



Access to Finance in The Biotechnology Sector AFIBIO Network

WP4 – Policy Recommendations

Synthesis report on Biotech National and EU Policies

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Synthesis report on National and EU Policies

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Main objectives of the this report

The report reviews biotech financing related policy documents at the member state and community level. The working paper has been prepared in order to provide an overview of the state of the art of health biotech funding related policy measures in Europe, and serves as such in the context of AFIBIO project as a basis for further development of policy recommendations. The report includes the overview of the policies identified by AFIBIO partners as most important documents in the domain. As such this report is not an exhaustive overview of all kinds of broad policies affecting biotech investment in Europe.

The approach

This review was prepared by the Institute of Baltic Studies (IBS) in the framework of the AFIBIO project based on various national policy documents on biotech funding identified by the members of the AFIBIO consortium.

The member states covered by this report are the United Kingdom, Italy, France, Germany, Belgium, Sweden, Denmark, Ireland, Austria, Estonia, and Malta. Additionally European policies and reviews of the biotech related activities of the 7th RTD Framework Programme, and a limited number of more general documents and news articles on biotech funding were taken into account (see “References” below).

The following is based on the analysis of the profiles of the policy documents prepared collectively by the AFIBIO partners. Whenever the policy documents under discussion were available in English, the authors consulted during the preparation of this review additionally also original documents.

The policies discussed in that section are divided into three categories: policies designed to support enterprises, policies designed to support research institutions, and policies designed to support both enterprises and research institutions in the area of funding.

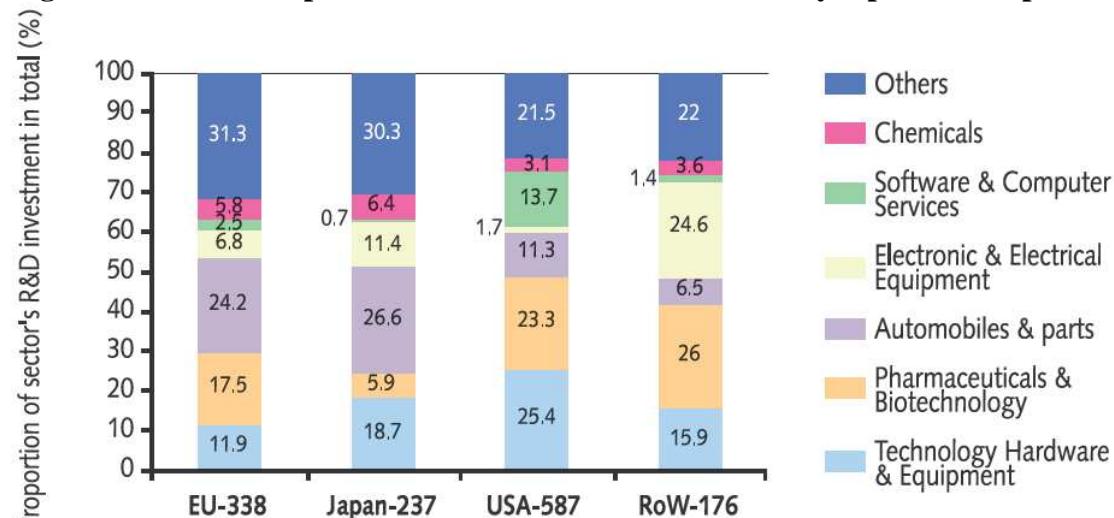
The Role of Biotech in Science and Technology Policy

Virtually all member states have set, at least at declarative level, to follow the EU Lisbon (Barcelona) objective to increase their R&D investments by 2010 (or slightly) later to 3% of GDP, 2/3 of which should come from industry. This is of course grossly generic objective, which needs quite some interpretation and locally rooted policy thinking before in each of the member states a pragmatic way forward could be established.

A closer look to the global private sector R&D reveals that industrial R&D investment worldwide continues to be highly concentrated both in terms of industrial sectors and in terms of the number of companies. A fairly small number of companies in a limited

number of industries (such as ICT equipment, pharmaceuticals and biotechnology, and automobiles) account for vast majority of the global industrial R&D investment.¹

Figure 1. Shares of top 6 sectors in total R&D investment by top 1338 companies



Source: *The 2006 EU industrial R&D scoreboard*, European Commission, 2007.

Furthermore, pharmaceuticals and biotechnology continue to be the industry with the fastest increase of R&D intensity², while R&D intensity of the automotive industry which is still highly prominent in European industrial employment, is actually declining.

Thereby, vast majority of the European backwardness in business R&D investment in comparison with the U.S. and Japan stems simply from the difference industrial specialization. This implies that the increase of industrial R&D investment and consequently also the European 3% target can be only achieved with a change in the composition of the European industry towards certain new knowledge intensive sectors such as ICT, bio- and nanotechnology.

We live, thus, in post-Fordist world which is driven by the on-going ICT revolution, and the rapid increase of bio- and nanotechnology investment seen over the last 10-20 years gives us relatively strong reasons to believe that bio-nanotechnologies may form the basis of the next technology revolution.³

¹ *Analysis of the 2006 European industrial R&D investment scoreboard*, European Commission, 2007.

² Both in terms of cross annual growth rate of industrial R&D investment in 2002-2005 and in terms of the increase of R&D/capital investment ratio.

³ See for example: Marek Tiits *et al*, *Made in Estonia*, Institute of Baltic Studies, 2006; Carlota Perez, *Technological Revolutions and Financial Capital. The Dynamics of Bubbles and Golden Ages*, Edward Elgar Publishers, 2002; Raymond Vernon, "International Investment and International Trade in the Product Cycle," *The Quarterly Journal of Economics*, Vol. 80, No. 2. (May, 1966), pp. 190-207; Louis Wells (ed), *The Product Life Cycle and International Trade*, Harvard University, Boston, 1972.

This is the context review in following the latest trends policy trends with regard to biotechnology investment. The great difficulty in analyzing the policies affecting biotech investment in Europe is that virtually all science and technology policies across Europe have a significant impact on development of biotech – even though vast majority of such policy papers (e.g. national science and technology strategies) do not necessarily give to biotech a special focus. Furthermore interpretation of various biotechnology policies is grossly dependent on detailed knowledge of the local context of individual regions or countries, which is unfortunately beyond the scope of this work.

The following should be therefore taken as an illustration on recent trends in biotechnology policies in Europe rather than a comprehensive analysis of the impact of policies for biotech finance in Europe.

Recent Trends in European Biotech Policies

The main action lines of the European biotech strategy are (every action line includes several specific actions – for more information see

http://ec.europa.eu/biotechnology/docs/com_2007_175_en.pdf):

- **Promote research and market development** for bio-based products and improve the uptake of new technologies including: the generation of knowledge under the 7th Research Framework Program; the establishment of public-private partnerships to mobilize research funding; the exploration of lead market initiatives for eco-efficient bio-based products.
- Foster competitiveness by facilitating **knowledge transfer and innovation from the science base to industry**, including: the development of best practices in licensing of genetic resources; improving links between research organizations and industry; facilitating the patenting system for Small and Medium-Sized Enterprises (SME's); and considering incentives for Young Innovative Companies.
- Encourage **informed societal debates** on the benefits and risk of life sciences and biotechnology.
- Ensure a sustainable **contribution of modern biotechnology to agriculture** and use the potential of plant science for energy and environment applications, in particular to replace chemical processes and fossil fuels.
- Improve the **implementation of the legislation** and its impact on competitiveness. Unnecessary administrative burdens on research and industry should be identified and removed. The regulation should encourage, not hinder, innovation. Policy coordination should be improved, especially on cross-cutting issues and on newly emerging issues.

In the following, a short review of different policy measures devives recently across Europe is presented.

Policies to promote biotech research

Each and every country in Europe invests quite considerable amounts into public R&D, including biotech research and development. The funding criteria differ (not surprisingly) across member states, but the general idea is similar: to advance the knowledge pool of the human kind and to prepare for the forthcoming bio-economy.

In Italy the legislative decree of 27th July 1999 n 297 has been ratified. It establishes a financing program which is based on industrial research projects and aims to support pre competitive development of products/processes/services. The following institutions may apply for the support: universities, the National Agency for Energy and Environment, and the Italian Space Agency. A similar measure is also the regional grant for industrial research and pre-competitive development. This program focuses also on the entrepreneurial side (see the following sub-section).

In the UK the amount of money invested into research institutions increases year after year. The government of the UK is implementing the Dual Support system, which combines the core funding with the project and program one. The latter introduces a competitiveness aspect to the funding of research institutions. In addition, the government also invests money into the infrastructure important to research institutions for doing research. One of the important institutions in the UK in the area of biomedical sciences is Wellcome Trust. The Wellcome Trust has invested over £600 million into capital renewal of the UK's university research infrastructure and major facilities in partnership with the Research Councils. It has also invested in science learning centers to support professional development of science teachers, and supported joint research programs with the Government (for example in veterinary science).

In Estonia there are also several institutions that fund research activities. Funding is organized through the distribution of grants and funds according to the requirements of competition. In several cases these grants are usually small and have a short-term focus. In general research in biotech area needs bigger funds than currently available in Estonia and these projects usually have a long-term perspective. Therefore funds coming from EU projects are more useful for Estonian research institutions. But still there is a need for more funds targeted directly to biotech research.

Other stream of policy measures designed to help research institutions is the financial support to train world class researchers, attract and increase the quality of science teachers, and increase the popularity of science degrees (like in the UK, Belgium). Through the latter, a sufficient number of engineers and science graduates would then enter the labor market and the quality of research done in research institutions increase. Otherwise the lack of skilled workers could become a serious obstacle for biotech companies. In the strategy document „Life Science and Biotechnology – a strategy for Europe” the European Commission draws attention to educational issues and the importance of promoting university degrees with a major component in scientific disciplines.

In Belgium there are several fiscal measures introduced to support the R&D activities in research institutions. Public and private universities and research organizations do not have to pay taxes from up to 50% of researchers' wages. These savings must be directly re-invested in new scientific projects. There are also tax exemptions for hiring additional employees in the research and development areas, and subsidies to facilitate the hiring and training of employees. The Directorate General of Technology, Research and Energy subsidizes research expenses including 100% of the salary of researchers in universities or young start-ups. For having a greater impact these measures should be broadened to include regional centers of research, scientific institutions and researchers from the private sector. The latter would help increase private R&D investments. To support the cross-national collaboration activities, the Belgian government has introduced financial measures to bring back Belgian researchers working abroad, and attract researchers from Eastern European Countries (grants and abolition of requirement to have a working permit if he/she works under a contract with Belgian universities) and other European countries (social protection). Tax relieves for foreign researchers are also introduced in Denmark. Additional measure is VAT deduction on equipment bought by researchers working in Belgium.

Policies in support to development of biotech companies

Policies designed to support enterprises could be divided mainly into two: publicly-backed funds for the early-stage development and/or research activities of companies, and tax incentives of various types. In this part of the deliverable some of these policy measures existing in different European countries are discussed.

Although there are a number of VC funds across Europe, there is still a funding shortfall among European bioscience companies. The EC estimates this shortfall to be 1 billion euros. It is acknowledged that there is a need for funds especially during the first stages of the development (pre-seed, seed funds, and funds for start-ups). When the company is larger and more established, there are possibilities to raise funds from private VC funds. In Europe several countries are focused on funding early-stage and start-up companies. Many publicly-backed funds are created with a special focus on these development stages of enterprises, but companies still find that there are not enough financial resources available on the market. Therefore it is crucial to design different measures to support enterprises during the early stages of development. Countries designing these measures may learn from the measures and experiences described below.

In Estonia VC funds for biotech are almost absent. VC for Estonian companies is available from international funds but these funds are more focused on the IT sector where the projects have lower risk and the time for getting profits is shorter than in the biotech sector. Also getting bank loans is very difficult for starting biotech companies and the reasons for that are similar to the reasons for not getting VC. For funding their product development enterprises can apply for grants provided by

Enterprise Estonia. Although the situation in Estonia might be worse than in the rest of the Europe in the area of VC funds, the factors hampering the process of receiving VC funds are quite similar. Therefore it is necessary to design policy measures to support the biotech companies in their fund raising attempts.

In the UK, there are several opportunities to get funding. One of them is the Regional Venture Capital Fund created to provide funds up to 500 000 pounds to small businesses during their early stage of development. The government is one of the investors in this fund. However, the investments available through this fund are not usually sufficient for covering biotech companies' needs. This financial gap is partly covered by business angels in UK though. In the UK a Small Firms Loan Guarantee Scheme is also implemented to guarantee loans from banks and other financial institutions for small firms with viable business proposals that have nevertheless failed to get a conventional loan because deemed to be too risky. The latter is more focused on the latter stages of development (a similar scheme is also present in Malta). Moreover, an Enterprise Capital Fund has been created, which aims at channeling "soft" government loans to leverage private capital and bridge the equity gap between business angels and private equity houses.

In Scotland Scottish Enterprises created Scottish Co-investment Fund (SCF) in 2003 with the capital of 45 million GBP. This fund invests into companies to help them to take innovative ideas to the first stage of commercial credibility. The Fund is opened to SMEs based principally in Scotland, in an approved business sector with up to 250 employees and net assets of less than £16 million. SCF invests only in partnership with private sector investors (corporate ventures, institutional investors, professional fund managers and investors, business angel syndicates, and private individual investors), with all investment decisions made by those private sector partners. The Partner finds the investment opportunity, negotiates the investment deal and invests own money along with SCF money on equal terms. For more information about SCF see the report 1.2. of the AFI-BIO project. One additional instrument in Scotland is Scottish Enterprise's Business Growth Fund launched in 1999. The fund provides loans and equity investments to businesses which show ambition to grow. They must also satisfy several criteria relating to their size and commercial viability.

There are other measures designed to help SMEs. For example companies having an idea for an innovative product, process or service, but which are not sure if they are ready to take it forward successfully, may receive help under a Grant for Investigating an Innovative Idea. The grant reimburses some of the costs of consultants chosen to provide expert advice on identified 'barriers' to the successful implementation of the new concept, service or product. In Scotland the similar instrument is Proof of Concept funding. Through this instrument pre-commercialisation of leading-edge technologies emerging from Scotland's universities, research institutes and NHS Trusts are supported. The UK has also introduced a government-funded scheme that enables businesses to access the skills and resources of the UK knowledge base by enabling high quality graduates to work in companies on knowledge transfer projects. Small companies can participate in this project, and benefit from the expertise of



academics and researchers from a higher education institution or research-based organization, or the knowledge of a graduate.

“High-tech Founders Fund” has been created in Germany as an initiative of the Federal Ministry of the Economy and Technology. This fund supports the founders of companies in innovative research fields. It was designed to help research based start-ups by providing funds during the first two years.

The amount of public spending directed to the biotech sector in Sweden is quite small. There are at least 4 channels for investing public money, but from these channels biotechnology companies have not obtained many financial resources. Therefore Swedish biotech firms need more funding sources. There is currently not enough capital for early stage development. One suggested action line is to create a pre-seed fund with the aim to enable innovators to validate the technical and commercial concepts, and business potential of product/service/process resulting from basic research (there is a need for public pre-seed capital also in Denmark). Another suggestion is to create seed and bridge funds to co-invest with private investors. The latter would allow the possibility to raise the amount of capital received from private funds by enterprises because of the additional guarantee represented by the involvement of the public sector.

The French Coordination Committee of Communication Sciences and Technologies (*Comité de Coordination des Sciences et des Technologie de la Communication* – CCSTIC, Ministry of Research) is currently working on the creation of “Innovation Financing Companies” financing pre-development stage projects (“Société de Financement de l’Innovation”, called SOFINNOV). This institution would act as vehicle for negotiable debt securities. Similar institutions already exist for traditional industrial sectors (movie industry and fisheries) in France. The support to early-stage biotech companies is also one of the aims of Enterprise Ireland. This institution not only invests into companies, but also supports applied research projects and promotes the development of the private sector seed and VC environment.

The situation of accessing VC funds is quite satisfactory in Belgium. There are more than 100 VC companies ready to invest in biotech enterprises. VC and seed funding is available through publicly-backed and private funds. Also many banks have separate funds directed to start-up companies in the biotech sector. There is a good mix of early-stage and later-stage funding possibilities.

In Belgium, enterprises can share the risks of investing in R&D projects with an institution called Directorate General of Technology, Research and Energy. This institution has also other financial incentives and subsidies to support enterprises in different development stages. One of the measures is an interest free loan covering up to 70% of applied or development research expenditure of enterprises. It is reimbursable as an annual fee representing a percentage of product sales. Other possibilities include grants for feasibility studies and technology transfer. Another important Belgian institution for biotech enterprises is SRIW which is located in the

Walloon region. SRIW provides long-term financing to companies in Belgium and abroad. This institution participates in enterprises through direct equity participations, convertible or non-convertible loans, subordinated or senior loans, warrants, and so forth.

A second group of support measures are tax incentives for young and/or high-tech companies. In the UK for example there are tax incentives for companies investing into R&D including modifications in the corporate tax and R&D tax credit systems. A similar system has also been introduced in France through tax incentives for investments in R&D. This measure is not very helpful for bioscience companies who have to deal with long periods of loss before gaining any profits from their investments into R&D.

In the UK, tax incentives are more favorable to small companies than medium and large size companies. For example small biotech companies are given a tax incentive related directly to the amount of money they invest into R&D (also introduced in France). One possibility to make this measure more favorable also to larger companies is to provide tax incentives according to the age of the company not according to size. One possible initiative in this area is the so-called Young Innovative Company Status implemented in France. The company falling under this status has to have at least 15% of their expenditures on R&D and be less than 15 years old. The fiscal aids for companies are the following: reduction of social costs (social security, unemployment and pensions) by 100% for the first 15 years; no tax on revenues for the first 3 profitable years; 50% reduction over the following 5 years and 35% reduction over the following 7 years. This measure also includes incentives for investors, such as no tax on capital gains on shares or stock options that have been held for a minimum of 3 years. In addition to previous one, also a system of extra tax credit based on R&D spending with refundable investments is implemented in France. Among the eligible expenditures are patent, research staff, standardization, and technological foresight costs. In Belgium, enterprises can deduct investments into R&D projects from a taxable sum. All these measures motivate enterprises to invest more into R&D projects. In Sweden there are proposals to introduce similar systems, but right now they are not yet in place.

In addition to publicly-backed funds and tax incentives for young companies, SMEs and/or R&D investments, also other measures might be considered useful by enterprises. In Italy for example an initiative to support the process of protection of intellectual property rights has been introduced. Also, the public sector provides financial support for the patenting process of SMEs.

Policies to support knowledge transfer from research to industry

The policy measures belonging to this group is mainly focused on creating the collaboration activities between enterprises and research institutions with the aim of increasing the responsiveness of research results to market and/or business sector needs. Sometimes also the whole industry or region is engaged in the process.

Through increasing the collaboration activities the private R&D investments may increase and research results may have a more commercialized focus. Therefore the knowledge transfer is becoming more and more an important aspect in designing policies.

In Italy regional grants for industrial research and pre-competitive development have been introduced. Through this measure grants to research focused on the improvement of new products, processes or services are distributed. Also grants to research on pre competitive development like definition of prototypes, new products, processes and services are given.

The collaboration between enterprises and research institutions is supported by one interesting initiative – Bioiniziativa – in the Lombardy region. The aim of this initiative is to promote the economic development and entrepreneurial activities in the biotech field. The expert team consisting of people coming from industry chooses projects for licensing or sponsored research. The projects for selection are presented to the team by research institutions and the projects are divided into three categories: potential new spin-offs, know-how and patents available for licensing, and projects to be further developed through sponsored research. This initiative supports the commercialization of research results through finding funds or industrial partners for research institutions. This measure is designed to support both enterprises (in 2005 5 new spin-offs were created) and research institutions (commercialization of research results through support to business plan development and sponsored research).

In Germany on 30th August 2006 the High-tech Strategy was adopted. The main aim of this strategy is to create linkages between enterprises and research institutions, connecting science and economy. Biotech is identified as a very important research field in this strategy. The strategy includes several policy measures like funding competitions, and funding programs. One of these measures is the Go-Bio funding program that could be compared to the program BioChancePLUS presented below. The focus of the German program is to support and facilitate collaboration activities between industry and research institutions already during the early-stage of product/process/service development and through the previous help to bring profitable research results to market. Another measure to facilitate the cooperation is providing bonuses to research institutions if they can receive the collaboration contract with SMEs. In the UK also the existence of collaboration activities between research institutions and business sector influences positively the process of getting research funding from the public sector. Separate funds for supporting collaborative R&D are available and knowledge transfer networks and Technology Transfer Offices have been created in the UK (TTO exist in Denmark, similar initiatives also in Malta and Scotland).

In Scotland the Enterprise Fellowship is created to support university researchers to form companies with the aim to commercialize their work. This fellowship supports researchers for a year to develop their business idea, build the start-up team, and raise the first round of private investment. The Fellowships also include structured

entrepreneurial and business training, business mentoring and access to professional networks.

In France there is a law on innovation and research which promotes the transfer of research results to industry and the creation of new innovative companies. The law regulates the areas of innovation and research. Law is divided into 4 sections: the mobility of researchers towards industry (ability to get paid from original organizations while creating a company during the start-up phase, rights of being shareholder of the company while still working in research establishments etc), the cooperation between public sector research establishments and companies (the right to set-up incubators by research institutions etc.), the fiscal framework for innovative companies (liberalization of company founder's share warrants scheme, innovation investment fund scheme, modification of research tax credits system), and the legal framework for innovative companies (extending the scope of the simplified joint stock company scheme). The last two sections are directed to supporting enterprises.

The collaboration activities are not so developed in new EU member states. Mainly the research done in universities in these countries is not industrially oriented. Also if the country is small like Malta, only one or very few research institutions are able to do any research in biotechnology field. Therefore the introduction of competition between these institutes is not possible. At the same time industry is not yet ready to cooperate with universities in those countries, but when because of increased competition the pressure to innovate grows, enterprises will be more ready to change their strategy and collaborate with research institutions.

Although there is not much cooperation going on between enterprises and research institutions in new EU countries there are still some programs and projects designed by the public sector with the aim to increase these kinds of activities. For example the SPINNO program in Estonia. This program has ended already but it was designed to increase the technology transfer from universities to enterprises. Also, the Institute of Technology of Tartu University has been established with the aim to generate new ideas and technological solutions and support the setting up of spin-off companies based on these ideas. These measures have not yet been able to change the cooperation environment. The cooperation activities in Estonia are assessed as being almost non-existent and the framework conditions for developing collaboration as being unfavorable.

Quite a new approach is the creation of centers of excellence (or competence centers) in Europe. Several countries support the creation of these centers through public funds to promote the cooperation between industrial and academic partners (i.e. Austria, Italy, UK, Estonia). Different countries have requirements to be fulfilled in slightly different guises by these centers but generally the aim is to support high quality research in its engagement in the business sectors of the country. In addition to centers of excellence many countries establish testing centers (i.e. the UK, Belgium, Germany, Malta, Estonia etc). Availability of testing center enables enterprises to

decrease the R&D investments (no need to buy expensive laboratory equipment) and facilitates the cooperation between enterprises and research institutions even more.

There are also policy measures supporting the creation of clusters. In Italy for example there is a specific project called “Metadistretti Project” including funds directed to biotech. The cluster created through this project has to have at least 3 industrial partners from one specific region (Lombardia) and also partners from university, private research centers, public administration etc.

The biotechnology cluster, Genopole outside Paris, was founded in 1998 in France through the collaboration between the Ministry of Research, the city of Evry, and the local University with the objectives of accelerating biotech research and improving academic excellence. Genopole receives its funding by the French Government and offers incubator services such as rebated lab space and shared research equipment. In Sweden the UppsalaBio program, funded by Vinnova with 100 million SEK for the duration of ten years that should be matched by industry or regional funding, is the largest similar Swedish program so far.

In Germany the creation of clusters is encouraged, and the collaboration between research institutions and industry is supported. There have been three competitions initiated by the Federal Ministry of Education and Research and directed to create competitive companies in the biotech area at the regional level. These competitions were BioRegion, BioProfile and BioChancePLUS. Through the competition BioRegion four regions gained access to public funds (in total 90 millions of euros). Competition BioProfile was also directed to regions. Winning regions were regions with good conditions for transforming the biotech know-how into products, services, processes. Three regions were chosen and a fund of 50 millions of euros was divided between them. The program BioChancePLUS was created to support the projects from biotech enterprises and research establishments.

In Belgium many clusters in biotechnology exist. The cooperation between research institutions, firms, hospitals and VC is working. Belgian VCs are quite active in investing in biotech firms. In addition to publicly and privately backed VC funds, also universities have created VC funds to provide early stage capital for their spin-off companies. The academic personnel of universities is interested in cooperating with industry and tries to increase the industrial value of its research results. The latter increases the motivation of industry to work with research institutions. In Belgium also many centers of excellence in biotechnology have been created. These centers are mainly funded from public sector or through EU projects.

In addition to direct policy measures designed to support and facilitate the problems with funding in health related biotech, European countries should also think about other support measures. These measures are for example the harmonization of regulations related to cross-border private equity financing, the harmonization of IPR rules, and the introduction of a system for the provision of licensing of drugs in Europe. The regulatory environment must be harmonized but at the same time the

stability of this environment has to be guaranteed as much as possible. In the strategy document „Life Science and Biotechnology – a strategy for Europe” the European Commission suggested an action line to finalize a strong, harmonized and affordable European IPR protection system because the process of patenting is quite expensive especially for SMEs.

At the European level there is also a greater need for projects able to connect regions from different countries. The funding for these kinds of projects must come from the supra-national level and therefore it should be supported by the EU. In the 6th FP life sciences and biotechnology were the priority areas. FP7 is also designed to support projects from these sectors and to facilitate the development of a European Knowledge Based Bio-Economy. The 7th Framework Program started in 2007. Within its Cooperation Program, funds amounting to € 8 billion are directed to life sciences and biotechnologies. € 6 billion of which will support health research and the remaining € 2 billion supporting research on food, agriculture and fisheries, and biotechnology. The target group for about 1,2 billion euros of these funding are SMEs. FP7 is also encouraging frontier and riskier research in Life Sciences through the new European Research Council. FP7's People Program will support training and networking researchers, career development and industry-academia partnerships. Actions addressing the ethical and socio-economic aspects will continue to be supported. Building on the success of the European Technology Platforms (developed to support public-private partnerships at European level) the next level of public and private research partnerships is the so-called Joint Technology Initiatives. The Commission expects to propose in the near future a JTI on Innovative Medicine. The latter is in accordance with the Lisbon Strategy and Sustainable Development Strategy, both stating that modern biotechnology is one of the key enabling technologies of the 21st century.

Based on the previous and results of the report “Bencmarking of public biotechnology policy” following results could be brought out. The analysis of the policy development over time indicates that, in addition to direct interventions, the provision of a favorable environment for biotechnology is gaining importance (see Annex . Policy instruments for that purpose include fiscal policies, regulatory approaches and demand-oriented policy activities, comprising for example initiatives for exploring the benefits, costs and risks of the application of biotechnology. However, this trend towards paying more attention to the demand side is restricted mainly to the old Member States. (Reiss, Mangematin, Enzing, Senker 2005: iii)

Conclusions and recommendations

Generalization of the lessons to be drawn from the above brief review of policy actions on biotech finance taken by individual member states is not a trivial task. We have, however, concluded based on our earlier theory work and the review of policy documents conducted in AFIBIO project for this report at the following policy lessons:

Getting the timing right

Both the ICT and biotechnology companies lived in late 1990s through a period of exuberant technology optimism. With the NASDAQ crash in 2000 this optimism largely vanished. The ICT sector which had witnessed for a few years extraordinarily rapid development of infrastructures and expansion of client base was hit with the crisis harder than biotechnology, where the stock market bubble was smaller and optimistic mood of private investors was sustained for a little longer, until it became finally clear that the promise of ‘personalized medicines’ and a number of other breakthrough products and technologies is true, but it will take much longer and much more resources to be actually able to deliver the respective products.

This type of downturn of investor optimism seems to be also one of the key reasons behind difficulties around the world face in attracting additional finances to continue the development of their products. Thus, the most important lesson for future biotechnology strategy in Europe is probably about ‘getting the timing right’. Biotechnology is still largely in embryonic phase of development (think of ICTs in 1960-1970s for an analogue), and given this, devising policies for biotech funding which can socialize the risks of the investment into broadening and strengthening of the biotech related knowledge base⁴ with possibly even 10-15 years to market is the key.

What you put in is what you get out

There is no ‘European paradox’. Europe invests into knowledge generation and R&D less than our main strategic competitors, and the relative backwardness of Europe is the price of this underinvestment. Europe needs to invest much more in its future. The respective policies (for biotech finance) have to take strong account of a local context by building on existing strength.⁵

We witness a strategic policy competition, whereby many countries in the world aim at becoming a very favorable location for future biotechnology industry. The policy situation around modern biotech is in many ways similar to the better days of the British industrial revolution in 18-19th century, when every self-respecting sovereign wanted to create its ‘own Manchester’. Only a very few of them succeeded.

Serious entry into future biotech industry needs wise investment for founding the bases for this today. Unfortunately, however, many of the policy documents seen in Europe over the recent years carry a strong component of copy & paste policy making with little actual understanding of what needs to be done and commitment. It is a kind

⁴ The transformational potential of biotechnology as platform technology is by no means limited with red biotech, which happens to be one of the earliest markets. The use of new biotechnology solutions in the areas of earlier economic specialization of the individual countries is the key.

⁵ Christopher Patten, „Europe pays the price for spending less”, *Nature*, vol 441, 8 June 2006.

of casino, where bets need to be done now, despite the fact that rules of the game will be known only later when the game has truly started...⁶

European policies tend to push the researchers too early in development of new knowledge and ideas to the commercialization of new (yet immature) technologies. Public research investment which takes into account much longer time horizons should play in European biotechnology a much stronger role.

A methodological note

It is virtually impossible to assess based on the current type of relatively limited analysis of policy documents the actual impact of the policies which have been put in place in different regions or states in Europe. One could see this type work as an analogue of the *European Innovation Trendchart* of the European Commission DG Enterprise, which reports on recent policy developments in individual member states providing thereby other countries or regions with background information on policy developments in Europe.

The main difficulty with this is that the time-wise limited desk research into policy documents neglects largely the actual techno-economic background of the specific countries under discussion. The actual policy learning from each of the reported policy initiatives would require much more detailed understanding of the specific context of the respective countries.

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⁶ W. Brian Arthur, „Casino of Technology Strategizing“, *Across the Board*, 40, 1, 48-49.

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Annex 1 – Overview of biotechnology policies in 21 EU member states

Table 4.1: Overview of biotechnology policies in the old EU Member States, USA and Canada in 1994/95 (*expert's assessment*)

Policies	AT	BE	DE	DK	ES	FI	FR	GR	IL	LU	IT	NL	PT	SE	UK	US	CA
1. Education																	
1.1 biotech curricula		✓	✓	✓	✓	✓	✓		✓	n. d.	✓	✓	✓	✓	✓	✓	
1.2 business issues		n. d.		✓						n. d.			n. d.	n. d.			
2. Research																	
2.1 biotech promotion	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3. Exploitation																	
3.1 entrepreneurship/spin-offs		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
3.2 industry/PSRO collaboration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4. Industrial development																	
4.1 availability of capital	✓	✓	✓	✓		✓	✓		✓		✓	✓	✓	✓	✓	✓	✓
4.2 business supp. f. start-ups		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
4.3 industrial research (bt specific)	✓		✓		✓	✓			✓		✓	✓	✓		✓	✓	✓
4.4 clusters		✓	✓	✓	✓	✓	✓	✓		n. d.			✓	n. d.	✓	✓	✓
5. Fiscal																	
5.1 tax incentives for innovation			✓			✓	✓		✓	n. d.	✓	✓	✓	✓	✓	✓	✓
6. Regulation																	
6.1 task innovation					✓	n. d.	✓		n. d.	n. d.	✓		✓	✓	n. d.	✓	✓
7. Demand																	
7.1 explore bt benefits	✓	n. d.	✓	✓		✓	✓			✓		✓	n. d.	✓	✓	✓	✓
7.3 adoption		✓	✓							n. d.			n. d.	n. d.	✓	n. d.	

✓ = policies in place, n. d. = no data, blank = no such policies in place.

AT: Austria, BE: Belgium, DE: Germany, DK: Denmark, ES: Spain, FI, Finland, FR: France, GR: Greece, IL: Ireland, LU: Luxemburg, NL: Netherlands, PT: Portugal, SE: Sweden, UK: United Kingdom, US: USA, CA: Canada

Source: Reiss, Mangematin, Enzing, Senker 2005: 18. For additional information see Annex 4 of the report.

Table 4.2: Overview of biotechnology policies in old EU Member States in 2004 (national policy-maker's assessment)

Policies	AT	BE	DE	DK	ES	FI	FR	IL	LU	IT	NL	PT	SE	UK
1. Education														
1.1 biotech curricula	√	√	√	√	√	√	√	√		√	√	√	√	√
1.2 business issues	√				√	√	√	√		√	√	√	√	√
2. Research														
2.1 biotech promotion	√	√	√	√	√	√	√	√	√	√	√	√	√	√
3. Exploitation														
3.1 entrepreneurship/spin-offs	√	√	√	√	√	√	√	√	√	√	√	√	√	√
3.2 industry/PSRO collaboration	√	√	√	√	√	√	√	√	√	√	√	√	√	√
4. Industrial development														
4.1 availability of capital	√		√	√	√	√	√	√	√	√	√	√	√	√
4.2 business supp. f. start-ups	√	√	√	√	√	√	√	√	√	√	√	√	√	√
4.3 industrial research (bt specific)		√	√	√	√	√	√	√	√	√			√	√
4.4 clusters	√	√	√	√	√		√	√		√	√			√
5. Fiscal														
5.1 tax incentives for innovation	√	√		√	√		√	√		√	√	√	√	√
6. Regulation														
6.1 task innovation	√		√	√	√	√	√	√	√	√	√	√	√	√
7. Demand														
7.1 explore bt benefits	√	√	√	√	√	√	√	√	√	√	√	√	√	√
7.3 adoption				√	√	√	√	√				n. d.	√	
8. Policy processes														
8.A Impact assessment				√			√	√		√	√		√	√
8.B Policy coordination	√	√		√	√	√	√	√		√				√

√ = policies in place, n. d. = no data, blank = no such policies in place.



Source: Reiss, Mangematin, Enzing, Senker 2005: 19. For additional information see Annex 4 of the report.

Table 4.3: Overview of biotechnology policies in the new EU Member States in 2004 (*national policy-maker's assessment*)

Policies	CZ	EE	HU	LT	PL	SK	SI
1. Education							
1.1 biotech curricula	√	√	√	√	√	√	√
1.2 business issues					√		√
2. Research							
2.1 biotech promotion	√	√	√	√	√	√	√
3. Exploitation							
3.1 entrepreneurship/spin-offs		√	√	√			√
3.2 industry/PSRO collaboration	√	√	√	√	√		√
4. Industrial development							
4.1 availability of capital		√	√	√			√
4.2 business supp. f. start-ups	√	√	√				√
4.3 industrial research (bt specific)			√				
4.4 clusters							√
5. Fiscal							
5.1 tax incentives for innovation			√			√	
6. Regulation							
6.1 task innovation			√		√	√	√
7. Demand							
7.1 explore benefits	√	√			√	√	
7.3 adoption		√		n. d.			
8. Policy processes							
8.A Impact assessment		√					
8.B Policy coordination							

√ = policies in place, n. d. = no data, blank = no such policies in place.



Source: Reiss, Mangematin, Enzing, Senker 2005: 20. For additional information see Annex 4 of the report.

ANNEX 2 – Summaries of Policy Documents

Name of the Policy Document/Report in original language Bioiniziativa
Name of the Policy Document/Report in English Lombardia - Bioiniziativa
Year of the preparation of the document 2004 -
Name of the organization(s) which has prepared/adopted the Document Assolombarda (Association of the industries and third market realities in the milan area) e Finlombarda (the Financial Society of Regione Lomabradia)
Coverage of the document i.e national, regional, European Regional
What type of biotechnology is concerned by the publication Food- Agriculture, human and animal health, industry and environment
Main conclusions in the document related to Biotechnology financing This is an initiative of Assolombarda and Finlombarda to promote the economic development and entrepreneurial activities in the biotechnology field in the Lombardy region Each year through this initiative 100 different projects, presented by research centres, universities, science parks within the Lombardy region, have been selected by a group of experts coming from industry. The projects have been classified as 1. potential new spin off 2. know how and patents available for licensing 3. project to be further developed through sponsored research The 2005 selection succeeded in creating 5 new spin offs, 10 in development and 15 projects available for technology transfer through licensing or sponsored research.
Main recommendations in the document related to Biotechnology financing Great opportunities for creating innovation stay within universities and research centres. We should provide intellectual and economical means to develop and grow these innovative ideas to nurture the economical strength of the region and consequently the country.
Have some of the recommendations been implemented yet, if yes, which ones The initiative has been repeated also in the following years
Other relevant information

Name of the Policy Document/Report in original language
Metadistretti
Name of the Policy Document/Report in English
Lombardia - Metadistretti
Year of the preparation of the document :
Name of the organization(s) which has prepared/adopted the Document
Regione Lombardia
Coverage of the document i.e national, regional, European
Regional
What type of biotechnology is concerned by the publication
Non food biotechnology, ICT, new material.
Main conclusions in the document related to Biotechnology financing:
The aim of the initiative is to sustain local innovation, by public financing and promoting aggregation between different industrial and academic partners in order to generate technological center of excellence.
Main recommendations in the document related to Biotechnology financing
Initiative is dedicated to new cluster formed by: At least 3 industries based in Lombardia, with an industrial expertise in field of interest; Other partner: big industries within the Region, university, private research centers and research foundation.
Have some of the recommendations been implemented yet, if yes, which ones The project evaluation provides different contributes based on the stage of development of the invention in particular two different class of project have been classified: R&D support up to the protection trough patents of results; R&D support up to the production and commercialization stage;
Other relevant information Projects will be evaluated and a score will be assigned in order to build a list of priorities: Project: 0-30 pt; Project team (number of participant, level of expertise, and management): 0-30 Impact (new employees; tech transfer evaluation; generation of new product; health



and safety): 0-40 pt.

Timelines: 45 day to score the companies; three months to provide financial support.

Name of the Policy Document/Report in original language
Decreto legislativo 27 luglio 1999 n 297
Name of the Policy Document/Report in English
<i>Italy - Decree legislative 27th July 1999 n 297</i>
Year of the preparation of the document
Name of the organization(s) which has prepared/adopted the Document
Italian Republic
Coverage of the document i.e national, regional, European
National
What type of biotechnology is concerned by the publication
Research activities in biotechnological field (no specific indication)
Main conclusions in the document related to Biotechnology financing: The aim of the document is to support the national research activities, to increase the Italian competitiveness, and implement the production of new technologies and finally, increase the number of employees in the field of research. The financing program is based on industrial research projects and aims to support pre competitive development.
Main recommendations in the document related to Biotechnology financing The financing program is accessible to: University; ENEA (National Agency for Energy and Environment); ASI (Italian Space Agency).
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language Bando regionale per la ricerca industriale e lo sviluppo precompetitivo per l'anno 2006
Name of the Policy Document/Report in English <i>Regional grant for industrial research and pre-competitive development for 2006</i>
<u>Year of the preparation of the document</u> 2006
Name of the organization(s) which has prepared/adopted the Document Piemonte Region
Coverage of the document i.e national, regional, European <u>Regional</u>
What type of biotechnology is concerned by the publication <u>Biotechnology and life science</u>
Main conclusions in the document related to Biotechnology financing The grant will support 50% of industrial research focused to the improvement of new products, productive processes or services. The grant will support 25% of the pre-competitive development research meaning, definition of new product, productive processes or services, or definition of a prototype not yet usable for commercial purposes. The admitted costs are the following: personnel, instruments, software, materials, travel costs.
Main recommendations in the document related to Biotechnology financing The purpose of this regional grant is to favour the collaboration between industrial partners and research centres and university
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
BioRegions in Germany – Strong impulses for the national technological development
Name of the Policy Document/Report in English
<i>BioRegions in Germany – Strong impulses for the national technological development</i>
Year of the preparation of the document 2006
Name of the organization(s) which has prepared/adopted the Document
Federal Ministry for Education and Research
Coverage of the territory by the document i.e national, regional, European
National, Germany
Main conclusions in the document related to Biotechnology financing
Various competitions since the mid-90s have given lasting momentum to the development of biotech in Germany. 1997 Rhineland, Munich and Heidelberg (selected out of 17 applicants) received special awards and privileged access to special bmbf project funding. BioProfile competition as part of the framework of the Federal Government's Biotechnology 2000 program. GoBio funding program is an early cross-linking of the commercial and scientific branches (150 Mio€ for about 10 years)
Main recommendation in the document related to Biotechnology financing
Partnering between research and biotech companies (SMEs with market experience) is essential. One must increase the number of collaborations, mergers and take-overs. Contests and competitions are a tool to support collaboration.
Other relevant information
Not mentioned in this report: High Tech Founders' Fund (a common funding activity of bmbf and industry for SMEs in biotech and ICT

Name of the Policy Document/Report in original language Bioechnologietage 2006
Name of the Policy Document/Report in English <i>Biotech days in Germany 2006</i>
Year of the preparation of the document 2006
Name of the organization(s) which has prepared/adopted the Document Bmbf, Ministry for Education and Research
Coverage of the territory by the document i.e national, regional, European Germany
Main conclusions in the document related to Biotechnology financing This report summarizes several presentations and discussion forums. Introduction to High Tech Founders' Fund / gaining capital by IPO /new therapies / new diagnostics / pharmacogenomics / regenerative medicine Communication link between scientist – company founder and investor could be solved via technology transfer organizations who could as well coach the process and therefore become “low cost business angels”
Main recommendation in the document related to Biotechnology financing Important key issues for the development of biotech industry Innovation – excellence – strengthen strengths Improvement of technology transfer Connecting the different fields of biotechnology – red, white, green Use of existing programs (be it BioFuture, Go Bio, EU programs)
Other relevant information

Name of the Policy Document/Report in original language <i>A Mapping Study of Venture Capital Provision to SMEs in England</i>
Name of the Policy Document/Report in English <i>A Mapping Study of Venture Capital Provision to SMEs in England</i>
Year of the preparation of the document 2005
Name of the organization(s) which has prepared/adopted the Document
Small Business Investment Tasksforce (= independent advisory body appointed by the secretary of state to advise on access to finance issues for SMEs);
Coverage of the territory by the document i.e national, regional, European
UK
Main conclusions in the document related to Biotechnology financing
The supply of venture capital to SMEs in England varies regionally. The uneven distribution is buffered by some publicly-backed funds with an explicit regional focus wanting to address regional equity gaps. So these have a very complementary function. Half of all active funds are located in and around London. Almost 60% of specialist funds are based in London, but there are also a significant number of specialists based around technology clusters in the South East and Eastern regions. Sizes: large funds with about 60m £ by Venture Capital firms, around 23 m£ Venture Capital Trusts, around 13 m £ publicly-backed funds, regional venture capital funds (RVCF). Source of money: for vc funds: institutional investors like pension funds, insurance companies, asset managers or funds of funds for RVCFs: local authority pension funds Investments: Largest funds – managed by VCs predominantly invest in technology sectors which are highly capital intensive, require large amounts of money to build profitable businesses. The large amounts are a function of the capital sources
Main recommendation in the document related to Biotechnology financing
Complementary rather than competitive investments by several investors organized as VC firms, public and private investors
Other relevant information

Name of the Policy Document/Report in original language Report of the Alternative Investment Expert Group
Name of the Policy Document/Report in English <i>Report of the Alternative Investment Expert Group</i>
Year of the preparation of the document 2006
Name of the organization(s) which has prepared/adopted the Document Expert Group on Private Equity (February – June 2006) with European Commission Internal Market and Services DG
Coverage of the territory by the document i.e national, regional, European Europe
Main conclusions in the document related to Biotechnology financing The private equity industry gives an important contribution to the regeneration of the economy by nurturing new enterprises and re-energising existing companies so leading to sustained growth and job creation. The industry could even make greater contribution if the regulatory and tax environment in Europe took better account of the specificities of this business. That means that local advisors should not be regarded as permanent establishment for tax purposes. Private equity plays an important role in bringing private companies into public markets and facilitating the adoption of advanced and transparent governance rules. Europe's national regimes are heavily fragmented and do not interlink. International financing reporting standards, Markets in Financial Instruments Directive should be harmonized. Sensible and pragmatic approaches are needed to facilitate the cross border activities of private equity industry.
Main recommendations in the document related to Biotechnology financing Member states should learn from each other and create optimal conditions at local/national level to facilitate the development of private equity financing. That means a consistent approach to issues affecting private equity industry and when implementing national or EU laws not to introduce obstacles (and create inappropriately drafted or targeted legislation). Fund structuring and tax. Treat private equity funds the same way as public equity investments. Facilitation of cross border placements of private equity funds
Other relevant information



Name of the Policy Document/Report in original language
Science & innovation investment framework 2004-2014
Name of the Policy Document/Report in English
<i>Science & innovation investment framework 2004-2014</i>
Year of the preparation of the document :2004
Name of the organization(s) which has prepared/adopted the Document
HM treasury, Department for Education and Skills, Department of Trade and Industry
Coverage of the document i.e national, regional, European
National, UK
What type of biotechnology is concerned by the publication
General biotechnology
Main conclusions in the document related to Biotechnology financing
<ol style="list-style-type: none"> 1. Research & development expenditure is 1.9% GDP in 2004 in UK, target to 2.5% in 2014.
Main recommendations in the document related to Biotechnology financing
<ol style="list-style-type: none"> 1. Strengthening the UK science base by providing the secure and rising investment which will enable successful research centres to grow with confidence. 2. Increasing business investment in R&D. The government will commit additional resources through 2007-2008 to help bridge the funding gap between commercial application of new technologies and the underpinning research. 3. Universities will be incentivised to build on the progress made in commercializing their research and working collaboratively with business, through increased funding for the Higher Education Innovation Fund. 4. Global partnerships, devolved administrations and the regions
Have some of the recommendations been implemented yet, if yes, which ones
<ol style="list-style-type: none"> 1. The average annual growth rate in science growth funding through the DTI and DfES ,in the spending Review 2004 period is 5.8% in real terms 2. The Higher Education Innovation Fund will rise to £110 million a year by 2007-2008. 3. The Government's Chief Scientific Adviser will lead a cross-government Global Science and Innovation Forum to develop an international strategy based on an analysis of UK performance.

Other relevant information

Name of the Policy Document/Report in original language Bioscience 2015
Name of the Policy Document/Report in English UK - Bioscience 2015
Year of the preparation of the document 2003
Name of the organization(s) which has prepared/adopted the Document Bioscience Innovation and Growth Team, Department of Trade and Industry
Coverage of the document i.e national, regional, European National, UK
What type of biotechnology is concerned by the publication Healthcare
Main conclusions in the document related to Biotechnology financing <ul style="list-style-type: none"> 1. Bioscience companies, like pharmaceutical companies, depend on clinical trials in appropriate patient populations to develop and secure approval for their treatments. Developing a successful new prescription drug takes 10-15 years from discovery to approval, and costs averagely ~£500 million. Approx half of the time and cost of successful medicine development is spent in clinical development phases. The collaboration with NHS will create a powerful magnet for bioscience sector and improve patient care. 2. Regulation of drug development and use of innovative medicines in the UK. <ul style="list-style-type: none"> 2.1 Implement the EU clinical trials directive in an effective manner consistent with the aim of achieving global leadership in clinical research. 2.2 Introduce a system for provision licensing of drug in the UK and EU. 2.3 Create a collaborative relationship between the EU and UK drug approval regulators and the bioscience industry. 3. Bioscience financing <p>Support measures to improve liquidity of emerging bioscience companies in order to advance self-sustainability.</p> <p>Many of the ideas coming forward from universities for commercial funding are at too early stage of development, and have insufficient commercial focus to be fully exploitable. Bridge fund such as pre-commercial funding is necessary for pre-company entities. Strength technology transfer offices in UK.</p>
Main recommendations in the document related to Biotechnology financing <ul style="list-style-type: none"> 1. Build a mutual advantageous collaboration between the NHA and industry for patient benefit through the creation of a National Clinical Trials Agency (NCTA). The NCTA, sponsored by the Department of Health (DH) in collaboration with Research Councils UK, should support excellence in clinical trials and clinical research within the NHS. 2. Create a public and regulatory environment supportive of innovation. <p>This includes improving regulatory support for the development, approval and use of innovative medicines in the UK, through effective collaboration between industry, regulatory agency and government.</p>

3. Ensure sufficient and appropriate funding is available.

This includes supporting measures to improve the liquidity of bioscience companies, through adjusting pre-emption rights and corporate venturing, and investing in the ‘bridge’ between idea generation and commercial financing.

Have some of the recommendations been implemented yet, if yes, which ones
Strength Technology transfer office in universities

Other relevant information

Name of the Policy Document/Report in original language Recommendations for Industrial biotechnology
Name of the Policy Document/Report in English <i>Belgium - Recommendations for Industrial biotechnology</i>
Year of the preparation of the document 2004
Name of the organization(s) which has prepared/adopted the Document EuroStaf
Coverage of the document i.e national, regional, European Belgium, Worldwide
What type of biotechnology is concerned by the publication Human
Main conclusions in the document related to Biotechnology financing To attract new investors, new development possibilities are invented. Mixed sort of investment, venture capitalists need to be strengthened.
Main recommendations in the document related to Biotechnology financing 'In order to enhance Industrial Biotech R&D and innovation, a regulatory framework should be created that stimulates venture capital for Industrial Biotechnology start-ups and investments, enables subsidizing application research and promotes investments in pilot equipment and plants.' 'Because of the federal structure of Belgium, there is a permanent risk of funding parallel or redundant R&D and industrial efforts in all three regions. Whilst there is an obvious rationale for regional funding and incentives, there is an equally obvious need for coordination and collaboration across the regions barrier. We see here a particular task for the federal government science agencies for facilitation of inter-regional research collaboration. [...] It must be possible to collaborate across the regional barriers, regardless the fact that such research programs are funded by the respective regional research agencies.' 'Finally, present research programs at regional and federal level must be improved. Indeed, these programs are not appropriate to promote and finance interdisciplinary research: budgets are too small to support the critical mass of researchers needed to carry out interdisciplinary projects.'
'A central, continuously updated website [...] would increase the attractiveness of Belgian partners for participation in EU RTD Framework Programme (FP) projects, all the more so since some FP projects are only partly funded with EU money and will typically require complementary funding at federal and regional level.'
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://www.belspo.be/belspo/home/actua/2006_03_30_BIPIB_en.pdf

Name of the Policy Document/Report in original language
Life sciences and biotechnology – a strategy for Europe
Name of the Policy Document/Report in English
<i>Life sciences and biotechnology – a strategy for Europe</i>
Year of the preparation of the document
2002
Name of the organization(s) which has prepared/adopted the Document
Commission of the European Communities
Coverage of the document i.e national, regional, European
European
What type of biotechnology is concerned by the publication
Any
Main conclusions in the document related to Biotechnology financing
<ul style="list-style-type: none"> - “Structurally, biotechnology SMEs are very capital-intensive available, and investments have long payback periods. Risk capital funding has been increasingly available, but does not appear to be sufficient at all stages of the long company development process.”
Main recommendations in the document related to Biotechnology financing
<ul style="list-style-type: none"> - “Stronger interregional co-operation, e.g. through a network of biotechnology regions. Crossborder and interregional co-operation can receive funding from the Interreg programmes.” - “Networks of biotechnology clusters. In addition, the Commission will organize a European competition between Biotechnology Innovation clusters, to highlight their capability to develop a cluster with a focus of excellence in a specific scientific field.”
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf

Name of the Policy Document/Report in original language	Attirer les capitaux dans les grandes sociétés... quand elles sont encore petites
Name of the Policy Document/Report in English	<i>Attract capital into big companies... when they're still small</i>
Year of the preparation of the document	1997
Name of the organization(s) which has prepared/adopted the Document	Cordis - Europa
Coverage of the document i.e. national, regional, European	European
What type of biotechnology is concerned by the publication	Any
Main conclusions in the document related to Biotechnology financing	<p>- Une des responsabilités majeures pour l'Union européenne est l'harmonisation du cadre opérationnel (environnement réglementaire et fiscal). Cependant certaines actions peuvent être soutenues par les pouvoirs publics à condition qu'elles soient gérées et conduites par les opérateurs privés en respect des règles du marché. Enfin, puisque l'innovation comporte une dimension culturelle cruciale, les pouvoirs publics doivent soutenir la promotion de son financement par l'échange des bonnes pratiques et la mise en réseau des opérateurs au niveau européen.</p> <p>Le premier Plan d'Action européen pour l'innovation a identifié quatre niveaux d'actions pour améliorer le financement de l'innovation :</p> <ul style="list-style-type: none"> • Encourager l'investissement en capital-risque et en fonds propres, en particulier pour les nouvelles entreprises (capital d'amorçage) et les entreprises à forte croissance, qui constituent une importante source de création de nouveaux emplois; • Développer un marché transeuropéen des capitaux pour les entreprises innovantes, apte à être le pendant du Nasdaq américain; • Améliorer les interfaces entre les acteurs de l'innovation, à commencer par les participants aux programmes de recherche communautaires et les milieux financiers; • Promouvoir l'accès aux financements bancaires à long terme pour les entreprises opérant dans le secteur des technologies de pointe. <p>- One of the main responsibilities for the EU is to harmonize the agenda (legal and regulatory framework). However, some actions can be supported by the public sector if</p>

they are managed by private operators within the market laws. Finally, since cultural aspects are crucial for innovation, the public sector must go on promoting funding with the exchange of best practice and the networking between European operators.

The first European Action Plan for innovation has identified four levels of action to improve the innovation financing:

- To encourage investments in venture capital and in personal funds, especially for new companies and start-ups (important source for job creation)
- To develop a panEuropean market of capital for innovative companies
- To improve interaction between actors and participants of research and financial sector
- To promote the access to funds for companies that are in the high technological sector.

Main recommendations in the document related to Biotechnology financing

- Develop the four points above

Have some of the recommendations been implemented yet, if yes, which ones

Other relevant information

<http://cordis.europa.eu/itt/itt-fr/97-6/dossier2.htm>

Name of the Policy Document/Report in original language
Business Opportunities in the Biotechnology Industry
Name of the Policy Document/Report in English
<i>Business Opportunities in the Biotechnology Industry</i>
Year of the preparation of the document
2000/2001
Name of the organization(s) which has prepared/adopted the Document
Embassy of Belgium; Washington DC
Coverage of the document i.e national, regional, European
National
What type of biotechnology is concerned by the publication
Any
Main conclusions in the document related to Biotechnology financing
<ul style="list-style-type: none"> - Today, Belgium has about 100 companies active in biotechnology and, with a net revenue of 1.6 billion of dollars, the biotech sector in Belgium witnessed a growth of 30% in revenues in 2000. Annual R and D budgets increased on average by 40% each year over the past five years. Belgian biotech companies figure prominently among the fastest growing companies in Europe. - Tax exemptions for additional personnel employed for scientific research and the development of technical potential. - Regional investment aid is available up to 24% of the eligible investment. - The regional and federal authorities subsidize the hiring and training of employees. - More than 100 VC companies, including many of the major European venture capital companies, are ready to invest in the biotech sector.
Main recommendations in the document related to Biotechnology financing
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://www.diplobel.us/TradeInvestment/Publications/Biotechnology.pdf

Name of the Policy Document/Report in original language Biotechnology in Europe: 2006 Comparative study
Name of the Policy Document/Report in English <i>Biotechnology in Europe: 2006 Comparative study</i>
Year of the preparation of the document 2006
Name of the organization(s) which has prepared/adopted the Document EuropaBio
Coverage of the document i.e national, regional, European European
What type of biotechnology is concerned by the publication Any
Main conclusions in the document related to Biotechnology financing <ul style="list-style-type: none"> - In 2003 in Belgium, 26 million of euros were venture capital investments. In 2006; VC investments amounted to 100 million euros. - Belgium: 2002-2004 <ul style="list-style-type: none"> 1. VC: 127 Million of euros 2. Total Equity: 175 Million of euros 3. Public Equity: 23 Million of euros 4. Debt: 26 Million of euros - In 2005, Devgen initiated a public offering of 27 million of euros. - In 2004, Diatos raised venture capital rounds above 31 million of euros, and Ablynx 25.
Main recommendations in the document related to Biotechnology financing <ul style="list-style-type: none"> - The insufficient and unsustained stream of finance for biotechnology lead to the following consequences: - Many companies are founded, but most are distracted from the business of building value by the preoccupation of staying in business. - European biotechnology firms grow far more slowly than their better funded counterparts in the USA. - Young European firms are overtaken by their competitors and thereby relinquish any competitive edge they had at the outset. - European firms, on average, do not compete well in international markets for the substantial tranches of finance needed to propel them towards economic competitiveness and sustainability. - A series of relatively mature European biotechnology firms have been acquired by better funded US counterparts: some of those that remain are looking to establish a presence in the USA specifically to access the more generous financial market. This often means that value-creating research, development and manufacturing jobs are, in effect, exported. - In Europe, venture capitalists invest largely in 'old' companies, and do not feel comfortable getting involved at early stage financing schemes.

Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://www.europabio.org/CriticalI2006/Critical2006.pdf

Name of the Policy Document/Report in original language
La consolidation du secteur mondial des biotechnologies humaines
Name of the Policy Document/Report in English
<i>Human biotechnology's consolidation worldwide</i>
Year of the preparation of the document
2004
Name of the organization(s) which has prepared/adopted the Document
EuroStaf
Coverage of the document i.e national, regional, European
Worldwide
What type of biotechnology is concerned by the publication
Human
Main conclusions in the document related to Biotechnology financing
<ul style="list-style-type: none"> - To attract new investors, new development possibilities are invented. - Mixed sort of investment, venture capitalists need to be strengthened.
Main recommendations in the document related to Biotechnology financing
<ul style="list-style-type: none"> - Increase VC investments.
Have some of the recommendations been implemented yet, if yes, which ones
N/A
Other relevant information
http://www.eurostaf.fr/fr/catalogue/conso_sect_mondial_biotech/sommaire.html?P_HPSSESSID=p9k77qss6q6t4k69u8eesadji0

Name of the Policy Document/Report in original language Working Paper – Venture Capitalists’ selection process : the case of biotechnology proposals
Name of the Policy Document/Report in English <i>Working Paper – Venture Capitalists’ selection process : the case of biotechnology proposals</i>
Year of the preparation of the document June 2005
Name of the organization(s) which has prepared/adopted the Document Universiteit Gent
Coverage of the document i.e national, regional, European National
What type of biotechnology is concerned by the publication Any
Main conclusions in the document related to Biotechnology financing <ul style="list-style-type: none"> - In contrast with the US and the UK where most studies on venture capital are done, Belgium has a Continental European financial system. The venture capital industry is nevertheless quite well developed in Belgium compared to other European countries. Biotech investments are high in Belgium compared to the UK, except in 2003. This shows that Belgian VCs are active in the biotech sector and that the research setting is appropriate to study the investment behaviour of Continental European VCs. The major players within the Belgian venture capital sector are independent VCs, public sector VCs and semi-captives, with respectively 62%, 17%, and 12% of the total number of investments in 2003. - [...] we estimate that the total population of Belgian VCs with a potential interest in biotech proposals amounts to 25 of which 16 (64%) are included in the sample. There is a good balance between early stage and later stage VCs in our sample, ranging from seed financing specialists to pre-IPO investors, but most VCs have a broad investment strategy covering several stages of development. Eight out of sixteen VCs are independent and private. - See figure 2: Investments in Biotechnology as a percentage of GDP Belgium vs. UK
Main recommendations in the document related to Biotechnology financing
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://www.feb.ugent.be/fac/research/WP/Papers/wp_05_313.pdf



Name of the Policy Document/Report in original language Belgique

Name of the Policy Document/Report in English <i>Belgium – research and technology review</i>

Year of the preparation of the document April 2004
Name of the organization(s) which has prepared/adopted the Document Ministère des Affaires étrangères
Coverage of the document i.e national, regional, European National
What type of biotechnology is concerned by the publication Any
Main conclusions in the document related to Biotechnology financing
<p>Les mesures fiscales en faveur de la R&D</p> <ul style="list-style-type: none"> ▶ Réduction du précompte professionnel : Depuis la fin 2003, les universités, écoles supérieures ou organismes de recherche (comme le FNRS ou le FWO) bénéficient d'une réduction fiscale équivalent à 50 % de précompte professionnel dû sur les rémunérations des chercheurs. Cette économie fiscale doit être directement réinvestie dans de nouveaux projets scientifiques. En termes de chiffres, cette mesure représente une ristourne annuelle de près de 30 millions d'euros. Cette mesure pourrait s'étendre aux centres de recherche régionaux, aux institutions scientifiques, voire aux chercheurs du secteur privé. ▶ Réduction des charges sociales pour les entreprises embauchant de nouveaux chercheurs : cette mesure existe depuis plusieurs années et consiste en une déduction fiscale de 10 000€ pour le recrutement d'un jeune chercheur supplémentaire et de 20 000€ lorsqu'il s'agit d'un chercheur hautement qualifié. ▶ Diminution de la TVA sur le matériel acquis par des chercheurs. <p>Mesures financières favorisant l'attractivité « scientifique » de la Belgique</p> <ul style="list-style-type: none"> ▶ Mandats de retour pour les chercheurs belges travaillant à l'étranger : Dans le cadre de la promotion de l'Espace européen de la Recherche, la Politique scientifique fédérale a initié l'octroi de Mandats de retour destinés à rapatrier les chercheurs hautement qualifiés (docteurs ou expérience équivalente) travaillant depuis au moins 2 ans dans un centre de recherche situé hors UE, ou au moins 4 ans pour les pays de l'UE. ▶ Bourses pour chercheurs de pays de l'Est. ▶ Suppression de la nécessité d'avoir un permis de travail pour les chercheurs étrangers venant travailler sous contrat dans une université belge (sur le modèle du visa scientifique français) ▶ Protection sociale assurée par la Belgique aux européens et ressortissants de pays avec

qui la Belgique a conclu des accords (chercheurs ‘postdoc’ ou doctorants).

Fiscal measures in favour of R&D

Tax relief: Since the end of 2003, universities, private universities or research organisations (like the FNRS or the FWO) benefit from a tax relief up to 50% off the researchers' wages. This fiscal saving must be directly re-invested in a new scientific project. In terms of numbers, the measure equals 30 million of euros per year of savings. This measure could be broadened to regional centres of research; scientific institutions or even to researchers from the private sector.

Tax exemptions: For any additional personnel employed for scientific research. This measure has existed for years and equals a 10 000 euros saving for each person employed, and 20 000 euros for a highly qualified researcher.

VAT deduction on equipment bought by the researcher.

Financial measures aimed at increasing the scientific attraction of Belgium:

Belgian researchers working abroad: In the objective of promoting the European Research programmes; the federal government decided to stress the need for the high qualified researchers (PhDs or equivalent experience) who have worked outside of the EU for more than 2 years or inside for more than 4 years in a research centre to come back to Belgium.

Grants for Eastern European researchers.

No need for working permits for foreign researchers who work under a contract with a Belgian universities (Following the scientific Visa French model)

Social protection provided by Belgium to Europeans / other contracted countries (researchers PhDs or Masters)

Main recommendations in the document related to Biotechnology financing
Tax incentives are key to the development of biotechnology.

Have some of the recommendations been implemented yet, if yes, which ones

Other relevant information

http://www.diplomatie.gouv.fr/fr/actions-france_830/education-universite-formation_1043/forum-curie_4931/fiches-curie-recherche_4959/europe_5435/belgique_14774.html#sommaire_4

Name of the Policy Document/Report in original language
Pharmaceutical Biotechnology in Luxembourg
Name of the Policy Document/Report in English
<i>Pharmaceutical Biotechnology in Luxembourg</i>
Year of the preparation of the document
September 2005
Name of the organization(s) which has prepared/adopted the Document
International Business Strategies
Coverage of the document i.e national, regional, European
National
What type of biotechnology is concerned by the publication
Pharmaceutical
Main conclusions in the document related to Biotechnology financing
<ul style="list-style-type: none"> - Competitive Business Advantages in Luxembourg
Main recommendations in the document related to Biotechnology financing
N/A
Have some of the recommendations been implemented yet, if yes, which ones
N/A
Other relevant information <u>http://www.internationalbusinessstrategies.com/data/TOC/34670509Luxembourg_biotech_pages1-2.pdf</u>

Name of the Policy Document/Report in original language
The Bioeconomy to 2030: Designing a Policy Agenda
Name of the Policy Document/Report in English
<i>The Bioeconomy to 2030: Designing a Policy Agenda</i>
Year of the preparation of the document
6 March 2006
Name of the organization(s) which has prepared/adopted the Document
OECD
Coverage of the document i.e national, regional, European
Worldwide
What type of biotechnology is concerned by the publication
Any
Main conclusions in the document related to Biotechnology financing
Main recommendations in the document related to Biotechnology financing <ul style="list-style-type: none"> - Provide an assessment of the long-term prospects for the bioeconomy. - Identify potential problems and define key elements of the policy framework needed for realizing the potential development. - Identify areas for private/public co-operation in the development of applications. - Develop a framework for the articulation of bioeconomy metrics. - Facilitate dialogue among diverse interests. - Identify areas where international co-operation could be strengthened.
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://www.oecd.org/dataoecd/26/29/36972476.pdf

Name of the Policy Document/Report in original language
OECD Biotechnology Statistics 2006
Name of the Policy Document/Report in English
<i>OECD Biotechnology Statistics 2006</i>
Year of the preparation of the document
2006
Name of the organization(s) which has prepared/adopted the Document
OECD
Coverage of the document i.e national, regional, European
European
What type of biotechnology is concerned by the publication
Any
Main conclusions in the document related to Biotechnology financing
<ul style="list-style-type: none"> - In 2003, 16% of companies reported raising venture capital funds. - From 2001 to 2003, the total venture capital investments in biotechnology amounted 124 million of dollars. - Investments go at first to the Proteins/Molecules type of Biotechnology. - There is no official data on Luxembourg.
Main recommendations in the document related to Biotechnology financing
<ul style="list-style-type: none"> - Investments should stress the importance of the DNA Biotechnological Research in the near future.
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information http://www.oecd.org/dataoecd/51/59/36760212.pdf

Name of the Policy Document/Report in original language Biotech in Wallonia

Name of the Policy Document/Report in English Biotech in Wallonia

Name of the Policy Document/Report in English Biotech in Wallonia

Year of the preparation of the document 2005

Name of the organization(s) which has prepared/adopted the Document Recherche technologique Wallonie

Coverage of the document i.e national, regional, European Regional

What type of biotechnology is concerned by the publication Any

Main conclusions in the document related to Biotechnology financing

<ul style="list-style-type: none"> - ‘Evaluating and funding scientific projects is the task of the Direction générale des Technologies, de la Recherche et de l’Energie (DGTR). Companies can ask to share the risk of investing in innovative research and development. The experienced staff at the DGTR has designed a comprehensive series of financial incentives and subsidies to meet the needs of companies from start-ups to established enterprises. This is a real engine if growth for the sector in Wallonia and a strong stimulant for companies to exploit research results.’ - ‘Beside its traditional core activities, the Société Régionale d’Investissement de Wallonie (SRIW) has participated in the creation of several VC funds, i.e. Start-It, dedicated to investment in start-up companies in the biotech and high tech sectors, E-Capital targeted at fast growing companies and some university funds - has expanded outside the country’s boundaries through the creation of Cossom, a subsidiary handling foreign international investments- works actively in cooperation with the eight stage financing and with university funds for seed capital – networks regularly with venture capital and private equity funds to grant substantial financing rounds and to secure sequential investments for rapidly growing companies.’ - ‘To obtain its required funding the biotechnology sector in Wallonia can also count on an active and rapidly growing pool of private venture capitalists and private equity funds and on strong university support.’ - ‘Specialized venture capital funds [...] support Wallonia biotechnology companies through equity or mezzanine financing. In addition, these investors participate in mixed funds together with universities and local and regional investment companies.’
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Main recommendations in the document related to Biotechnology financing Public and private sectors must cooperate more.
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Have some of the recommendations been implemented yet, if yes, which ones

Other relevant information

http://recherche-technologie.wallonie.be/servlet/Repository/Biotech_in_Wallonia_Report.PDF?IDR=862

Name of the Policy Document/Report in original language <i>Life Sciences and Biotechnology: A strategy for Europe</i>
Name of the Policy Document/Report in English <i>Life Sciences and Biotechnology: A strategy for Europe</i>
Year of the preparation of the document 2002
Name of the organization(s) which has prepared/adopted the Document European Commission
Coverage of the document i.e national, regional, European Europe
What type of biotechnology is concerned by the publication Topics relating to health, ageing, food and the environment and to sustainable development
Main conclusions in the document related to Biotechnology financing European investment in R & D is lagging behind the United States. Moreover, Europe suffers from fragmentation of public research support, and from the low level of interregional cooperation in R & D, among companies and institutions from different regions of several States. (Page 13) Risk capital funding has been increasingly available, but does not appear to be sufficient at all stages of the long company development process. (Page 16) Biotechnological inventions require high capital investment, long development cycles and comprehensive regulatory approval. Effective patent protection is a crucial incentive to R & D and innovation and an essential means of guaranteeing return on investment. (Page 22)
Main recommendations in the document related to Biotechnology financing The Commission and the Member States should also in collaboration with the European Investment Fund (EIF) develop a competitive bioinformatics infrastructure in support of biotechnology research and focus support for the development of research in computational biology and biomedical informatics. (Page 35) The Commission should, together with the European Investment Bank (EIB) and the European Investment Fund (EIF), strengthen the capital base for the biotechnology industry by: a) seeking to stimulate investments in research and technological innovation via complementary financing on the basis of the cooperation agreement, signed in June 2001, between the Commission and the EIB group; b) seeking to stimulate investments in business incubators through the EIF start-up facility; c) studying measures to support technology transfer mechanisms, such as financing of patent pools or other methods for patent exploitation; d) studying measures to encourage commercial financing of companies based on a medium term investment perspective. (Page 36) The Commission will strengthen the work of the Biotechnology and Finance Forum by the inclusion of relevant major stakeholders to provide advice in policy development in the field of capital supply. (Page 37)
Have some of the recommendations been implemented yet, if yes, which ones

Other relevant information
Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>Biotechnology in Sweden: A National Biotech Agenda For Growth</i>
Year of the preparation of the document 2003
Name of the organization(s) which has prepared/adopted the Document The Swedish Biotechnology Industry Organization
Coverage of the document i.e national, regional, European National, Sweden
What type of biotechnology is concerned by the publication Swedish biotech industry is highly focused on healthcare.
Main conclusions in the document related to Biotechnology financing Sweden provides few tax incentives to invest in biotech R&D (Page 14) Sweden invests too little public money into biotech research (Page 16) Swedish biotech companies suffer from a lack of capital in early stages (Page 19)
Main recommendations in the document related to Biotechnology financing Increase the funding for competitive biomedical R&D projects (Page 33) Stimulate R&D investments through tax incentives (Page 33) Co-fund a 2 year Post-Doc program for the life science industry (Page 34) Focus R&D funding to 3-4 geographic centers-of-excellence (Page 35) Focus R&D funding to key scientific areas (Page 35) Create a pre-seed fund to enable innovators to validate the technical and commercial concept (Page 36) Encourage business angels to invest in early stage, biotech ventures (Page 36) Create a seed and bridge fund to co-invest with private investors (Page 37) Create an outsourcing fund for companies to collaborate with universities (page 37) Encourage pension funds to invest in biotechnology (Page 37)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>The Bio-Health Industry in Denmark</i>
Year of the preparation of the document 2002
Name of the organization(s) which has prepared/adopted the Document Danish Government Vision Round Table
Coverage of the document i.e national, regional, European National, Denmark
What type of biotechnology is concerned by the publication Bio-health
Main conclusions in the document related to Biotechnology financing The vision for a Danish bio-health strategy should be that Denmark – particularly Medicon Valley in co-operation with the other Danish regions – in 2010 should be among the most competitive bio-health regions in Europe both in terms of scientific achievement and industrial growth. The realisation of this vision requires a committed focus on key issues: <ul style="list-style-type: none">• Substantial investments targeted on excellent research, innovation and infrastructure• Access to equity capital in all phases of company development• Public legislation and taxation conducive to entrepreneurship, partnerships and product development (Page 4)
Main recommendations in the document related to Biotechnology financing 2. Competitive public funding of world class research <ul style="list-style-type: none">• Research investments are long-term investments that should not be neglected in the light of short-term fiscal problems. Investments must be targeted on the excellent researchers and research groups – and not evenly spread.• In comparison to the competing countries/regions Denmark has previously been a late arriver when it comes to research investments. It is therefore important that public research investments are deployed earlier in new scientific fields that rest on existing pillars of strength. Multidisciplinary research combining biotechnology with other technologies such as, e.g., nano-, information- and materials technologies should be a high priority investment area.• Danish universities compete not only with each other but also with the best European and other foreign universities. Research investments should therefore be based on assessments of the capacity of the universities to excel in science and education. Universities should compete for resources in order to ensure excellence in research teams.• The future Danish research priorities for the bio-health area should be more aligned with the EU 6th Framework Programme in order to attract maximum funding. (Page 7-8) 3. More industrial co-financing of public research <ul style="list-style-type: none">• Industry should increase co-financing of research projects, Graduate Schools of

Research etc. at public institutions of industrial interest.

- The public sector should support industrial co-financing by developing models for co-financing of a simple and transparent character while safeguarding the independence of research. **(Page 8)**

7. Continuous access to equity capital

- It is important that the capital market can supply swift and competent capital for all phases of the development of new products and firms. The Danish venture capital market has improved considerably during the last decade. However, there is still a need for public pre-seed capital, which the private market cannot supply alone.
- The Growth Fund should refrain from competing with private venture funds and act more like a business angel. It should expedite the deployment of capital, offer loans with less strings attached and accept higher risks. A company receiving loans from the Growth Fund should be given the option to repay the loan when it manages to attract further finance or to convert the loan into shares which are given to the Growth Fund.

(Page 10-11)

Have some of the recommendations been implemented yet, if yes, which ones

Other relevant information

Name of the Policy Document/Report in original language Towards a Biotech Ireland: Building Biotech Business
Name of the Policy Document/Report in English Towards a Biotech Ireland: Building Biotech Business
Year of the preparation of the document 2001
Name of the organization(s) which has prepared/adopted the Document Enterprise Ireland
Coverage of the document i.e national, regional, European National, Ireland
What type of biotechnology is concerned by the publication
Main conclusions in the document related to Biotechnology financing Science Foundation Ireland will, during the period 2001 to 2006, invest around €320m in supporting leading-edge bio-research within Irish Third Level institutions. (Page 2) The returns from successful biotechnology development are potentially great, and are sufficient to justify the challenges in terms of commercially viable proprietary technology development and the need for business strategies attractive to providers of long-term capital. (Page 2) A vibrant Venture Capital market, focused on investing in biotechnology, is an essential component in developing the industry (Page 9)
Main recommendations in the document related to Biotechnology financing Within the National Strategy framework, Enterprise Ireland's Biotechnology and Life Science Industry Strategy aims to: Nurture the development of early-stage biotechnology companies Promote and support the development of the private sector seed and venture capital environment in Ireland, open to investing in commercially attractive biotechnology companies. (Page 6) Enterprise Ireland will play a key role in nurturing the development of early stage companies by: Supporting applied research projects Funding early-stage business development activities (Page 7)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>Malta National Strategic Plan for Research and Innovation 2007-2010</i>
Year of the preparation of the document 2006
Name of the organization(s) which has prepared/adopted the Document Malta Council for Science and Technology
Coverage of the document i.e. national, regional, European National, Malta
What type of biotechnology is concerned by the publication Health-Biotech
Main conclusions in the document related to Biotechnology financing
Main recommendations in the document related to Biotechnology financing Recommendation No 2 Government financing and State intervention over the period of this strategy should focus on the following areas; designated as platforms of strategic importance: Health-Biotech with focus on human genetics, bio-informatics for support of clinical trials including pharmacogenetic ones and bio-technology for transition of generic pharma. (Page 42)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>Realising a Thriving Maltese Biotechnology Industry by 2015: Vision Report on the eFORESEE Malta Biotechnology Foresight Pilot Project</i>
Year of the preparation of the document 2003
Name of the organization(s) which has prepared/adopted the Document eFORESEE and Malta Council for Science and Technology
Coverage of the document i.e national, regional, European National, Malta
What type of biotechnology is concerned by the publication Healthcare applications, Agriculture and food production
Main conclusions in the document related to Biotechnology financing
Main recommendations in the document related to Biotechnology financing The vision for 2015: Funding for Research and Development <ul style="list-style-type: none"> • Increased budgets of tertiary level institutions for research and development work. • Established of a National Program for Scientific Research, Technological Development and Innovation at 3% of GDP with participation of academic, public and private organizations (Public: Private contributions at 1:2). • Increased participation of private sector in funding research (60% of National spending). • Corporate Academy: linking academic research with business development. • Increased participation in EU framework and other R&D programs. (Page 27)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language Marine Biotechnology: A European Strategy for Marine Biotechnology
Name of the Policy Document/Report in English Marine Biotechnology: A European Strategy for Marine Biotechnology
Year of the preparation of the document 2001
Name of the organization(s) which has prepared/adopted the Document European Science Foundation
Coverage of the document i.e. national, regional, European Europe
What type of biotechnology is concerned by the publication Marine biotechnology
Main conclusions in the document related to Biotechnology financing Biotechnology is an area of key national and international importance particularly in R&D as a foundation for the growth of industry, technology and medicine. Unfortunately, Europe has remained uncoordinated in its approach to reaping the benefits of marine biotechnology. This, however, can be reversed through the development and execution of an integrated strategy involving the following elements: <ul style="list-style-type: none"> • Funding, in a coordinated manner, creative, well-planned multi- and interdisciplinary research programmes. (Page 16) • Europe must invest in expanding the knowledge base on marine life so that its intelligent management and application can be achieved. (Page 18)
Main recommendations in the document related to Biotechnology financing ...participants with commercial R&D, economic, business and marketing expertise should also be involved at some stage in the programme. Recognizing the large variety of approaches by which developments in biotechnology have been and are being commercialized (spin-off, start-ups, joint ventures, strategic alliances, limited partnerships, acquisitions etc.), the initiative will not focus on a specific mode of commercialization. (Page 15)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>Industrial (White) Biotechnology: An Effective Route to Increase EU Innovation and Sustainable Growth</i>
Year of the preparation of the document 2003
Name of the organization(s) which has prepared/adopted the Document Unlimited. DSM (www.dsm.com)
Coverage of the document i.e. national, regional, European Europe and National, Netherlands
What type of biotechnology is concerned by the publication White biotechnology
Main conclusions in the document related to Biotechnology financing Dutch-based life sciences companies have an overall yearly turnover of more than € 49 billion, invest € 950 million in research and development every year and employ 255,000 people. A substantial part of these life-sciences activities are devoted directly or indirectly to industrial biotechnology. (Page 11) Europe has considerable assets in the field of industrial biotechnology: for instance 70% of the world enzyme industry is European and a high level of knowledge in the field of food technology and fine chemistry is located in Europe. Moreover, there is a strong political and public sentiment to improve industrial sustainability in Europe (Gothenburg objectives10) and the objective to become the most competitive and dynamic knowledge based economy in the world by 2010 (Lisbon strategy11). Europe, however, invests less in R&D (1.9% of GDP in 2000 and even less after enlargement given that accessing countries have an average R&D level of 0.7%) than the US (2.7 % in 2000) and Japan (3% in 2000) ^{2,11} , and suffers from fragmented R&D funding and infrastructure. In the remaining six years, all Member States will have to take major steps to reach the Lisbon target of 3% by 2010. (Page 14)
Main recommendations in the document related to Biotechnology financing Dutch Government should take concrete steps to fully support the Dutch taskforce in order to: <ul style="list-style-type: none"> • propose special R&D programmes in order to fill the gaps in the industrial biotechnology R&D portfolio (e.g. systems biology, biomaterials); • select and launch two or three demonstration projects; • create a top Dutch institute on industrial biotechnology based on, or as a follow up of the existing industrial biotech R&D initiatives, which should operate as a European centre of excellence for science and education; (Page 13) In addition to these measures, it is proposed to create substantial (tax) incentives for all (new) start-ups, including those initiatives in white biotechnology, based on one of the following measures: <ul style="list-style-type: none"> • The French Young Innovative Company (YIC)⁸ status, which includes uncapped exemption of local business tax, exemption of social costs for employees involved in R&D for the first eight years, income tax exemption for the first three profitable years

and 50% (or €100,000) relief of income tax for the following two years; and • The UK's new fund vehicle, called Enterprise Capital Fund, based on the US Small Business Innovation Company (SBIC) model ⁹ . The main objective is to enable these Enterprise Capital Funds to use "soft" government loans to leverage private capital and <u>bridge the equity gap between business angels and private equity houses. (Page 13)</u> Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language Nationaler Forschungs- und Innovationsplan
Name of the Policy Document/Report in English National Research and Innovation Plan (Austria)
Year of the preparation of the document 2002
Name of the organization(s) which has prepared/adopted the Document Austrian Council
Coverage of the document i.e. national, regional, European National, Austria
What type of biotechnology is concerned by the publication
Main conclusions in the document related to Biotechnology financing
Main recommendations in the document related to Biotechnology financing A long-term secure financial base needs to be created for the Funds so that the necessary capital increases do not have to be financed year for year by fluctuating and, therefore uncertain, non-budgetary revenue or RTD special funds. (Page 48)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>ScanBalt Strategy 2006-2008</i>
Year of the preparation of the document 2001
Name of the organization(s) which has prepared/adopted the Document ScanBalt
Coverage of the document i.e. national, regional, European Regional, ScanBalt BioRegion, Finland, Estonia, Latvia, Lithuania, Denmark, Sweden, Poland, Norway, Russia, Germany, Iceland
What type of biotechnology is concerned by the publication
Main conclusions in the document related to Biotechnology financing ScanBalt hosts a number of activities, and a number of funding sources are involved. At the international level ScanBalt is presently receiving funding from The European Commission, the Nordic Innovation Centre and Norfa – “The Nordic Academy for Advanced Study”. At the national/regional level ScanBalt are presently involved in a number of projects with partnership based co-financing.
Main recommendations in the document related to Biotechnology financing Communication and Transparency: attract human and financial resources
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English Ireland - ICSTI Statement: Strategic Technology Platforms
Year of the preparation of the document 2004
Name of the organization(s) which has prepared/adopted the Document Irish Council for Science, Technology and Innovation
Coverage of the document i.e. national, regional, European National, Ireland
What type of biotechnology is concerned by the publication
Main conclusions in the document related to Biotechnology financing ICSTI subsequently agreed that the Technology Foresight recommendations were still valid, that their implementation in key areas was on track, and that there was a need to maintain this momentum. It was agreed that the focus on excellence in the ICT and biotechnology areas remains appropriate to Ireland's development. However, it was recognized that this is a long-term investment. (Page 9) BERD in pharmaceuticals is, by comparison, relatively low. The pharmaceuticals sector has been identified as the largest employer in the biotechnology sector in Ireland, but it is characterized by lack of innovation locally. ICSTI highlights the need to address how the significant public investment in biotechnology can be best used to leverage increased business R&D and value-adding activity in Ireland; (Page 15) ICSTI concludes that Ireland has scope to increase R&D investment by business in the high technology industries by leveraging the strategic national investment in biotechnology and ICT. However, Ireland cannot be competitive in all areas, and even the selected areas of ICT and biotechnology are very broad. Investment needs to be strategically focused on those areas of greatest relevance to Ireland's enterprise and to its strengths in natural resources. In particular, there are opportunities for Ireland in pharmaceuticals, print, paper and publishing, as well as in food and beverages. (lk 15)
Main recommendations in the document related to Biotechnology financing ICSTI recommends that Strategic Technology Platforms be developed as a mechanism for: <ul style="list-style-type: none">• Selecting areas of research for funding;• Setting an industry-focused applied research agenda;• Creating industry-led clusters, involving small and large firms, both indigenous and foreign-owned;<ul style="list-style-type: none">• Stimulating research in industry, or funded by industry, or commissioned by industry with State support;<ul style="list-style-type: none">• Attracting targeted Foreign Direct Investment;• Focusing the activities of State agencies. (Page 19)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information



Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>Industry Strategy for Malta 2007-2010</i>
Year of the preparation of the document
Name of the organization(s) which has prepared/adopted the Document The Prime Minister and the Ministry for Investment, Industry and Information Technology
Coverage of the document i.e. national, regional, European National, Malta
What type of biotechnology is concerned by the publication
Main conclusions in the document related to Biotechnology financing Government believes that the following are the Sectors and Activities that Malta should target: Biotechnology, Bio-informatics and Pharmaceuticals: Malta has managed to build a successful pharmaceutical industry through certain patent legal provisions. The challenge is to transform this industry into a permanent feature of our industrial landscape. The evolution of excellent centres for bio-equivalence testing as well as clinical trials would constitute an anchor that could successfully generate further growth in this regard; particularly when coupled with the favourable cost and skills of Maltese labour. Malta has a comparative advantage in the bio-technology and bio-informatics areas. This arises from the fact that the Maltese population is relatively young and thus comparatively undiluted in terms of its genetics. This provides a ‘founding’ effect where genetics ‘errors’ can be identified by use of smaller clusters of population sample resulting in a higher identification of genetic ‘errors’ than what would be required for research undertaken in other societies. This can enable better ‘quick-to-market’ transition from genetic error identification to the development of new medication. (Page 34-35)
Main recommendations in the document related to Biotechnology financing This Strategy strongly argues that for R&I to flourish fundamental and critical enabling frameworks must be put into place. The Strategy sets out the following recommendations: Health-Biotech: with focus on human genetics, bio-informatics for support of clinical trials including pharmacogenetic ones and bio-technology for transition of generic pharma. (Page 88-89) Whilst focus of State financing and intervention should not be diluted from the designated platforms of strategic importance, flexibility should be retained in both planning and in responding to arising opportunities. (Page 89)
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information



Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English Austria: Land of Research
Year of the preparation of the document
Name of the organization(s) which has prepared/adopted the Document Das Zukunftsministerium
Coverage of the document i.e. national, regional, European National, Austria
What type of biotechnology is concerned by the publication
Main conclusions in the document related to Biotechnology financing The Sixth Research Framework Programme, which is funded with a total of EUR 9.2 billion and will run until the end of 2006, is also proving very successful. Just over halfway through the Sixth Research Framework Programme, Austrian researchers are involved in 5.6 percent of all successful project proposals, i.e. a total of 945. Most of Austria's receipts come from the two programmes IST (Information Society Technologies) and Genomics and Biotechnology for Health. (Page 11)
Main recommendations in the document related to Biotechnology financing
Have some of the recommendations been implemented yet, if yes, which ones
Other relevant information

Name of the Policy Document/Report in original language
Name of the Policy Document/Report in English <i>Research on the Estonian biotechnology sector innovation system</i>
Year of the preparation of the document 2003
Name of the organization(s) which has prepared/adopted the Document Fraunhofer Institute Systems and Innovation Research
Coverage of the document i.e. national, regional, European National, Estonia
What type of biotechnology is concerned by the publication Biotechnology research and industrial biotechnology
Main conclusions in the document related to Biotechnology financing The annual institute budget varied in 1999 between 1.45 million EEK and 20 million EEK, in 2001 between 1.7 million EEK and 30 million EEK. The average budget of the six answering institutions rose from 6.6 million EEK in 1999 to 8.6 million EEK in 2001. Taking the inflation into account the net average annual budget of the research institutes rose by 7.1 % in 2000 and by 10.2 % in 2001. These numbers are relatively high and illustrate the efforts which are undertaken to support biotechnological research in Estonia (table 2.4). The share of the institute's budget spent for biotechnology research varied between 20 % and 100 %. (Page 24)
Biotechnology-related research projects are equally financed by Estonian funding and EU funding. Taking this, 40 % to 50 % of research was carried out on EU funds. Taking the overall financial situation of the institutes that answered the questionnaire, which includes both expenses for teaching and research, 35 % of the average annual institute's budget originates from basic public funding. Nearly 40 % originates from Estonian project funding and 12 % are research funds of the EU, 6 % national funds others than Estonian ones (e. g. USA, Sweden, Finland), and 7 % originate from industry, contract research or clinical trials and service. Contract manufacturing or counselling contributes only with 2 % to the total institute's budget. (Page 24-25)
Due to the small size of most Estonian biotech companies, the investments used in the founding period were rather low. People mostly preferred to use their own money instead of applying for loans from either ESTAG or commercial banks. (Page 40)
The availability of venture capital for small biotech companies is rather the exception than the rule in Estonia. Venture capital is available in Estonia primarily from international funds. In addition, venture companies active in Estonia do not have knowledge and experience in the area of biotechnology and thus, are in particular hesitant to invest in this sector. Often unrealistic expectations concerning time frame for the return of investment appear by potential investors. (Page 41)
In order to finance R&D activities, very few biotech firms also applied for funding from the European Commission e. g. within the framework of the CRAFT

Programme. Consortia were organised with academic institutions and other companies. The application procedure appeared to be more difficult than expected. Based on the experiences made it was acknowledged that in the future external support would be needed and asked for in the process of writing proposals. (**Page 42-43**)

In Estonia, hardly any venture capital is available for the pre-seed and seed phase of companies in particular in high technology fields. Again the high levels of risk of companies which have been just founded was mentioned as the main reason for the low amount of available investment capital for these early stages. In particular in the biotechnology field seed-financing was regarded as a high-risk business which needs a "long financial breath" and specific experience in the biotechnology and pharmaceutical field which does not seem to be available in the venture capital companies active in Estonia. (**Page 59-60**)

Altogether, it can be stated that low availability of private financing possibilities and a limited set of (commercial) instruments in this area represent a major constraint for company founding and growth in the biotech field in Estonia. Another specific constraint represents the extreme short-term view of potential Estonian private investors which does not match with the needs of most biotech companies for mid- or long-term financing. (**page 61**)

After the re-organisation of the recent Estonian Innovation Fund, whose organisation and procedure were criticised as being complicated and not efficient the Estonian Technology Agency (ESTAG) was established in 2001 in order to develop Estonian business through the support of technological and innovative projects. ESTAG is one of seven agencies that form Enterprise Estonia and administers the financial means which are allocated to innovation policy by the Ministry of Economic Affairs and Communications of Estonia. (**Page 61-62**)

Main recommendations in the document related to Biotechnology financing
We suggest to establish a special seed fund for high technology companies with an initial volume of 108 million EEK. Biotechnology should be a focus of the fund but it should also invest in other high technology areas. (**Page 115**)

The suggested seed fund should be regarded as a starting point for (semi-)public activities in order to improve the financing situation of biotech and other high-tech companies in Estonia. (**Page 115**)

Have some of the recommendations been implemented yet, if yes, which ones

Other relevant information

Name of the Policy Document/Report in original language Loi de Finance 2004
Name of the Policy Document/Report in English 2004 Budget Act
Year of the preparation of the document 2004
Name of the organization(s) which has prepared/adopted the Document Parliament
Coverage of the document i.e national, regional, European France Fiscal incentives for enterprises and taxpayers
Synthèse The 2004 Budget Act creates <ul style="list-style-type: none"> - The « Young Innovative Company » (YIC) status (Jeune Entreprise Innovante). In particular, The YICs benefit from <ul style="list-style-type: none"> o Tax relief on profit for 3 years, then 50% for the two next years o Reduction or tax relief on local taxes o Tax relief on social taxes for R&D staff for the first 5 years - The “Research Tax Credit” (« Crédit d’impôt recherche»), a fiscal disposition incentivizing R&D activities within companies. Among the eligible expenditures are patent, research staff, standarisation, and technological foresight costs
Other relevant information http://www.enseignementsup-recherche.gouv.fr/technologie/mesur/cir/index.htm

Name of the Policy Document/Report in original language Financer l'innovation précoce dans les biotechnologies
Name of the Policy Document/Report in English <i>Funding early innovation in biotechnologies</i>
Year of the preparation of the document 2007 (April)
Name of the organization(s) which has prepared/adopted the Document InsermTransfer, Société Générale, Meditech Conseil, with the support of France Angels
Coverage of the document i.e national, regional, European France The document is focused on three biotech investment models : 1. Business Angels (BA) 2. Investments from Big pharma through corporate funds 3. Debt financing
What type of biotechnology is concerned by the publication Any
Main conclusions in the document related to Biotechnology financing The report analysis starts from a well known issue - the lack of VC money for biotech companies – and explores three additional financing models : 1) BA's investments in the field of biotechnology is low, for 4 reasons : <ul style="list-style-type: none"> ▪ Biotechnology projects are complex ▪ Investments needed are heavy ▪ Biotechnology projects are long-term projects (10 years) limiting investment returns ▪ Few IPO exit opportunities in Europe 2) Big pharma investments in biotech companies, through corporate funds, provide to young entrepreneurs an industrial expertise and credibility vis-à-vis to potential VC investments. However, it can make less attractive the biotech companies for VC, in the extent to which Big Pharma investments can be seen as the first step toward the absorption of the biotech companies, then limiting IPO opportunities. 3) The report states that debt financing can facilitate SMEs development namely in the field of biotechnology. It recommends the development of “Titres de Crédit Négociables” (“negotiable debt securities”) and the creation of a specific “vehicle” ensuring their diffusion.

Main recommendations in the document related to Biotechnology financing

1) Business Angels Investments :

Create a Biotech-oriented Business Angels Network :

- The aim is to overcome the complexity, heavy costs and lack of IPO exits which limit biotech investments. Such a BAs network :
 - Could help entrepreneurs in drafting good business plan
 - Could be focused on medtech projects (less expensive, less complex and faster to develop)
 - Could offer visibility on exit opportunities from the starting point of the project
- The network would create a dedicated fund offering legitimacy and a critical mass for negotiating with VC

2) Big Pharma Investments :

Support the creation of foundations and proof of concepts funds, through public-private partnerships involving Big Pharma companies

3) Debt Financing:

The French Coordination Committee of Communication Sciences and Technologies (*Comité de Coordination des Sciences et des Technologie de la Communication* – CCSTIC, Ministry of Research) is actually working on the creation of “Innovation Financing Companies” financing pre-development stage projects (“Société de Financement de l’Innovation”, called SOFINNOV). The company would act as vehicle for negotiable debt securities issuing. Such a model already exists in France for traditional industrial sectors (movie industry and fisheries)

Have some of the recommendations been implemented yet, if yes, which ones

No

Other relevant information