OECD Case Study on Innovation:

The Finnish Biotechnology Innovation System

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1 Introduction

1.1 Background

“When an inventor in Silicon Valley opens his garage door to show off his latest idea, he has 50% of the world market in front of him. When an in inventor in Finland opens his garage door, he faces three feet of snow.”

J.O. Nieminen, CEO of Nokia Mobira, 1984

The process of translating a basic science invention into a commercially viable innovation is a complex process and getting even more so. Both markets and technologies are becoming increasingly complex. The rapid advance of the scientific frontier and the increasing breadth and depth of knowledge available across all scientific fields have contributed to this acceleration of technological complexity. Today, even large corporations are limited in their capability to bring together all the skills and resources required for in-house development and commercialisation of science-based technologies. Factors such as the shortening of product life cycles and the combination of several technologies within a single product or service mean that the company increasingly depends on external inputs, in the form of skills, advice, proprietary technologies, cooperation networks, for successful innovation.

Measured in relation to GDP, Europe devotes more resources to academic research than either the United States or Japan, and research in Europe is highly diversified. However, Europe performs significantly worse in translating research into innovation, also described as the “European paradox”: an impressive quantity and quality in R&D but a less impressive performance in terms of innovation.

One important reason might be that innovation policies in Europe focus more on technological innovation and the generation of knew ideas and knowledge. It can be speculated, however, that limits to growth might not lie as much in the ability to generate new ideas, but in the ability to process an abundance of potentially new seed ideas into usable forms. In addition, other forms of innovation, as social, organizational or market innovation might be as important to support economic growth. Therefore, weaknesses in organisational, presentational, value added and business model innovation might be as relevant to the slow pace of progress towards the Lisbon goals as the lower level of business R&D spending.

Although the systemic model of innovation is now clearly prevailing, many measures put into practice to promote innovation are still based on the linear view, implicitly assuming a causal and linear relationship between input and output. Nevertheless, the pharmaceutical sector has demonstrated over the last years that increases in R&D spending do not necessarily translate into increased performance and productivity. One further problem is that performance indicators for non-technological forms of innovation, and market factors, are at present less well captured by innovation statistics, and less subject to analysis, than those linked to research. This might lead to a further focus on input measures rather than outcome indicators.

It can be speculated that the systemic model has yet to be fully reflected in the way that innovation policy is devised and implemented, monitored and evaluated. Innovation and innovation policies in biotechnology is therefore a very complex, multidimensional issue and many problems facing companies, policy makers, public and private investors cannot be fixed in an easy, straight-forward way due to the complex, multidimensional “nature” of innovation, and no straight- forward policy recommendations can therefore be offered. However, we will try to describe the frame and the challenges the National innovation system has to face in Finland to realize the promises Biotechnology has the potential to fulfil: to improve health and quality of life, and to support a sustainable economic development.

As more research is being performed,the view on innovation and innovation systems is constantly evolving. Since even terms as “invention” and “innovation” are often not used in a very consistent and sometimes even somewhat interchangeable form in the literature, we would like to introduce some basic definitions[1].

A ***technological innovation*** is the successful implementation of a technical idea, which is new to the institution creating it. The essence of technology-based innovation is the systematic and successful use of science to create new forms of economic activity. Technology-based innovation thus represents a subset of all innovation. The distinction between technology-based innovation and incremental product enhancement is based on the extent of novelty in the science or technology.

A ***commercial innovation*** is the result of the application of technical, market, or business-model ingenuity to create a new or improved product, process, or service that is successfully introduced into the market.

An ***invention*** is distinguished from an innovation by its character as pure knowledge. An invention becomes an innovation with the first commercial transaction. An innovation is thus a commercialised invention

The direct products of a technological invention are not goods or services, but the recipes used to create them. This may result in patents, or more broadly in new firms or business units within existing firms. A patent refers more to an invention than an innovation. ***Inventions are the necessary seed for technological change, but it is innovation that generates the economic benefit***.

1.2 Goals of the research

“*Fundamentally, biotechnology is a business built on the exception of trust and optimism*” (Russo & Russo, 2003). Biotechnology has been foreseen to become the next economic growth motor, promising better innovative medicines and therapies, diagnostics, and supporting sustainable innovation in many other sectors as food, biomaterials or industrial enzymes. In Biotechnology a decade is often required for the transition from invention to innovation, which makes that field dependent on long term financing from public and private sources before it can even start to fulfil its promises. Many countries have invested a significant share of their public R&D investment into this sector and public expectations towards Biotechnology are high.

Today, only about three dozen biotechnology companies- mostly US-based, and many of them already started in the 80s- generate profits. Both the pharmaceutical and the biopharmaceutical sectors are more dominant in the US compared to Europe. Table 1

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[1] Adopted from: Between Invention and Innovation: An Analysis of Funding for Early-Stage Technology, Lewis M. Branscomb, Philip E. Auerswald (2002) http://www.atp.nist.gov/eao/gcr02-841/gcr02-841.pdf

shows a comparison between some indicators for the biopharmaceutical industry. Europe's biotech companies have a market capitalization of around 26 billion USD, but very few have therapies close to the market that could drive sales and earnings in the near future.

Table 1. European and US biotechnology: major indicators. Source: EFPIA, 2001.

Indicator	Europe	US
Turnover (€ million)	15,327	31,808
R&D expenditure (€ million)	8,354	17,522
Net loss (€ million)	1,699	7,701
Number of companies	1,879	1,457
Number of employees	87,182	191,000

In contrast to the situation in the pharmaceutical industry before the mid to end 90s, the latest data show that the US is currently also the major source of new chemical entities (NCEs). Out of the 29 NCEs launched in 2001, 13 were developed in the US, 8 in Europe and 7 in Japan. Similarly, 70% of the sales of NCEs launched between 1998 and 2002 have been in the US, as compared to 18% in Europe, and 4% in Japan.

The pharmaceutical industry is currently in clear favour of deals with more advanced stage biotech companies, which is a less risky strategy and the current supply of interesting companies is good. In addition, a process of M&A from stronger, cash-richer US biotech to select the most interesting, cash-constraint Biotech companies in Europe has recently been observed. Europe's Biotech industry is therefore still inducing less confidence to investors than their US counterparts. Despite the recent trends to restored confidence into the sector, given technical and market uncertainties, private capital still prefers to wait and finances products and technologies much closer to the market than only some years ago.

While many hope that the current situation is nothing more than a transient situation in the ongoing funding of biotechnology companies, this view might be short-sighted. The radical restructuring of the pharmaceutical industry and the restructuring of investors investment strategies have created a much less forgiving environment for biotechnology companies. The companies that will succeed under these conditions are likely those that can establish a straightforward path to profitability, and innovative financing schemes that provide substantial upside for equity investors.

With this background, the report addresses the following questions:

- What systemic failures are responsible for a sub-optimal performance of the pharmaceutical/medical biotechnology innovation system, especially in the business system?
- Is there a relation between the openness of a national innovation system and its performance, and if so, how open should the system be when performance maximisation is pursued?'

- What specific demand-side factors influence the biotechnology innovation processes and what are the effects on the innovation outcomes?'
- What elements of framework conditions and horizontal innovation policies are key to foster innovation?
- To what extent and how should innovation policies be customised to the particular needs and features of the features of the biomedical/biopharmaceutical innovation system?

Questions addressing the central issues in the project are:

- What are key systemic failures that justify national innovation policies?
- What conclusions can we draw on the relation between specific policy approaches and the performance of the systems?
- Are 'systemic best fits' (best practise models) available? What experience has been made?
- What does a highly internationalised biotechnology innovation system, illustrated for example by the different international locations of business functions in the case of multinational pharmaceutical companies, imply for public policies?
- What is the relation between market driving forces (e.g. the configuration of health care systems) and input/push driving forces in fostering innovations and what does this imply for public policies? Have 'integrated policy approaches' emerged in countries that take into account the various different actors, functions and interactions that make up the pharmaceutical biotechnology innovation system?

1.3 Approach

The four main methods used for the preparation of this report were:

1. Descriptive analysis of the national biotech innovation system based on a desktop research of statistics collections and reports from various sources. Sources for primary data will be cited in the report, an overview of the most important secondary sources will be given in the bibliography. For this report, we extensively used the primary data obtained from several studies based on a large company survey performed by ETLA: (1) *Findings of the ETLA survey on Finnish biotechnology firms* by R. Hermans and T. Luukkonen, ETLA (2002); (2) *Ownership and financial structure of biotechnology SMEs: evidence from Finland* by R. Hermans A-J. Tahvanainen ETLA (2002);
2. Bibliometric and patent analyses. Bibliometric analyses were performed by Fraunhofer ISI; the OECD secretariat was responsible for the patent analyses.
3. Company Survey on Co-operation. A survey on co-operation was posted to the companies members of the Finnish Bioindustries Association. The company survey on collaboration had such a low response rate that the results could not be used for the report.
4. Twelve interviews with selected companies, sector experts and demand side actors were conducted for the report.

1.4 Country characteristics

1.4.1 General figures and indicators

Finland has a population of 5.2 million, with an average of 17 inhabitants per square kilometre. Finland has two official languages: Finnish, spoken by 91,3% of the population and Swedish by 5,4 % of the population.

67% of the population live in towns or urban areas, while 33% live in rural areas.

The principal cities in Finland are Helsinki (560,000), Espoo (221,000) and Vantaa (182,000), making up the Helsinki metropolitan area with a population of about 1 million people, followed by Tampere (199,000), Turku (174,000) and Oulu (124,000).

Finland’s population will peak in the early 2020s at about 5.3 million people, but labour force will already start to decline in 2004 by 0.5% annually. Population ageing is among the most rapid of any OECD country and will have a major impact on public finances. The old-age dependency ratio (population over 65 years as a percentage of the working age population) will rise from 23 % currently to about 37 % by 2020, the fastest rise in the OECD area. Ageing will continue with the dependency ratio reaching 45 % around 2030, dependency ratio will plateau at just under 50 % over the period 2040-50.

Finland is a small open economy, which is susceptible to cyclical swings. An attempt to discuss the important implications of that for the biotechnology innovation system is done further in the report. In 1995 Finland became a member of the European Union, which has further opened the country to the world.

The business expenditure on R&D (BERD) in Finland as a percentage of GDP was 2.68 in 2001, which is second highest worldwide after that of Sweden. The public R&D expenditure (GERD-BERD) as a percentage of GDP was 0.98 in 2001, which is second highest worldwide. However, on an international level, the share of government funding in business R&D is low.

Table 2.GERD and BERD and R&D personnel for Finland between 1994-2000. Source: EUROSTAT R&D statistics.

	1994	1995	1996	1997	1998	1999	2000
Gross domestic expenditure on R&D (GERD) (million euro)	2008.3	2172.4	2503.6	2904.9	3354.5	3878.8	4354.4
Business enterprise expenditure on R&D (BERD) (million euro)	1249.8	1373.4	1656.7	1916.7	2252.8	2643.9	3096.5
Total R&D personnel	32331	33634		41256	46517	50604	

Table 3. Government expenditure, debt and R&D appropriations in 1995-2003. Source: Statistics Finland, 2003.

Year	€ million			R&D funding -share of government expenditure, % *	Real change, %		
	Government expenditure	Government expenditure excl. debt	Government R&D funding		Government expenditure	Government expenditure excl. debt	Government R&D funding
1995	33,357	29,222	930.4	3.2	0.0	-2.0	3.9
1996	33,541	28,658	938.8	3.3	0.0	-2.5	-1.7
1997	31,737	27,831	1,183.9	4.3	-5.9	-3.5	23.4
1998	32,678	27,676	1,249.7	4.5	1.6	-1.9	2.7
1999	35,608	27,309	1,275.2	4.7	7.7	-2.5	0.2
2000	38,472	28,141	1,299.6	4.6	4.9	0.0	-1.8
2001	36,072	29,672	1,351.2	4.6	-8.5	2.9	0.6
2002	36,261	31,571	1,392.1	4.4	-1.3	4.5	1.4
2003	35,722	32,160	1,416.7	4.4	-3.6	-0.3	-1.2

Table 4. R& D expenditure by sector in 1991-2002 and GDP share of R&D expenditure. Source: Statistics Finland, 2003.

Year	Business enterprises		Public sector		University sector		Total	R&D expenditure share of GDP
	€ million	%	€ million	%	€ million	%	€ million	%
1991	975.1	57.0	357.5	20.9	378.0	22.1	1,710.6	2.04
1993	1,048.5	58.4	379.7	21.1	367.5	20.5	1,795.8	2.17
1995	1,373.4	63.2	374.4	17.2	424.6	19.6	2,172.4	2.30
1997	1,916.7	66.0	408.6	14.1	579.5	20.0	2,904.9	2.72
1998	2,252.8	67.2	443.9	13.2	657.9	19.6	3,354.5	2.89
1999	2,643.9	68.2	470.1	12.1	764.8	19.7	3,878.8	3.22
2000	3,135.9	70.9	497.4	11.2	789.3	17.8	4,422.6	3.37
2001	3,284.0	71.1	500.9	10.8	834.1	18.1	4,619.0	3.40
2002	3,446.7	70.7	520.8	10.7	905.2	18.6	4,872.7	3.47

Finland has been consistently ranked highly in the different indices. According to the global competitiveness report by the World Economic Forum [2], Finland was the most competitive economy in 2001. The Finnish success in recent years competitiveness rankings has brought Finland a lot of positive attention worldwide. Rising R&D intensity and educational level, as well as liberalization and deregulation of the economy helped to build the foundations for this.

Finland, together with Ireland and France, holds a leading position in S&E (natural sciences and engineering) graduates; together with Sweden and Netherlands in public R&D expenditure and EPO high tech patents; together with Sweden in business R&D; together with Sweden and the UK in population with tertiary education; again with Sweden and Denmark in the number of high tech USPTO patents related to population. Despite this impressing performance, the GNP per capita in Finland (corrected with purchasing power) was only 15th in the world. Finland had no leading position in new capital raised, home Internet access, or ICT expenditure.

Finland ranks consistently high also in the European Innovation Scoreboard. In 2002 it is among the three leading countries in 8 out of 14 indicators. Similarly almost all other indicators are above or close to EU average. The strongest current performance is for high tech patent applications.

In the 2002 Global Competitiveness Report, Finland ranked second in a National innovation capacity index (See Porter, M. and Stern, S., 2002). Finnish strengths were typically related to innovation, technology, and the general functioning of society. Finnish weaknesses were related to the size and financing of the public sector, as well as to inflexibilities in the labour market.

In spite of the above weaknesses the innovative capacity of Finnish companies through all sectors are close to EU average [3]. The share of turnover of Finnish companies coming from new or renewed products and services was 22 %, corresponding to EU average. The average percentage of investment dedicated to innovation was 24% compared to an average of 27% (among 15 EU countries examined). Innovative efforts in Finnish companies were mainly concentrated on the development of new products, cited by 50% of the companies (average for the EU 15 was 38%), which highest number after Sweden, and new production processes, cited in 58% of the cases (highest number cited, average for the EU 15 was 35%). Companies mentioned fewer efforts directed at organizational changes- in 18% (the average for the EU15 was 46%), which was the lowest number in EU.

Access of advanced technologies for Finnish companies was mainly obtained through:

- Cooperation with suppliers or customers- mentioned in 58% of answers (EU15 average 59%);
- Acquiring of machinery or equipment- in 54% of answers (EU 15 average 41%);
- Conducting in-house R&D- in 30% of answers (EU15 average 31%);

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[2] WEF, 2001, www.weforum.org/gcp

[3] Innobarometer 2002, available from http://www.cordis.lu/innovation-smes/src/innobarometer.htm

- Cooperation with University or R&D specialist- in 11% of answers (EU15 average 14%)
- Licensing- in 4% of answers (EU15 average 9%), i.e. second lowest in EU.

It is important to keep in mind that the measures used in the global competitiveness reports are dominated by the performance of the ICT-sector, and here, Nokia plays a very dominating role. The pharmaceutical/biopharmaceutical sector is comparatively small and therefore it is unlikely that it plays any significant role in this type of composed indices. It might therefore be inappropriate to simply transfer the results from the different scoreboards and apply it to the interpretation of the performance of the biopharmaceutical/pharmaceutical sector in Finland.

1.4.2 Main industries

Finland has three important clusters: ICT, wood and pulp, and metal. In 1999, electronics and telecommunications had become the leading sector, followed by pulp and paper, chemicals, and machinery and equipment. Exports of goods and services corresponded to 40.1 % of GDP in 2001, while imports of goods and services were 31.7% of GDP.

Electronics and electrotechnical goods account for about 27.5% of exports, metal and engineering products account for about 27.1% and forest industry products account for about 26.5%. The fourth biggest export sector is the chemical industry. Finland has a greater exposure to markets in Asia, due to electronic products and Russia and the Baltic countries each accounting for just under 10% of Finnish goods exports. Finnish industry is particularly dependent on imports of raw materials, machinery and components that it needs for manufacturing products for both domestic and export markets. Consumer goods, including textiles, clothing and cars, make up almost 25% of total imports.

Table 5.Contribution of main sectors to the GDP of Finland. Source: Statistics Finland, 2003.

	2001, % total 2001		**% contribution to GDP growth**				
	GDP	Exports	1998	1999	2000	2001	2002
Wood, pulp, paper	5.1	26.6	0.2	0.2	0.3	-0.4	0.2
Electrical and optical equipment	8.0	27.5	1.4	1.4	2.4	0.1	0.7
Nokia			0.8	1.0	1.8	0.0	
Other metal products and equipment	6.0	27.9	0.2	0.0	0.4	0.1	-0.3
Other manufacturing	7.1	15.9	0.3	0.1	0.3	0.0	-0.1
Total manufacturing	26.1	98	2.2	1.7	3.4	-0.2	0.5

Nokia has a strong influence on the Finnish economy and therefore, some of the facts are presented in the box below (Ali-Yrkkö & Hermans, 2002)

Nokia is the worlds leading producer of mobile phones. Nokia's share of total Finnish exports is almost one quarter, while the Finnish market accounted for only 1.5% of its turnover. The share of Nokia to GDP growth is given in Table 5. In 2001, Nokia's share of total R&D input was one third and 47% of business R&D. Nokia's R&D spending including all foreign R&D was about 3.5 billion euro compared to 3.5 billion euro for total private business R&D in Finland.

While Nokia has substantial influence on Finnish growth, exports and R&D, it stands for only 2% of total employment in the business sector. Almost 60% of the Finnish staff works in R&D.

At the end of 2001, Nokia's shares were 63% of the market value of the Helsinki stock exchange and foreigners held 93.1% of the shares of the company.

Important is also the network of small companies cooperating with Nokia in production and R&D: in 2000 it included 300 companies with around 20.000 employees in Finland.

1.4.3 Size and structure of the pharmaceutical industry

Currently, there are three pharmaceutical companies manufacturing products for the international market in Finland (Leiras, Santen, Orion). Orion is the leading company in Finland with a 19% market share. In the 90s, a restructuring of the pharmaceutical industry in Finland occured. Orion aquired a majority holding in Farmos Corporation at the end of the 1980s and merged finally in 1990. In May 1995, the shares of Orion Corporation were listed on the Helsinki Exchanges. Leiras OY was acquired by Schering AG in 1996. In 2003, Schering Oy was formed by merging Leiras Oy and

Schering Oy. Santen was established in Finland in 1997 when the Japanese Santen Pharmaceutical Co., Ltd. acquired the business of the Finnish pharmaceutical company Oy Star Ab. Santen's European Preclinical and Pharmaceutical Research and Development unit is located in Tampere and Clinical Research department in Helsinki. Also the manufacture of Santen products for the European and American markets is located in Finland. Orion is the only pharmaceutical company that is still under Finnish ownership.

Table 6 shows some statistical data for the pharmaceutical industry in Finland in 2001. Investments into R&D amounted to 213 million euro. (In comparison, Pfizer's R&D budget in 2001 was around 5 billion USD).

Table 6. Finnish pharmaceutical industry facts. Source: Pharma Industry Finland, 2002.

Pharmaceutical production 2001 (€ million)	666
Employment (no personnel)	6810
Pharmaceutical market value (Ex factory prices) (€ million)	1282
Pharmaceutical exports (€ million)	330
Pharmaceutical Imports (€ million)	849
Pharmaceutical trade balance (€ million)	-519
Pharmaceutical R&D (€ million)	213
Payment for compulsory health insurance systems and National Health Service (€ million)	768
Total spending as percentage of GDP (in 2000)	6.6
VAT applicable to medicines for prescription and OCT (2003)	8%

In 2002, the Finnish pharmaceutical industry exported pharmaceuticals to a value of 437 million euro and bulk drug substances for 42.8 million euro. EU accounted for 48% of the exports, and the US for 18.3% of the exports.

Finland's most exported pharmaceutical products are the intra uterine hormonal conception devices Levonova/Mirena and the Parkinson drug Comtess/Comtan. Finland is currently importing more pharmaceuticals than it is exporting, leading to a negative trade balance of pharmaceuticals. In Europe, countries with a negative trade balance of pharmaceuticals include: Austria, Finland, Greece, Norway, Portugal, Spain, and Turkey. The overall trade balance of the EEA is positive with 33 829 million euro. In several European countries, the pharmaceutical industry ranks among the top five exporters in the manufacturing sector. The restructuring of the pharmaceutical industry also induced the formation of new biopharmaceutical companies by former employees of the larger pharmaceutical companies. Currently, there are about 12 companies actively developing drugs in Finland (including the three larger pharmaceutical companies), out which four are under foreign ownership. This is a decrease by four companies through M&A during the last two years. An estimate of the development pipeline of all drugs currently developed in Finland is shown in Table 7.

Table 7. Estimated Number of Drug Development Projects in Finland[4]

	Preclinical	Phase I	Phase II	Phase III
No. Projects	27	9	9	5

Only one Finnish drug development company has so far performed an IPO- BioTie Therapies, which had an IPO at the Helsinki stock exchange in June 2000 with a transaction size of € 21,1 million.

The two main associations connected to the pharmaceutical sector are Finnish Bioindustries and Pharmaceutical Industry Finland.

Finnish Bioindustries (FIB) http://www.finbio.net/home.htm, Finland's biotechnology industry association established in 1997, represents companies from all life science areas, including health care, functional food and biomaterials. In addition, industry organisations such as the Chemical Industry Federation, Pharma Industry Finland, Finnish Food and Drink Industries' Federation, Finnish Forest Industries Federation and Finnish Crop Protection Association are members of FIB.

Pharma Industry Finland (PIF) http://www.pif.fi/showPage.php?page_id=114

Pharma Industry Finland (PIF) is an association supervising the industrial policy interests of the research-based pharmaceutical industry in Finland, representing the research-based, generic, OTC and veterinary pharmaceutical industry.

The PharmaCluster Finland (http://www.pharmacluster.com) was set up in 1998 as a project of the national Centre of Expertise Programme under the Ministry of the Interior. Its aim is to facilitate development of a pharma network and to act as a national co-operation platform to expand pharmaceutical expertise in Finland. Cluster members represent established pharmaceutical companies, networked pharmaceutical development, technology and service companies, units from universities and other institutions of higher education, research institutions, Finnish Bioindustries and Pharma Industry Finland, financiers, science parks and technology centres.

Each year, around 40 companies conduct 400 to 500 clinical trials in Finland. From the 440 clinical trials performed in 2002, 160 were started in 2002 and most were clinical phase III. The number of trials has been almost constant between 1995 and 2002, while the number of patients and healthy volunteers increased from 32,000 in 1995 to 61,000 in 2002. The largest therapy group studied were systemic anti-infectives (in 2002), medicines for diseases of the nervous system (in 2001), cardiovascular medicines (1997-2000) and medications for genitor-urinary organ disorders and sex hormones (in 1995 and 1996). The number of medical substances studies in 2002 was 270.

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[4] The estimate is based on different data sources: a screening of companies' WebPages for development pipeline information, an email survey query to subsidiaries of foreign companies with R&D activity in Finland, and search of the IMS *R&D Focus* database (update of June 2003). The estimate includes drugs developed by the foreign subsidiaries.

2 Overview of national R&D technology and innovation policies

2.1 Introduction

Until the mid 1970s, a linear concept of innovation was dominant with basic research seen as the most important source for innovation. In the late 1970s and the 1980s this model was gradually replaced by a model where interaction with different players was emphasized. Already in the late 1970s a decision has been made to raise the share of R&D inputs in relation to GNP to the level of other industrial countries and this increase was maintained even during the deep recession in the beginning of the 90s. In 1983, the National Technology Agency (Tekes) was funded. Tekes' primary objective was to promote the competitiveness of Finnish industry and the service sector by technological means. Technology programmes were established that included collaborations between universities state research institute and firms as well as developmental projects proposed by companies. Tekes rapidly grew into the most important funding organization for applied R&D.

The Science and Technology Policy Council was established in 1987 as a successor organization to the Science Policy Council.

The concept of the "National Innovation System" (NIS) has been adopted in the beginning of the 90th as the theoretical framework for science and technology policy. In the beginning of the1990s, the focus had shifted from the single firm to networks of actors (innovation networks) and from university and research funding and technology programmes to a more holistic view that interconnected the former separate entities.

It is, however, important to understand this new concept of a "National innovation system" in both a historical and political frame with an instrumental function for policy makers rather than a scientific theory. During the period of 1990 to 1993 Finland suffered the most severe economic crisis, when real GDP dropped about 14 and unemployment rose from 3 % in 1990 to almost 20% in 1994. This crisis was very important for the rapid adoption of the new policy frame[5]. Since then, both definitions and contents of the NIS have changed and they continuously keep changing.

The following main reforms were conducted in the 1990s:

- A regional innovation policy was established: the regional development act came into force at the beginning of 1994. 14 regional centres of expertise were created for the period of 1999 to 2006.
- Launching of the cluster programme in 1997: the purpose was to reinforce the utilization and commercialisation of technology by establishing technology centres, incubators and licensing offices in the universities. Eight cluster programmes under six ministries were formed.
- Emergence of VC capital activity, with Sitra as a forerunner.

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[5] For an overview over the development of science and technology policy in Finland, see Tarmo Lemola, 2002.

- Increased funding at the end of the 1990s; creation of centres of excellence (initiated in the late 1980s); strengthening of the use of research programmes and establishment of the graduate school system in 1995.

A change in the structure of research funding can be observed in the period between 1990 and 1998 when the proportion of competitive funding increased from 26% to 41%, funding for technological research through Tekes almost doubled, and funding Tekes' university increased from 11% to 23%.

Science and technology policy, innovation financing and education policy still constitute the core of the Finnish innovation policy. Finnish science policy is based on the government's five-year development plans for education and research, and the triennial reviews of the Science and Technology Policy Council of Finland.

The latest policy guidelines, "Knowledge, Innovation and Internationalisation", are setting the core dimensions of innovation policy. The priority areas for the innovation policy in 2002 were:

- Promotion of clustering and cooperation for innovation;
- Protection of intellectual and industrial property; intensified cooperation between research companies, universities and companies.

While previously the focus was on "technological" innovation, currently a wider view on innovation is emphasized: social, business, innovation within the low-tech sector, etc. (Georghiou et al., 2003). The new trends emphasise a focus on regional rather than national innovation systems and aim to define and solve institutional bottlenecks instead of holistic planning.

2.2 Main Actors in Policy Making and Policy Programme Management

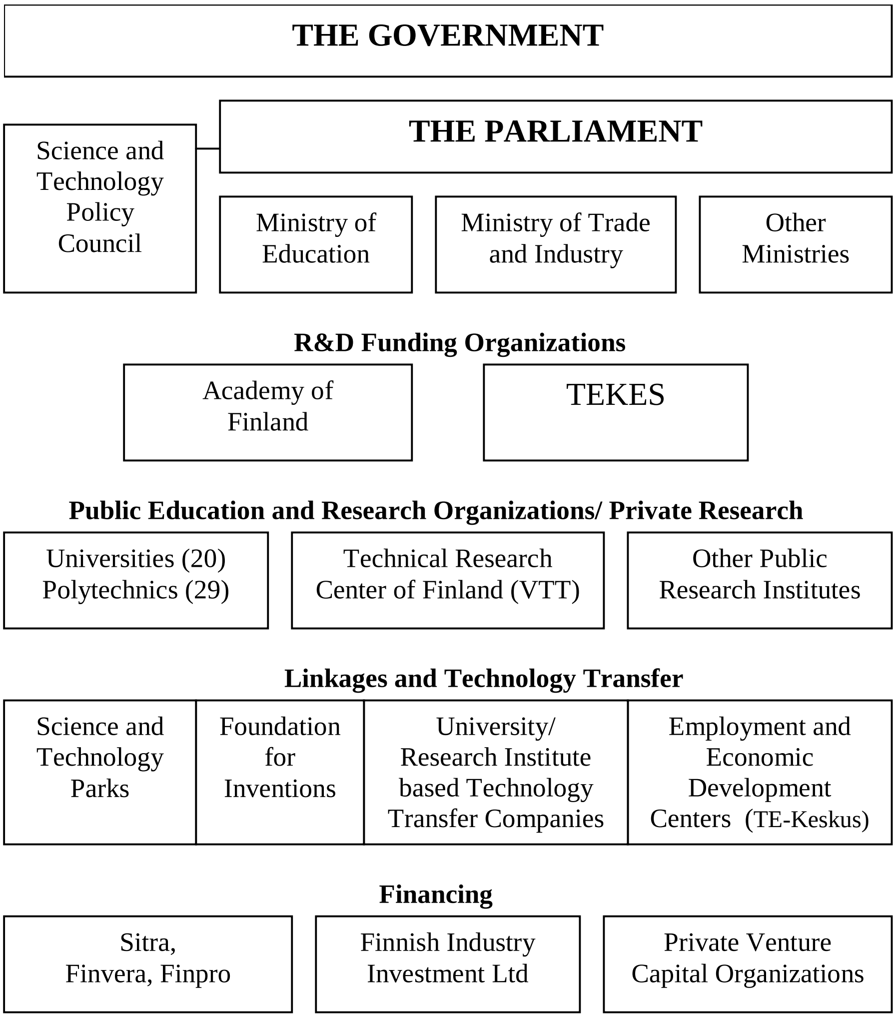


Figure 1. Actors in the Finnish Innovation System (adopted from P. Kutinlahti, 2002)

The Science and Technology Policy Council is the main advisory body to the Finnish government and its ministries.

The main ministries responsible for Finnish research policy are the Ministry of Education, and the Ministry of Trade and Industry. These ministries allocate almost 80% of public research funding.

Most of the public funding for research and development in Finland is channelled through Tekes and the Academy of Finland, the main public research funding organisations. In addition to these two research bodies, government ministries and research institutions are also increasingly channelling their research funding into programmes. Research in the public sector is mainly performed in universities and state research institutes.

2.2.1 Policy making organisations

The Science and Technology Policy Council of Finland is responsible for the strategic development and coordination of Finnish science and technology policy as well as of the national innovation system as a whole. The Science and Technology Policy Council is led by the prime minister and consists of seven Ministers and ten other members, with representatives of the Academy of Finland, the Technology Development Centre, universities and industry as well as employers' and employees' organisations. The Council also coordinates the cooperation between the Ministry of Education and the Ministry of Trade and Industry. The strategy for Finland's Science and Technology policies is in formulated six triennial reports:

- Science and Technology Policy Review 1987
- Guidelines for Science and Technology Policy (1990)
- Towards an Innovative Society: A Development Strategy for Finland (1993)
- Finland: A Knowledge-based Society (1996)
- Review 2000: The Challenge of Knowledge and Know-how (2000)
- Knowledge, innovation and internationalisation (2003)

The main responsibility of **the Ministry of Education** in science policy is to promote the development of basic research and its infrastructure. All the universities (20) and the Academy of Finland (the Finnish research council organisation) are in the administrative field of the Ministry. Development of biotechnology research and training has been a priority area for the ministry since the mid-1980.

The **Ministry of Trade and Industry** (MTI) is responsible for industrial and technological policy and for the development of frame conditions for the Finnish industry. Tekes, and the public research institute VTT are under the administration of the MTI. Since 2001, the MTI is responsible for the coordination of biotechnology issues within the public administration in Finland. However, the detailed strategy planning for biotechnology concerning MTI is mostly performed by Tekes.

The MTI is vested with the coordination of an unofficial ministerial working group on national and global issues touching on biotechnology and requiring political decision-making. The work group consists of representatives of the Ministry of Trade and Industry, the Ministry of the Environment, Ministry of Agriculture and Forestry, Ministry of Health and Social Welfare and contributes to coordinating issues concerning biotechnology. This informal group convenes as necessary but has no power of decision. The R&D budget for biotechnology that is directly channelled through the MTI ministry or indirectly through The National Technology Agency (Tekes).

2.2.2 Policy management organisations

The Academy of Finland is the central financing and planning body in basic research for all scientific disciplines. The majority of Academy funding is channelled to basic research conducted in universities. The funding of the Academy comes from the state budget and was 187,1 million euro in 2001. 84% of that amount funding went to universities (including university hospitals).

The Act regarding the Academy of Finland (1994) sets the function and structure of the Academy as follows:

- To foster scientific research and its utilization
- To promote international scientific cooperation
- To serve as an expert organ in science policy questions
- To grant appropriations for scientific research and other fostering of science

The Academy of Finland consists of four Research Councils that decide on research funding within their respective fields:
1) Research Council for Culture and Society
2) Research Council for Natural Sciences and Engineering
3) Research Council for Health
4) Research Council for the Environment and Natural Resources

The main funding instruments used by the Academy of Finland are project funding (open to general applications), research programmes, centres of excellence programme, and the Academy of Finland research posts. The Academy of Finland also funds a significant portion of researchers' international mobility.

The National Technology Agency (Tekes) is the main financing organization for applied R&D in Finland. Tekes offers its services through its own personnel at the regional TE-Centre offices, through its headquarters in Helsinki, and also through four offices abroad. *The Act on the National Technology Agency (429/1993)* sets the objective for Tekes[6]: "to promote the societal welfare and stable development by improving directly or indirectly the technological evolution and competence of industry to enhance its ability to develop internationally competitive products, processes and services". Tekes plans, finances, and administers R&D projects that promote the development and utilization of technology. It funds and consults in ventures aimed at the development of products, processes and services as well as promotes widespread utilization of international technological know-how and cooperation, and technology transfer. In addition, Tekes takes part in the planning of Finnish technology and innovation policies along the lines given by the MTI.

Tekes financing is decided and determined annually and funded from the state budget. It does not have a requirement for self-sufficiency. The main financing instruments consist of industrial R&D grants and loans, capital loans for R&D, and research funding. In addition to funding various kinds of R&D projects using these instruments, Tekes organizes technology programs in selected strategic areas. The aim of these programs is to promote the competitiveness of industry and enhance technological cooperation and networking.

Tekes can grant subsidies and loans (including capital loans) to companies and other associations for the purpose of technological research and development. Where finance is granted to large companies, some degree of networking or other cooperation is required. The loan interest rates charged by Tekes are below the market

[6] Translations from A. Hyytinen & L. Väänänen (2002).

rate and the maturity of its loans can be up to ten years. The repayment of the loan can be terminated if the R&D project fails or does not lead to profitable business.

In companies' product development projects Tekes' typical share of total project finance for SMEs is 35% in R&D grants, 45% in capital loans, and 70% in R&D loans. These figures are higher for SMEs than for large companies. For companies' research projects the respective figures are 50%, 60%, and 70%.

From 1997 to 2001 Tekes' financing granted to small firms has increased by 42% in real terms, and that to medium-sized firms has gone up by 32% in real terms.

Tekes financing in the year 2003 will be €363 million. €137.7 million is the share of financing to universities and research institutes, €153.7 million R&D grants to companies, and €1.9 million in R&D capital loans to companies.

Tekes is also administrating EU structural funds with a contribution of €10 million from national sources and €10 million from the EU. Tekes plans to buy technology services including development and evaluation of programmes for €2 million.

The main funding instruments and biotechnology budgets of Tekes are described in.

2.2.3 Actors contributing to policy implementation

Sitra is an independent public foundation under the supervision of the Finnish Parliament. The fund was set up in conjunction with the Bank of Finland in 1967, and transferred to the Finnish Parliament in 1991. Sitra cooperates with both private investors and public-sector bodies such as the National Technology Agency (Tekes), Finnish Industry Investment Ltd, Finnvera, Finpro, the Academy of Finland, the Employment and Economic Development Centres (TE-Centres) and the Foundation for Finnish Inventions (Keksintösäätiö).

Sitra offers its services through its office in Helsinki. *The Act on the Finnish National Fund for Research and Development (717/1990)* sets the objectives for Sitra. According to Act, these are "to promote stable and balanced development, business activity and its quality, as well as international competitiveness and cooperation of Finland by undertaking such ventures, which have the effect of more efficient use of resources or improving the standard of research and education, or which explore future development opportunities"(Hyytinen & Väänänen, 2002). The operations of the fund are financed from Sitra's endowment capital.

Sitra finances through:

- Direct equity financing into domestic companies
- Investments into Finnish venture capital funds
- Investments into international VC funds

At the end of 2001 Sitra had invested into 34 international investment funds and 10 funds having Finland as their main investment target. Similar to investors around Europe, in 2002, Sitra's deal flow fell and Sitra concentrated mostly on financing of portfolio companies.

Sitra's business financing activities are targeted at four areas: technology, life sciences, regional operations and early stage SMEs. In addition to its funding activities, Sitra monitors closely venture-capital investment both in Finland and on international markets and invests in international venture-capital funds concentrating on high-tech.

According to Sitra, its venture capital operations focus on start-up companies, companies in the phase of product development, and especially on “innovative technology companies”. The focus has recently changed to also include service companies. Cooperation with international partners is becoming increasingly important.

Finnvera is a state-owned specialized financing company administered by the MTI and aiming at providing risk capital to SMEs. It also is Finland’s official Export Credit Agency and acts as an intermediary between the European Union’s financing programs and Finnish SMEs. Finnvera plays only a minor role for biotechnology financing. Finnvera’s services are offered both through its own national network of 16 regional offices and through the cooperation network of other public organizations providing services for enterprises.

Finnvera obtained its present form in the beginning of 1999. Its activities are regulated by a number of Acts. The *Act on the State-Owned Specialized Financing Company (443/1998)* describes the objective of Finnvera: “to promote and develop particularly SME operations as well as firm internationalisation and export operations, by offering financing services”(Hyytinen & Väänänen, 2002). In its activities, the institution must also promote government’s regional policy measures. The operations must be directed at correcting any deficiencies that exist in the provision of financial services. The company practices financing activities by providing and managing credit, securities and guarantees as well as other commitments. The company also conducts research related to business finance, and provides business development services and advice. The Act on Credits and Guarantees Provided by the State-Owned Specialized Financing Company (445/1998) sets that the finance must be directed primarily at SMEs. It also sets that credit can be granted without sufficient collateral or with no collateral, and that for special loans the government pays interest subsidies to Finnvera that it channels to the firms.

The Foundation for Finnish Inventions (FFI) was established in 1971 and supports early activities related to inventions through offering legal services related to patents and other forms of IPR. Its task is to support and promote Finnish inventive work and the development and exploitation of inventions. FII conducts evaluations of inventions, and provide expert assistance on the protection of inventions. The FFI has a staff of 23 persons at Espoo Innopoli, and in addition 26 invention agents at the main universities and at the regional TE-Centres. FFI has the possibility of using outside experts, mainly from universities and research institutions, in the evaluation of invention proposals. The FFI’s budget is around 5 million euro coming from the governmental budget.

Finnish Industry Ltd. (FII) is a state-owned equity investment company, administered by the MTI. The FII promotes early stage financing through “fund-in-fund” financing. FII is also investing directly into companies to a minor extent. The *Act on Finnish Industry Investment Ltd. 1352/1999* sets the objective for FII as: “to improve the conditions particularly for SME operations by investing equity into venture capital funds”. FII can also “make equity investments directly into target companies particularly in business ventures requiring long-term risk taking.”

“Investments are directed to targets, where the market does not channel sufficient funds”.(Hyytinen & Väänänen, 2002).

The company’s activities should be profitable in economic terms. In individual investment decisions, the company is allowed accept lower expected returns and higher risks than normally (Act 1352/1999).

Finpro is a service organization having as a main objective to support Finnish firms in the internationalisation of their operations. In addition to the Helsinki office, Finpro has 52 Finland Trade Centres in 40 countries. Finpro is a member organization consisting of over 500 companies, the Confederation of Finnish Industry and Employers and the Finnish Entrepreneurs Organization.

Employment and Economic Development Centres (TE-Centres) is an organization consisting of 15 regional offices, which provide various business related and finance services for SMEs. TE-Centres operate under the supervision of MTI, Ministry of Agriculture and Forestry, and Ministry of Labour. The general administration is a responsibility of the MTI.

The Act on the Employment and Economic Development Centres 23/1997 sets the tasks of the TE-Centres to promote specified areas of business activity, labour issues, as well regional development by offering financial, training, development, and other services to promote particularly SME operations.

TE-Centres offer entrepreneurship grants for unemployed people to become self-employed. TE-Centres also partially finance enterprise investment and development projects. Grants are the dominant form of financing. The most financing instruments are: regional investment aid, small business aid, development aid, aid for improving operational conditions for firms, internationalisation aid, and energy subsidies. The grants can cover up to 50% of the costs of the project, and vary across the EU objective regions of Finland. Total financing granted annually has increased by about 8% in real terms from 1997 to 2001. Most of the financing, about two thirds, consists of investment subsidies, which are also responsible for the increase in total financing.

2.3 Main policies

2.3.1 Policies for knowledge-based support

Technology programmes

Technology programmes are used to promote development in specific sectors of technology or industry. Technology programmes are the main financing instruments of Tekes accounting for about half of Tekes’ research. In 2002, Tekes provided 204 million euro for financing of technology programmes.

Technology programmes focus on technological research and development and aim to create links and networks between companies, universities and research institutions thereby supporting cooperation. Appendix C gives a detailed description of the current technology programmes that focus on Biotechnology.

Research Programmes

Research programmes are targeted to a specific field and run for a fixed time period. General objectives of research programmes include upgrading of the scientific quality of research in a field; Research Programmes in the area of Biotechnology include:

- Biological Functions, Life 2000 (2000-2003)

- Health Promotion Research Programme, TERVE (2001-2004)
- Microbes and Man Research Programme, MICMAN (2002-2006)
- Systems Biology and Bioinformatics, SYSBIO (2004-2007)

Centres of excellence

In 2002, a total of 42 centres of excellence were funded through the national centre of excellence programme. 16 of these began work at the start of 2002. The first three-year term of the 26 centres of excellence and seven core facilities organisations involved in the first centre of excellence programme from 2000-2005, ended in 2002

The Academy of Finland is the foremost source of financing: the budget of the 2000-2005 programme totals € 24.6 million and the budget of the 2002 - 2007 programme totals € 16 million. The programme is further financed by the National Technology Agency Tekes (€ 5.2 million and € 2.5 million) and by the universities and research institutes, providing a substantial share of the funding.

A unit selected as a centre of excellence is a research unit or researcher-training unit which comprises one or several high-standard research teams of international relevance with clearly defined research goals and a common leadership.

The Centres of Excellence involved in Biotechnology Research are the following:

2000-2005

- Cell Surface Receptors in Inflammation and Malignancies
- Centre of Excellence in Disease Genetics
- Helsinki Bioenergetics Group
- Molecular Biology and Pathology of Collagens and Enzymes of Collagen Biosynthesis
- Plant Molecular Biology and Forest Biotechnology Research Unit
- Program in Cancer Biology: Growth Control and Angiogenesis
- Programme of Molecular Neurobiology
- Programme on Structural Virology
- Technical Research Centre of Finland, Industrial Biotechnology
- The Human Development and Its Risk Factors Programme
- Tissue Engineering and Medical, Dental and Veterinary Biomaterial Research Group
- Åbo Akademi University Process Chemistry Group

2002-2007

- Applied Microbiology Research Unit
- Bio- and Nanopolymers Research Group
- Centre for Environmental Health Risk Assessment
- Centre of Excellence for Research in Cardiovascular Diseases and Type 2 Diabetes
- Centre of Population Genetic Analyses
- Developmental Biology Research Programme
- Finnish Research Unit for Mitochondrial Biogenesis and Disease (FinMIT)

- Helsinki Brain Research Centre (HBRC)
- Research Programme on Male Reproductive Health

Graduate Schools in Life Sciences

The system of Graduate Schools was started in 1995 to improve quality and effectiveness of graduate training and education. The Finnish Graduate Network in Life Sciences FinBioNet is a national network of graduate schools in health and biosciences to promote research training cooperation and coordinate research courses. There are now 24 graduate schools in Finland in this area. They offer a 4-year research-training programme consisting of thesis research and 20 to 40 credits of formal studies. The following Graduate Schools are involved into Biotechnology Research:

University of Helsinki:

- Clinical Drugs trial graduate school
- Doctoral programmes in public health
- Finnish Graduate school of Neurosciences
- Graduate School in Computational Biology, Bioinformatics and Biometry
- Helsinki Biomedical Graduate School
- Helsinki Graduate School in Biotechnology
- The Finnish Graduate School on Applied Biosciences: Bioengineering, Food&Nutrition, and Environment

Helsinki University of Technology:

- Functional research in Medicine Graduate School

University of Joensuu:

- Graduate School of Forest Ecology

University of Kuopio:

- A.I. Virtanen Institute Graduate School
- Doctoral Programme in Social and Health Services management and Economics
- Finnish Graduate School in Nursing Sciences
- Graduate school in Pharmaceutical Research
- Kuopio Doctoral Programme of Medical Sciences
- Structure and Function Graduate School

University of Oulu:

- Biocenter Oulu Graduate School

University of Tampere

- Tampere Graduate School in Biomedicine and Biotechnology

University of Turku:

- Biological Interactions Graduate School
- Drug Discovery Graduate School
- Finnish Graduate School in Muscelo-skeletal Problems
- Turku Graduate School of Biomedical Sciences

Abo akademi University

- Graduate School in Information and Structural Biology

Biocentres

The Bio centre programme originated in the mid 80s to stimulate life sciences in Finland. Biocentres receive earmarked. There are currently 5 Bio centres. KTL has sometimes been included in the list of bio centres due to structural similarities, it is,

The Biocentres :

- Helsinki hosts two Biocenters which are overlapping in their organization. The Biocentrum Helsinki was founded in 1994 as an umbrella organization with 20 research groups: 10 groups are housed in the Institute of Biotechnology and 10 groups are hosted in the Biomedicum building, forming a separate campus.
- Kuopio Biocentre: A.I. Virtanen Institute for Molecular Science
- Oulu Biocentre was the first Bio centre to be established in Finland
- Institute of Medical Technology (IMT) at the University of Tampere
- Turku Biocenter: Bio center devoted to core facilities in collaboration between University of Turku and Åbo Akademi

Proact

Proact is a Tekes programme for advanced technology policy (www.tekes.fi-/ohjelat/proact) to increase the understanding and knowledge of the effects of technology, research and technology policy on society and economy. The results will be used in the development of technology policy, research cooperation economy and economy policy to better utilize research results emerging from public research. 20 projects are conducted in the following areas:

- Challenges facing Finland's innovation system
- New perspectives on innovative activity
- Technology policy and civil society
- Cooperation and interaction in innovative activity
- Biotechnology and society

National Cluster programmes

National cluster programmes are extensive research and development entities involving several sectors of Finnish society and coordinated by government ministries (except for the Wood Wisdom forest cluster). Most cluster programmes were implemented in 1998-2000. The first cluster programmes were:

- Food Cluster (Ministry of Agriculture and Forestry)
- Forest Cluster (Ministry of Agriculture and Forestry)
- Telecom Cluster (Ministry of Transport and Communications)
- Transport Cluster (Ministry of Transport and Communications)
- Well-being Cluster (Ministry of Social Affairs and Health)
- Environmental Cluster (Ministry of the Environment)
- Workplace Development Cluster (Ministry of Labour)
- The Finnish Pharma Cluster (Ministry of Internal Affairs)

Finnish competence clusters are promoted by, for example, Tekes, the Academy of Finland and the Technical Research Centre of Finland by their research and technology programmes.

The Finnish industrial cluster policy was evaluated as part of the international evaluation of the additional appropriation for research in 1997-1999: http://www.Sitra.fi/Julkaisut/raportti2.pdf.

Sfinno project

The Sfinno project contains data on 16000 successful Finnish innovations and survey data on 800 innovations collected by VTT between 1980s and 1990s. The aim of the project is to get an understanding at the innovation level on the industrial renewal process in Finland.

Technology clinics

Technology clinics is a Tekes programme launched in 1992 offering scale research services for SMEs to help small companies in solving specific technological problems and establish new methods in companies. Usually, these services are offered by research institutes and universities. Technology clinics aim to the rapid and flexible transfer of technology and competence. Average costs are 10 000 euro, half paid by Tekes and half by the commissioning company.

2.3.2 Policies for commercialisation support

The Centre of Expertise Programme

The Centre of Expertise Programme aims to increase the cooperation between research centres and local companies. There are 14 centres of expertise including Spinno, (www.spinno.fi). The spin-off programme was established in 1990 and is a joint venture between scientific institutions, research centres, public authorities and business in the Helsinki area to promote the creation of high-technology companies. The main target group for this programme are scientists. Spinno is managed by Innopoli Ltd, a privately owned science park company and financed by Tekes, the Ministry of trade and Industry and Culminatum.

Entrepreneurship programme

The Entrepreneurship Project (2000-2003) reflects the political priority given to entrepreneurship and small business creation by the government. The entrepreneurship programme is implemented in cooperation with various administrative sectors and consists of more than 100 versatile measures to reduce administrative burden and to open public services to competition. Measures are directed to different life cycle stages of a company. As an example, Venture Cup Finland is regarded as a successful measure in the promotion of entrepreneurship during the years 2000 - 2003. Other policy measures targeting at the small and medium-sized business sector include key financial instruments, structural funds, research and development support, and support for vocational training.

Innosuomi prize

The Innosuomi prize is awarded annually in recognition of exceptional innovation and entrepreneurship to promote innovations and the creation of new companies, and to improve co-operation between entrepreneurs, funding organisations and the public sector.. The President of the Republic is the patron of the award, giving the prize high visibility (http://www.innosuomi.fi).

Technology incubators

Technology incubators aim to promote business activities by offering premises, facilities, and business services to new start-up companies. Technoloy incubators with biotechnology profiles include:

- Helsinki Science park,
- Kuopio Technology Centre Teknia Ltd.
- Oulu Medipolis,
- Tampere finn-Medi Research Centre Ltd.
- Turku Business Centre DIO

Intro

Intro is a programme for early stage companies in the frame of the PreSeed funding services provided by Sitra. It screens new companies before preparing and introducing them to private investors. The idea is to create a market place for start-ups which would not be disturbed by turbulences in the VC industry. Small investments (up to 100.000€), which might be too small for Venture capital can be made through that programme. The most important group of investors participating in the programme are private investors or business angels, which also bring their expertise to the companies, and often might get involved on the operational level.

Liksa

Liksa is a programme that is jointly provided by Tekes and Sitra. Companies with technology based business ideas with potential fro remarkable international growth, can apply for Liksa.

Liksa provides money for professional services as marketing information for business plan development (max 40.000 €)

Most companies come from the ICT sector as the leading technology sector in Finland, (40%), the share of Biotechnology companies in this programme is around 17% .

Tuli

The Tuli programme is a Tekes programme sipportingcommercialisation of results generated at universities or research institutes. The maximal amount is 10.000 euro and can be used for example for market research, business plan development or services concerning IPR.

2.3.3 Policies with a socio-economic or ethical dimension

Two online services have been started to facilitate the use of public innovation services:

www.Research.fi

Research.fi contains data about different factors in the Finnish innovation system and contains links to the most important documents, publications, statistics etc.

The service provides information about areas, as the centres of excellence, technology programmes, international scientific cooperation, and high-tech production, as well as descriptions of equal opportunity and research ethics. Especially the extensive link collection is very useful as entrance point.

www.yrityssuomi.fi

YritysSuomi is a public online service to facilitate the use of public innovation services for enterprises, entrepreneurs and future entrepreneurs.. The service provides access to a comprehensive range of public services, providing assistance in issues such as setting up a business, growth and development measures and international business activities. In English it is available under the name *Enterprise Finland* and is aimed at foreigners and immigrants.

3 Structure and dynamics of the biopharma system

3.1 National public R&D system

The National Funding organisations (Academy of Finland and Tekes - the National Technology Agency) and the ministries have been presented in 2.2)

There are 20 Universities (10 Multi-faculty universities, 6 specialised universities and 4 Art academies), 29 Polytechnics and 19 Research Institutes in Finland. From these, 10 Universities are engaged in Biotechnology research. Biocentres are important elements of the biotechnology innovation system

Biocentres

- A. I. Virtanen Institute for Molecular Sciences (AIVI), University of Kuopio
- Biocenter Oulu, University of Oulu
- Biocentrum Helsinki, University of Helsinki
- BioCity Turku, University of Turku
- Institute of Biotechnology, University of Helsinki
- Institute of Medical Technology (IMT), University of Tampere

Universities with a biocentre

- University of Helsinki
- University of Kuopio
- University of Oulu
- University of Tampere
- University of Turku
- Åbo Akademi University

Universities without Biocentre

- Helsinki University of Technology (HUT)
- Tampere University of Technology (TUT)
- University of Joensuu
- University of Jyväskylä

Research Institutes

- Agrifood Research Finland (MTT)
- Finnish Environment Institute (SYKE)
- Finnish Forest Research Institute (METLA)
- Finnish Institute of Occupational Health (FIOH)
- National Public Health Institute (KTL)
- National Veterinary and Food Research Institute (EELA)
- VTT Biotechnology (Technical Research Centre of Finland
- Other National Infrastructures
- Finnish Genome Center (FGC)
- Finnish DNA Microarray Centre
- Scientific Computing Ltd (CSC).

3.2 Business system

3.2.1 Biotechnology companies and characteristics

There are currently approximately 120 firms active in Biotechnology in Finland. From 134 firms established by the end of 2001, 15 have ceased to exist as independent firms active in the field. Five of these 15 firms have merged with other firms, six have ceased to exist without formal notification, three have gone bankrupt, and one is inactive.

Table 8. Economic data according to the sector. Source: Brännback et al., 2001.

Sector (year 2000)	Companies	Turnover EUR million	Personnel
Pharma: small,	17	19	335
Pharma medium	3	1197	6615
Diagnostics	30	254	2020
Biomaterials	9	14	136
Food	12	250	1000
Industrial Enzymes	3	73	287
Agro	6	11	50
Services	28	27	270
Other	15	15	10813
Total	123	1860	4178
Total excl. medium Pharma	120	663	

39% of the companies are located in Helsinki, 25% im Turku, 13% in Kuopio and 8% in Oulu and Tampere, respectively, which corresponds well with the location of the Biocentres and Universities with biotechnology research activity.

One can observe the following specialization profiles:

- Helsinki: Genetics and molecular biology
- Turku: pharmaceuticals, diagnostics and biomaterials
- Kuopio: molecular biotechnology and animal biotechnology
- Oulu: molecular and cellular biology
- Tampere health technology

The Finnish Biotech Industry should be considered an immature industry, with most of the companies being quite recently established. Figure 2 shows the number of Finnish Biotechnology companies by year of foundation. 25% were started before 1991, 28% between 1991 and 1996 and 47% were started not before 1997.

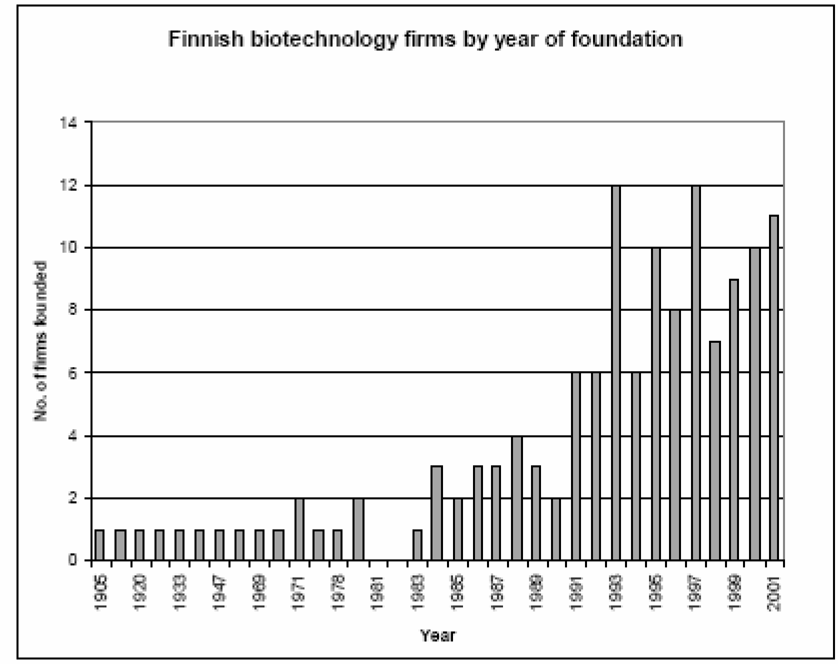


Figure 2.Finnish Biotechnology firms by year of foundation. Source: Hermans & Luukonen, 2002.

The average size of companies is small, with 106 companies that can be classified as small or medium sized.

The majority of the firms (77%) is smaller than 50 employees independent of the age group and 41% of the companies are having less than 10 employees. In companies founded since 1991, companies with less than 10 employees account for around 60 % of the companies, while 40% of the oldest firms have more than 250 employees. Figure 3 shows the number of employees for the different age groups.

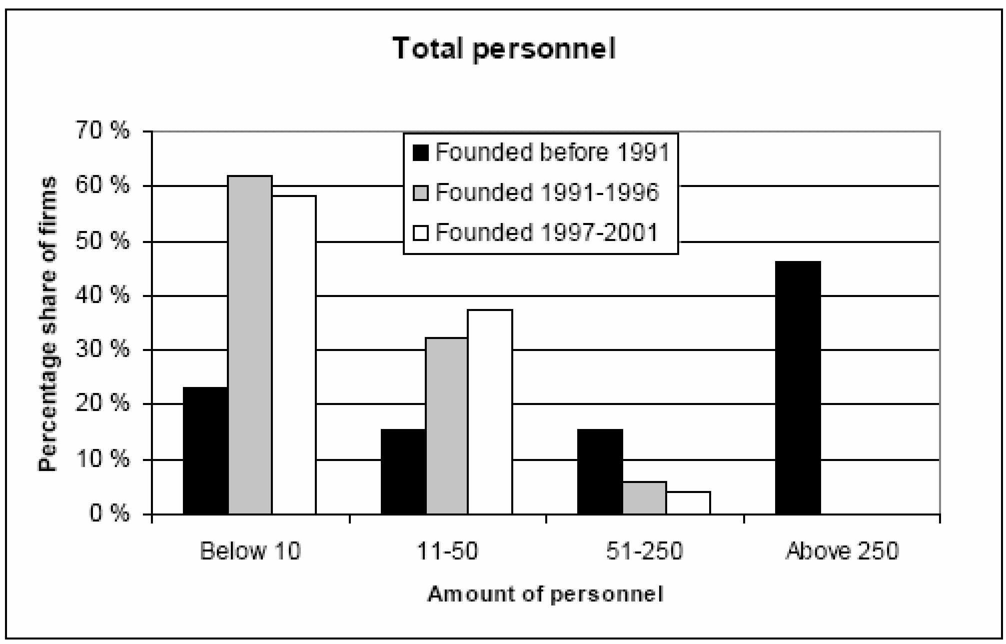


Figure 3.Number of employees by company age for Finnish biotechnology companies. Source: Hermans & Luukonen, 2002.

50% of the companies were located in a bio centre or a science park. For younger firms, this proportion was even higher. 67 % of the firms were spin-offs from research; 19 % from other companies and 8% of the companies were spin-offs from both research and other companies. In 91% of the research spin-offs, the person(s) who had founded the company had been involved in the research leading to the innovation and the foundation of the company.

Almost 70% of the companies founded before 1991 had a turnover of 1 million euro or less. Figure 4 shows the distribution of turnover depending on company age.

40 % of the companies founded after 1991 are creating negative earnings. About 20% of the companies started after 1996 and 35 % of the companies started between 1991-1996 generated profits over 5% of turnover.

In 2000, the 106 small and medium sized biotechnology companies in Finland employed 1735 persons, had 141 million euro sales, 114 million euro R&D costs and negative earnings amounting to 96 million euro.

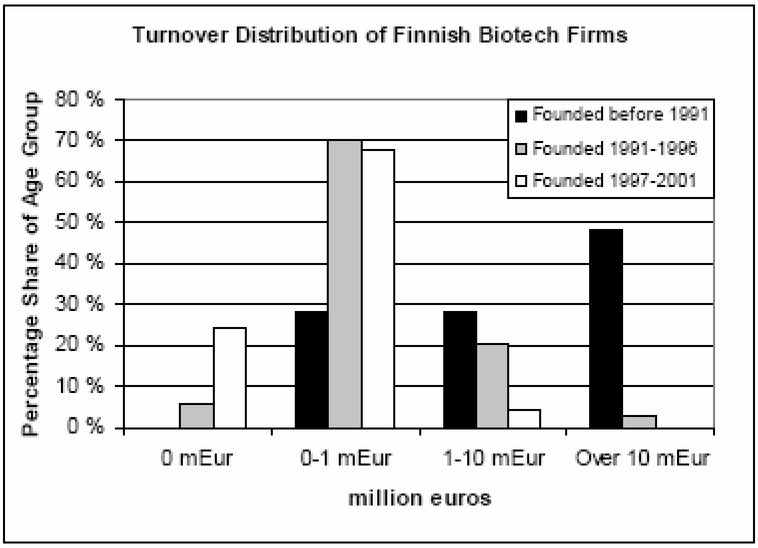


Figure 4. Turnover distribution of Finnish biotechnology companies by company age.Source: Hermans & Luukonen, 2002.

When R&D intensity is analysed by firm age, older companies do invest less money into R&D compared to younger companies. However, the total sum of R&D investments is still much higher for the older compared to the younger companies. According to an estimate, companies founded before 1991 had R&D investments of about 160 million euro in 2001, the younger companies spent less than 100 million euro in R&D activities altogether.

40% of all companies manufactured products while 33% were service-oriented and 20% aimed at both products and services.

61% of the companies had some exports to the EU. 35% of the companies exported to North America. Asia was also a fairly important export target area (26%). Over 90 % of the biotechnology firms were planning exports to the EU area in the next five years. SME Companies expected an average sales growth of 45% annually between 2001 and 2006. (Hermans & Kauranen, 2003).

All Biotechnology firms had a large proportion of academically qualified personnel. Additionally, 60% of all firms had personnel with some university position or tasks. Figure 5 shows the main sources of finance for Finnish biotech companies, last accounting year, and total sum 387 million euro.

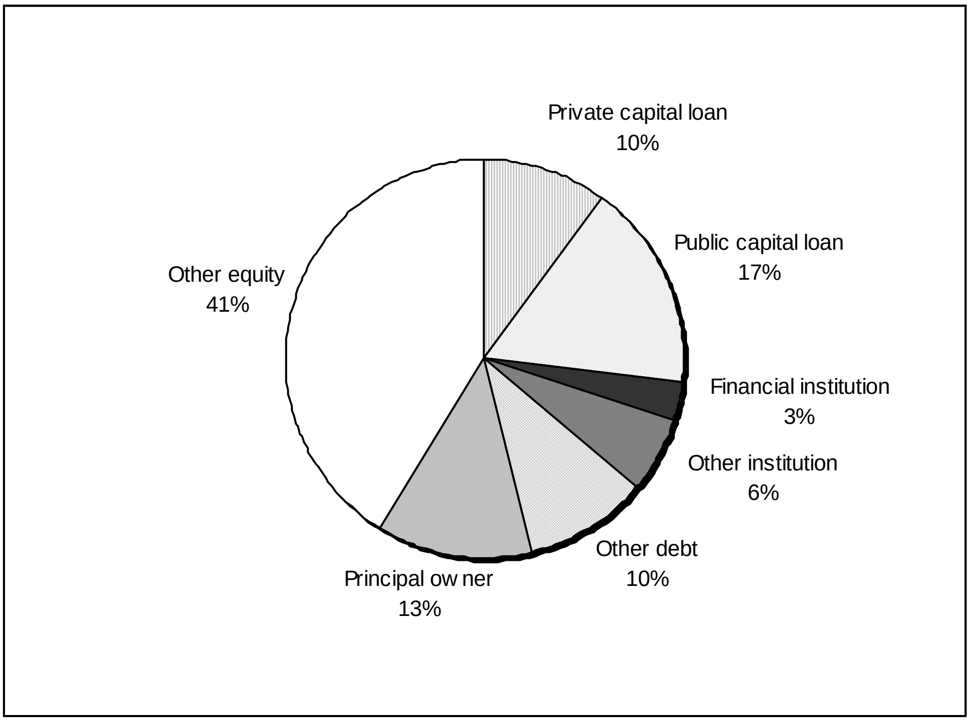


Figure 5.Main sources of finance for Finnish Biotech companies. Source: Finnish Bioindustries, 2003.

3.2.2 R&D co-operation

The response rate of the survey was so low, that the results cannot be analyzed. The following findings were made in the ETLA survey.

Collaborations with Universities and Research institutes are the most frequent types of collaborations for all companies, independent of age. 20 to 30% of all companies collaborated with Finnish Universities and Research Institutes, while around 10% collaborated with Universities and Research Institutes abroad.

Collaborations was in general more frequent within Finland with two exceptions: companies founded before 1991 collaborated more frequently with international customers than with national ones. Collaboration with international competitors was more frequent for companies founded before 1996. However, only about 5% of the companies had established collaboration with competitors. Collaboration with other companies were found for about 10% of all companies (Figures 6-8).

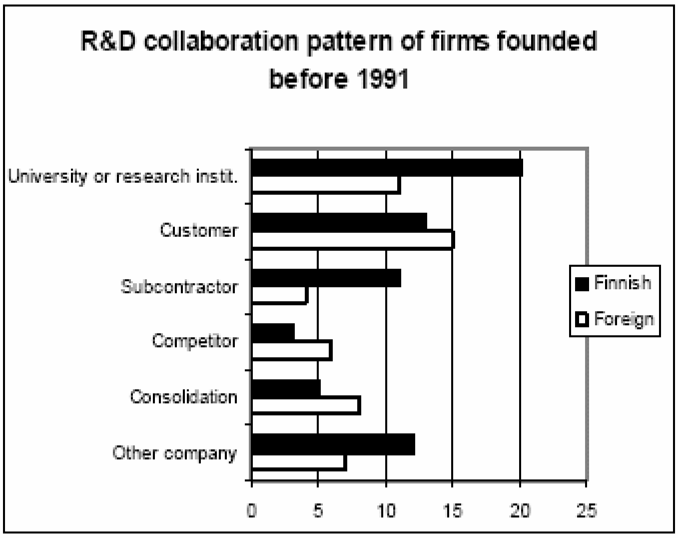


Figure 6.R&D cooperation of Biotechs founded before 1991. Source: Hermans & Luukonen, 2002.

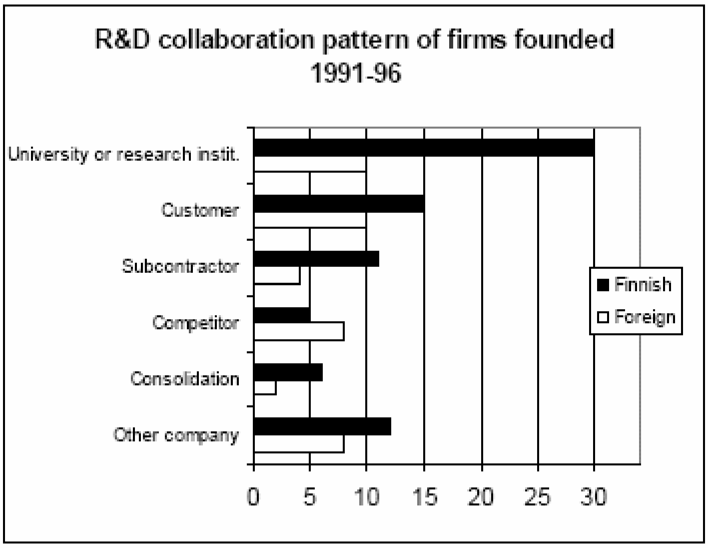


Figure 7 R&D cooperation of Biotechs founded 1991-1996. Source: Hermans & Luukonen, 2002.

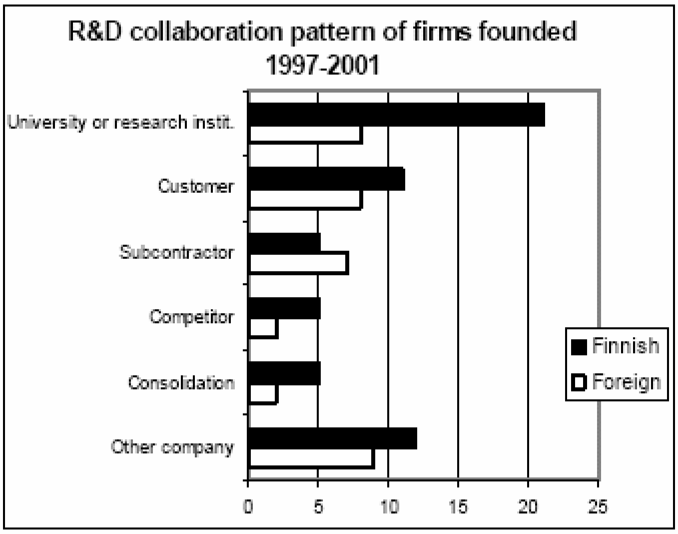


Figure 8.R&D cooperation of Biotechs founded 1997-2001. Source: Hermans & Luukonen, 2002

When compared with other firms, research spin-offs collaborated more often locally, as often with universities or research institutes elsewhere in Finland, but less often abroad. Research spin-offs tended to be even more locally oriented than other firms of the same cohort.

However, one needs to keep in mind that the findings only represent formal collaborations, while informal networks are not captured through surveys but still might represent a frequent and significant share of a company's network.

3.2.3 International dimension of the system

The challenges to internationalise the NIS has been formulated in the Science and Technology Policy Councils latest strategy document (Knowledge, Innovation and Internationalisation, 2003) "on a more general level, the internationalisation of the innovation system involves two challenges: on the one hand, the Finnish system must be able to compete for competent researchers and other research resources, projects and business research and development with other countries systems, and, on the other hand, Finnish players must be able to enter and make use of the opening markets.

The challenges to internationalise the NIS are on several levels and apply both to the scientific, as the business system.

The amount of knowledge produced in Finland, as measured in number and impact of publications can be considered good in natural and medical sciences, (biotechnology) and to a lesser extent in biopharmaceutical publications, if related to size of the population or number of researchers. However, in absolute numbers, the amount of knowledge that is produced in Finland is marginal (for publications around 1%, for patents around 0.5%). That means that most of the knowledge (or practically all of it) is produced outside of Finland. In addition, many scientific units in Finland are small and might lack critical mass, which makes it very important to build up international networks. It is therefore well acknowledged that it is of uttermost importance to support the international dimension of the NIS.

International project collaborations (as measured by co-publications)

In 1998, the number of internationally co-authored papers in Finland was 40%. The share of papers co-published with EU countries did increase much faster than North America, reflecting increasing participation in EU projects. Collaboration EU countries is dominated by Sweden, UK, Germany, France, the Netherlands and Denmark. (Persson et al., 2000)

EU projects

Finland's involvement in EU projects started in 1987. It became a full EU member 1995. According to Kafatos et al. (2002), there were 446 participation in EU Biotechnology Projects, out of which 106 as coordinators in the time period from 1996 to 2001. The University of Helsinki predominated with 136 participations, (30% total), followed by Turku University and Åbo Academy with 96 participations (22%),VTT with 67 participations (15%), the University of Tampere/IMT (35 participations, 18%) and KTL (32 participations and 7%). For the Quality of Life frame programme out of 1524 applications, 350 projects were funded, equalling a success rate of 23%, and 74 of the projects were coordinated by the Finnish part.

Mobility of Researchers

Mobility of Researchers is an important mechanism to generate knowledge transfer and establish collaboration networks. Internationality is an integral part of research in a global environment with a fast-moving "state of the art" front. In this respect, Finland's greatest challenges are the, compatibility and international networks.

Win and loss from a country's perspective will depend on the length and nature of mobility.

Researchers will move out of the country, usually to obtain some form of training, as doctoral or postdoctoral studies. It is increasingly expected that potential research leaders have international research experiences and high prestige fellowship will help building a career. In addition, researchers might provide valuable links to their home community. The total annual duration of international visits by Finnish researchers amounted to 840 person years. In 1999, the Academy of Finland had bilateral agreements with 33 scientific organizations in 26 countries and spent 4.8 million euro on bilateral research exchange (same as 1995).

Most of the researchers would generally like to return home, however, they encounter often barriers to do so. This situation might lead to "Brain drain" and therefore, mechanism of start up grants for returning scientist are often suggested.

Factors that influence return rates might as well relate to institutional rigidities and lack of transparency, but also in a lack of attractive career opportunities in home institutions. Mobility of researcher schemes need therefore also to build up research attractiveness of research environments at home.

Factors that influence attractiveness

- Good position for researchers
- Good laboratories
- Avoiding barriers
- Networking abroad
- Barriers to return: often, post docs from abroad return to their Ph.D. labs.

Higher search costs and higher uncertainty might also lead to a bias preferring local candidates from international ones.

The Academy of Finland funds a significant part of researcher mobility. Mobility is funded through different forms of funding. The Academy supports mobility as part of research projects, research programmes, funding for centres of excellence and grants for researcher training and research work abroad. In addition, mobility is funded through bilateral researcher exchange agreements. The Academy of Finland grants subsidies for a researcher's return to Finland

The Sixth Framework Programme's Human Resources and Mobility (HRM) activity has a budget of €1,580 million and is largely targeted on the financing of training and mobility activities for researchers. These activities, known as the Marie Curie Actions, are aimed at the development and transfer of research competencies, the consolidation and widening of researchers' career prospects, and the promotion of excellence in European research.

Research exchange between pubic and private sector is still minor. A rate of 5% moving from public sector to industry has been calculated for Belgium, Finland, Sweden, UK and USA. Besides the lack of efficient programmes, disparity of earnings have been an important factor

3.3 Performance of the system

3.3.1 Educational output

In 2000, the relative number of doctorates completed by people aged 25-34 in Finland was the second highest in the European Union after Sweden. The number of doctorates increased sharply in Finland during the 1990s. In 1989, the number of doctorates was 402, and increased to 1224 in 2002. During the last three the number of doctoral degrees has no longer shown any substantial growth. During the period from 1989 to 2002, a total of 11,577 persons earned a doctorate; at the same time 142,119 higher academic degrees were completed.

Medical fields accounted for 24 % of all PhD degrees awarded in 1989-2002, the natural sciences accounted for 22 %, and engineering sciences for 15 %. Together, these three major fields accounted for 61 cent of all PhD degrees during this period.

The absolute number of people with a PhD as a proportion of R&D staff increased during the 1990s, but in relative terms there have been no major changes since 1993. In 2001, a total of 7,441 research jobs, or 11 %, were occupied by people with a PhD. In 2001, over 60 % of R&D staff that had a PhD worked in universities, and 14 % in business companies. (source: Survey on PhD (May 2003) Academy of Finland)

Promoting post graduate education decision in the late 90s to start up an extensive postdoctoral research system. From the additional funding that the academy received 28.3 million euro were allocated to the postdoctoral research system.

The number of Academy professors and senior fellow increased from 1999.

Aim: one out of 5 graduates taking up a professional research career. About half of the postdoctoral researchers who received funding through additional funding programme in 1998 are engaged in business and industrial research projects that are run jointly with universities.

Table 9. shows the number of Ph.D from 1996 to 2001 in Biotechnology. Total numbers are not identical to the sums of the columns, since Universities and Biocentres are overlapping in their organizations, and therefore, PhD are counted under both organizations.

Table 9. PhD graduates in Biotechnology in Finnish institutions 1996-2001 (source: Kafatos et al., 2002).

Year	1996	1997	1998	1999	2000	2001	Total
No. Doctoral degrees	153	152	180	206	206	180	1057

3.3.2 Publication performance

Finnish publications are dominated by Natural Sciences and clinical medical Science. Both areas together account for 85% of all publications. In 1993, 4663 papers were published compared to 6605 papers in 1999, an increase of 6.9% annually.

Medical Papers in dominate in all Nordic countries representing about 40 % of the publications. The relative publication index in the field of clnical medical science was well above 1, but slightly decreasing between 1993 to 1999.

Table 10. Finnish -Natural Sciences publications source: Persson et al., 2000

Natural sciences	1993	1999
No publications	2328	3502
Share of all Finnish publications	42.7	45.2
Share of world pub in the field	0.7	0.89
Relative publication index	0.88	0.94

Table 11. Finnish Medical Science publications. source: Persson et al., 2000

Medical Sciences	1993	1999
No publications	2335	3103
Share of all Finnish publications	42.9	40.1
Share of world pub in the field	1.22	1.32
Relative publication index	1.52	1.39

In 1998, the number of internationally co-authored papers in Finland was 40%. The share of papers co-published with EU countries did increase much faster than those co-published with the US. This might reflect the increasing participation in EU projects. Collaboration within EU countries is mainly with Sweden, UK, Germany, France, the Netherlands and Denmark.

In the study, size and impact were positively correlated, indicating the risk of loss of research impact when research activities are organized in very small units. It seems that a volume of 250 and more papers a year is needed to reach a fairly high and stable impact level.

Collaboration between Universities and Industry was more or less constant. Nevertheless, industry publishes most of its papers in collaboration with universities. In 1998, 56 % of all papers from the industry were co-authored with Universities. Most of the publications are originating from researchers in the pharmaceutical industry. Companies that published most were Orion, Alko, Neste Corporation, Farmos Group, Wallac, and Leiras.

Table 12. Source: Institute for Scientific Information, NSIOD 1981-1999 (The State and Quality of Scientific research in Finland)

		OECD Rank
Number publ 1999/GDP USD million	66.3	3
Number publ 1999/R&D expenditure in Universities and Research Inst	76.3	12
Impact factor OECD Natural Sciences	4.65	11
Impact factor OECD Medical Sciences	5.35	8
Relative citation impact Natural Sciences 1995-1999	1.08	11
Relative citation impact Medical Sciences 1995-1999	1.12	8
Percentage of each countries total publ Natural Sciences	44.1	25
Percentage of each countries total publ Medical Sciences	40.9	3

Table 13. Contribution of different actor types to Finnish biopharmaceutical publications. Source: ISI, 2003.

	1994		1999	
Actors	Publications	Contribution %	Publications	Contribution %
Pharma companies	18	1,4 %	8	0,4 %
Biotech companies	6	0,5 %	6	0,3 %
Universities	1001	80,1 %	2037	90,0 %
Hospitals	42	3,4 %	52	2,3 %
PSRO	137	11,0 %	139	6,1 %
Other	45	3,6 %	21	0,9 %
Total	1249		2263	

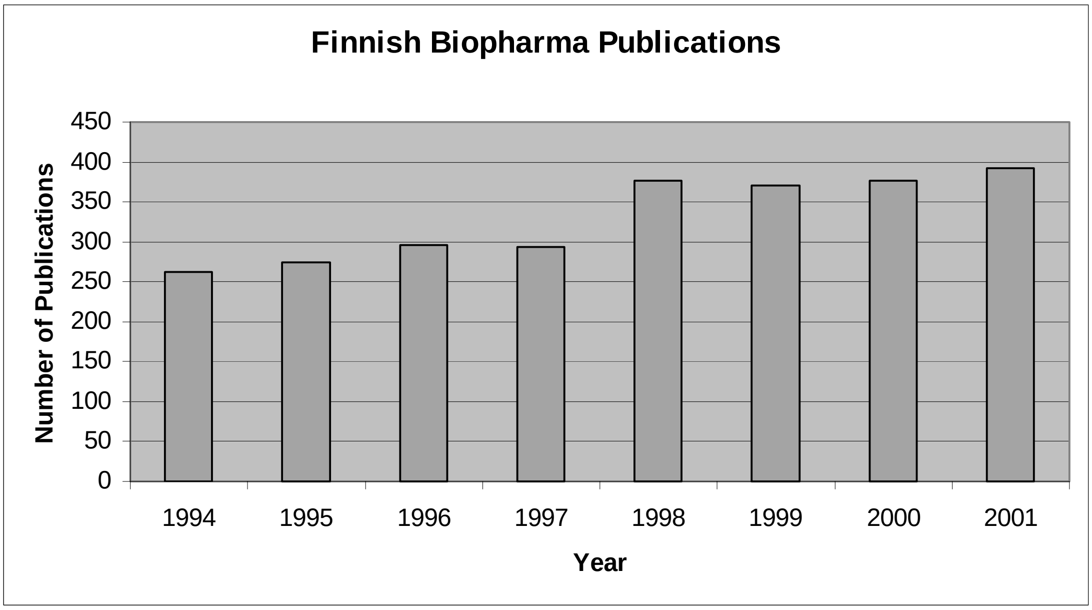


Figure 9. Finnish biopharma publications 1994-2000. Source: ISI, 2003.

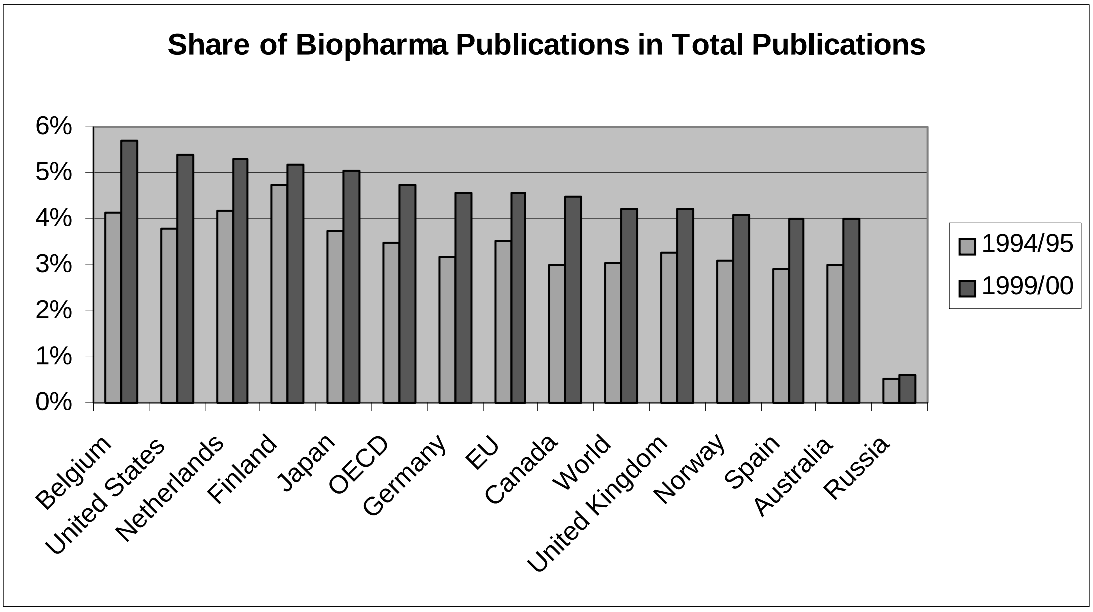


Figure 10. Share of biopharma publications in total publications. Source: ISI, 2003.

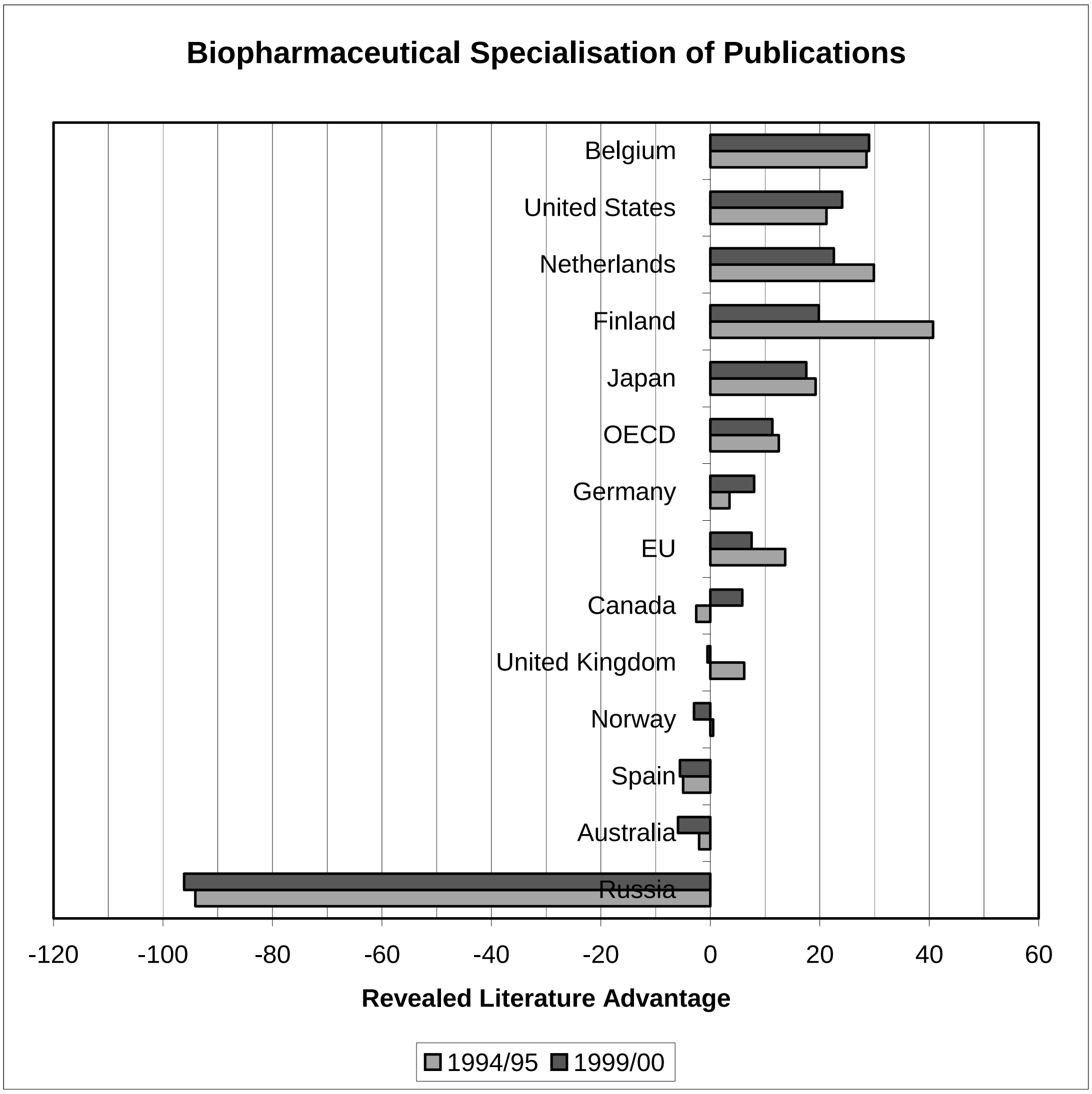
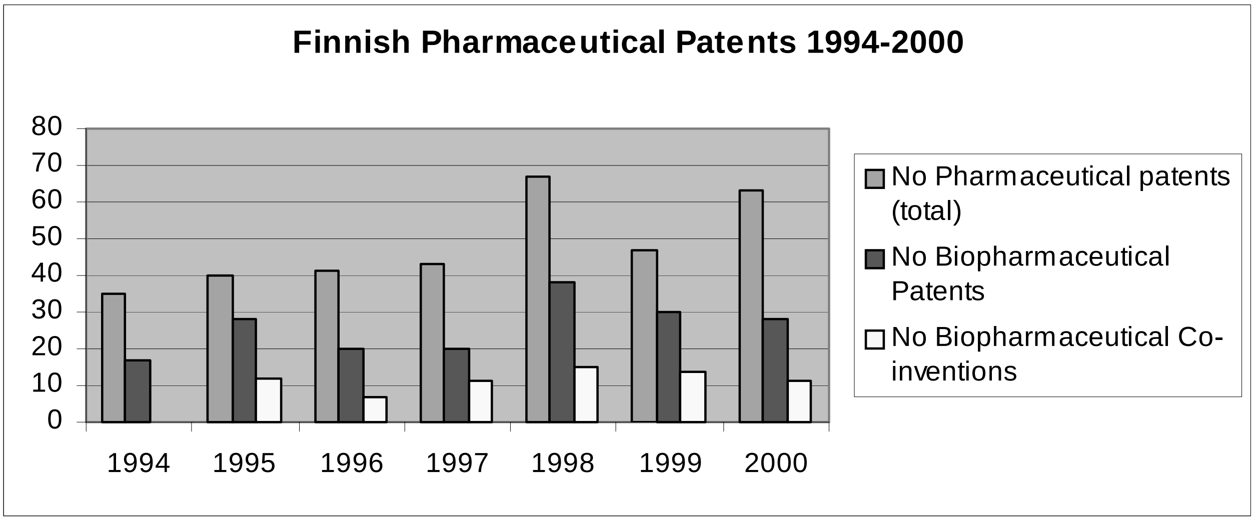


Figure 21. Biopharmaceutical specialisation of publications. Source: ISI, 2003.

3.3.3 Patenting performance



Source: ISI, 2003

Figure 3.. Finnish pharmaceutical patents, biopharmaceutical patents and biopharmaceutical co-inventions. Source: ISI/OECD, 2003.

Table 14. Finnish patent statistics. Source: ISI, 2003.

Finnish Patents	1994	1995	1996	1997	1998	1999	2000
Pharmaceutical Patents	35	40	41	43	67	47	63
Biopharmaceutical patents	17	28	20	20	38	30	28
All patents	903	936	1 103	1 327	1 535	1 816	1 882
% biopharma / pharma	49 %	70 %	49 %	47 %	57 %	64 %	44 %
% biopharma / patents	1,9 %	3,0 %	1,8 %	1,5 %	2,5 %	1,7 %	1,5 %
% Pharma patents/ World pharma	0,5 %	0,5 %	0,5 %	0,5 %	0,6 %	0,4 %	0,5 %
% Pharma patents/ EU pharma	1,5 %	1,7 %	1,5 %	1,4 %	1,8 %	1,1 %	1,4 %
% Biopharma patents / World biopharma	0,6 %	0,8 %	0,5 %	0,4 %	0,7 %	0,5 %	0,4 %
% Biopharma patents / EU biopharma patents	1,8 %	2,8 %	1,7 %	1,3 %	2,2 %	1,5 %	1,5 %

Table 15. Revealed Patent Advantage of Finnish patents: Two-year averages. Source: ISI, 2003.

	RPA of Finnish Patents			
	Pharmaceuticals		Biopharmaceuticals	
Years	1994/95	1999/00	1994/95	1999/00
RPA	0,5	0,3	1,3	1,0

Table 16. Countries major parties in Finnish co-inventions. Source: ISI, 2003.

Major Finnish Co-Invention Parties 1994-2003	
Australia	7
Germany	5
Japan	2
Sweden	16
Switzerland	2
UK	8
USA	27

4 Innovation barriers and drivers

The special features of the biotechnology sector that relate to the entrance barriers and special requirements are:

- High-tech industry with, inherent high risks, especially for the development of disruptive technologies
- Long product development times
- Capital intense- need for international capital
- Need for global markets
- Need for sophisticated customers
- Need for highly skilled personnel
- Highly regulated environment with high compliance costs
- Shortening product life cycles
- Industries with health care sector: demand on cost-efficiency, regulatory issues on prices for cost containment, difficulties with increasing regulations,

Entry barriers in Biotechnology are therefore often connected to financing requirements, proprietary technology, access to distribution channels, and access to skilled personnel

For a group of early-stage companies -- those that are technology-based -- intellectual property represents almost the entirety of their assets. Intellectual Property Rights regimes and procedures play an important role in the survival and growth of a firm. Also access to qualified personnel has been discussed as important barrier to growth.

4.1 Knowledge sources

The results of the survey on collaboration are not available for Finland due to the low response rate the survey attained (for R&D cooperation of Finnish Biotechnology companies see chapter 3.2.1), and therefore no detailed information on aim and type of collaboration is available.

Knowledge can be seen as a production factor to produce results. This process can be divided into 1) Knowledge creation 2) Knowledge transfer 3) Knowledge application. Knowledge can have different qualities:

Know-what: a broad knowledge about facts, quite similar to information; **Know-why**: understanding of scientific principles; **Know-how**: specific skills and **Know-who**: networks: know who has the know-how.

Sources and mechanism of knowledge transfer are dependent on the type of knowledge. While Know-what and Know-why most closely resemble information, that are quite easy to acquire and transfer at relatively low costs, know-how and know-who are tacit forms of knowledge, connected to people or what one would call “experience”.

Different types of knowledge are required for transferring an invention into an innovation. Knowledge needs therefore vary between firms in different sectors and at different stages of their life cycle. The extensive discussion on this issue, however, has been centred on knowledge creation and transfer of knowledge, often focussing on technological or scientific and less on business or organizational knowledge.

Most of the Finnish biotechnology companies are spin-offs from academia (67% are spin-offs from University research), and these firms have a high percentage of academically qualified personnel. (60% of all companies had personnel with some university position or task). The founders are often those, who had the idea that originally led to the creation of the company. Therefore, one can assume that knowledge (Know-what, know-why, know-how and know-who) concerning scientific and technological capabilities are good in those companies. Collaboration between University and Companies is also reflected in the number of contract research and research collaborations. Contract research in biotechnology performed by the universities was 100 million euro in 1995 and increased to a volume of 136.8 million euro in 1999. Research funding from business to companies (1999) amounted to 36 million euro in 1999.

However, knowledge concerning other aspects of the commercialisation, as product development, business development, marketing, sales, financing and regulatory requirements are usually less developed in biotechnology start-ups, seriously compromising the capability of the company to apply that knowledge in form of a successful innovation. Usually it means that the companies lack the human resources with the required competence (practical experience) and the financial means to employ them.

This problem is well known but difficult to solve. Different forms of solutions to transfer business knowledge into start-up companies have been tested, mostly in the form of consultancy, business incubators and entrepreneurship programmes. One serious problem with this approach is the time needed to acquire the critical (tacit) knowledge. Even with well-targeted help from the outside, time is required to gain experience and build up the right networks. But time is something that young start-up companies do not have. Time to market is a critical factor for profitability, and delays in product to market times can seriously endanger profitability of a product. This is becoming even more decreasing product life cycle. One effort to solve this issue has been Sitra's initiative in the frame of the Intro programme to interest private investors with business experience to participate in daily operations of a company.

Large companies might face completely different problems when using outside knowledge sources. Companies that used to develop innovations in-house are coming into a position where they need more input from the outside to sustain their innovative capacities to stay competitive. Those companies need to build up their competence to use knowledge developed outside the company. The costs for knowledge acquisition and transfer are very difficult to analyse on the company level, as they depend on so many different factors, and consist of both internal and external costs.

It is also important to remember that most of the available knowledge (around 99%) is produced outside of Finland. Finland should therefore be regarded as a country that depends on being able to use outside knowledge, not only in the scientific area, but also in the form of human resources and outside expertise.

Knowledge creation as a target outcome should be critically evaluated – and the possibility to replace this by more result oriented outcome measures.

Collaborations between academic laboratories and international pharmaceutical companies or large foreign biotech companies are uncommon.

4.2 Human Resources

The importance of human resources for the success of the biotechnology sector is well acknowledged, especially with business and management experience- as are the problems of most start-up companies to acquire – and finance such staff. While there is no current shortage of personnel in the Biotechnology sector in Finland, this might be more a consequence of the extremely difficult financing situation that compromises growth in many companies, than a reflection of an abundance in qualified personnel. Human resources might well become the next growth barrier in the case of a recovery of the financial markets (for an analysis of the Finnish education system in connection to the pharmaceutical industry see: Brännback et al., 2001). Many of the biotechnology companies are small and possibilities to support the start-up of larger, fast growing companies has been limited, possibly due to the fact that most of the capital comes from national sources.

Finland is a small country and therefore possibilities to educate and train certain specialists are limited. To support high growth in this sector, Finland would need to attract people from abroad. Possibilities to attract foreign staff, are limited by relatively low salary levels, partly caused by high-income taxation, including heavily taxed stock-options. For the academic sector, quality of the research environment and career prospects are of prime importance to attract highly qualified scientist. The graduate school system has improved academic education in biotechnology. Between 1996 and 2001 around 1000 graduates finished their PhD in Biotechnology. Development of biotechnology applications in the area of agriculture, environmental applications, forestry, pulp and paper industry has been explained by a lack of research funding for these areas. This situation is caused by a lack of scientist working in these areas, and therefore a lower amount of research applications. This creates a catch 22 situation- and a more proactive approach through for example hiring of international scientific experts.

Other important barriers that have been discussed are the harsh Nordic climate and the language, however, those barriers are difficult to target with policies in the frame of the innovation system. Human resources are becoming increasingly important for a company to qualify for international venture capital. Management teams and human resources of new companies are more rigorously evaluated than some years ago .If the management team is thought inadequate, possibilities to receive VC capital from international markets are marginal. Highly qualified people are not only needed within companies, but also in the financing sector, the public sector to evaluate and to monitor companies, in technology transfer, business consultancy and financing services. The availability of a sufficient number of specialists with the necessary (practical) expertise on evaluating, funding and assisting high-technology firms, has been considered a barrier to innovation by our interviewees.

The human capital pipeline needs improvement on different levels. There is a gap in positions for young promising scientist that makes it difficult to retain scientists with high potential at the universities. In many research laboratories, the number of post-doctoral fellows is low, especially compared to numbers of Ph.D. students. A transition to a tenure-track system was recommended

4.3 Financing

While only 5% of all SMEs in Finland regarded availability of capital as the most significant obstacle, 50% of the growth oriented SMEs indicate availability of financing a problem. In the Global Entrepreneurship monitor Finland ranks 16 (among 29) on how well VC market, angel financing and IPOs work. The dominating issue during the interviews with sector experts were financing issues, and therefore, much room will be devoted to this discussion. Both factors that influence demand and supply side will be discussed.

4.3.1 Public funds and framework conditions

Government can provide appropriate framework conditions that stimulate private sector investments, including efficient financial markets and an incentive structure that adequately rewards risk-taking. Government can also take a more active role in cases of “funding gaps”, where access to financing is a major business constraint, where investors are not willing to provide funds in small amounts or where regional imbalances are too pronounced. But the demand side is also important, including the availability of promising ideas and entrepreneurs suitable for investment, which can be affected by appropriate framework conditions conducive to creativity, innovation, risk-taking and entrepreneurship. Policies can influence both the demand and supply of capital. Taxation is another important policy area that affects both supply of and demand for private risk capital. For example, many governments choose tax incentives, particularly investor tax credits, to stimulate the supply of venture capital. A reduction in capital gains tax rates can also stimulate venture capital activity.

In general, one can differentiate between four different types of measures:

- Market-based, or indirect schemes, like tax incentives and personnel based schemes
- Targeted (direct measures) which form the bulk of public measures, as grants and subsidies, R&D contracts
- Guarantee schemes for loans and equity

Support for VC capital

Finland abandoned R&D tax credits in1987 within the frame of a large tax reform. They were not considered an efficient tool due to problems of defining R&D activities precisely enough to avoid relabelling of R&D activities and the high administrative costs connected to the scheme. Main instrument to support R&D activities in Finland are therefore direct subsidies in the form of R&D grants and loans with favourable conditions

Advantages of indirect measures are their less distortive effects on the market since it is left to the firm to decide how to make the most of the incentives

Advantages and disadvantages of the respective schemes have been widely discussed and most countries use both types of schemes to support R&D activities.

As most of the EU-countries and the US, Finland allows the accelerated depreciation for capital expenditure on R&D infrastructure and equipment, providing companies with an incentive to invest in modern equipment and so stimulating advances in products. Both free and accelerated depreciation offer a delay in the payment of taxes rather than an actual tax reduction. Table 17 shows the most important Tax incentives by country.

Table 17. Tax incentives policies in EU and USA (source : European Comission; DG Enterprise, Innovation directorate, (2001)

Tax incentives for policy target areas of innovation activity, by country

Red dots indicate schemes that match good practice criteria
Source: Study authors

Tax incentives for innovation	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Luxembourg	Netherlands	Portugal	Spain	Sweden	United Kingdom	United States
Business expenditure on R&D		•			•				•		•	•	•		•	•
R&D capital expenditure	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
Technology transfer								•					•			
Industrial design and process engineering					•								•			
Quality certification					•								•			
ICTs and electronic commerce													•		•	
Software					•		•						•			
Patent applications		•			•		•									
Training					•				•	•			•			
Contracting of researchers					•				•		•	•	•	•	•	•
Co-operation with research institutes		•			•				•			•	•		•	•
Creation of innovative start-ups					•											
Share ownership in start-ups			•		•			•	•	•	•	•	•		•	

Finnish Legislation contains two Acts on the use of government funds in granting government aid and business subsidies in general. These provide information on the general aims and conditions of government support. The Act on government aid 688/2001 applies to the use of government funds in government aid. It refers to the granting of subsidies, loans and other financing, interest subsidies, guarantees, and other similar benefits.

The Act on the general conditions on business subsidies 786/1997 applies to the granting of business aid directly or indirectly from government funds. Business subsidies refer to government aid and interest subsidies as well as loans, guarantees, or other financing, which involve a subsidy to the recipient.13 Section 3 describes the general objectives of a business support program: “A business support program must promote the growth potential of the economy as well as increase the efficiency of business activity. A business support program must be targeted primarily to such purposes, which remove deficiencies in the market.”

“A business support program must be composed in such a way that the distortion on competition is minimized.”

The source of all the quotes on the legislation is the database at www.finlex.fi .

Important EU legislation[7]

[7] 12 Article 87 of the EC Treaty, 87(1): “1. Save as otherwise provided in this Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, insofar as it affects trade between Member States, be incompatible with the common market.” 13

In Finland, the government has empowered the MTI to create and implement policies that provide an environment conducive to the establishment of new businesses and their growth. According to the MTI, “the objective is to improve the financing environment by measures corrective of operative deficiencies of the market and by actions promoting market operations.”

Finnvera, Tekes, TE-Centres, and FII serve as the public special financing infrastructure in the Finnish economy administered by the MTI. In addition, Sitra and various regional governmental and semi-governmental venture capital firms provide funding to Finnish firms. A good overview over business funding available from the different governmental resources can be obtained from Invest in Finland [8] .

Finnvera is clearly the largest player by the volume of financing (about 50%), followed by Tekes (about 20%) and that the relative shares of the total financing granted to SMEs by the various institutions have been quite stable (the importance is different for the biotechnology sector, though). Sitra has increased its SME financing share from 4% in 1997 to about 7% in 2001.

It is important to note that government’s direct funding to SMEs increased more rapidly during the two boom years of 1999 and 2000 than during 1998 or 2001, coinciding with increases in the availability of external finance on the market, more than 18% in real terms during the period.

For Finnvera, Sitra and FII, there is a requirement for self-sufficiency in financing. The requirement for self-sufficiency is not consistent with the idea that Finnvera and FII are supposed to rectify market failures (for a discussion see Maula and Murray, 2002).

4.3.2 Public R&D funding

The development of Research Funding during the 90s

In 1991, universities accounted for 22.1 % of the total R&D expenditure in Finland, corresponding to international average. By 1997, the figure had dropped to 17.7 and core funding dropped from 67% in 1991 to 54% in 1998. Core funding at universities

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Section 2 also defines a business support program: “A business support program refers to a system, which is based on legislation or official decision, where the target, form and amount of the business subsidy is defined, and by virtue of which individual business subsidy decisions are made.” (Authors’ translation)

“A business support program must be directed primarily at research, product development, education, internationalization or other intangible business development or improving the competitiveness of SMEs in the long term. For financing typical large company investments and working capital, business subsidies can be granted only on special grounds.” (Authors’ translation)

Section 5 describes the general conditions on business subsidies:

“Business subsidies can only be granted for such business activity, which is estimated to have the requisites for continuous profitable activity. The giver of the subsidy, when making the business subsidy decision, must establish the amount of public support as well as the total financing, profitability and effects on competi-tion of the project in question.” (Authors’ translation)

8

http://www.investinfinland.fi/business/fact%20sheets%20june%202003/Investment_Incentives_03.PDF is tied to performance: universities are expected to produce a certain amount of degrees and qualifications. Two thirds allocated on teaching performance (master degrees, no), and 35% on basic research performance (doctorates earned, no)

Core budget for universities also increased in the same time period, however, no significant net increase in research funding occurred because part of the money was earmarked for real estate expenses, which universities did not have to cover previously

The main trends that have affected universities in recent years were:

- A decline in the government R&D funding
- A decline in the share of the government sector in the total R&D funding
- A change in the nature and allocation criteria of public funding
- Closer international integration with the innovation system and increased cooperation between organizations
- Continued structural and operational reform of science and national innovation system
- Increase cooperation within and between universities
- Increased international interaction in research

Growing concerns about the quality and quantity of research personnel

The Academy of Finland saw the fastest growth of research resources between 1995 and 2000. Funding volume increased by almost 80 % in real terms from 76.7 million euro to 153 million euro.

Funding allocated through Tekes increased 40%, or from 250 million euro to 403 million euro. In 1999, 2060 companies had R&D projects that were partially funded by Tekes and Tekes funding represented less than 7% of the total R&D spending from the business sector

Core funding for research institutes remained more or less constant. Similar changes have been experienced in the other western industrial countries.

In 1997, public funding for R&D to the business sector was 4.1% of the total investment (OECD average: 10.2).

The total amount of funding in the Finnish R&D system corresponds to less than 2% of the funding available to research in the US.

4.3.3 Public R&D funding to biotechnology

Finnish public investment in biotechnology amounted to approximately 115 million euro in 2000 (Statistics Finland, 2002) and 145 million euro in 2001 (Kafatos et al., 2002). From a total research expenditure of 4459.6 million, 70.2% were financed by the industry, and 26.2% from public sources (1168.4 million euro). Investment from public sources into biotechnology can therefore be estimated to be around 10% of total investment. Scholarships from the 5 most important foundations in biotechnology amounted to 11 million euro (6.9% of total funds) and company funding to Universities and Research Institutes was estimated at a maximum of €10 million. Contract research in Biotechnology at universities amounted to 100 million euro in 1995 and increased to 136.8 million euro in 1999.

In Natural sciences, the amount of external funding in 1998 has been 53%. (from 185.8 million euro research expenditure) and 37% in Medical sciences (from 87.3 million euro).

The amount of public funding into Biotechnology from the different sources is described below:

Ministry of Trade and Industry

Direct Funding:

Funding to VTT: the funding for Biotechnology was estimated to 3.7 million euro and 3 million euro were used for direct financing of Biotechnology research.

Indirect funding via The National Technology Agency (Tekes):

Tekes financing for Biotechnology amounted to 39.9 million euro in 2001, corresponding to about 10% of the total budget (387 million euro). The funding instruments and the amounts are shown in Table 18.

Table 18. Tekes funding for Biotechnology (Kafatos et al., 2002)

Funding Instrument	Biotechnology Funding (million euro)	Total funding (million euro)	% Biotechnology funding
Research Funding for Universities and Research Institutes	19.8	146	13.6%
Industrial R&D grants	11	160	6.9%
Capital loans	6.3	34	18.5%
Industrial risk loans	2.8	47	5.9%
Total	39.9	387	

Ministry of Education

The Ministry of Education allocates funding for Biotechnology research through direct University budget funding, earmarked-funding, mostly directed to the biocentres, and graduate schools. Graduate schools are funded directly by the Ministry but evaluated by the Academy of Finland and resources are allocated on a competitive basis. Competitive Funding is also channelled via the Academy of Finland.

The amount for biotechnology research financed by the Academy of Finland was estimated at 39.2, corresponding to 21% of the total budget (184 M€). Funding is dived between six main funding instruments:

1. Research programmes targeted to certain research fields (11.4%)
2. Research projects (non targeted) (43.2%)
3. Research posts (Academy professors, 5 ys group leaders (11.3%)
4. Researcher Training Grad school courses, post docs (12.8%)
5. International researcher exchange (2.4%)
6. Centres of excellence (16.8%)

Ministry of Social Affairs and Health:

The Ministry of Social Affairs and Health Direct directly funds KTL and €4.4 million or 22% of the total budget (21 M€) were allocated to for biotechnology research.

Ministry of Agriculture and Forestry funded biotechnology research with 0.4 million euro in 2001.

Ministry of Environment funded biotechnology with 0.03 million euro.

Figure 4 shows main sources of public research funding in biotechnology. Total: 140 million euro

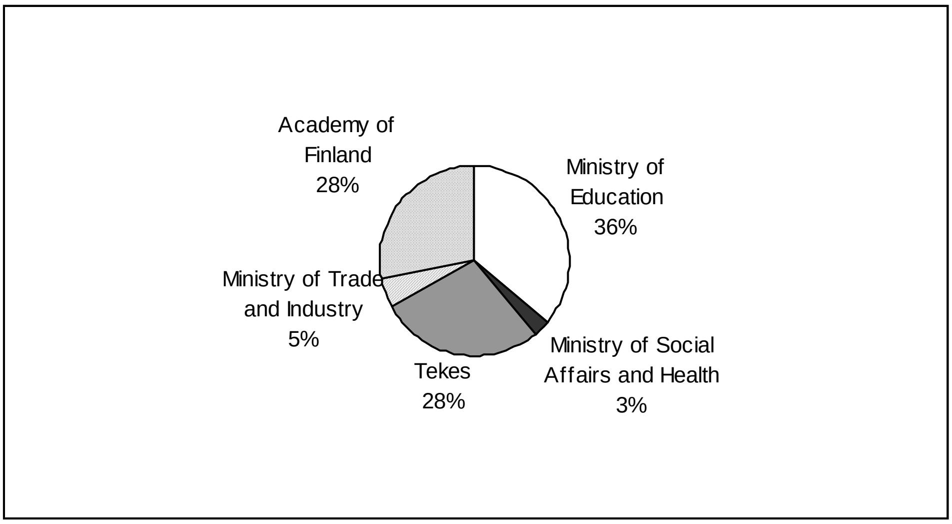


Figure 4. Breakdown of public research funding for Biotechnology. Source: Kafatos et al., 2002

Sitra

Sitra Life Science operations accounts for 46% of Sitra's venture-capital operations. The current focus is to increase operational capabilities of the principal portfolio companies. Sitra evaluates the following factors before deciding to provide capital: the market potential of the company's products, the uniqueness of the technology and whether it can be protected, the company's prospects for growth, the weakness and strengths of the company's management, and the company's competitiveness finances firms mainly using equity and equity-linked instruments.

Sitra's investments into biotechnology has grown to an annual level of EUR 34 million. In 1999, Sitra's biotech investments totalled EUR 8.4 million and EUR 20.2 were invested in 2000. Investment into life science operations amounted to 26 million euro in 2002, with 6 million as first time investment and 19 millions in further investment. The Life Science portfolio of Sitra comprised 40 companies in 2002, a reduction from previous 50 companies due to M&A and partial and complete exits from certain companies. Further consolidation is planned. Sitra reports that the barrier to make a favourable investment decision has increased. In 2002, only three financing decisions were made: one for new, and 2 for portfolio companies.

Figure 5 and Figure 6 show the percentage of firms that received funding from the different public funding sources. Almost 80% of all companies have received governmental aid or loan guarantees from Tekes.

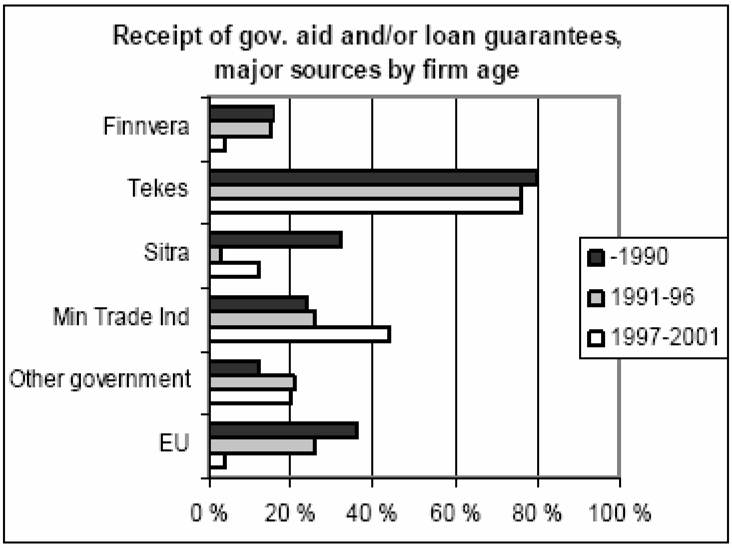


Figure 5.Percentage of companies receivers of government aid or guarantees by source and years of funding (source: Hermans & Luukkonen, 2002).

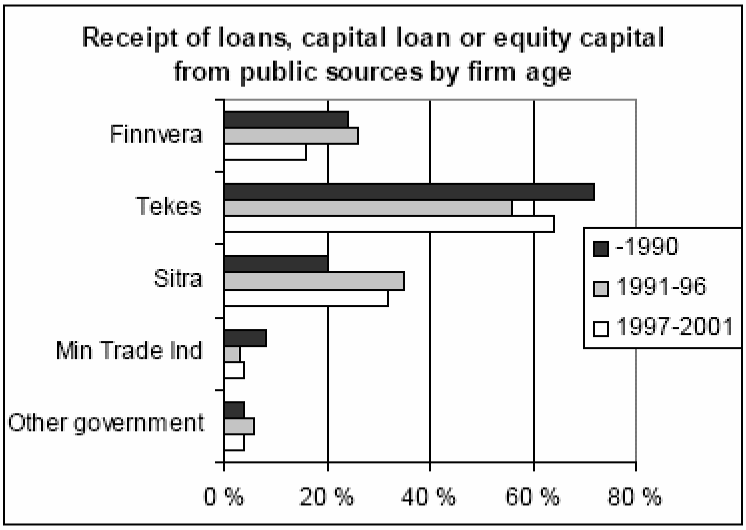


Figure 6. Percentage of firms receivers of capital by source and years of funding. (Source: Hermans & Luukkonen, 2002).

From the above, it is clear that funding for biotechnology R&D and training in the public sector comes largely from the Ministry of Education, directly or through the University budgets or through the Academy of Finland; the Ministry of Trade and Industry (directly or via TEKES) is the second most important funding organization, and the Ministry of Social Affairs and Health is the third. The Ministry of Agriculture and Forestry and the Ministry of Environment devote only smaller amounts to biotechnology R&D.

4.3.4 Taxation

Taxation has an influence as innovation barrier/driver through taxation of personal income and capital gain taxes (CGT). This matters, both on the demand side (the high growth SMEs seeking finance) and the supply side (the institutional and individual investors). The stability and predictability of the overall tax environment is also important.

Personal income taxation

Finland is -together with the other Nordic countries one- of the most equal countries in terms of income distribution and taxation on earned income is high. The tax system has further been designed to compress the already rather flat primary income distribution. The highly progressive rate schedule implies a heavy tax burden at higher wage levels while the Finnish industry specialisation requires a highly-qualified workforce. The steep progressiveness of labour income taxes also reduces the return for an individual investing in education. Tax revenue is equivalent to more than 45 % of GDP, making Finland particularly susceptible to tax-related inefficiencies and more vulnerable to tax competition.

The effective tax wedge on labour is the third highest in the EU after Sweden and Denmark (7 points higher than EU average), and differences are higher for higher income brackets. Also the marginal tax rate wedges remains very high, despite recent tax reductions. In Finland, roughly two thirds of a salary increase due to improvements in an employers productivity is streamed into the public sector through various channels and only one third raises the after tax disposable income of the employee. As human capital is assuming greater importance for the growth of productivity, the weak after-tax profitability of labour might seriously hamper retaining qualified labour force in Finland or recruiting from abroad.

The taxation of capital gains

The taxation of risk capital and equity investments has a direct effect their attractiveness. Capital gains tax (GGT) affects investors through two channels.

CGT applies to the disposal of assets and hence affects the rate of return on investments. It influences decisions by individual investors, financial institutions and venture capitalists to invest in early start-up companies.

In Finland, taxation of capital income (including taxes paid on interest income of private persons, investment fund gains, dividend income, rent income and capital gains is 29 %, which is one percentage point above EU average.

It treats almost all forms of investments equally. Exceptions are lower tax rates for owner occupied housing and private pension insurance, but no other tax

As a comparison, in the United States capital gains are taxed at 10% to 28% depending on the individual’s tax bracket. Half of the gain is excluded if the investment was made to a qualifying small business and held for five years. favourable capital gains taxes may be a significant incentive for individuals to start new businesses. No similar tax benefits are available in the Finnish taxation system. For an overview over capital gain taxation in the different member states see[9]:

CGT can affect the remuneration packages that are in the form of assets, usually stock options. The ability of start-ups to offer stock options is often needed to attract qualified personnel and achieving growth. For many smaller high-growth companies they also provide one of the few available remuneration options. In the United States, stock options may also have contributed to the emergence of many small, innovative firms, particularly in the information technology sector.

4.3.5 Venture Capital financing

The Nordic financial system has been traditionally bank-centred. At the beginning of the 80s, the financial system were heavily regulated limiting both the quantities and rates at which banks could lend, as well as foreign capital flow. The financial markets were liberalized effectively between 1984 to 1986. Some restrictions concerning foreign direct investments and certain cross border capital movements remained in effect until the beginning of the 90s. The VC market remained underdeveloped the entire 1980s and much of the early 90s. Still in the early 90s, the amount of funds raised was very low. Sitra was becoming a player in VC financing and the Finnish government provided funding through the Finnish Investment Ltd. The year 1999 was the most active fundraising year in Finland with record high investment levels (570

[9] Benchmarking business Angels, European Commission 2003 Best Report No 1 http://www.eban.org/download/benchmarking_ba_en.pdf

million euro). During the period from 1996 to 2000, the Finnish proportion of European private VC funds reached the level predicted by its GDP share.

During the last 10 years, 30% of the total investment was, on average invested in early stage firms, which is higher than the average European share of 14 to 19% (1995-2000). Investments on ICT dominated the Finnish investment sector with an average above 40% since the mid 90s. The Finnish Venture Capital association (www.fvca.fi) had 48 member companies at the end of 2002. Nearly 60% of the currently operative Finnish Venture capital firms have been established between 1996-2001. Insurance companies and pension funds serve as the main sources of funds.

VC firms have, on average, 21 investee companies in their portfolios, but in 33 companies, the portfolio consists of only ten or fewer companies. The average size of investment has been 4.5 million euros, however, in about 40% of the VC firms the average investment was less than 1 million euros. Sixty-three per cent of the VC companies had no biotechnology company in their portfolio, and 30 per cent of them had a share of up to 25%.

On average, less than 50 exits were made annually over the period between 1991 to 1998. The most common exit routes were trade sale (37%) management buy-out (27%) and IPO (16%). Average duration of an investment has been 2.6 years.

Until now, only one biopharmaceutical company made an IPO in Finland, BioTie Therapies, which went to the market in June 2000 with a transaction size € 21,1 Million.

As a whole, the first IPO wave in Finland in the late 80s was strong also by international standards, the latter Finnish IPO wave in the late 90s has clearly been moderate; in per capita terms, the Finnish IPO activity, has outpaced only that of Germany. The Finnish stock market can therefore not be considered a particularly attractive exit market for venture capitalists. Liquidity is concentrated on large firms as the turnover of small firms and particularly that of the firms listed on the so called new market “NM-list” is rather low. The lack of an efficient exit market has been mentioned as serious barrier for the availability of risk capital by several of our interviewees.

One additional problem was the lack of experience and maturity in the venture capital firms, not only in Finland but probably in whole Europe. The early venture capitalists were inexperienced to guide their portfolio firms over the difficult market conditions, which began starting 2001/2002. In general companies in Finland have been badly under-financed.

In an evaluation of the taxation and legal environment concerning private equity and VC activity in Europe done by the European Venture Capital Association (EVCA) in 2002, Finland was rated among the less attractive European countries (11^{th} out of 15 examined). In spite of the “mechanical” and concise nature of the investigation, it gives an idea of the comparative standing of Finland in “race” of attracting foreign capital and putting private capital to work.

Other issues which were seen in the evaluation made by the EVCA as less favourable for the private equity industry were the scarcity of fiscal incentives for business R&D expenditure, the lack of fiscal technology transfer support, lack of preferential tax rate for SMEs, comparatively high capital income taxation, the lack of incentives for private individuals to invest in private equity, the taxation of stock options and the liquidity regulations concerning pension funds and insurance companies. The entrepreneurial environment has equally been seen as an unfavourable one in the same report. (EVCA, 2003).

Current development VC investments

In 2002, the capital under management in the Finnish private equity industry totalled 3 170 M€. The total amount increased 14 per cent compared with the end of previous year. The active portfolio included some 715 investee companies.

The private sector investors held 3 017M€ of the total capital under management (95 %), while the public sector investors held 153M€ (5 %). Table 19 shows the source of funds.

Table 19. Source of funds governed by Finnish VCs. Data source: FVCA (2002)

Source	Amount financed (million €)	% total
Pension funds	278	42
Insurance companies	189	29
corporate investors	76	12
public sector	58	9
banks	16	2
fund of funds	16	2
capital markets	10	1

In 2001 the Finnish private equity and venture capital companies invested 340 M€. The number of investments was 449 and were made in 294 companies.

In 2002, the Finnish private equity and venture capital companies invested 391 M€. The number of investments was 462 and were made in 256 portfolio companies. Compared to the previous year the amount invested increased by 15 percent, while the number of first time investments slightly decreased. A large part of investment was dedicated to follow-on investment. Figure 7 shows the development of Annual Investment between 1991 and 2002.

Private sector investors were responsible for 89% of the total amount invested (349M€). The Public sector invested a total of 42 M€ (11%). Seed stage financing and turnaround financing attracted mainly public sector investors. Expansion stage financing and investments in buyouts was made by private funds

Similar to other countries, the Finnish private equity and venture capital companies concentrated financing to later stage companies. Seed stage companies (29 M€; 7%), start up companies with the amount 35M€ (9 %) and the early stage companies with the total amount of 33 M€ (8 %).

In terms of the investment numbers, the focus is still on early stage companies. The seed stage companies attracted (21%), altogether 95 investments, the start up companies 84 investments (18 %), the other early stage companies 106 investments

(23 %), the expansion stage companies 132 investments (29 %) and the MBOs/MBIs 29 investments (6%) (FVCA, 2002). See also Table 20.

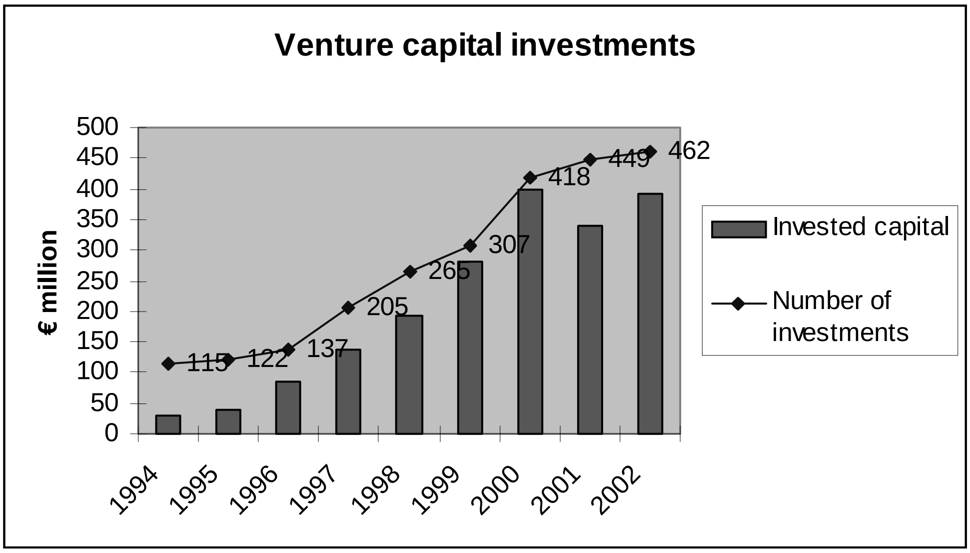


Figure 7. Amount of capital invested by VCs and number of investments. Data source: FVCA (2002)

Table 20. Investments and active investment portfolio of VCs by sector in 2002. Data source: FVCA (2002)

Industrial sector	**Initial Investments**		**Follow-on Investments**		**Total Investment**	
	M €	Nbr	M €	Nbr	M €	Nbr
Services (other)	106	22	6	25	112	47
ICT	31	34	30	109	61	143
Life Sciences	20	18	36	68	56	86
Electronics	42	14	8	27	50	41
Industrial Prod & Serv	22	20	3	22	25	42
Other	61	28	26	75	87	103
Total	282	136	109	326	391	462

Business investment into R&D

It is difficult to estimate R&D expenditure in Biotechnology in the Business sector since not all R&D in companies using biotechnology will be devoted only to biotechnology research. However, an upper limit of 233 million € can be estimated, or 7% of total R&D costs.

Table 21. Investment into R&D by sectorsin 2000 (Source: Statistics Finland)

Branch	Total R&D million euros	R&D in firms using biotechnology	%
Food products	62.7	37.0	59
Chemicals incl Pharmaceuticals	231.0	117.4	50.8
Research and Development	135.8	24.8	18.2
Other branches	2706.5	43.7	1.6
Business enterprises total	3135.9	222.8	7.1

4.4 Entrepreneurship

While "Entrepreneurship" remains difficult to define, it has been recognized as a major contributing factor for the creation of economic growth and is seen as the driving force to translate an invention into an actual innovation.

Entrepreneurship is usually associated with the generation of small growth oriented companies and less with large, mature companies. However, also large companies can behave "entrepreneurial".

The political priority that the Finnish government places on the development of entrepreneurship and small business creation is reflected in the large Entrepreneurship Project that has been carried out by the Ministry for Trade and Industry. In addition to the project, other policy measures targeted at the small and medium-sized business sector include key financial instruments, structural funds, research and development support, and support for vocational training.

For entrepreneurial activity, three important elements are required: (1) the perception of opportunity for entrepreneurial firms, (2) the existence of individual entrepreneurial capacity to develop, implement, and manage a new business, and (3) the existence of sufficient motivation to actually pursue an entrepreneurial career option.

Finland is among the top-three GEM 2001 countries both in terms of perception of opportunity and in terms of entrepreneurial capacity. However, in terms of entrepreneurial motivation, Finland only ranks as 20th among the 29 GEM countries. The lack of motivation can partly be explained by the lack of an efficient incentive financial structure, but also through cultural values that are usually slow to change. The Finnish GEM team concludes in her report that " the technological infrastructure is in excellent condition, but there are weaknesses in the innovative ability of small and medium-sized entrepreneurial firms. The problem with innovative SMEs is not necessarily one of insufficient capability for R&D. On the contrary, Finnish SMEs are among the world leaders in terms of the use of sophisticated technologies. The bottleneck, as some Finnish key informants see it, is more in the area of technology commercialization. Whereas large Finnish companies have excellent strengths in this area, creating viable technology-based new ventures is problematic"

Universities are an important source of scientific and technology inventions in Biotechnology and the "third mission" targeting the commercialisation of research results will be included in the new amended University Act. The development has been reflected in the increasing collaboration with industry and in the rapidly increased share of external contract research as a source of funding. However, it is not clear if and what structural changes are needed within the Finnish university system, to accomplish this third mission.

Commercialisation of research results can be achieved by technology transfer to established companies, in the form of licensing, research collaborations, contract research or through the generation of academic spin-off companies. Previous uncertainties with IPR in universities are reacted on by the Finnish government and planned amendment of the corresponding legislation is discussed in detail in Section 4.5.

Technology transfer and IPR have been handled very differently by the different Universities, both support and financial resources and policies varying considerably. One direct consequence is the limited availability of data concerning IPR as number of disclosures, number of patents, licenses or spin-off creation. Often, patenting issues are handled by innovation and research units at the universities and some of them work in close collaboration with the Finnish foundation for inventions. Some but not all universities offer financial support for patenting activities. Some Universities and Bio centres prefer to recommend collaboration of the scientists with the technology transfer companies that are active in the area of biotechnology:

- OY Aboa Tech Ltd., Turku
- Licentia Oy, Helsinki
- OuluTech Oy, Finland
- Tuotekehitys Oy Tamlink Tampere
- Finn-Medi Tutkimus Oy, Tampere

A third possibility is that the link goes via the Science parks, that offer services connected to commercialisation and IPR.

At the moment it is not possible to foresee the consequences the new legislation will actually have on patenting or licensing activities or the creation of university spin-off companies. So far, the old practice has not led to satisfactory results concerning the commercialisation of academic research results. While collaborative and contract research activities are extensive in international comparison, the number of patents in Biotechnology is below OECD average and much below the country rate of patenting in other high-technology areas as ICT.

The creation of academic university spin-off companies poses a different set of challenges. Academic spin-off companies are the most frequent type of biotech start-up companies, comprising 67% of all companies. Many of those have founder teams with purely academic background.

The key question remains if partnership between academia and business should be developed, rather than trying to turn academic people into entrepreneurs. Generating ideas, developing them into a product and bring the product on the market does not necessarily have to be done by the same person.

Many support schemes target the transformation of the academic into an entrepreneur through education, businesses support services and consultancy. In Europe, there are currently 300 spin-out support programmes. In Finland, technology centres located near universities are the main support for spin-out programmes

Under the assumption that this model is successful, the major draw back might still be the time that is required by the founding team to gain the necessary experience which may slow down product development to such a degree that it becomes unprofitable.

The transformation of academics- often qualified professors – into entrepreneurs might also lead to a loss of scientific competence and talent at the university – and – purely speculative- the most inventive scientists might not automatically become the most gifted entrepreneurs. There is also the danger that the scientist that becomes CEO of his own company will compromise his research competence while acquiring the necessary business competence, or will focus unduly on research, thereby compromising the capability of the company for successful product development.

In a study of the growth path of biotechnology companies three types of companies emerged:

1) Technological companies with low growth, focused on the local market, and acting as “research boutiques”. “Research boutiques” are funded by public-sector grants, and start with minimum capital but there is a danger of continuing research and consulting without developing the company further

2) Companies where the founder is willing to let the company grow but without clear direction, and those

3) Companies with explosive growth plans from the beginning –the “born globals”

The number of entrepreneurship courses at universities is continuously increasing, and in polytechnics and vocational high schools, entrepreneurship teaching has recently been made a mandatory component of all degree studies. A specific Diploma in Entrepreneurship teaching will be started in vocational high schools in 2002, and the Ministry of Education is currently working on defining the requirements of a special vocational diploma intended for practicing entrepreneurs. Entrepreneurship teaching has also been extended in adult education and in employee re-training courses. Important tools have been support programmes for business plan development (Tuli, LIKSA) and business plan competitions. While entrepreneurship education continues to increase in quantity, qualitative challenges remain.

Positive trends that have been perceived in Finland connected to entrepreneurship:

- Entrepreneurial culture improving in Finland
- Some role models emerging for rapid growth and internationalisation
- Technology ventures becoming increasingly professional
- Finnish VCs have developed internationalisation strategies

- Finnish VCs have developed international syndication relationships and internationalisation support capabilities

4.5 Laws and regulations influencing the biopharmaceutical industry

4.5.1 Regulations touching on medical research

National regulations

Medical research involving human subjects includes research on identifiable human material and/or identifiable data. In the field of scientific research involving humans, there are many laws, both national and international, and ethical codes to be complied, and in them, data protection and obligations covering the status of research subjects have a high priority.

Of the national regulations, the most important in scientific research involving humans are the Constitution (731/1999), Act on the Openness of Government Activities (621/1999), Personal Data Act (523/1999), Act on the Status and Rights of Patients (785/1999), Medical Research Act (488/1999), Medical Research Degree (986/1999), Act on the Medical Use of Human Organs and Tissues (101/2001), Government Decree on the Medical Use of Human Organs and Tissues (594/2001) and Decree on the National Advisory Board on Health Care Ethics (494/1998). The administrative order by the National Agency for Medicines specifies Clinical Trials on Medicinal Products in Human Subjects (1/2001), too. Available legal frameworks in areas related to genetic testing

Convention on Human Rights and Biomedicine (Council of Europe)

Finland has signed (1997, Oviedo; 1998, Paris) but not yet ratified the Convention. For Article 12 on predictive genetic tests, Finland does not intend to make any reservations

The Constitution of Finland guarantees the freedom and the rights of individuals. The personal integrity of an individual shall not be violated and no one shall be treated in a manner violating human dignity. On the other hand, the freedom of science is guaranteed by the Constitution, but the rights of individuals have a higher priority than the freedom of science. The Constitution includes articles on prohibition of discrimination and on protection of privacy, which have remained unchanged.

By *the Act on the Openness of Government Activities*, all official documents shall be public, and access to a secret document or its contents is not granted. However, any person whose right, interest or obligation in a matter is concerned shall have the right of access to the contents of a document that is not in the public domain, if they may influence or may have influenced the consideration of his/her matter.

The *Personal Data Act* ensures that the privacy, interests and rights of data subjects are not violated without cause. The data subject has the right of access to the data pertaining to him/her, the right to have erroneous data corrected and to prohibit the use of the data for given purposes. The data subject must also be voluntarily provided with information e.g. on the purposes for which the personal data is being processed.

Later processing for purposes of historical, scientific or statistical research is not deemed incompatible with the original purposes. The Act is regarded as “secondary legislation” meaning that it may be superseded by another applicable act or decree. It covers activities carried out by public authorities, private organisations and individuals, but exceptions are made for personal use data collection.

This Act prohibits processing sensitive data. Personal data are deemed to be sensitive, if they relate to e.g. the state of health or the medical treatment of an individual. Sensitive data may only be used for specific purposes, such as by health authorities for treatment of a medical condition, by an insurer for insurance activities concerning data collected for the purpose, or for scientific or statistical research. The prohibition does not either prevent processing of data in cases where the data subject has given an express consent. Sensitive data must be erased as soon as the basis for its processing ceases to exist. The basis and the need for processing must be re-evaluated at five-year intervals at the longest.

The Act contains also explicit provisions on the processing of personal identity numbers, so as to prevent their unnecessary processing. Transfers of personal data to countries not offering the same level of data protection as the EU states are possible only under the preconditions laid down in the Act. In such cases, the transfers must usually also be notified to the Data Protection Ombudsman.

Protection of personal data and confidentiality of medical data is regulated by several acts, e.g. *Personal Data Information Act* (1999) and *Act on the Status and Rights of Patients* (1993). The first addresses the right to know whether a file includes data about oneself, the right to demand and in most cases get such information, the right to require the correction of incorrect information on one's file, the right to demand compensation for damage caused by incorrect personal information, etc. The second addresses confidentiality of medical data.

The Medical Research Act and the Medical Research Decree regulate research involving human beings. Research plans must be submitted to the ethics committees of a hospital district for prior evaluation, and the most important things concerned are the consent of the research subject and the risks, pain and inconvenience inflicted on him or her compared to the benefits to be gained from the research. Before the start of a clinical trial the research subject is entitled to comprehensive information of the trial and his/her rights shall be clearly stated. The trial subject must sign a written consent to participate and he/she can discontinue whenever. Medical Research Act (1999)

This Act regulates the general conditions governing medical research: respect of the inviolability of human dignity, favourable opinion of the ethics committee, informed consent of a research subject, etc. It also states that every hospital district (20) should have an ethics committee and makes specific provisions concerning research on persons unable to give consent: minors, pregnant women and nursing mothers, prisoners, embryos and foetuses. Medical Research Act (1999)

The Act on Use of Human Organs and Tissues regulates the removal, retention, storage and use of human organs, tissues and tissue samples. Tissue samples taken for medical research purposes may be surrendered and used for medical research other than that stated in the consent document only with the consent of the person concerned. If the said person has died, the National Board of Medicolegal Affairs may, however, grant permission for such research if justifiable cause exists. Using tissue samples to establish the hereditary character of a disease diagnosed in another person is allowed only if the person from whom the sample was taken gives his/her consent.

Human material (DNA, tissue samples, cells etc.) is collected in biobanks, but Finland has no specific regulations regarding these biobanks. The recently approved *Act on the Removal of Human Organs and Tissues for Medical* Use (101/2001) and the Medical Research Act (488/1999) provide some regulations regarding biobanks.

Gene Technology Act (1995) aims to promote the safe use and development of gene technology in an ethically acceptable way and to prevent and avert any harm to human health, animals, property or the environment that may be caused by the use of genetically modified organisms. It does not, however, apply to modification of human genetic material by genetic techniques.

Medical Devices Act (1994) states that any instrument, apparatus, appliance, material or other article, whether used alone or in combination, or intended to be used, e.g. for the purpose of diagnosis, must be suitable for this intended purpose. Use of the device must not compromise the health or safety of a patient, user or other person. A proposition to amend the Act, to include in vitro diagnostic medical devices, is now before Parliament.

Coercive Measures Act (1997) allows the use of DNA testing in investigation of serious crimes; however, storage of personal information (e.g. health) in such a context is not allowed.

Aliens' Act (amended 2000) allows the use of DNA testing to examine family ties when a residence permit is applied for on these grounds. It states that voluntary, informed and written consent of a person who applies for a residence permit is required prior to testing.

International regulations

By *the Convention on Human Rights and Biomedicine (ETS 164)*, the interests of human beings must come before the interests of science or society. The Convention bans all forms of discrimination based on the grounds of a person's genetic make-up and allows predictive genetic tests only for medical purposes. The Convention stresses expressed consent and stipulates patients’ right to be informed about their health, including the results of predictive genetic tests. It recognises, however, the patient's right not to know, too.

The scope of *the Directive 2001/20/EC* is wide and covers the whole process of conducting a clinical trial on human subjects involving medicinal products in the EU.

The Directive includes a paragraph affirming that “The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration.” It also lays down standards for the manufacture, import and labelling of investigational medicinal products (IMPs) and provides for quality assurance of clinical trials and IMPs. To ensure compliance with these standards, inspection systems for Good Manufacturing Practice and Good Clinical Practice must be set up.

There is also *the Recommendation (90) 3 by the Council of Europe: Committee of Ministers* which states that medical research should never be carried out contrary to human dignity.

Gene Technology Act (377/1995) and Gene Technology Decree (821/1995)

The Finnish Gene Technology Act (377/1995) and Decree (821/1995) brought the Finnish legislation concerning genetically modified organisms (GMOs) in line with the relevant EU Directives. A revision of the Finnish legislation took place e.g. during 2001-2002, due to the comprehensive revision of the EU Directive on deliberate release of GMOs (2001/18/EC).

The EU Directives 90/219/EEC on the contained use of genetically modified organisms and 90/220/EEC on deliberate release of genetically modified organisms (which can be viewed on UNIDO's BINAS server) are implemented by the Act. Besides what is prescribed in these Directives the Act covers the use of genetically modified plants and animals in contained use.

Ethical guidelines

The Declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects” was drafted and adopted by the World Medical Association in 1964 and has been amended several times. It is a fundamental document and has had considerable influence on the formulation of international, regional and national legislation and codes of conduct. Finland has legislative provisions that expressly endorse the Declaration of Helsinki.

The Guidelines for Research, Operational Guidelines for Ethics Committees that Review Biomedical Research, and *Guidelines on Good Clinical Practice (GCP) for Trials on Pharmaceutical Products* by *the WHO* are important in the field. The purpose of these guidelines is to set globally applicable standards for the conduct of biomedical research on human subjects. They are based on provisions already promulgated e.g. in Finland.

The Council for International Organisations of Medical Sciences (CIOMS) has developed e.g. the following guidelines *Ethics and Research on Human Subjects: International Guidelines (1992), International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993)* and *International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002).* The guidelines relate mainly to ethical justification and scientific validity of research, ethical review, informed consent, vulnerability of individuals, groups, communities and populations, women as research subjects, equity regarding burdens and benefits, choice of control in clinical trials, confidentiality, compensation for injury, strengthening of national or local capacity for ethical review and obligations of sponsors to provide health-care services.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH*)* brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions. The purpose is to make recommendations to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. ICH states that "Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki."

Ethics committees

Finland has four major national ethics committees concerning biomedicine and research.

The Board for Gene Technology (GTLK)

The Board for Gene Technology is constituted by the Gene Technology Decree (No. 821/1995). It acts both as national authority and towards the European Community processing notifications concerning the use of genetically modified organisms. The board supervises the implementation of the Act on Gene Technology. The aim is to promote safe and ethically acceptable use of gene technology and to prevent any harm that might be inflicted to human health, snimals or the environment. The board is appointed by the council for five years by the government upon referall of the Ministry of Social Affairs and Health.

The National Advisory Board for Biotechnology (BTNK)

The Gene Technology decree (821/1995) also sets the functions of the Advisory Board for Biotechnology. The board has no rights to legally binding decisions and is appointed for three years by the Council. The board is devided into five working groups: EC legislation, national legislative work, environmental issues, bioethics and information services. It publishes a journal and organizes discussions and seminars in the field. The board monitors progress in biotechnology as well as their health and environmental consequences and promotes international collaboration. The board promotes cooperation between authorities and develops and promotes information and education in biotechnology. .

The National Advisory Board on Health Care Ethics (ETENE)

The Advisory Board on Health Care Ethics was founded by an amendment to the Parliamentary Act on the Status and Rights of patients as an expert committee dealing with ethical issues related to health care and the status and rights of patients. The board does not issue legally binding decisions but has the right to issue recommendations, statmenets and advisory opinions.

The subcommittee on Medical Research Ethics (TUKIJA) supports the regional ethics committees in ethical issues concerning medicines and health care and submits national opinions on international multicenter clinical trials.

The National Advisory Board on Research Ethics (TENK)

The decree on The National Advisory Board on Research Ethics (1347/1991) assigns the tasks to the council. They make proposals on legislation concerning research ethics and act as expert committee to resolve issues of research ethics. They follow and coordinate international cooperation, disseminate information and lead discussions on the topic. The board issues guidelines for good science practice, procedures to handle fraud and misconduct . The third, revised guidelines came out in 2002. The board is appointed by the Ministry of Education for three years.

Regional and institutional Ethics committees

Ethics committees of Hospital disctricts. According to the Medical Resesearch Act (488/1999) an independent ethic committee has to preevaluate a clnical trial before it can be started. The ethics committees are appointed by the hospital districts and registered by the provincial state office. Finland has 30 etics committees. The functions of the committees include prior evaluation of research projects based on conformity to the provisions of the Medical Research Act, data protection legislation, the international obligations covering the status of research subjects and the rules and guidelines that govern medical research. The most important are the Council of Europe Convention on Human Rights and Biomedicine (ETS 164) and Directive 2001/20/EC on Good Clinical ractice in the conduct of clinical trials . The committees do not make final decisions on the conduct of research but they issue an opinion on its approval. Without the approval of the committee, the research cannot be conducted, and the ethics committee of some other public or private health care unit, institution, community or company cannot deliver this kind of opinion.

Committees on Animal Experimentation. Under the Decree on Animal Experimentation,(1076/1985, amended in 1996) all institutions conducting animal experiments must have a committee to evaluate research plans involving animal experiments to ensure compliance to animal welfare regulations. New legislation on animal experimentation is presently under preparation at the Ministry of Agriculture and Forestry.

4.5.2 Protection of Intellectual Property Rights

As a result of the historical process of close cooperation among the Nordic Countries in drafting of Intellectual Property (IP) legislation, the Finnish legislation on IP shares common features with that of Sweden, Norway and Denmark.

Finnish legislation on Intellectual Property (IP) has been harmonized to correspond to the applicable EC Directives and Regulations to the extent that legislation is governed by the European Union.

The main types of IP in Finnish legislation are patents, trademarks, copyrights, designs, utility models and trade secret protection. Issues relevant to the protection of IP rights concerning the actors in the biotechnology sector are an object of (at least) the following pieces of Finnish legislation:

- Finnish Patent Act (550/1967)
- Finnish Patent Decree (669/1980)
- Finnish Trade Mark Act (7/1964)
- Finnish Trade Mark Decree (296/1964)
- Finnish Unfair Business Practice Act (1061/1978)
- Employment Contract Act (55/2001)
- Finnish Criminal Code (39/1889)

The most relevant issues of IP protection for the biotechnological and biopharmaceutical inventions are patents as well as trade secret protection. The protection of trade secrets is addressed in the The Finnish Unfair Business Practice Act (1061/1978) and is not further reviewed.

4.5.2.1 Patents

The right to a Finnish patent is settled in the Finnish Patents Act (550/1967, latest amended June 30th 2000). Concerning the EC Directive on Legal Protection of Biotechnological Inventions (Directive 98/44/EC), Finland was one of the first EU member states to implement the Directive in its legislation. The corresponding amendments have been introduced into the Patents Act as of June 30th, 2000.

Inventions can be patented even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions, but an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may, where the requirements for patentability are fulfilled, constitute a patentable invention, even if the structure of that element is identical to that of a natural element. Concerning biotechnological inventions, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Concerning process patents, the protection of a patented process extends both to biological material directly obtained through the process and any biological material derived from that material possessing the same characteristics. The protection conferred by a patent on a product containing or consisting of genetic information extends to all material, in which the product is incorporated and in which the genetic information is contained and performs its function. Concerning the protection of pharmaceuticals, it has to be noted that prior to 1996 only process patents have been available under Finnish legislation. Currently pharmaceuticals may be protected by a product patent.

Patents are not granted for plant or animal varieties, unless the technical feasibility is not confined to a particular plant or animal variety, neither patents are granted fro essentially biological processes for the production of plants or animals. Patents are not granted for inventions the commercial exploitation of which would be contrary to *ordre public* or morality. As unpatentable the Act lists in particular the following cases :

1) processes for cloning human beings;

2) processes for modifying the germ line genetic identity of human beings;

3) uses of human embryos for industrial or commercial purposes;

4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

A notable limitation of the patent’s owner exclusive right of use is the possibility for compulsory licensing, which is given by the Patents Act.

Applications for a Finnish patent are to be filed at the National Board of Patents and Registration of Finland. An alternative route for achieving a patent protection in Finland is through an European patent application (a patent granted by the European Patent Office under the European Patent Convention) and having Finland as a designated state in that application. Upon approval of the European patent application, it comes in force in Finland with the corresponding terms as a national patent. An application for an European patent is to be filed with the European Patent Office (EPO), but it may also be filed with the Finnish Patent Authority to be transmitted to the EPO.

The World Intellectual Property Organisation WIPO has on 24 September 2003 unanimously approved the National Board of Patents and Registration of Finland as international PCT Authority, which makes Finland the eleventh state in the world authorized to carry out searches and patentability examinations in respect of international patent applications. That would be inevitably beneficial for Finnish applicants, since statistically Finland has been one of the biggest users of the PCT system in the world.

4.5.3 Ownership of Research Results

4.5.3.1 Ownership of Innovations within an Employment Relationship

The ownership of research results made by employees is addressed in a separate piece of Finnish legislation, namely, the Act Concerning Rights to Employee Inventions (656/1967). The Act concerns inventions of employees both in private companies and in the public sector, with the notable exception of teachers and researchers in universities or similar institutions of higher education, which will be further discussed below. The Act is applicable to inventions, which are patentable under Finnish legislation.

Under the Act the initial ownership of the invention is of the employee, who has the same right over the invention as any other inventor, unless otherwise stated. The employer may obtain rights over the invention to a different extent depending on the employees duties, the circumstances under which the invention has been done and the business of the employer. The closer the link of the invention with the employees duties, the experience acquired under the employment relationship and the line of business of the employer, the stronger standing has the employer in acquiring rights over the invention.

The employee is obliged to inform the employer without delay about any inventions of the kinds described in the Act Concerning Rights to Employee Inventions (656/1967). The employer is given a stated in the Act period of time (4 months) to react to the employees information, during which the employee may not disclose any information related to the invention. The employee may, however seek a patent for the invention, before the end of that period, provided that the employer is informed one month ahead of the application.

The rulings of the Act are not mandatory the concerned parties may agree otherwise. In Finland collective agreements do not regulate issues of employee inventions, hence companies formulate their own agreement practice. See also [10] Finnish Bioindustries

[10] Finnish Bioindustries "A Guide for Bioindustry on How to Draft a Code of Practice for Employee Inventions" based on the Finnish legislation. http://www.finbio.net/download/invention-guide.pdf

4.5.3.2 Immaterial property rights at Universities

The research done in universities and other tertiary education institutes as well as governmentally run research institutions has an important role in the Finnish innovation system. One of the principal goals of universities has been to increase the general knowledge base of the society through fundamental scientific research. However, it is increasingly expected from the research done in universities and in the above-mentioned institutions to have more direct impact on the economy and the well being of society. An important prerequisite for the exploitation of the research results in the economy is the securing of immaterial in university research. The Finnish University Act (645/1997) gives the main objectives of the university system in Finland, which are still those of free scientific research and the training based on that research. The proposed amendment to the Act adds a so-called “third objective” to the current objectives. It has been formulated in the amendment proposal as an objective of “ interaction of the university with society and assuring that university research gives its positive impact on the development of society”. The legal framework concerning rights of university researchers and researchers in equivalent institutes or their employers in research results is not a subject of European legislation, but is of the competence of the different member states and the arrangements vary from one state to the other. It has to be mentioned, that the rules for participation in a European Community Framework RTD programmes are currently reshaping the actual practice of how research results are handled and act for the convergence of that practice.

With view of the importance of the issue to the biopharmaceutical industry, we shall cover shortly the current status of the discussions and the proposed future development concerning the matter.

Currently, the Act Concerning Rights to Employee Inventions (656/1967) contains an exception for teachers and researchers in universities or institutions of higher education having a similar status (e.g. as meant in the University Act 645/1997). These persons are given the right to freely use the inventions that they make in their own work. The exception is based on the notion of the scientific freedom in the universities. The exception is not extended to other university personnel and the result of their work, under the Act, stays a property of the employer, e.g. the university. The exception is not extended either to researches of other governmental institutes or researchers of the Academy of Finland. There is no legislation ruling on the rights over products, materials or prototypes produced in relation to the research and which may have commercial value and thus such materials stay property of the university. What concerns research in biotechnology, such can be the case of biomaterials, which are not patentable, but can still have commercial value.

In 1997 the Finnish Ministry of Education appointed a work group[11] charged with the evaluation of the issues concerning immaterial rights of researchers in the Finnish

[11] Chaired by Ossi V. Lindqvist

Universities and the Finnish Academy of sciences as well as the need for development in the exploitation of research results.

The work group suggested a revision of the Act Concerning Rights to Employee Inventions (656/1967), so that the researchers employed in universities and institutions are treated similarly to other researchers in an employment relationship. Other suggestions were that the university activity should be developed by drafting strategies for the exploitation of research results and questions concerning immaterial rights should be taken better into account when making contract research agreements. The work group underlined the importance of the adoption of a clear practice for the exploitation and protection of immaterial rights. Equally, it was pointed that the universities should be given the needed resources for that.

A University Invention Work Group, appointed by the Ministry of Trade and Industry up to identify the legislative and other means that could be used to both prerequisites and sufficient incentives promote commercialization of inventions made at the universities included proposed drafts of amendments to be made to the University Act (645/1997) and the Act Concerning Rights to Employee Inventions (656/1967) as well as a draft of a new Act providing for the rights to inventions made at universities.

The proposed new version of the Act would allow universities:

- to take shares in companies promoting the exploitation of research results or promoting regional development. Under the present Act, the universities are not able to take shares without the consent of parliament. Decision making power would be conferred to the university rector, as is the current practice with other university resources, and the decision would have to be done in line with the university council guidelines.
- to establish technology transfer and licensing companies alone or together with other partners without the consent of the Finnish parliament.
- To organize any returns from innovation activity, as well as other external funds into funds, managed outside of the governmental budget of the university and used for university activity.

The Finnish government has presented the proposal for an amendment of the University Act to the Parliament. The comments to the Government proposal are due to the Ministry of Education by October 31st, 2003. The planned coming into force of the amendment is August 2005.

4.5.3.3 Proposed legislation

Proposal for changes in the Act Concerning Rights to Employee Inventions

The proposed amendment to the Act Concerning Rights to Employee Inventions (656/1967) includes a change of the so-called “researcher exception”. It is proposed that the “researcher exception” be extended to concern all university personnel, personnel in institutes for higher vocational training and the researchers of the Academy of Finland. The change is meant to reflect the new reality in university research, which is done increasingly in groups of researchers and might involve personnel from different institutions or employees other than researchers. In that way all involved in university research could be treated equally and problematic concerning ownership of research results would be left to be resolved in a new piece of legislation- an Act for inventions made at the universities.

Act on the rights to inventions made at universities

The proposed new Act concerns rights to inventions made at universities (as meant by the University Act 645/1997) and the institutes of vocational higher education (as meant by the Act on vocational higher training 255/1995) as well by researchers of the Academy of Finland. The Act would concern as well students participating in research projects, while being employed by the universities. Everyone involved in research in the above mentioned institutes should be covered by the Act without respect of employment arrangements or position. Other students or researchers, which are not employed by the university, would be treated as independent inventors, and possible transfer of rights should be arranged on the basis of a separate contract between the university and the student or researcher. The proposed Act is not meant to be mandatory and is applied unless otherwise agreed upon. The proposed Act concerns only inventions that can be patented.

Under the proposed Act, the initial ownership of rights over an invention would belong to the inventor or to the group of inventors, who have participated in the invention. The university could acquire, however, rights over the invention depending on the circumstances under which the invention has been made. The Act would impose on the inventor the responsibility of notifying the university about an invention. The rulings of the Act regarding the duty of the inventor to inform the university of an invention would be mandatory.

It is proposed that research be divided in three different categories, independent research, joint research and contracted research, which are defined more precisely in the text of the proposal.

In independent research, the inventor would preserve all rights to decide on the exploitation or any publications of the invention. The inventor would be obliged to notify the university of the invention and the university could acquire rights to the invention in the cases, where the inventor has not made efforts to exploit the invention, has not made a publication or informed of having made preparations for the exploitation of the invention within a stated period.

In the cases of joint research or contractual research, the university would have right to acquire the rights over an invention within a stated period.

The Act would recognize the right of the inventor to make a scientific publication and exploit the invention in teaching or research, excluding the cases of contractual research, unless otherwise agreed. In the cases where the university is entitled to taking the rights over an invention, the researcher would have to abstain from publication of information, which can endanger the securing of the immaterial rights and damage the interests of the university or other concerned parties. The inventor would be equally entitled to a rightful compensation for transferring the rights to an invention to the university.

5 Markets

5.1 Background

Health care costs have been rising steadily in all European countries in relation to GDP sine the 70s and 80s. This has mostly been due to advances in health technologies. New medicines are usually much more expensive than those already on the market.

Most European countries have therefore different mechanisms for pharmaceutical price controls in place. Such attempts have been somewhat successful in curbing pharmaceutical costs in the short term, but were less successful on longer-term spending trends. While drug development processes have been harmonized recently, large variations still exist in pricing and reimbursement schedules across Europe, with the countries controlling prices and demand with very different policies. In this respect, Europe is far from being a single market.

At the same time, the departments of Industry and Trade are often interested in supporting innovative activity in the pharmaceutical industry to develop new therapies and pharmaceuticals, create jobs, growth in export etc. Although this conflict between health care objectives and industrial policies is widely recognized, there are no easy solutions and the balance between health objectives and industrial policy differs between the different countries.

An obvious conflict in policies exists for the critical issue of price control and level of reimbursement. Pricing negotiations are increasingly becoming a bottleneck in launching new medicines, the so-called “fourth hurdle”

The effect of price controls and other equivalent regulations is to reduce the expected return on investment in R&D and therefore, lower the demand for R&D.

In addition to reducing the overall R&D investment in a country, greater market intervention also seems to shape the innovative output of a country’s pharmaceutical industry. If companies expect lower returns on their R&D investments as a result of market interventions, they might hesitate to develop marginal products or perform highly innovative R&D projects associated with very high risks.

The production of drugs for international and global markets is concentrated in companies based in relatively free markets. A study suggests that products developed in countries with more market intervention reach fewer other markets i.e., are more likely to remain local. In countries with substantial market intervention, local companies might focus their product development on products that can succeed within the local regulations rather than produce medicines for the global marketplace. It would be interesting to investigate if this would also be the case for a country with a small home market, such as Finland.

Governments are confronted with a fundamental dilemma: how to ensure patient access to new current and future therapies and at the same time control limited resources available. European patients already have to wait, on average, two years longer until they can access new pharmaceuticals. In Finland, only 40 % of the drugs with market authorization are actually available on the market. This will become even more pressing in the future:

The impending enlargement of the EU will further increase differences in standard of living, consumption of pharmaceuticals, distribution costs and health care systems within the EU. High pharmaceutical prices might significantly undermine the possibility of the new member countries to offer necessary pharmaceuticals to all their citizens.

Also the changing demographic properties of the European population, the aging population, will generate a significant burden not only in the health care system, but also in the pension system and in the form of reduced tax revenues due to a reduction in the amount of the working population. Finland is one of the countries that will experience those changes first, reaching its population top already in 2020.

What also seems typical for the health care market is that nearly all supply creates its own demand. In fact, patients (as well as health care providers) often equal "more medicine" and "expensive medicines" with "better health". The level of correlation between health care spending and patient satisfaction, although, is limited. And while provision of the essential medicines leads to substantial health gains, high national investments might only produce further marginal gains. In the US, recent growth of direct to consumer advertising in the US has worsened the problem that health return on financial investment has been decreasing.

Most economists argue that government intervention is the worst way to achieve these goals because it invariably leads to unexpected second and third order consequences. Instead, they argue that free-market competition is a better impetus toward lower prices. One flaw with this argumentation might be that there is no free, competitive pharmaceutical market in the first place, due to the highly regulated nature of the sector.

Arguments for pricing control are these special characteristics- and imperfections in the pharmaceutical market and there are several reasons why governments want to intervene. Decision making is often delegated to a public regulatory agent on the assumption that profit incentives and market competition are unlikely to generate a socially optimal level of information or to produce a socially desirable decision by pharmaceutical companies

As patented products, individual pharmaceuticals are not subject to direct competition. The demand for medicines is not controlled by the final consumer but by the physician who has neither to pay for the product nor to consume it, the government, as the single payer in most instances, having to pay the bill.

Often, medicines are perceived as a matter of 'life and death' and the fear is therefore that pharmaceutical companies as a result can set whatever price they like.

Various diseases that are cured by pharmaceuticals have a significant impact on the health and well-being of a country. Governments may intervene in the pharmaceutical market in an effort to ensure that drugs are made as widely available as possible, on a socially equitable basis.

Nevertheless, the problem remains that price regulations will lower the demand for R&D and the possibilities of pharmaceutical companies to recoup their investment. The chain of innovation, productivity gain and economic growth, or profitability is broken by strict price control.

But what is actually the amount of really innovative medicines?

A recent study in the US has shown that a large share of the drug development cost are related to intense marketing efforts, and that only a fifth of the costs might be attributable to R&D costs in a strict sense of the word. Empirical research underlines the fact that the pharmaceutical industry spends huge amounts on R&D, but only a small proportion of its R&D outlays (estimated at 4-5 %) are spent on research in radically and fundamentally new areas for the discovery of innovative therapies.

5.2 Organisation of national health care system

5.2.1 Health care system

Each inhabitant of Finland is covered by public health insurance. The health insurance is managed by the Social Insurance Institution (Kansaneläkelaitos, Kela). By the Constitution of Finland, public authorities have to guarantee adequate health care services to everyone in Finland , as provided in more detail by an Act of Parliament. The general aims of health care are set for the whole period of office of each Government. The Government Programme is a cooperation contract between the state and the municipalities, which have the main responsibility in organising health care services. The Programme includes also a decision on the resources of health care that are revised annually in connection with the approval of the Government budget, when the Parliament makes the final decision on how much will be allocated to the municipalities as state subsidies for organising different services e.g. health care services.

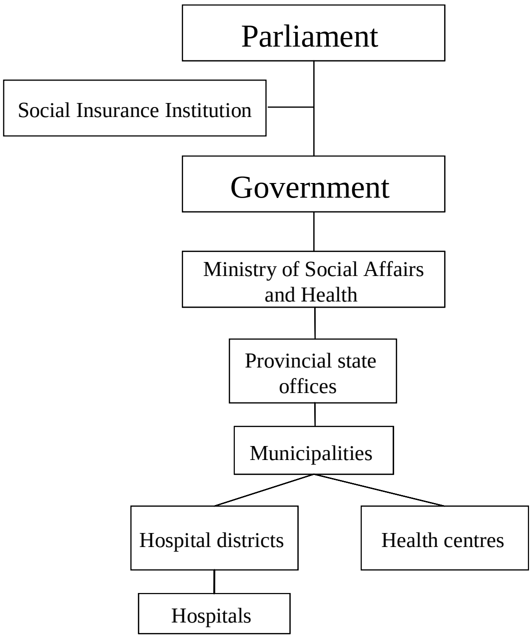


Figure 18. Finnish public healthcare system.

The Social Insurance Institution falls under the authority of the Parliament (Figure 18). It is responsible for implementing social security programmes that give protection to everyone living in Finland in a variety of life situations e.g. by the means of the National Health Insurance. The Social Insurance Institution has about 400 local offices around Finland.

The Ministry of Social Affairs and Health defines the main lines of health policy and guides the policies concerning health. The aim of the Finnish health policy is to lengthen the active and healthy lifetimes of citizens, to improve quality of life and to diminish differences in health between population groups. The Ministry also prepares legislation and key reforms in health care, supervises their implementation and handles the necessary links within the political decision-making process. Numerous institutions and agencies take care of research, development, statistical and supervising functions in cooperation with the Ministry of Social Affairs and Health.

For the purposes of central government administration, Finland is divided into five provinces. Each province is headed by a provincial state office, and the health departments of these offices are responsible for guidance and supervision of health care in their areas. Regional responsibility for health care in the autonomous Province of Åland comes under the Provincial Government.

The legislation lays down a framework of health care for the municipalities, but it does not include any details concerning the scope, content or way of organising the services. As the responsibility and decision-making power have been devolved to the local level to a great extent, and in the municipalities, the trend has been towards delegating power from municipal councils to various committees and leading officials, the services offered to inhabitants in different municipalities differ. To guarantee a certain minimum level of municipal health services, the Basic Security Council attached to the Ministry of Social Affairs and Health can investigate whether deficiencies exist in the services on the initiative of the Ministry.

To organise primary care, a municipality can have *a health centre* of its own for providing the services independently or it can join with neighbouring municipalities to set up a joint health centre. A municipality can also buy services from other municipalities or from the private sector.

Health centres offer a wide variety of services: preventive care, outpatient care, inpatient care, family planning, maternity care, child care, school health care, dental care, physiotherapy and occupational health care. In 2001, there were 277 health centres; 206 municipalities had a health centre of their own, and thus, the number of joint health centres was 71. The number of the municipalities was 448, and the populations of the municipalities varied greatly, from less than 1000 inhabitants to about 500.000.

For secondary and tertiary care, each municipality belongs to *a hospital district*. In 2001, the number of the hospital districts was 21, including Åland. a municipality can organise these services through another district or a private service provider, but the latter options are used rarely.

In Finland, there are about 400 *hospitals*, of which five are university hospitals. In the hospitals, both inpatient and outpatient care is provided. Except emergencies, access to specialist care in a public hospital requires a referral by a physician from the public or private sector. Primary care physicians act as major gatekeepers to hospitals, but in other respects, primary and secondary care is not always very well coordinated.

In 2001, there were about 17.000 physicians of working age in Finland. Of the physicians, about 1400 were full-time private practitioners, 7300 worked in hospitals, 3600 in health centres and 700 in occupational health care. The majority of physicians working in the private sector are specialists, who have a full-time job in a public hospital or a health centre.

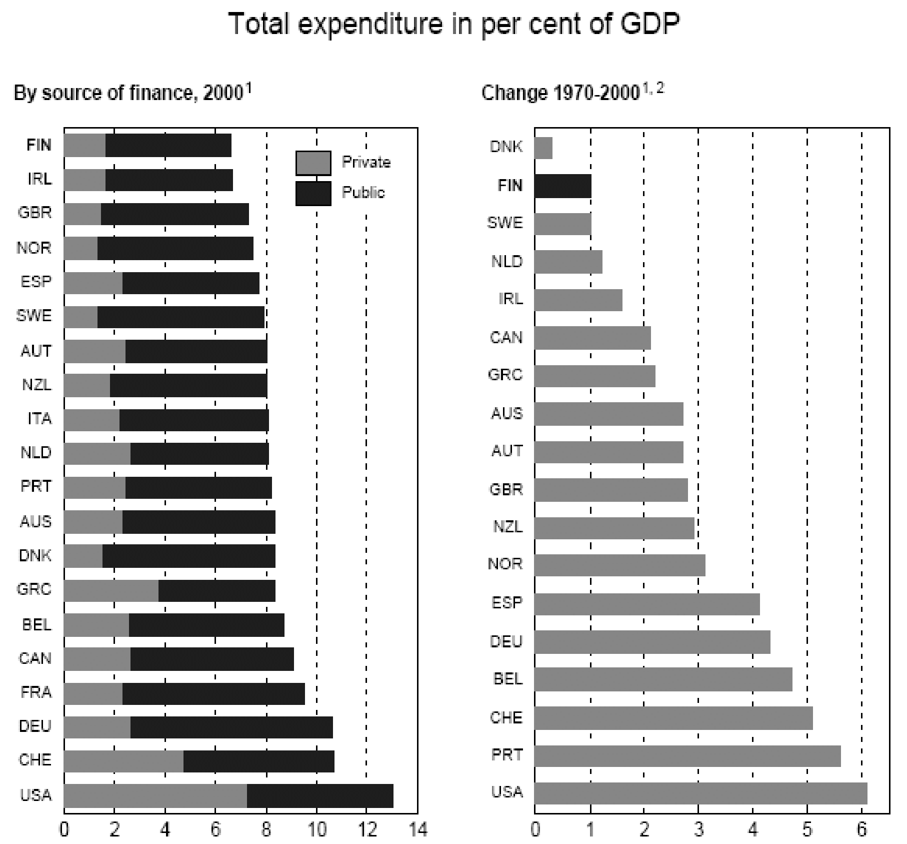
Health centres and public hospitals are non-profit organisations, and the federations of the municipalities own public hospitals. The Board of Health in each municipality prepares the budget for its health care, and the Municipal Council approves the total municipal budget, and within the budget, the resources allocated to health care. The Council of each hospital district determines the budget for hospital care within its area. Hospitals get their revenues mainly from the member municipalities in proportion to their inhabitants' use of the services.

Alongside the municipal system, private and occupational health services are provided. Private health care comprises mainly ambulatory care, provided in large towns in the southern parts of the country. About one third of all doctors (both general practitioners and specialists) operate practices which the state supports by partially refunding the fees charged There are relatively few large-scale private-sector operations, such as hospitals.

Employers are obliged to arrange preventive occupational health care for their employees by law. In addition to the obligatory preventive health services, which are necessary to prevent health risks caused by the work, employers can provide voluntarily also other health care services for their employees. Employers are partly reimbursed by the National Health Insurance for the costs of occupational health care.

5.2.2 Health care expenditure

Total health care expenditure grew by 8.6% in 2001, and accounted for 7.0% of the GDP. The GDP share was one of the lowest in the OECD. Also increase in health care costs has been comparatively low in Finland compared to other OECD countries.



1. 1998 for Sweden instead of 2000.
2. Instead of 1970: 1971 for Australia and Denmark, 1972 for Netherlands.

Source: *OECD Health Data 2002*, 4th edition.

Figure 19. Healthcare expenditure in international comparison. Source: OECD Health data 2002

In absolute figures, the health care expenditure amounted to €9,5 billion, which was about €750 million more than in 2000 (Figure 20). Per-capita expenditure amounted to €1820. The greatest increases took place in investment expenditures on primary and specialised health care (22%) in expenditures on dental care (14%) and medicines (7%). Medicine expenditure has increased steadily since the beginning of the 1980s. It accounted for 1,1% of the GDP in 2001 and was about €1,5 billion. Sales for medication for inpatient care are around 20% in Finland (2002).

To contain the raise in pharmaceutical costs, government has responded with a number of measures over the past few years including: stricter assessment of retail outlets, greater assessment of the therapeutic and cost effectiveness of new drugs, special prescription arrangements for expensive drugs, retail price regulation that reduces incentives to sell more expensive drugs and a programme aimed at changing doctor’s prescribing practices. In December 2002 the Parliament passed a bill requiring pharmacies to offer substitution with cheaper generic drugs. The new law came into force in April 2003. It is interesting to note that a system of generic substitution had been implemented in 1994, but abandoned in 1996 in favour of generic prescription.

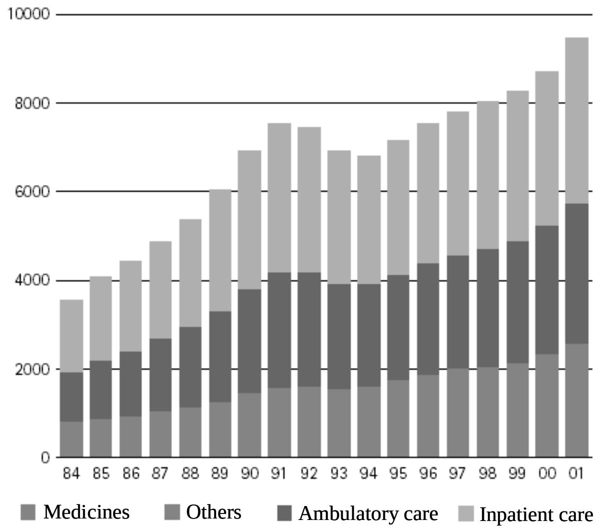


Figure 20. Health care expenditure, 1984–2001 (€ million)

5.2.3 Financing health care

In Finland, health care services are financed mainly from taxation revenue; partly from local taxation and partly from state subsidies. The criteria of the state subsidies are based on the number, age structure and morbidity of the inhabitants of a municipality. In 2001, the municipalities were the most important source of financing for public health care services, accounting for 43% of the total financing. The state contribution was 17%, and the Social Insurance Institution accounted for 16%.

Over the 1990s there has been an increase in out-of-pocket payments in the health system. User charges for municipal services were increased over the 1990s, tax deductions for drug and other medical expenses were abolished in 1992 and there have been reductions in the reimbursement of pharmaceuticals by the national insurance scheme. Households’ out-of-pocket payments in health care were about 20% and among the highest in the EU. Particularly, out-of-pocket payments in medicines were high, approximately 37% of the prices of reimbursable medicines. There has been concern about the consequences of the high fees, such as the accessibility of health care services to those on lower incomes. In case of inability to pay, the social welfare system may offer support.

5.2.4 National Health Insurance

Coverage

All individuals with permanent residence in Finland are insured in case of disease by the National Health Insurance (NHI) (Finnish: Kansaneläkelaitos, Kela). The role of voluntary or private insurance is insignificant and mainly includes health care costs paid out of accident and life insurance schemes.

The NHI provides partial reimbursement for prescribed medication, private medical care (i.e. private physicians' and dentists' fees as well as examination and treatment ordered by them), occupational health care, student health care and rehabilitation and transportation costs. The NHI also pays for the loss of earnings during disease, pregnancy and childbirth and compensates for the loss of earnings that parents of a sick child incur during the treatment and rehabilitation of the child.

The NHI refunds are determined in different ways. Physicians' and dentists' fees as well as examination and treatment charges are refunded according to a fixed scale (60%) of the charges defined by the Ministry for Social Affairs and Health. If the actual fee exceeds the charge defined, the refund is calculated on the basis of the charge.

All medicines that have a wholesale price approved by the Pharmaceutical Pricing board are entitled to basic refund, but restrictions are made for some especially expensive medicines (refund group with limited patient access). Refund rules require that their therapeutic value must be shown for each patient individually.

In 2001, the NHI offered coverage concerning the use of medicines in three refund categories:

– basic refund category: 50% of all prescription medicine costs in excess of the fixed minimum per purchase of €8,41 , and
– lower and upper special refund categories in specified conditions: 75% or 100% of costs exceeding €4,20.

The Higher Special Refund Category includes 36 chronic illnesses. The category covers illnesses where drug treatment is necessary and effective to maintain the patient's health status and where the drug restores or replaces normal bodily functions. Drugs used to treat diabetes and cancer are examples of drugs belonging to the Higher Special Refund Category.

The Lower Special Refund Category consists of ten chronic illnesses. The category includes illnesses where drug treatment is necessary to maintain the patient's health status. The Lower Special Refund Category includes, for example, drugs to treat long-term hypertension, asthma and cardiac insufficiency.

Patients whose annual expenditures on reimbursable medicines exceed a critical threshold, 580,20 euro in 2001, become entitled to an additional refund, from which joint all medicine costs are refunded in full until the end of the particular year.

Also a small number of OTC drugs are reimbursable in some conditions, if a physician has prescribed them.

Generic substitution was introduced in Finland on 1 April 2003. A prescribed medicinal product is substituted in a pharmacy by the cheapest, or close to the cheapest, generic alternative. Both the prescribing physician and the purchasing individual have the power to forbid the substitution. A list of substitutable medicinal products is provided by The National Agency for Medicines.

In 2001, a total of €768 million was paid in reimbursements for medicines to 3,4 million insurers. The number of the insurers eligible for refunds grew by 1,2%.

The working group on reimbursement of medical expenses 2003 has drafted a suggestion for the renewal of the system, that is suggested to come in force by 2006. The aim of reforming the NHI reimbursements for medicines is to be as cost-neutral as possible.

The major change proposed is that the new system should have only two refund categories: a basic refund category and a special refund category. The amount of special refund would be 90% of the price of the medicine. Serious and chronic illness would be defined more accurately.

The basic refund for medicines would be 50% and the fixed deductible abandoned.

5.2.5 From marketing authorisation to sales of medicines

The National Agency for Medicines

The National Agency for Medicines (NAM) monitors the safety of medicines, medical devices and blood products in cooperation with the EU competent bodies and member states. The tasks of the NAM include medicine control and surveillance of medical devices, drug information, general planning and control and surveillance of pharmaceutical service. The NAM works under the Ministry of Social Affairs and Health.

The NAM is responsible for the safety of medicines from the very first clinical trials and pays special attention to the safety and appropriate manufacture of biotechnological and biological products. To obtain marketing authorisation, a medicinal product must meet the requirements set by the authorities for efficacy, safety and quality. The consumption and safety of medicinal products that have obtained marketing authorisation and have been put on the market are monitored, too. In the event that safety risks appear, action is taken immediately by restricting their indications or, in extreme cases, by banning their use entirely.

Marketing authorisation

Marketing authorisation for a medicinal product can be applied for through the national procedure, mutual recognition procedure or the centralized procedure.

At present, the national procedure is mainly used in cases where marketing authorisation is being applied for in Finland as the first country within the EU. This procedure is also possible when the applicant applies for authorisation for a new strength or pharmaceutical form, for example for a product originally approved under the national procedure. Under the national procedure, the NAM must process applications for marketing authorisation within 210 days of their submission.

In the mutual recognition procedure, national marketing authorisation is first applied for one member state. Then other member states are requested to recognize the marketing authorisation granted by the first one. In this procedure, the pharmaceutical industry decides whether to apply for marketing authorisation in all member states or only in a limited number of them. In the centralized procedure, the European Commission grants marketing authorisation for the entire EU. For example, biotechnological medicines and most of new chemical entities are handled with this procedure.

In 2001, national marketing authorisation applications accounted for 46% of the 556 applications submitted to the NAM. More than half (187) of the national marketing authorisation applications were for generic medicinal products. The above average proportion of applications for essentially similar preparations may be affected by the short period of data protection in Finland; except for 'high-tech' medicines, the period is six years, while in many EU countries it is ten.

In 2001, the NAM granted marketing authorisations for 371 medicinal products. The number of decisions increased, especially in the mutual recognition procedure, and 100 more decisions were made than in 2000. Processing times for marketing authorisation applications remained within the 210-day framework. The average time needed to process an application for renewal of a marketing authorisation was three months.

At the end of 2001, marketing authorisation was in effect for a total of 4990 medicinal products. OTC products accounted for around 13% of the market authorisations and veterinary medicinal products for some 8%.

Medicines are authorised through quicker and more efficient marketing authorisation processes than before, but nonetheless medicines are not necessarily available to patients. In 1993, all the authorised medicines were available on the market. Currently, of the medicines with nationally granted authorisations in force in Finland, 77% are available on the market. 700 marketing authorisations have been issued centrally in the EU, but of the medicines, 40% are available in Finland. It is ordinary that pharmaceutical companies more often than before apply to the NAM for marketing authorisation, using Finland as a so-called reference member state, but of these products (about 260 marketing authorisations, mainly generics), only 20% are on the Finnish market.

The availability problem concerns all therapeutic categories. There are many reasons for this: the small size of the Finnish market, and the problem related to the pricing negotiations to admit the medicine into the reimbursement system. In addition, additional costs are related to the appropriate packaging and patient information leaflets needed both in Finnish and Swedish.

Pricing

Prices of medicines can be set freely, but the reimbursement provided under the Sickness Insurance Act is payable only if the Pharmaceuticals Pricing Board (PPB) operating under the auspices of the Ministry of Social Affairs and Health has accepted a reasonable wholesale price for a medicine. This wholesale price refers to the maximum price at which a medicine can be sold to pharmacies and hospital pharmacies.

The reasonable price is set on the basis of several criteria:

- Costs and benefits expected from using the new medicine as compared with alternative treatments, by the patient and by the social and health care services, from the perspective of total expenditure
- Budget impact analysis projecting sales volumes
- The products accepted price and grounds for reimbursement for other EEA countries
- Any other brand names under which the product is marketed and respective prices
- A health economic report: In Finland since 1998 such studies are mandatory in price applications for drugs containing a new medicinal substance.
- The costs associated with therapeutic alternatives
- Manufacturing, research and development costs
- A written statement on how reasonable or fair the whole sale price or price increase seems in terms of the Sickness Insurance Scheme and how other costs are anticipated to change

Since 1998, the decisions are made for a fixed period only, and prices are valid for up to five years, and up to three years for products with a new active ingredient. In the past, prices were issued on a ”valid until further notice” Under the current regulation, the price of a drug is reduced if its indications had been significantly expanded, if the same pharmaceutical product is available for a significantly lower price or if the price of the drug is significantly lower in the other Nordic countries or in the EU member states

When the PPB approves a reasonable wholesale price for a pharmaceutical product, the prescription product automatically qualifies for reimbursement in the basic refund category.

The Government decides which diseases and medicines are included in lower or upper special refund categories, and the Social Insurance Institute confirms the reimbursement principles concerning a single product. All new products remain in the basic refund category for two years. The Council of State also makes decisions regarding the “significant and expensive” drugs, and illnesses which justify their reimbursement. This sub-group was introduced at the beginning of 1999. The most common drugs to be classed as non-reimbursable are products intended for short periods of self-care use. In addition, a number of drugs, including certain drugs for treating multiple sclerosis, Alzheimer's and erection disorders, are reimbursable only in closely defined situations.

Margins to wholesalers and pharmacists:

The retail price of a medicine is determined by a combination of the wholesale price, the pharmacy’s profit margin at the rate set by the Government and the value-added tax (VAT). Wholesale margins are not fixed, but average 5% of the manufacturers selling price. The pharmacy margin is added to the wholesale price using a graduated mark-up, the higher the wholesale price, the smaller the pharmacy margin. Pharmacies are in addition paid a fixed dispensing fee per prescription. VAT is 8% both for prescription and OTC drugs, compared to the standard 22% VAT.

Hospital procurement

Hospitals can procure pharmaceuticals from a wholesaler, retail pharmacy or manufacturer. Under certain conditions, they are allowed to self-import. Most hospitals have a pharmaceutical advisory board that proposes a list of stock medicines, which are then procured by competitive tender.

Promotion and advertisement

In Finland, only OTC drugs can be marketed directly to consumers, but Finland has not banned advertising of OTC drugs. The prohibition of prescription medicine advertising does not apply to vaccination campaigns carried out by the industry and approved by the authorities.

The dissemination of information to consumers can be carried out on the following conditions: acquired immune deficiency syndrome, asthma and chronic broncopulmonary disorders (bronchitis) and diabetes.

If marketing rules are violated, the NAM can prohibit continued of renewed marketing of the product. In the interest of drug safety, it can also order the offending party to provide a correction of the original marketing material. The Agency can also impose a conditional fine to reinforce its prohibition or correction order. Finally, it can withdraw the sales license for a product that has been marketed in a way that grossly violates the existing regulations.

The pharmaceutical industry also voluntarily controls marketing practices in accordance with a strict code of ethics. The renewed Code for the Marketing of Medicinal Products came into force in 2001. The principles behind this Code are based on legislation relating to medicinal products, consumers and competition and on the International Code of Advertising Practice and the provisions introduced by the Council Directive 92/28/EEC on the advertising of medicinal products for human use.

All members of Pharma Industry Finland have undertaken to comply with the Code. The compliance with the Code is monitored by the Supervisory Commission for the Marketing of Medicinal Products and by two Inspection Boards working under the Commission. Inspection Board I monitors all marketing of medicinal products to the general public and Inspection Board II marketing activities directed towards health care personnel.

If a marketing practice is found to contravene the Code, the company concerned may be admonished or requested to discontinue the practice. A request to discontinue a marketing practice shall be made in cases in which a violation is major. The practice must then be discontinued immediately.

Disagreements between companies concerning activities violating the Code shall be submitted for examination to the system set forth in the Code before they may be brought to the attention of the relevant authorities.

In 2001, the use of generics was modest. Generics accounted for 3-4% of the outpatient prescription drug market at retail prices. Also parallel import products accounted for only a small share of the market.

5.3 Role of users

Stakeholders' participation in the science and technology policy-making has become an important trend in many Western countries. For describing the participation, for example the nature of communication is feasible, and on this ground, three options to participate can be distinguished: one-way communication, two-way communication and multiple-way communication. Informing and mapping opinions are examples of one-way communication, personal contacts and lobbying politicians examples of two-way communication and workshops and public hearings examples of multiple-way communication.

For an overview of the different models the concept of public understanding of science can be based on and the consequences for communication between the different stakeholders see [12]. With regard to Finnish authorities and agencies in biotechnology policy, the main channels for informing public are official internet-pages. For a more devoted public there is also a bulletin of the Advisory Board of Biotechnology, in which there are news about latest research and regulation of biotechnology. In the grammar of the PUS models, these activities falls into the enlightenment category, and represent better the public intake of science than public inclusion in science policy.

[12] http://www.hut.fi/Yksikot/Rakennus/Ymp/Julkaisut/ymsynRaskPaper.rtf

5.4 Lead market feature

An innovation may be invented and designed in one country, but first accepted and adopted in another country from where it spreads further to other countries. The market that first adopts the innovation and shapes the global market by the demand it creates is called a lead market. The stimuli of the adoption of innovations include demand preferences formed by tastes and environmental conditions, the budgets of possible adopters, the relative prices of innovation designs and prices of complementary goods and local externalities. In the presence of local externalities, countries can adopt different innovation designs even if all other local conditions are equal. The local availability of innovations can vary as well as the market side factors, such as demand articulation, local competition, and technological capabilities of local firms.

The lead market phenomenon can be explained e.g. by the following five factors: demand advantage, price advantage, transfer advantage, export advantage and market structure advantage.

It is obvious that Finland as a small, highly price controlled market with low overall health care spending and a comparatively weak own pharmaceutical sector does not play a role as lead market. Delays for price and reimbursement negotiations are comparatively long.

5.5 Role of demand

Before considering demand side factors, it is important to establish who are the relevant customers.

Biopharmaceutical companies and pharmaceutical companies have different primary customer and will therefore be discussed separately. However, all the issues that are mentioned as important for pharmaceutical companies, should also be considered by biopharmaceutical companies already in early drug development.

One could say that large pharmaceutical companies, VC companies, and to some extent public funding organizations are the primary customers of small, biopharmaceutical companies. While public funding organization are mainly acting domestically, large pharmaceutical companies, and VC companies are mainly located outside of Finland. The domestic pharmaceutical sector and also VC sector are too limited in scope to support growth of the biopharmaceutical industry in Finland to a larger extent. The factors that shape the demand side have been discussed in chapter 4. National demand side factors should therefore play no major role in Finland.

In the case of the pharmaceutical industry, there are even more customers to consider:

The government in Finland acts through pricing control as monopolistic buyer.

Insurance companies have no relevance in Finland.

Hospitals buy pharmaceuticals with direct procurement, and clinicians that often involved in clinical trials and introducing new medications and therapies might fulfil an important role as opinion leaders.

Physicians prescribe the medications, and are therefore the target to intense marketing efforts.

Patients consume medication, and are direct consumer in the case of OCTs, and in cases were direct to consumer advertisement is authorized.

Patient organizations in Finland are comparatively small.

The Finnish pharmaceutical market is not very attractive. For example about 700 marketing authorisations have been issued centrally in the EU, but of these medicines, 40% are available in Finland and the availability problem concerns all therapeutic categories. There are many reasons for this: the small size of the Finnish market, problem related to the pricing negotiations to admit the medicine into the reimbursement system, the work and costs related to the appropriate packaging and the patient information leaflets needed both in Finnish and Swedish.

In 2001, the health care expenditure accounted for 7,0% of the GDP in Finland, and the GDP share was one of the lowest in the OECD. Households' out-of-pocket payments in health care were about 20% and among the highest in the EU.

It is therefore unlikely that local demand side factors play a larger role for the system.

5.6 Socio-economic and ethical aspects

General confidence in science

According to the Finnish Science Barometer 2001, the Finns have unwavering confidence in science and research and trust scientific institutions more than the legal system or the church. A large majority of the Finns (80 %) give the standard of the sciences and research good overall marks and most (59 %) think that the research community operates responsibly and knows its social responsibilities. About 70% of the Finns perceive that medicines are safe to use. (Wiio 1993; Tiedebarometri 2001)

Engagement with biotechnology

In 1996, 72% of the Finns had heard about biotechnology. Television was the most frequently cited source of information (53%) and newspapers were in second place (30%). Radio and magazines were less important, 15% and 12% respectively. Of the Finns, 45% had never talked with someone about biotechnology and 38% had talked occasionally.

In 1999, 47% of the Finns thought that they were likely to disagree the statement that "I would sign a petition against biotechnology" and 88% disagreed that "I feel that I am adequately informed on biotechnology".

The proportion of those engaged with biotechnology is higher in Finland than in other EU member states on average. The engaged are more likely to be male, better-educated, white-collar workers, urban dwellers and younger than 55. The most engaged are "generalists" with interests in a wider range of public affairs. Thus, public opinion on biotechnology is likely derived in part from views about the credibility of wider political and scientific institutions, as well as those solely related to biotechnology.

In Table 22 the opinions of the Finns about biotechnology in general in 1996 are presented. The opinions of the Finns about the benefits, risks, acceptability and need for further development concerning various applications of modern biotechnology are presented in Table 23.

Table 22. Opinions about biotechnology, 1996

	% tend to agree	% don't know
Traditional methods are as effective	54	13
Researchers will always do what they want	50	13
Current regulation is sufficient	33	18
We should accept some degree of risk	32	10
I would buy genetically modified fruit	30	9
Religious organisations should have their say	24	10
Biotechnology is too complicate to public	20	6
Regulation should be left to industry	18	9

Table 23. . Opinions about various applications of modern biotechnology, 1996

	Benefits (% agree)	Risks (% agree)	Morally acceptable (% agree)	Should be encouraged (% agree)
Food*	69	40	58	59
Plants*	80	31	70	72
Medicines*	81	29	71	73
Research*	63	40	44	48
Transplants*	48	52	32	37
Detection*	84	21	75	77

*

Food) Using modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change the taste.

Plants) Taking genes from plant species and transferring them into crop plants to make them more resistant to insect pests.

Medicines) Introducing human genes into bacteria to produce medicines or vaccines, for example to produce insulin for diabetics.

Research) Developing genetically modified animals for laboratory research studies, such as a mouse that has cancer-causing genes.

Transplants) Introducing human genes into animals to produce organs for human transplants, such as into pigs for human heart transplants.

Detection) Using genetic testing to detect diseases we might have inherited from our parents, such as cystic fibrosis, mucoviscidosis, thalassemia etc.

In 1996, 63% of the Finns were optimistic as to the anticipated benefits of biotechnology, and 16% did not have any opinion. 68% thought that curing most genetic diseases is likely to happen in the next 20 years as a result of developments in modern biotechnology, 67% thought that dangerous new diseases would be created and 27% believed in producing “designer” babies.

During the period 1996-1999, optimism about biotechnology decreased in Finland, but after this declining period, optimism has increased (Table 24). In 2002, the index value varied from 0,12 to 0,71 in the EU member states.

Table 247. Eurobarometer’s index of biotechnology optimism, 1996-2002

1996	1999	2002	Mean % “don’t’ know”
0,24	0,13	0,31	20

There are differences in support of different biotechnological applications; the attitudes to medical and environmental applications are more positive than the attitudes to genetically modified (GM) food.

In 1996, 5% of the Finns opposed genetic testing and in 1999, the figure was 9%. The numbers of the opponents to GM food were 23% and 31%, respectively. Thus unlike most government officials, the Finnish population is wary of agricultural applications of biotechnology.

In 1999, the levels of support and opposition for seven applications were the following:

- genetic testing, medicines and bioremediation strong support,
- clone human cells, GM crops and GM food weak support and
- clone animals weak opposition.

In 2002, the levels of support and opposition for six applications were the following:

- genetic testing strong support,
- clone human cells, enzymes, GM crops and GM food weak support and
- xenotransplantation weak opposition.

The “second hurdle” of public opinion constitutes a crucial challenge for the scientific, industrial and political supporters of biotechnology. A biotechnological application is unlikely to receive public support, if it does not have any clear benefits. The individuals engaged in biotechnology are, on average, more supportive than the less engaged.

The Finns know facts of biotechnology and genetics a little better than the Europeans on average, but the Finns’ knowledge has not improved during the years 1996-2002

In 1996, 34% of the Finns considered the universities the most trusted source of information on biotechnology (of the organisations presented). 24% trusted most in consumer organisations, 16% in environmental protection organisations and 16% in public authorities.

Other sources that could tell the truth regarding biotechnology in addition the most trusted source were universities (32% trusted also in universities though universities were not considered the most trusted source of information), consumer organisations

(31%), environmental protection organisations (26%), public authorities (23%), animal welfare organisations (15%) and industry (10%).

Organisations best to regulate biotechnology

In 1996, 41% of the Finns considered international organisations of the options presented the best to regulate biotechnology, 30% considered scientific organisations the best, 10% the EU, 5% ethics committees, 4% the Parliament and 4% public authorities.

6 Synthesis and conclusions

The Biotechnology Innovation system in Finland is shaped through distinct interactive forces acting on different levels, both nationally and internationally. It is therefore not possible, or even desirable to describe the system in the frame of a National Innovation system. It is clear that the building of a viable biotechnology sector cannot be adequately addressed with local or even national resources. These requirements will pose major challenges to the biotechnology innovation system in the coming years, since the demands that an internationalisation of the sector poses are very high in terms of competitiveness, focus, cultural changes and collaboration demands in an environment that is currently felt to be unstable and insecure.

The promises of the biotechnology sector are yet to be fulfilled, and this is true not only for Finland. While it is important to be realistic about possible (economic) outcomes and time frames required to reach both scientific and economic targets, it is also important to keep general confidence in the sector, and in the exiting voyage on which new scientific breakthroughs can take us (http://www.nature.com/nsu/)

Current Policy discussions: Biotechnology

Many issues identified as systemic failures have been analysed in various evaluation reports and necessary changes are currently being discussed. Therefore, we will start with a short summary of the current policy discussions and the planned changes concerning both the biotechnology innovation system, as important framework conditions. One important study in this respect has been the recent evaluation of Biotechnology in Finland (Biotechnology in Finland, Impact of public research funding and strategies for the future, Publications of the Academy of Finland 11/02, 2002) and the follow-up report of the work group established by the Ministry of Education. The proposed measures mainly address issues within the field of influence of the Ministry of Education. It is not clear, however how those measures will be implemented in the future. The following recommendations were made in the report:

The Higher Education Evaluation Council should evaluate undergraduate education in the life sciences, relevant teaching arrangements and the performance of the degree programmes. The life sciences should increase cooperation with chemistry, physics, information technology and medical research. Interdisciplinary cooperation should also be developed through linkages between the natural sciences and law, marketing and management education.

Long-term, comprehensive development of biotechnology research should be continued as recommended and the core funding of the five biotechnology centres should be maintained at least at the present level. Seven million euro will be additionally allocated as special funding for research, equipment acquisitions and new development projects during the three-year period 2004–2006. The Academy of Finland and TEKES should explore ways to contribute to the financing of universities' and research institutes' equipment procurement. Joint use of large, expensive research equipment should be increased.

Cooperation in researcher training between sectoral research institutes, universities and graduate schools must be intensified and the resources of the graduate schools increased. Graduate schools should include more education and research in technology transfer, intellectual property rights and business know-how in their programmes.

It is deemed that no new technology transfer units are needed. Instead, the performance of the existing units should be enhanced and developed to better serve researchers, research institutes and businesses.

It is suggested that FII acts in closer cooperation with Sitra for the funding of early stage biotechnology companies.

The group proposed the setting up of a committee representing biotechnology research, education, product development, technology transfer and business to review the implementation of the recommendations of the international impact analysis of public biotechnology funding in 2005. The work group also encouraged a strengthening of the cooperation between the respective ministries and subordinate organisations and institutions to promote further development of biotechnology research, product development and training. The quality and financing of biotechnology research should be developed in the agriculture, forestry and environment sectors, and cooperation with other partners, especially universities and industry, should be stepped up. Planned changes in the Act Concerning Rights to Employee Inventions (656/1967) and the University Act 645/1997 have been reviewed in chapter 4.6.2.

Current Policy discussions: Frame conditions

The Finnish welfare state rests on the financial foundation provided by taxation. According to OECD studies, Finland’s high taxation has had negative impact on entrepreneurship, employment, international competitiveness and inward investment. International tax competition resulting from international mobility of goods and production factors and further integration of the European Union will also pose serious challenges to the system in the future. In addition, aging of the population will result in increased spending in pensions and health care costs will increase the burden on public spending. While the taxation burden in Finland has been slightly decreased in recent years, Finland’s overall position in comparison to other OECD countries did not significantly change due to parallel tax cuts in other countries.

The necessity of changes in the frame conditions, especially concerning taxation issues are therefore widely recognized. While Finland’s economic growth and competitiveness will continue to be based primarily on knowledge and utilisation of new technology according to the new governmental programme, some important changes concerning corporate and capital gain taxation are announced to be made at the end of 2003. A lowering of corporate and capital gain tax have been discussed to strengthen the international competitiveness of the Finnish Tax system, but the exact amount and conditions are not defined yet. Dividend taxation will be changed; the avoir-fiscal system abandoned, making dividends partially subject to double taxation. Foreign venture capital will be taxed on a consistent basis. In addition, measures to increase the amount of investments made into Finnish VC funds are planned.

The planning of practical measures has not been initated yet, but future focus areas of the governemental programme are largely in place. R&D funding of Tekes, the National Technology Agency of Finland, will be increasingly shifted from R&D loans to research funding for public organisations and to R&D grants for companies. Funding will also be allocated to areas such as branding, commercialisation and R&D

in the service and new technology sectors and to know-how and innovation that support sustainable consumption and production.

Quality assessment and performance monitoring of projects seeking public R&D funding will be more rigorous to ensure that the financing is used as effectively as possible.

Closer cooperation will be sought between the various organisations that support innovation on a regional level. Focus will be on entrepreneurship to foster company start-ups, growth and internationalisation. The government will investigate possible incentives for entrepreneurship, ways of promoting operation of SMEs in the start up and growth phase. The legislation will be adapted to the needs of both small and large companies and incentives in the form of improved social security provided for entrepreneurs. Legislation on bankruptcies, corporate restructuring and other insolvency proceedings will be overseen.

Conclusions

Many of the challenges to build a viable biotechnology sector in Finland are similar to those experienced by other European countries, while some country-specific challenges remain.

It is felt that both the pharmaceutical industry, as well as the whole biotechnology sector has become subject to increasing competitive pressure during the last 5 years. The restructuring of the pharmaceutical industry, mainly caused by decreasing R&D efficiency and increased pressure on drug price containment has also influenced the structure of the biotechnology industry. The pharmaceutical industry has been an important customer for the biopharmaceutical sector, the diagnostic sector and service companies. The overall strategy to acquire development projects is now moving towards later stage deals which carry considerably lower risk.

After the boom years 1998-(mid) 2001, the availability of financing has become a major concern of the majority of biotechnology companies and the decreasing availability of VC capital has become a significant barrier to the development of the biotechnology industry. Also here, a move to favour less risky late stage deals is becoming more pronounced.

In addition, many countries are currently devoting considerable amounts of public resources in national programmes to the development of the biotechnology sector and policies to promote innovation. This suggests that competitive pressure between nations will not significantly decrease in the near future. Rather, reshaping and restructuring will continue.

In Finland- as in most other EU countries, market failure in Biotechnology seems less to be related to the supply of knowledge, especially of "technological knowledge" but more to knowledge required for commercialisation. This fact has been described as the "European paradox".

In the EU, the current legislative framework exempts support for R&D from the general control of state aids, but despite the general acceptance of the systemic model of innovation, it is in practice based on the outdated 'linear' model of innovation. It therefore makes no provision for non-R&D innovation activities. While it is often the case that more mature industries benefit more from knowledge networks promoting technological knowledge, newly established high tech companies often lack other forms of knowledge and therefore promotion of "technological knowledge" might have a very limited influence on the success of the company. Large, established companies might benefit most from support of high-risk R&D activities that drives the innovative capacity of these companies, while high technology start-up companies should benefit most from support for commercialisation activities.

What are the factors that will shape the future of the biotechnology sector in Finland?

Finland is a small open economy that is sensitive to cyclic changes in the world economics. It is also important to remember that while performance in relation to the size of the country in many cases is impressive, Finland produces only a small part of the scientific knowledge and a small part of world innovations in absolute terms. Only about one %of the scientific knowledge is produced in Finland, 99% abroad. The challenge to obtain critical mass is therefore very real and the need to focus on certain key areas very strict. R&D programmes in Finland have been targeting knowledge generation and technology development, leading to an increase in the support of basic research and pre-competitive research. While this might be a logical approach to maximize benefits from public supported R&D in a larger country, small countries have limited human and financial resources to translate technological knowledge into commercial products. This might lead to a mismatch between knowledge producing and knowledge absorbing capacities which decreases the efficiency of the innovation process. Support of R&D activities is mainly regulated by the European legislative framework, however, possibilities to support R&D activities after the pre-competitive stage should be stressed.

The Pharmaceutical sector in Finland is comparably small, both in number of companies, personnel employed and size of exports. In contrast to the European Union as a whole, pharmaceutical exports are smaller than imports, leading to a negative trade balance for pharmaceuticals in Finland.

The small market size for pharmaceuticals and a strictly regulated pricing and reimbursement policy makes Finland an unattractive location for multinational pharmaceutical companies. For these reasons, there is both a lack of strong, domestic, as well as international players among the Finnish Pharmaceutical and Biopharmaceutical companies that could act as collaboration partners and as drivers to build up a dynamic, competitive cluster structure. The lack of strong national companies implies also that most of the knowledge generated in Finland will be sold abroad, as most of the licensing deals and trade sales will be performed with international companies.

Finland is also too small as a market for growth-oriented biotechnology ventures. Even small service companies need to establish themselves outside of Finland. Without effective internationalisation of growth-oriented firms, both in terms of sales and financing, the growth of the industry will be limited. In practical terms, both international finance and international human resources are needed to support a significant growth of the Biotechnology sector. This means that most of the companies will have to acquire an international orientation right from the beginning.

Finland has a remote location, which poses a challenge in itself. When investing abroad, venture capitalists have to seek opportunities that justify the costs of operating in foreign markets. Therefore the incentives for investing in Finland should justify the more difficult communication and more expensive travelling. Also information asymmetry is more pronounced for remote locations, which increases risk. Opportunities must therefore be perceived as excellent to justify investment in

Finland by international investors. Finland is too small as an exit market. This is not only true for Finland; European economies generally are insufficient to support market liquidity in volatile, high-risk industries such as biotechnology. Without sufficient flow of international exits, however, it will be difficult to grow the Finnish VC market. The most frequent exit form has been trade sales, since the IPO market has been almost completely closed. For Finland this means that most of the companies will go to foreign ownership, which poses many challenges. Entrepreneurs need to consider costs and benefits of foreign ownership, especially in the case of exit. Foreign venture capitalists and foreign investors may help to lower the barrier for going public abroad. This is especially important if the entrepreneur wants to regain control over the company. Foreign investors might on the other hand influence decisions such as location of headquarters composition of personnel etc. At present there is a significant cultural barrier against foreign ownership in Finnish public opinion and the high-tech companies themselves. All aspects of internationalisation will be key to the ultimate success and sustainability of the Finnish biotech sector.

Finland has few or no tax benefits for R&D in place; R&D support is mainly in the form of direct subsidies, such as R&D grants and loans, or loan guarantees. In contrast, other countries are introducing new tax incentives to stimulate innovation, entrepreneurship and the establishment of VC markets. It is not clear how this will influence the competitive position of Finland in the long run.

Technology Transfer in Finland has been quite fragmented and every university decides on their own policies concerning intellectual property rights. Practices and support for patenting therefore vary considerably between Universities. This is also reflected in the very limited availability of data on patenting, licensing and spin-off companies on the level of the universities and bio-centres. Patenting rate in biotechnology on the level of EPO patents has not been satisfactory in Finland (note: concerning USPO patents in biotechnology Finland is actually leading among the European countries, data are not very concise and need to be discussed further)

It is currently not clear in what time frame and how the 'third mission' of the Universities will be put into practice. While reforms of the Act Concerning Rights to Employee Inventions (656/1967) and the University Act (645/1997Act) have been a necessity to clarify the legal status of IPR in universities, there has so far been no increase in resources that would reflect this new mission. It should therefore be discussed if the change in legislation in itself is sufficient to increase the efficiency of translating basic research results into commercial products.

One of the problems of the study has been a lack of primary data. While considerable amounts of money has been invested into the biotechnology sector, systematic efforts to collect data for monitoring and evaluation purposes have been limited and mostly consisting of ad-hoc data collections. It is therefore not possible to draw firm conclusions on the success or failure of the sector and much of the evidence is based on interviews with experts. A change in public opinion against public financing of the biotechnology sector can be seen. Public support could decrease significantly due to a perceived lack of success in the sector. To prevent this, it seems crucial that all stakeholders agree on increased transparency, monitoring, and evaluating of the biotechnology sector.

The competitiveness of the biotechnology regarding regulations might be more determined by the European legal framework than through national regulations. The European market is quite fragmented in terms of regulations concerning pricing and reimbursement resulting in high compliance costs. A true “European patent” has been long on the agenda. Therefore, currently, patenting costs in Europe are very high compared to US.

As positive developments can be seen that local venture capital investors are forming syndicates with foreign venture capital investors to improve visibility of the Finnish Life Science sector and access to international VC capital. Selection of companies is becoming more competitive.

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