requirements of projects in order to be able to differentiate the real therapeutic innovations from those products with low value.
7. To fix a higher level of requirements for clinical trials in such a way that the inadequate use of the human and technical potential could be avoid.

This Promotion Plan was positively assessed and decided to be prolonged in several editions along the subsequent years.

The evolution of the firms and their characteristics involved in the Promotion Plan is recorded in the Table 1.

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Funding of further steps in the innovation pipeline rests on the responsibilities of CDTI (Centro para el Desarrollo Tecnológico Industrial). This line of public funding to the firms consists in the allocation of credits with zero rate of interest and with a large period for pay-off. The credits assume till the 60% of the project costs. CDTI only supports projects assessed as technically and economically viable, but does not demand general guarantees to the firms proposing the project. The funds allowing the funding activity of CDTI proceed from the own resources of the organism and from the European Fund for Regional Development (FEDER). These credits include a clause related to technical risk according to which in the case a project does risk the technical objectives, the firms are exempted of redemption of the credit (See Table 2).

Orphan drugs and their incentives

The production and commercialisation of the no-called “orphan drugs¹⁵” (drugs without a commercial interest) have the benefit of incentives and subventions all levels. Europe and Spain have joined the United States in this direction. The Spanish Law (Ley del Medicamento) defines them as “those (drugs) which being necessary for a certain set of treatments related to symptoms or pathologies with low incidence, show absence or deficit in their supply to the national market”. On its side, the EU considers “orphan” that drug aimed to prevent, diagnose or treat of rare diseases which should have serious difficulties for its commercialisation by the lack of sales perspective once being present in the market.

For it, the European Union approved the Regulation (EC) 141/2000 stating that, once the Committee for Orphan Drugs of the EU grants the qualification of orphan to a drug “the promoter owner of that drug will enjoy incentives and subventions that will be made effective when the application for its authorization, previous to the commercialisation step “is made”. There are two main types of incentives:

15. Rare diseases are defined, on a quantitative basis, as those which affect to less than 5 persons in 10,000 of the EU. In addition to matching this epidemiological criterion, this type of diseases must represent a disorder able to put into risk the life of the patient or to generate a chronic or severe handicap. The rare diseases are usually associated to a specific genetic defect (according to the WHO, there are 5,000 rare diseases known currently, 80% of which are based on genetic causes). This is the reason why biotechnology applications have become so important to treat them. Most of the drugs are proteins whose best method of production relies on the DNA recombinant techniques. Most of the traditional pharmaceutical laboratories confront difficulties for producing these molecules: they are separated from their pipeline of production, they are specifically failure and this can not serve as blockbuster. This is the reason for the need of businesses oriented in a specific manner to the biotechnological techniques and applications. Biotechnology-based Companies have emerged as the principal actors for the production of this type of drugs, whose development costs amount to one quarter of those of a conventional drug and whose commercialisation costs correspond to one seventh of the traditional ones. But their research and developed have needed a supplement through a series of incentives to attract the interest of the companies.

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1. Technical incentives¹⁶
2. Economic incentives¹⁷

Exist, as well, a special programme of the Spanish Institute for foreign Commerce (ICEX) entitled “Promotion of culture to export”¹⁸ aiming at to bring SMES about the export culture: its understanding, practice and promotion.

16. Technical Incentives:

- a) Automatic incorporation into the part B of the Annex to Regulation (EC) 2309/93. the promoter of an “orphan drug” can resort to the application of authorization according to the centralized procedure without the need to demonstrate that the drug combines the conditions to be included in such list.
- b) Assistance to protocol elaboration. The promoter of an “orphan drug” holds the right to ask the Agency (EMA) the report on the different assays and trials which ought to be presented to prove the quality, efficacy and safety of the drug.

17. Economic Incentives:

- a) Total or partial exemption of fixed prices rate. The Regulation on “orphan drugs” foresees the compensation to the Agency by the application of the fixed prices rate reduction (Art. 17, Reg. EC 141/2000). On the other hand, the Spanish Law on Drugs states “that are exempted of the fixed prices rate all the services giving of help or activities performed in relation to the production of “drugs without commercial interest”.
- b) Commercial exclusiveness according to it, a commercial exclusiveness is established for 10 years, during them the EU and the Member States shall not be able to accept, afford any authorization or lend attention to a new application asking for an extension of authorization for a drug with similar therapeutic uses. Nevertheless, there are some situations which could lead to a reduction or revocation of the exclusiveness period.
 1. Whether there are evidences after the fifth year that the drug is no more complying with the criteria used for its qualifications as “orphan drug”.
 2. Whether the holder of the authorization were unable to afford sufficient amount of product or whether there is a second solicitor able to prove that his/her product is more effective and/or has clinically higher uses than the former.
- c) Other incentives. The Regulation from EC (Art 9, Reg. 141/2000) establishes the need for the regulation of incentives aiming to promote research, development and availability of “orphan drugs”, pointing out that measures and instruments for help to the small and Medium Enterprises should be included in the Framework Programmes for research and technological development.

18. The programme, settled at national level, has resulted from an agreement of ICEX with the Higher Council of Commerce Chambers, the Autonomous Regions and the Commerce Chambers themselves to foster the foreign promotion and commercialisation of SMES. The Plan is a general one, not specifically addressed to biotechnology-based firms or biopharmaceutical companies, but to any business which can be labelled as SME and have its own product service, possessing a strong commitment to internationalise itself and willing to explore its commercial possibilities in foreign markets. The programme named as “Plan de Iniciación a la Promoción Exterior” (PIPE 2000) (Plan to Initiate Foreign Promotion) has as its main goal to get 3,000 new exporting companies for the period 2001-2006. The programme is qualitative in essence and integral providing to the companies individual and specific advice (by means of tutors, promoters and collaborators from PIPE 2000) as well as the economic support (during the two years the programme would benefit the firms, they will be supported by 80% of the expenses carried on by the firms).

Mixed programmes

1. The projects called Projects for Concerted Industrial Research¹⁹ developed and funded by CDTI have as main objective the funding of initiatives from precompetitive research (those researches whose results are not directly driven to commercialisation and involve a great technical risk).
2. Initiative: Torres Quevedo Programme²⁰: Programme targeted to businesses that are developing or looking to start R+D+I programmes as well as those which are willing to strengthen their innovative capabilities.
3. Petri projects²¹: The main goal is to foster the transfer of technologies from public research organisms (OPIs) and universities to the productive sector.

19. This type of projects are proposed by industrial companies and carried out in collaboration with Universities, Public Research Centres and/or Centres for Innovation and Technology (CITs). The grants are distributed in two stretches:

a) A first stretch non subjected to pay-off. This part covers 70% of the contract of the firm with the research centres with a maximum which can not exceed the 20% of the total project budget able to get funded.

b) A second stretch submitted to pay-off requirement which consist of credits till the 60% of the total project had get able to get funded.

In these projects, the period of pay-off can be prolonged from an initial term of 6 years to a 8 years period, depending on the geographical zone where the project is being developed and the size of the soliciting firm.

The public administration, through the Ministry of Science and Technology promotes a set of industrial projects which are targeted to innovative firms and public research organisms looking for technology transfer.

20. The programme aims to the following main objectives:

- a) To increase and strengthen the innovative capacities and the innovation action in the private sector and in SMES with particular emphasis.
- b) To increase the competitiveness of the businesses and the technological centres.
- c) To improve the uses and applications of the R+D+I results in the private sector.
- d) To make easy the realization of R+D+I activities in companies not yet used to perform them.
- e) To increase their skilled human resources.

To comply with these objectives, the Ministry of Science and Technology supports the contracts for doctors and technologists, opening by this way new horizons to doctors and skilled professionals with previous experience on R & D tasks.

The conditions for getting these supports are published in official calls (the Spanish Official Bulletin, BOE from its name in Spanish, Boletín Oficial del Estado).

The call for year 2003 call has ended in 30 June, 2003.

This programme affords economic help to the firms until 70,000 euro to contract for doctors and over 50,000 euro to contract for technologists during a maximum period of three years. In the 2002 call, 532 applications were presented with a final solution of 341 contracts. From this figure, 261 were allocated to small and medium companies (77%); 51% technological centres (15%) and 29 to big businesses (8%). The split off between doctors and technologists was 197 and 144, respectively.

21. The projects have yet produced results at laboratory level but they need economic support for transferring the application of the results from laboratory to industrial scales. The solicitors can be physical persons or juridical entities (Public Research Organisms, Technological Centres, etc.).

This line of research support has been functioning since the decade of the nineties representing an average of 3 millions of euro per year for 50 projects, during the last five years (Sanz Menéndez, 2003).

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The goal is attained by the allocation of subventions to on-going projects or research lines, either basic or applied.

4. Profit projects programme²²: This programme constitutes an instrument designed and managed by the Ministry of Service and Technology. By means of public grants, the programme attempts to get the mobilization of businesses and other organizations for developing research and technological development activities.
5. Other actions²³: Neotec and “Proyectos Colaboración P4”

The Ministry of Science and Technology launched a programme, “Programa Nacional de Potenciación de Recursos Humanos, Programa Ramón y Cajal” (National Programme for Empowering the Human Resources) whose fundamental characteristic is to hire through labour contracts along the year 2003 and for a five years period. The strategy from MCYT is based on allocating funds to allow the contracts to be started though there is a requisite for the gradual and progressive co financing by the receiving institutions. Candidates to these grants are the public R & D centres and non-profit private institutions.

SYNTHESIS AND CONCLUSIONS

All the analysis, data and indicators support the contention that the efforts carried out in Spain along the last half of the twentieth century have led to the

22. The lines for promotion are integrated into the scientific and technological priority areas and the sector areas of the National Plan of Scientific Research, Development and Technological Innovation (2000-2003) whose management corresponds to the Ministry of Science and Technology and its organs of direction.

The objectives of the Profit programme are among others:

- a) To foster the application of knowledge and the embodiment of new ideas to the productive process.
- b) To favour the conditions which may increase the capacity of firms to absorb technologies, as well as to the strengthening of the sectors and markets with fast growth.
- c) To make easy the creation and development of technology based firms.

During the year 2001, 700 millions of euro were approved as part of subventions; around 20% of the projects developed under the format of cooperation, but 83% of the approved projects had some type of relationships with other actors (Sanz Menéndez, 2003) from the research world.

23. Other initiatives worth of noting are the “Proyectos de Colaboración P4” and the initiative “Neotec”, under the frame of the R+D+I Plan. The first one (Collaborative Projects) aims to the precompetitive development with projects led by a public research organism but with the involvement of a company that is willing to develop a product. A single call was the outcome with 221 projects and subventions approved for a total of 40 millions of euro.

The second one, the initiative Neotec, intends as objective to help the creation and consolidation of new technology-based enterprises. The programme lays out several instruments depending on the phase of life cycle of firms (first phase “idea”; second phase “firm creation”; third phase “risk capital”). An important issue to emphasize is the creation of “Neotec Network”, whose essential objective is the launching of a physical and virtual support structure for the emergence of technological entrepreneurial projects with a viable business plan. The network is made up with all agents involved in any type of service to the new technological entrepreneurs (universities, technological parks, incubators, etc.).

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building of a National System with satisfactory scientific outputs. However its outcomes in relation to the building of innovation capacity in the biopharmaceutical sector have been rather limited. The Governmental and Research Subsystems and the Business Subsystem have followed separate path.

The analysis of the Governmental Subsystem manifest that in our country exist several mismatches between elements and actors of the system that reduce the system's overall efficiency.

We can point out that:

1. The Governmental Subsystems do not function in a suitable way mainly because the small public investment in R&D, the little interaction between the public research subsystem and the business one, the lack of appropriate mechanism to protect that kind of innovations and the inadequate and insufficient innovation policy, basically;

We can concluded that flexibility and ability to adapt are critical assets in this emerging, highly dynamic area of research where the flows of knowledge, techniques and applications are running over the traditional slow pace of Academia – Research Institutions – Government – Business – Capital Markets.

2. We have recognized systemic failures that reduce the overall efficiency of the National Innovation System:

- The absence of mechanisms of proactive transfer between the public and private sector
- The lack of a clear, focused and determined bet by the Government to foster the innovation
- The small public investment in research
- The weak linkage between the University and Businesses
- The poor level in R & D culture
- The absence of promotion measures to foster the profile researcher-entrepreneur
- The absence of entrepreneurial tradition
- The absence of seed capital
- The absence of a venture capital market with sufficient degree of development
- The risk perception associated to those processes
- The lack of appropriate mechanisms to protect the innovations
- The absence of an industrial web
- The lack of R & D promotion from the industrial sector
- The public opinion

3. The critical implications of the governmental policies are the follows:

- Some of the governmental policies have been/are instruments for making easy the innovation processes but other have been hurdles to it. From this way, the fiscal regulation in relation to innovation clearly favors the dynamics of the firms to innovate. Another instrument that helped to promote the scientific research in Spain has been the design and launching of the R & D National Plan in 1986. However, the very exhaustive and demanding regulation for the authorization of a new biopharmaceutical

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products, its advertising, the public intervention in the prices (established and regulated by the MSYC), the problems in the legal protection by patents, etc. are poorly supporting this type of innovative processes.

- The governments must act as promoters of the system
- There is an evident need to increase the investment in the public system of research. The public organisms are playing a great role for the positive evolution of the system, though these centers are totally dependent on the governmental policies and the State General Budget
- There is a need to launch specific policies targeted to the small biotechnology-based companies in order to foster their development and diminish the hurdles to management
- Necessity of a greater dynamism and flexibility of the system
- There is need for a real prioritization of the R+D+I activities for the Government.

4. Finally, in order to complete this study, we must remark the following factors that could contribute to a greater and better R & D and innovation activities in biotechnology and, in consequence, improve the overall efficiency of the Spanish National Innovation System in Biopharmaceuticals:

- A greater participation of the biopharmaceutical industry in joint projects with the Public Research Organisms;
- Higher support from the Public Administrations by the increase in the financing resources aimed to fund the processes of innovation;
- The development of a venture capital market which help the high costs of research;
- A clear governmental support to the creation of new companies based on biotechnology. Development of an ad-hoc regulation driven to foster and help the development of this industrial web;
- The creation of appropriate necessary infrastructures for the expansion of this sector;
- The development of an adequate system for protecting the innovations;
- The fostering of a culture of collaboration between traditional pharmaceutical and new biotechnological companies which can achieve good complementary agreements to share risks and costs of the processes of innovation;
- The generation of an environment able to foster the innovation by means of a stable regulation frame which may allow to plan investments for a long term, what could favor a sustainable growth of the market and give rise to a general climate in supporting these processes.

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TABLE 1.
EVOLUTION OF THE ECONOMIC DATA OF THE PHARMACEUTICAL FIRMS INVOLVED IN THE DIFFERENT
EDITIONS OF THE PROMOTION PLAN¹

CONCEPT	1987 Starting Year	1990 Final Farmal	1993 Final FarmalII	1995 Final FarmaIII	1996 Profarma Action	1997	1998	1999
Nº of firms involved	35	52	58	62	45	52	52	53
Sales of Ethical specialities	684.25	1,476.64	2,658.50	3,045.67	3,385.45	3,760.77	3,631.32	4,162.68
Total Investments	70.56	129.82	176.24	219.87	154.29	229.03	198.59	246.81
R & D Expenses	66.47	161.03	227.00	232.46	251.33	291.49	297.63	364.68
-Running Inventory	58.55	136.68	204.89	218.19	235.76	271.96	279.00	344.55
- Investment	7.92	24.35	22.11	14.27	15.57	19.53(e)	18.63(e)	20.12(e)
% Running expenses/ Sales of EE.	8.6	9.3	7.7	7.2	7.0	7.2	7.7	8.3

(1) Economic data in million of euro at the price of sale from the laboratories.

(e) Estimates.

Source: Farmaindustria.

*Study of the national policies and programmes...*TABLE 2.
CDTI PROGRAMMES²⁴

	Interest Rate	Term	Credit covers % of project budget
Projects for Technological Development ²⁵	0%	5 years	50%
Projects for Technological Innovation ²⁶	0%	5 years	25%
Projects associated to international programmes ²⁷	0%	8 years	35-60%
Projects of Concerted Industrial Research	0%	6-8 years	60%
Line of bank financing CDTI – Institute for Official Credit (ICO) ²⁸	Euribor – 0.82%	5-7 years	70%

24. Source: CDTI

25. Projects of Technological Development are those of an applied nature which are put into force by companies, either alone or in collaboration with technological centres. They address the creation or improvement of a process, a product or a service.

26. Projects of Technological Innovation are those of applied nature which are put into force by companies, either alone or in collaboration with technological centres. They imply the incorporation and active modification of new emerging technologies to the firms.

27. CDTI supports and helps the internationalisation of the R+D+I activities of the Spanish companies through a series of instruments.

1. Projects of Technological Promotion.
2. External Network of CDTI Representatives and Agents.
3. Catalogue of Technologies for International Promotion

28. The bank financing line on Technological Innovation carried out by CDTI and ICO (Institute for Official Credit). This line allows the firms not only to opt for the types of CDTI support but to take the option of having access to this line of credit. It permits to get funding for entrepreneurial projects of technological nature at a privileged interest rate and long term. These credits assume till the 70% of the project cost with a maximum limit of 1.5 millions of euro per year. The decision on the allocation of the credits does not rely solely on CDTI but require the intervention of the financing entities which collaborate with ICO in this initiative.