Handled by SIN Officer Finland
Johan Hendriks

Via Mak Stephen and Hazel Gibson (SIN Network) I received your request for views on the ethical issues posed by emerging biotechnologies.

Finland is a member of the Nordic Committee on Bioethics. The National Institute for Health and Welfare (THL) and the University of Helsinki are involved. Other country members are Denmark, Iceland, Norway, Sweden and observers from Faroe Islands.

The Committee's tasks are (taken from http://ncbio.org)
• *to identify ethical problems arising from genetic engineering and other biotechnology research, development and modification of microorganisms, plants, animals and humans.*
• *to promote Nordic collaboration among researchers, opinion formers and parliamentarians on bioethical issues by cooperating with national research institutions, authorities and ethics committees, and by the same token creating opportunities for the exchange of information.*
• *to contribute to a joint Nordic debate on bioethical questions by disseminating material that can be used in constructive discussions of bioethics issues.*
• *to monitor biotechnological developments in the Nordic region and internationally.*
• *to keep abreast of Nordic and international debate on ethical questions issuing from biotechnology research, development and application.*
• *to follow legislative developments within the sphere of biotechnology in the Nordic countries.*
One of the main activities of the Committee is to publish reports and other publications to promote Nordic and interantional debate on issues of bioethics.

From their publications I think that two slightly older publications give you a good comparative look on the different legislation in various biotechnological areas:

- *Legislation on Biotechnology in the Nordic Countries - An overview, 2006 (http://www.norden.org/da/publikationer/publikationer/2006-506/at_download/publicationfile)*
- *Assisted Reproduction in the Nordic Countries. A comparative study of policies and regulation, 2006 (http://www.norden.org/da/publikationer/publikationer/2006-505/at_download/publicationfile)*

There are a few bodies in Finland that report on ethical issues related to biotechnologies and health & welfare in general. The most important organisations in terms of ethical issues posed by emerging biotechnologies

are:

1. **National Board on Social Welfare and Health Care Etics (ETENE)**

The purpose of The National Advisory Board on Social Welfare and Health Care Ethics is to discuss general principles in ethical issues in the field of social welfare and health care and concerning the status of patients and clients as well as to publish recommendations on them.
Their publications, statements, press releases and materials can be found under: http://www.etene.fi/en/materials

2. Advisory Board on Biotechnology (BTNK)
The Advisory Board on Biotechnology is a consultative body of experts in issues related to bio- and gene technology appointed by the Government for a term of three years. (http://www.btnk.fi/en/index.html)
In legislation some decree's can be found that contain views on ethical issues in life sciences in general. The most interesting for you might be:
http://www.finlex.fi/en/laki/kaannokset/2010/en20100841.pdf

I attached for your information 2 general background documents on stem cell research and the Biopharma cluster.

Many kind regards,
Johan Hendriks
SIN Officer – Helsinki, Finland

Further links:
THL: http://www.thl.fi
University of Helsinki, Department of Social Research/Sociology:
http://www.helsinki.fi/socialresearch/
Symbio – Industrial Biotechnology (Tekes programma 2006 – 2011):
http://www.tekes.fi/en/document/44819/symbio_engl2010_pdf
05 July 2010

Content of this report

1. Finland – high potential for the stem cell business

Stem cell research and stem cell technology promises the potential to dramatically change the treatment of human disease as well as offering exciting possibilities for investment. As a target country for setting up business in this area, Finland holds great potential, drawing on solid stem cell technology know how, and focused and sustained development in the field of biotechnology.
There are several unique factors which single out Finland as a base for the stem cell business:
• Strong collaboration between universities, hospitals and the stem cell industry in developing and testing new treatments and products.
• Special support by The National Agency of Medicine (FIMEA) to advance expertise in the field of stem cells.
• Positive public and professional opinion towards stem cell research which facilitates product development and clinical testing.
• Comprehensive resources and services to support clinical studies including highly specialised Clinical Research Organisations, bioanalytics services, clean room facilities and so on.

2. Research - the foundation stone for the Finnish stem cell industry

Five of Finland's university towns (Helsinki, Turku, Tampere, Oulu and Kuopio) are engaged in both basic and applied stem cell research. For further information on stem cell research and background information on Finland's academic research organisations and institutions please visit:
http://www.aka.fi/en-gb/A/
http://www.research.fi/en
http://www.tekes.fi/eng/
http://www.minedu.fi/OPM/?lang=en
One greater hub of scientific and clinical activities for stem cell research is the Regea Institute of Regenerative Medicine in the Tampere region. The stem cell research conducted at Regea focuses on the differentiation of nerve, heart, retinal, bone and cartilage cells from different stem cells while the Regea Tissue Bank processes and supplies tissues for clinical use. Some of the Regea laboratory and cleanroom facilities and equipment are also available for rent to research groups and enterprises. One of Regea's more notable successes in the application of stem cell technology was the creation of new jaw bone grown from a patient's own stem cells. To read more about this success story go to:
http://www.reuters.com/article/idUSL012172320080201

2.1. Directions for business

Against a solid background of academic research, business opportunities are focused on the emergence of start-ups formed in incubators both related to stem cell therapies and technologies and services supporting this field. This emerging business is underpinned by several technology companies whose technologies and services are applicable to stem cell research and its eventual therapeutic use. Some examples of stem cell technology businesses operating in Finland include:
• ChipMan Technologies, which provides researchers around the globe with tools that enable them to study live cell behaviour in an optimised and stable environment and analyse the findings automatically.
• EvoStem, which develops and markets products based on stem cell and tissue technologies. Their main product based on stem cell technology is TendoStem®, a form of equine tendon treatment. The company is also expanding into the area of human medicine.
• FinnStem, established in 2004, specialises in the development of services for supporting the adoption of new regenerative stem cell therapies in health care and technologies and methods for the storing and handling of adult stem cells.
Finland has also emerged as a leader in functionalising biomaterials by combining them with stem cells; enabling implanted cells to prosper and subsequently repair the injured area – be it cranial

bone or myocardial tissue following a heart attack. Finnish companies active in the field of biomaterials include Inion, Scaffdex and Vivoxid, to name just a few.
Overall, despite these positive examples of Finland's emerging stem cell business, its development and future growth is presently being hampered by a lack of funding. Opportunities nevertheless exist for drawing upon the country's rich pool of research and well educated human resources.

3. Finnish legislation favours stem cell research

Finnish legislation is more flexible than many other countries in the advancement of basic stem cell research. Medical research using human stem cells is governed by the Medical Research Act (1999). According to this Act, embryos left over from fertilisation treatments can be used for research, providing that the donors have given written consent. Embryos must not be moved into a body and must be destroyed within 14 days of fertilisation. Eggs and sperm can be stored in liquid nitrogen for 15 years e.g. in cases in which an early adulthood disease leads to infertility. After 15 years, the eggs and sperm cannot be used in research and must be destroyed. More information on the legislation and the differences between nations can be found in e.g. Bionet Online [links see 1, 2]

To further clarify Finnish legislation, tissue bank operations must be non-profit organisations and the donors themselves do not receive payments. The authorisation for such operations is granted by the national agency for medicines (FIMEA) and quality requirements for such operations are very high.

3.1. Stem cells available where most needed

Adult stem cells are routinely used for treatment of leukemia and other blood/bone cancers. The collection of cord blood and the maintenance of a bone marrow register has been one of the core activities of Finnish Red Cross Blood Services for already a decade. The collection, handling and storage of stem cells for routine use takes place mostly in cooperation with hospitals in Helsinki but there are plans to expand this activity to other cities as well thus increasing the availability of raw material.

The stem cells used by research groups are collected from cooperating hospitals which are principally sourced from surplus or bad quality embryos received from fertilization clinics. Increasingly, however, also other tissue types are used as raw material.

The Finnish Red Cross Blood Services have also been conducting groundbreaking research analysing the surface structures of cells. This research enables improved targeting of stem cells in the organism and their improved use in the treatment of diseases.

3.2. Further information on legislation governing stem cell research internationally

[1] Bionet: What is legal?
http://www.bionetonline.org/english/Content/sc_leg2.htm
[2] National Institute of Health - Stem Cell Policy: World Stem Cell Map
http://www.mbbnet.umn.edu/scmap.html

4. Value chain

As the following diagram demonstrating Finland’s value chain in stem cell technology shows, there is still much room for development. The light blue colour boxes indicate those areas yet to bedeveloped.

5. Conclusions

As a whole, the stem cell industry is emerging steadily in Finland with many of the key elements required for its growth already in place. The lack of funding is, however, a clear factor slowing down the process. Strategic investment in those areas highlighted in the diagram above could yield benefits for both promising new lines of research and the business in general.

Many of the global giants in other fields of medical technology have acquired or established operations here (GE Healthcare, Philips, PerkinElmer, to name a few), providing evidence on the feasibility of such operations. The innovations and expertise related to stem cells offers great potential for investors and entrepreneurs alike to take them further.

The logistics chain is ready for providing good quality stem cells for research and therapeutic use, providing a fertile ground for companies active in the area. Services are available for support. Invest in Finland’s fact-based consulting services provide extensive guidance on the market entry strategy right for you as well as information on registration and compliance with the Finnish taxation system. For its part, Tekes (the Finnish Funding Agency for Technology and Innovation) provides R&D funding for projects. In this regard, foreign-owned companies registered in Finland can receive project funding on an equal footing with Finnish companies.

6. Links to organisations

Regea Institute for Regenerative Medicine: www.regea.fi
Finnish Red Cross Blood Services: www.veripalvelu.fi
National Institute for Medicine: www.fimea.fi
Tekes: www.tekes.fi
ChipMan Technologies: www.chipmantech.com
EvoStem: www.evostem.fi
FinnStem: www.finnstem.fi
Inion: www.inion.com
Scaffdex: www.scaffdex.com/index_en.php
Vivoxid: http://vivoxid.fi/
18 March 2011

Content

1. Executive Summary

This report deliberately describes only a selected few aspects of the BioPharma market, in order to highlight both the opportunities and difficulties of using Finland as an investment location.

One of the major factors that makes Finland an attractive business environment is the naturally interconnected and easy-access platform structure of its businesses, which include well-connected biopharma facilitators such as HealthBio cluster, regional clusters, Salwe programmes, FIMM, Tekes technology programmes, VTT-Technical Research Centre of Finland, etc. Another characteristic feature of Finland is the enabling network, which is an innovative environment that provides support and funding via bodies such as Tekes, Ely-centers and Yrityssuomi concept. These bodies finance, for example, technology programmes that are open to both national and international applicants.

The overall innovation support system of Finland serves as a model for many countries. It pays attention to producers, users and their interaction, and it recognises the essential roles of education, research, development and international collaboration.

Perhaps the outstanding features of Finnish SMEs are the qualified human resources: highly educated, committed professionals with excellent language skills. Due to the relatively small size of the domestic market, there are innovative companies looking for equity funding to finance their growth. Finland also offers opportunities for investors that have strategic views on European-level network creation and are interested in company consolidation. There are a number of examples of representative FDI cases.

Pharmaceutical distribution in Finland is particularly concentrated, with only two main wholesalers. Competition is intense and margins are lower than the European average. It is a market that is currently under pressure to change the structure within its system, and transitional times may create new types of business opportunities for new types of actors.

There are currently 34 companies that are authorised to manufacture pharmaceuticals in Finland. These companies include pharmaceutical companies, food supplement producers, global pharmaceutical companies, such as Roche and Novartis, importing and warehousing companies, contract research and manufacturing organisations, biotech companies and contract research organisations. Pure contract research organisations number approximately thirty and they operate in the fields of clinical trials, regulatory affairs, market authorisations, preclinical research and analytical services, among others.

However, the number of companies is not an adequate indicator of success. A high percentage of these companies are small, and fragmentation hinders the creation of larger companies with more robust prospects. Early competitiveness and exposure to international norms should be encouraged by the participation of international VC investors. Mergers and acquisitions between companies with obvious synergies should be developed.

Although Finland is a relatively small and remote market with many small companies, it has efficient business networks and a working official authority, as well as excellent travel connections all over the world. A member of the EU, the Eurozone and the European Monetary System (EMS), Finland enjoys a unique position as an interesting entry point to the Scandinavian countries, Central and Eastern Europe, the Baltic region and Russia. The Finnish Biopharma sector actively contributes to the ScanBalt BioRegion development.

2. The BioPharma network as a business platform

The Finnish market is relatively compact, but there are many players. During the past few years in particular, all the players have actively formed various networks in the biotech and pharma sector, in order to create an accessible platform to facilitate contact creation.
In addition to the biopharma network there is also a general innovation environment network, which offers various kinds of support and services to both domestic and foreign owned companies on an equal footing. This network consists of players such as Tekes, Finpro, Finnvera, ELY-centers and Regional Development Agencies, as well as members of the Finnish Science Park Association.
In 2009, there were approximately 200 biotech companies operating in Finland. Most of these (about 150) were companies exploiting biotechnology or other closely related technologies. Apart from these core companies there are a variety of support companies, consisting of mostly subcontractors or consulting firms.
More than half of Finland's biotech companies operate in the health sector, conducting research and developing or manufacturing drugs, diagnostics or biomaterials. There are about thirty companies developing drugs, with some forty companies engaged in in-vitro diagnostics and ten in biomaterials. All of these intend to place products on the international market. Finland also has a significant presence in industrial-scale enzyme production, with some companies concentrating on high-quality enzymes for research.
The complete list of biotech companies is updated annually in the BioFinland catalogue, which can be found at: http://www.healthbio.fi/healthbio.asp?viewID=328
Although Finland offers a performing, high-quality environment for biopharmaceutical business development, several surveys have clearly highlighted poor financing opportunities as the greatest concern to biotechnology companies in Finland. Those who have been particularly worried have been early-stage companies, who feel that early-stage venture capital has not been available.
The European Science Council (European Science Foundation www.esf.org) has also directed its attention to the financing of technology companies. It recommends that by the year 2030 venture capital for early-stage technology developers should be tripled. This would mean that venture capital would be raised by 0.15% of the gross national product (0.15% of GDP) in the OECD countries.
The following briefly describes some of the main initiatives that are intended to increase the market image and attractiveness of Finland.

2.1. The HealthBio cluster programme (OSKE)

The Centre of Expertise Programme (www.oske.net) provides networks and services for companies, universities, universities of applied sciences and research institutions, and reinforces innovation hubs that could be deemed desirable partners for international networks. One of the members of the Centre of Expertise programme, the HealthBIO, is a cluster programme (OSKE) and development

platform for health and associated biotech business (www.healthbio.fi/en). HealthBIO is financed by the Ministry of Trade and Employment of Finland as a part of the Centre of Expertise Programme for the fixed term of 2007-2013.
HealthBIO cluster's main goal is to **generate, develop and internationalise Finnish bio-business.** HealthBIO mobilises the best know-how of the sector in Finland via five independent and regional centres in charge of the co-ordination and management of several national/international initiatives. HealthBIO acts as a co-operation and growth booster along with other European networks, such as ScanBalt BioRegion, which comprises the Nordic-Baltic Sea region of Denmark, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland, Sweden, the northern part of Germany and north-western part of Russia. ScanBalt BioRegion represents over 2 500 life science-related companies, 1012 academic institutes and institutions, 238 hospitals and clinics and 112 investors. As an active member of the network, HealthBIO is an ideal partner to enhance life science and biotech-related cooperation
in the region.

HealthBIO's regional centres

In Finland, HealthBIO co-ordinates some key initiatives as 'National Spearhead Projects'. Below are three such projects:

2.1.1.FinnCRIN – Finnish Clinical Research Infrastructure Network

Finland has an excellent clinical research track record. FinnCRIN's objective is to strengthen Finnish expertise by enhancing the infrastructure of clinical drug research, improving the predictability of patient recruitment and increasing the use of the latest clinical research-specific ICT solutions. Finnish health care professionals have a wealth of recognised experience in conducting clinical trials and patient sub-grouping. Pharmaceutical companies may rely on local CMOs able to manufacture clinical batches of drugs in a cost-effective manner. Drug metabolism and drug interference studies are among Finland's specific competence fields. The positive attitude of the authorities, public and

investigators are also to be considered valuable strengths.

Ongoing clinical trials in Finland (Source: PIF 2009)

2.1.2. The National BioBank Network

The National Biobank Network collects and administers tissue archives compiled for diagnostic and research purposes together with the related patient data. The specimen base consists of samples collected in both normal healthcare and samples collected for specific studies. Its objective is to strengthen the competitiveness of companies that utilise the tissue banks and to help generate new business in the area.
The Finnish network's competitive advantages include a genetically and culturally homogenous population, excellent national patient registers, organised sample archives and high level scientific expertise in processing the tissues, all of which are combined with effective utilisation of IT.
Tissue bank operations are governed by Finnish law regarding the use of tissues and organs for medical use. Quality requirements for such operations are very high and the authorisation for these operations is granted by the national agency for medicines (FIMEA). Tissue banks must be non-profit organisations by law, and the donors must not receive payments.

2.1.3.Pharmaceutical Gateway China-Finland/Europe

Pharmaceutical Gateway China-Finland/Europe is a co-operative HealthBio cluster spearhead project of the University of Eastern Finland and Kuopio Innovation Ltd. The main co-operation partner in China is the Zhang Jiang Group (a science park organisation) in Shanghai.
Its overall aim is to increase pharmaceutical co-operation between Finland and China; Finnish and Chinese universities, pharmaceutical companies and development organisations are participating in this programme.
The initial start-up project laid the groundwork, and created an extensive network of contacts and developed operations models. The main objectives of the current 2008-2010 continuation project are:
• to increase Finnish-Chinese research co-operation
• to promote Finnish enterprise business activities in China by building a co-operation platform for Finnish and Chinese organisations, creating the preconditions for carrying out projects.
0
100
200
300
400
500
600
Phase IV
Phase III
Phase II
Phase I

This co-operation platform will produce so-called spin off projects in which both the European and Chinese parties will participate. The operating principle of the programme is highlighted in the figures below.
Fig.1 Pharmaceutical Gateway China-Finland/Europe programme.
Firstly, the PGCF team identifies and then evaluates suitable co-operation partners from China and Europe and organises joint seminars and partnering events (in China and Finland). The team also helps the spin off projects, mainly in project planning but also in seeking finance and in helping to identify the best operational model for their project. After the start-up period, it is anticipated that the spin off projects will be sufficiently robust that they can thrive on their own.
There are ten Finnish companies in the PGCF programme, representing the entire spectrum of the Finnish pharmaceutical industry. In addition to drug development and service companies, there are also manufacturing and marketing companies:
• BioTie Therapies Corp. (www.biotie.fi)
• Cerebricon Ltd. (www.cerebricon.com)
• Fennopharma Ltd. (www.fennopharma.fi)
• FoodFiles Ltd. (www.foodfiles.com)
• Hormos Medical Ltd. (www.quatrx.com)
• Leiras Finland Oy (www.nycomed.fi)
• Oy Medfiles Ltd (www.medfiles.fi)

• Orion (www.orion.fi)
• StatFinn Oy (www.statfinn.fi)

2.2. Salwe (SHOK)

In June 2006, the Science and Technology Policy Council (Research and Innovation Council) of Finland decided to establish new innovation policy instruments, or SHOKs, which are strategic centres for science, technology and innovation in fields that are important to the future of Finnish society. They aim to direct a large share of the Finnish public R&D subsidies towards more demandbased
and incumbent-driven innovation activity, business and industry. The strategic centres will carry out the research strategy and plan specified by the shareholders.
• The operational core will consist of research programmes based on the research agenda
• Testing and piloting environments and ecosystems constitute an essential part of the centres' operations.
• The Centres will have extensive national and international partner networks
• Long-term funding and operative continuity is ensured for selected areas.

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2.2.1.Salwe - Strategic Centre for Health and Wellbeing

Salwe's (www.salwe.org) mission statement is 'Improving individual health and well-being to foster related businesses'. The goal of the centre is to develop products, services and practices to prevent and treat diseases with major public health and economic impact, and comprehensively maintain and improve the functional capabilities of an individual.
The selected focus areas of Salwe are:
• Microbial infections and inflammation
• Obesity and metabolic syndrome
• Neurodegenerative and psychiatric diseases as well as a healthy brain under stress
• Malignant diseases, especially solid tumours

In June 2010, the Salwe programme launched its first research programme, entitled 'Intelligent Monitoring', which focuses on tumours. The programme involves 13 companies and seven research organisations, with Tekes the funding partner of the first part of the programme until the end of 2011. The participating companies are the best Finland has to offer in their field. They represent some 3 500 employees with a total turnover exceeding 550 million euros, and their R&D investments represent approximately 45 million euros per year. Ten per cent (10%) of these investments are dedicated to the 'Intelligent Monitoring' research programme.

2.3. TEKES

Many support services in the country exist to foster innovation and business development. Foreign companies which have established a legal entity in Finland stand on equal footing with domestic companies in terms of public support.
TEKES, the Finnish Funding Agency for Technology and Innovation, is the most important publicly funded expert organisation for financing research, development and innovation in Finland. Tekes does not derive any financial profit from its activities, nor does it claim any intellectual property rights. TEKES provides support either per separate application or in conjunction with programmes focusing on a particular area. The programmes are designed to provide opportunities for carrying out ambitious R&D projects and for developing business expertise and international co-operation. Wellbeing and health, including the life sciences sector and red biotechnology, is one of the strategic focus areas for TEKES.
The primary ongoing programme in the BioPharma sector is the Pharma – Building Competitive Edge 2008–2011 programme (http://www.tekes.fi/programmes/Pharma)
The Pharma – Building Competitive Edge programme promotes the international competitiveness of the Finnish pharmaceutical industry by eliminating bottlenecks through the creation of new tools and operational models, as well as development processes for products, services and methods. The programme focuses on the development of operational models and methods to intensify activity and networking within the industry.
The Pharma programme participates in EUROTRANSBIO Pro (ETB) ERA-NET projects within the EU's 7th Framework Programme. The strategic objective of the ETB is to foster the competitiveness of European's biotechnology industry by supporting the research-intensive small and medium sized enterprises and their strategic partnerships.

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Pharma also provides information on the EU's FP7 funding possibilities, closely follows activities within the Innovative Medicines Initiative (IMI) and informs companies about its funding opportunities.

The IMI is a unique partnership between the European Community and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The aim of IMI is to support the faster discovery and development of better medicines for patients and to enhance Europe's competitiveness.
The Tekes Pharma programme also promotes Finnish companies and research groups as they seek to build bridges with China. Pharma can finance Finnish companies' co-operative Sino-Finnish projects, while also creating networks and enhancing collaboration in China by arranging visits and providing contacts. Pharma also co-operates with HealthBIO's Pharmaceutical Gateway China-Finland/Europe cluster-programme.

2.4. FIMM

The Institute for Molecular Medicine Finland (FIMM) is a research institute that focuses on bridging the gap between the discovery of drugs and their medical application, focusing particularly on molecular medicine. The vital factor behind FIMM's creation is the high quality of Finnish clinical scientific research. FIMM was formally established on the 20th of September 2006 by the University of Helsinki Senate, and was commissioned by the Finnish Ministry of Education. It currently employs 130 people, and the specialised expertise of FIMM is built around genetics and bio banking.
Molecular medicine is part of a megatrend in pharmaceutical research and revolves around personalised medicine. This is a future trend that has the potential to be a real revolution throughout the entire healthcare, diagnostics, pharmaceutical and research and diagnostics systems. Mapping a person's genome can open up a huge range of opportunities in the future. Currently, the first applications are mostly in the field of oncology, but personalised medicine is applicable to the entire medicine field. It should be noted that patient empowerment is also a trend that is connected to personalised medicine.
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The financing was organised in an innovative public-private partnership, which collected initial funding (for the five first operational years) of 25 million euros from private funds and public institutions. However, the main source of financing for FIMM is the project financing for research projects, and those funds are mainly from EU financing sources.
FIMM's main activities can be divided into three areas:
• bio banking
• supply of research technologies and facilities
• research activities
a. contract research to academic researchers in Finland (and in the future in Europe)
b. own research (e.g. national research programmes)
As far as bio banking is concerned there are several bio banking activities present in Finland, mainly in Helsinki (Meilahti), Tampere, Turku and Oulu. FIMM manages the Meilahti facilities, which include around 200 000 DNA samples collected by THL from the Finnish population. This is an extraordinary resource and tool for molecular and genetic research. Bio banks are independent organisations and are developing their activity models while waiting for the Finnish bio bank law to be established, which is likely to occur at the beginning of 2011. The Finnish bio bank legislation is lacking when compared to other European countries, and therefore collaboration between the bio banks is ongoing in order to create a common bio banking framework in Finland.
FIMM operates in a highly networked environment at national, Nordic, European and international levels. FIMM is part of the Nordic EMBL Partnership for Molecular Medicine, together with the European Molecular Biology Laboratory (EMBL), the Centre for Molecular Medicine Norway (NCMM, University of Oslo) and the Laboratory for Molecular Infection Medicine Sweden (MIMS, Umeå University). At national level FIMM is a joint research institute of the University of Helsinki, the Hospital District of Helsinki and Uusimaa (HUS), the National Institute for Health and Welfare (THL) and the VTT Technical Research Centre of Finland. The national role has been strengthened by the exceptional model involving a network of public institutes including three different ministries and the University of Helsinki.
According to Olli Kallioniemi, director of FIMM, Finland could become a pioneering country in the field of advanced molecular medicine research. The clinical point of view is the fact that the application of innovative medicine in the every-day healthcare system on a large scale is still far from reality, but Finland is ready and equipped to become a forerunner in this field. Finland has a number of prerequisites, such as high-class research, well organised hospital care and, above all, a unique genetic databank of its population. All these factors enhance the gathering of top researchers, advanced knowledge, related industry and investment. Dr Jonathan Knowles, an ex- Research Director from Roche, is a prime example of how international researchers are attracted to Finland. As a globally renowned specialist of personalised medicine, he has agreed to work for FIMM as a

FiDiPro professor between 2010 and 2014.

2.5. Nordic and EU networks

Innovative Medicine Initiative (IMI) www.imi.europa.eu
Scanbalt www.scanbalt.org
Eurotransbio www.eurotransbio.eu
EFPIA www.efpia.org
EuropaBio www.europabio.org

3. FDI in BioPharma

The major Foreign Direct Investments (FDI) in Finnish bio and pharma sector companies between the years 2005 and 2010 are listed below:
2010 Healthcap (Sweden) invested 4m euros in Oncos
2010 Thermo Fisher Scientific acquired Finnzymes Oy
2010 Invesco Fund Managers Ltd (UK, USA) invested in Biotie Therapies Oyj
2009 Atacama Labs raised 2.3m euros from Finnish and international private investors
2009 Charles River acquired Cerebricon Oy in Kuopio
2007 Systems Biology Worldwide Oy was founded by Helsinki University Funds (50%) and Tooltech Global Engineering Pvt Ltd, India (50%)
2007 HealthCap (Sweden) and LSP (NL & Germany), together with Finnish investors Finnish Industry Investment Ltd. and Sitra, invested in Nexstim Oy in Helsinki
2007 DSM Venturing N.V. (Royal DSM, NL) invested in Jurilab Oy in Kuopio
2007 Bio Control Systems Inc. (USA) purchased the diagnostic part of Raisio Oyj
2006 Radiometer Medical A/S (Denmark) purchased Innotrac Diagnostic Oy in Turku
2006 B. Braun Medical Oy (B. Braun Melsungen, Germany) acquired MCP Medicare Oy in Loviisa
2006 Encorium Bio Solutions Ltd. (Covalent Group, USA) acquired Remedium Oy in Espoo
2005 QuatRx acquired Hormos Medical in Turku

3.1. Case Study: Thermo Fischer Scientific acquires Finnzymes

Finnzymes is a Finnish company established to provide integrated tools for molecular biology analysis, including reagents, instruments, consumables and kits. The headquarters is located in Espoo, Finland, and today Finnzymes has 90 employees and an annual turnover of 13 million euros (2009).
Finnzymes Oy was founded in 1986 by Pekka Mattila and Kari Pitkänen, both of whom studied at the Helsinki University of Technology and wrote their theses on enzyme restriction production. During the start-up phase of the company, financial support was received from the Finnish National Technology Agency, Tekes. A further enabling factor was the marketing of New England Biolabs (NEB) products in Finland. Their own product development started when Tuomas Tenkanen returned to Finnzymes, having completed further studies concerning restriction enzyme characterisation and purification at the NEB labs in the USA. The first product, DyNAzyme™ I DNA Polymerase, which was used for DNA amplification was launched in 1990. The enzyme was isolated from a bacteria strain found in

hot springs in Iceland. The product family has since been enlarged by DyNAzyme EXT and Hot Start products, while the latest product, PhusionDNA-Polymerase, is considered one of the most efficient enzymes on the market today.
Around 2005 the Bi-Rad and M J Research merger in the USA created market space for PCR device manufacturing, and Finnzymes decided to seize the opportunity by entering the PCR device markets. Finnzymes Instruments Oy was founded in 2005, with Finnzymes Oy retaining a 70% share of the new company. Other shareholders included the Japanese firm Daiichi Pure Chemical and Euro Clone from Italy. Two key people from MJR joined the company and Partner Tech from Sweden took care of the contract manufacturing. In 2009, Finnzymes Instruments Oy had a turnover of 544 000 euros and four employees.
Thermo Fischer Scientific is a multinational corporation operating in the field of science and research, providing products, systems and services. The headquarters is located in the US city of Waltham, Massachusetts. The company operates mainly through two brands, namely Thermo Scientific and Fisher Scientific. Thermo Scientific covers products from its own manufacturing and Fischer Scientific operates as a distributor network for outside brands. During 2008/2009, the company had a worldwide turnover of 10.8 billion US Dollars and employed 34 000 people. Their customer base is approximately 350 000, and is found in the pharmaceutical and biotechnology sectors, hospitals and clinical diagnostic laboratories, universities, research institutions and government agencies, as well

as environmental and industrial process control settings.
The Finnish subsidiary, Thermo Fischer Scientific Oy, was established in 1993, and employs 550 people in two locations: Vantaa and Joensuu. The Finnish subsidiary's turnover in 2009 was 117 million euros. The Finnish production site is located in Joensuu, where the production lines for liquid handling equipment, liquid handling tips, well plates, well plate instruments, magnetic particle processors, Konelab-instruments and automation systems for clinical chemistry are based.
A new company, formed under the Fischer Scientific brand, started its activities in Finland on the 8th of February 2010. The Finnish distribution operations of Fischer Scientific and Finnzymes merged during the autumn of 2010.
The acquisition news was published on the 1st of February 2010 and the acquisition process was concluded on the 3rd of March. Finnzymes will be integrated primarily into Thermo Fisher Scientifics' Analytical Technologies Segment, with some equipment and consumables product lines being added to the Laboratory Products and Services Segment.

4. Pharmaceutical distribution in Finland

4.1. Market Overview

Every step of the Finnish pharmaceutical distribution chain is subject to permissions and control by the authorities. The distribution chain is controlled by the National Agency for Medicines, which is also in charge of drug safety. In November 2009 a large restructuring of the Finnish public administration took place and there was a knock-on effect for the medicine agency. One of the results of the restructuring was the creation of Fimea, The Finnish Medicines Agency (www.fimea.fi). The activities, earlier located in Helsinki, will gradually be transferred to the new premises in Kuopio and other locations throughout Finland by August 2014. Fimea's main duties include authorisation and supervision tasks in the pharmaceutical sector, research and development, and production and dissemination of information on medicinal products with a view to improving the effectiveness of pharmacotherapy and the pharmaceutical service.
Owing to a tough competitive situation and the high centralisation of wholesale activities, the margins of the Finnish pharmaceutical wholesale business are among the lowest in Europe - only a few percent on average. This is due to several factors: one-channel distribution in addition to efficient and modern pharmaceutical wholesale, as well as automation and information technology-based recovery activities and fierce competition in the industry have increased its efficiency. Efficiency is vital for profitable business, and pharmaceutical wholesalers have, indeed, made great efforts in this respect. Their logistics and attached services have developed and intensified so that the actual transfer of a preparation from one place to another constitutes only a minor part of the wholesaler's operation. As a result of the intensified operation, wholesalers no longer run branch offices, but this is by no means reflected in poorer service at the pharmacy end. The objective of the pharmaceutical wholesalers is to supply the pharmacies with their drugs within 24 hours of the order. Low costs in the pharmaceutical wholesale business directly benefit the consumer, as it allows a lower wholesale price for the medicines.
Total pharmaceutical sales in Finland amounted to almost 2.3 billion euros in wholesale prices during 2009. The market had been growing steadily for a long time, but the reference price system had a sudden negative impact on the sector sales figures during the year. In fact, a decrease of 0.4% in 2009 occurred following many positive growth years.

4.2. The Reference Price System in April 2009

Pharmaceutical patents are expiring and therefore giving space for generic pharmaceuticals to be available for equivalent use for patients. This phenomenon has created the need to have an updated legislation and system in place for pricing. In April 2009 a new reference price system was adopted in Finland, with the objective of reducing government reimbursement costs. The practical effect was that margins were reduced dramatically, both in the retail sector (pharmacies) and in the wholesale sector. The reference price system is controlled by the Pharmaceuticals Pricing Board (Hila).
The Pharmaceuticals Pricing Board is subordinated to the Ministry of Social Affairs and Health's Insurance Department. The Pharmaceuticals Pricing Board confirms reimbursement and a reasonable wholesale price for medicinal products, clinical nutritional preparations and basic

ointments that are reimbursable under the Health Insurance Act. The board decide the reference

price groups and product included, as well as the pricing, on a quarterly basis. This decision is based on the quarterly price report made by the pharmaceutical companies, and all decisions are made at least seven days before the beginning of the three-month time period. The decision is valid for the whole time period and includes the wholesale price and retail price, including VAT, for all the products.
The Pharmaceuticals Pricing Board also monitors the effects of reimbursement and wholesale price decisions on reimbursement costs. The Pharmaceuticals Pricing Board's response times are, at the very most, 180 days, and for price increase application the maximum time is 90 days. The median response in 2007 for new pharmaceutical products was 128 days for positive decisions and 153 days for negative decisions.
As far as margins are concerned the breakdown of the retail price of a medicine in 2008 (shown in the graph below) was 6.3% for wholesale and 21.6% for pharmacists. In Finland the wholesale margins are lower than the European average, but the pharmacist margins are higher than the average. The average share of the pharmacy on the final price was 23% in 2008 and it stays at a similar level in 2009, with 23.5%, according to the Pharmacy Association's estimates. The wholesale margins in Finland are around 3-5%, which is significantly less than in other European countries.

4.3. One-channel system

Finnish pharmaceutical distribution takes place through the so-called one-channel system. The pharmaceutical's manufacturer makes a sole-distribution contract with one wholesaler and the products are only available through that wholesaler. Most other EU countries follow the multi-channel system whereby the pharmacies can order the manufacturer's products from any wholesaler that maintains a full inventory of the products on the market.
The one-channel system was introduced in Finland about 30 years ago, following the Swedish model at that time. The possible violations of competition legislation have been raised and scrutinised but so far the system has been allowed to continue due to its obvious advantages: the system ensures that the goods are available throughout Finland and that the pharmacies get what they order. Other benefits include the accurate estimation of drug consumption and the virtual elimination of the chance of fake drugs entering the market. From the pharmaceutical companies' point of view, this is a cost-effective system; the margin of the wholesalers has been significantly lower in Finland compared to the average European level. Often in the multilevel system there is an additional level in the value chain between wholesalers and manufacturers/importers.
Recently, the Swedish pharmaceutical distribution market has undertaken large structural change, and both one-channel and multichannel exist contemporarily. Apart from Finland, only two countries worldwide have the one-channel system: Cuba and North Korea. On the other hand, Europe has recently seen signs of contracts, particularly in the UK, between pharma companies and wholesalers that adhere to the one-channel system.
Because of the reference price system adopted in April 2009 the pharmaceutical distribution chain has experienced a general decrease in sector profitability. This has resulted in great pressure to find solutions that ensure the viability of the industry. According to Antti Vatanen from the Association of Pharmaceutical good wholesalers (Apteekkitavaratukku-kauppiaat ry) there could be two kinds of effects placed on the market: firstly re-design the wholesale fee system and secondly introduce value adding services to the pharmaceutical products.
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Wholesalers supply the drugs primarily to pharmacies and hospitals. Only a very small part of the drug is supplied directly to patients. The veterinary medicinal products are supplied in pharmacies and clinics and also directly to veterinarians on occasion. The same wholesalers also provide nonmedicinal
products and devices for health care institutions and pharmacies.

4.4. Value chain and players

Pharmaceutical Distribution in Finland
Value Chain

Distribution
Manufacturing Industry
Customers
Government

Retailers
Wholesale

1-channel system

The importers of medicines (manufacturer, marketer or wholesaler) supply their products to the wholesalers, who in turn deliver the drugs to the pharmacies or their subsidiaries and then further to the end users. A second route takes the drug from the wholesaler to the hospital pharmacies or the health centre medicine dispensaries. Certain products with a great demand volume may be delivered through an alternative route directly from the manufacturer to the hospital pharmacy. Animal medicines go from the wholesalers to the pharmacies or directly to the veterinary surgeons.
As far as the players in the wholesale business are concerned, there are three country-wide wholesalers that specialise in the wholesale distribution of medicinal products:
• Tamro Suomi: a part of Tamro Corporation, founded in 1983 (with roots as far back as 1895), operates in Finland, Sweden, Norway, Denmark, the Baltic regions and Poland. It is owned by an international pharmaceutical wholesaler, PHOENIX Group, which is based in Germany.

☐ 2009 net sales in Finland were 1.1 million euros, while the market share in Finland was 53.1 %

• Oriola-KD Oy: currently part of Dutch Media group, it operates in Finland, Sweden, Russia and the Baltic region.

☐ Its 2009 market share in Finland was 46.7 %

• Magnum Medical Finland Oy: a part of Estonian Magnum Corporation, founded in 2004 and received its licence in 2006. This company operates in Finland and the Baltic region.
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☐ Its 2009 market share in Finland was 0.8 %

There are around eighty other companies involved in pharmaceutical wholesale in Finland that perform the importation of drugs but not the storage and distribution. These companies are mostly international pharmaceutical companies marketing their drugs in Finland. Some enterprises also have the rights of a pharmaceutical company, which requires, inter alia, the importation of investigational medicinal products from outside the EU. The list is available at the Fimea website: http://www.laakelaitos.fi/laaketeollisuus/toimiluvat/laaketukkukauppaluvat/kotimaiset_laaketukkukaupat. Below you can see the development of the number of drug importer companies in Finland from 1997-2007.
Prescription and non-prescription medicines are distributed only through retail pharmacies, with the exception of nicotine replacement therapy drugs. There are over 800 pharmacies and branch pharmacies in Finland. At the end of 2009 there were a total of 617 pharmacies and 194 branch pharmacies, which employed 8300 persons between them. The private pharmacy sector had an overall turnover of 2.03 billion euros in 2009. In addition, hospitals have their own pharmacies; at present there are 24 hospital pharmacies operating in university hospitals, major hospitals and health centres. There are also so-called medicine centres (lääkekeskukset), which totalled 177 in 2007, operating under state or private operators, and sometimes under the control of municipalities.
Pharmacies are privately owned by pharmacists, but they cannot be owned by companies. One pharmacist can run only one pharmacy, although it also possible to run three subsidiary pharmacies. As an exemption, the University of Helsinki and the University of Kuopio have special rights to own pharmacies. Fimea is the competent authority for pharmacy permits, and in order to receive authorisation for a pharmacy the person needs to have an official title of pharmacist (proviisori) and must be a citizen of the European Economic Area.
Officially, ownership-based pharmacy chains are not allowed. However, there are several pharmacy networks, for example Avainapteekit, Hyvän Mielen Apteekit and OMA Plus. The Swedish legislation changes in pharmacy ownership have created some expectations for the Finnish market to also open up ownership to companies. The scenario would be that the wholesale companies could own the pharmacies, which would automatically mean shifting to a multichannel system and increasing

distribution costs.
From the difference of the wholesale price and the retail price (an average of around 26% of net sales), pharmacists must pay taxes, rent, salaries of employed personnel, and so on. The Value

Added Tax on medicinal products is 9%, and pharmacies also pay a graded pharmacy fee to the state which depends on their net sales (on average 6% of the turnover in 2009). The function of the pharmacy fee is to decrease the differences in income between pharmacies, but there are nevertheless major differences in profits between pharmacies (MSAH 2007a). In 2005, the average annual profit for a pharmacist was 280 000 euros (9.2% of the net sales) after overheads and running costs.

4.5. Pharma companies, Biotech, CROs, CMOs and other players

There are presently 34 companies that have the Fimea authorisation for pharmaceutical manufacturing in Finland. These include pharmaceutical companies (e.g. Orion, Santen, Bayer Shering Pharma), food supplement producers (e.g. Hankintatukku), global importing and warehousing pharmaceutical companies (e.g. Roche, Novartis), contract manufacturing organisations (e.g. Pharmatory), biotech companies (e.g. Ark Therapeutics) and contract research organisations (e.g. Medfiles).
The complete list is available at the Fimea website and is updated regularly:
http://www.laakelaitos.fi/laaketeollisuus/toimiluvat/laaketehdasluvat/kotimaiset_laaketehtaat
The complete list of companies with wholesale authorisation is also available at the Fimea website and it too is updated regularly:
http://www.laakelaitos.fi/laaketeollisuus/toimiluvat/laaketukkukauppaluvat. This list includes all the companies active in import activities without their own warehouse for distribution (e.g. Eli Lilly, Teva).
There are around thirty contract research organisations (CROs) in Finland, and they operate in the field of clinical trials, regulatory affairs, market authorisations, preclinical research and analytical services, etc.
There are around ten contract manufacturing organisations (CMOs) in Finland, including Biovian and Pharmatory.

4.5.1.Case Study: Magnum Medical Finland Oy

A company called Magnum was founded in 1990 and started its medicine wholesale in 1992, with Magnum Medical founded in 1993 in Tartu, Estonia. In 1998 Magnum Medical acquired its competitor Pro Med's market share in the wholesale business. The following year it began its international expansion when it acquired the Latvian medicine wholesaler SIA Pharma Service Riga and named it SIA Magnum Medical.
Magnum AS, as the holding company of the group, co-ordinates the group activities in Estonia, Latvia, Lithuania and Finland, with its headquarters located in Tallinn. Mr Leon Jankelevitsh is the current CEO of the Magnum AS group. The group employs about 1 000 people and its total turnover was 215 million euros in 2009. In 2006 80% of the Magnum Medical Groups shares were owned by a British capital investment company, but at present the founder of the company is the major shareholder.
A large company restructuring project took place in 2006, when the company activities were divided into a holding company and three fully owned subsidiaries:
1. Magnum Medical OÜ
wholesale of medicines (excl. logistics)
2. Magnum Health OÜ

wholesale and retail of non-medicines (incl. consumer goods)
3. Magnum Logistics OÜ
logistics and labelling of packages
In 2004 Magnum Medical established a 100%-owned subsidiary in Finland called Magnum Medical Finland Ltd. The Finnish subsidiary received wholesale authorisation in Finland in July 2006 after a year-long wait, which is significantly more than the standard 90 days.
Magnum Medical Finland Oy employs 15 people and its turnover was 10.5 million euros in 2009 - the estimate for 2010 was over 13 million euros. The product range distributed is divided equally between pharmaceutical products and other products (e.g. medical devices). The current managing director of the Finnish subsidiary is Lauri Varandi.
Its market share in Finland was still less than 1% in 2009. The one-channel system is a significant entry barrier to the market, as the pharmaceutical companies tend to have exclusive contracts for multi-year periods. According to Leon Jankelevitsh, chairman of the board of Magnum, the company wants to build up a 10-15% market share in Finland by 2013 - thus far, most of its distribution

agreements have been with medical device producers. Magnum Medical Finland signed an important distribution agreement with Fresenius in 2008 and, according to Jari Hanski, responsible pharmacist, Magnum Medical signed an important distribution agreement with a major company during the autumn of 2010. As a consequence the company is currently recruiting 22 further employees. Dentagent Oy is also part of this group, and it commercialises dental sector material and equipment.

4.6. Legislative aspects and permissions in pharmaceutical wholesale

Pharmaceutical wholesale in Finland is subject to a permit by FIMEA, the national agency of medicine. Pharmaceutical wholesale operations are based on legislation and regulations. Requirements focus on personnel training, product quality and safety of storage, as well as the availability of medicines and supplies. Throughout the years the requirements have constantly increased, meaning increased costs in order to meet these extra stipulations. The holder of the permit is obliged to communicate all material changes in its operations to the regulating authority, and every pharmaceutical wholesaler must have a responsible director with a Master of Pharmacy degree as well as a registration granted by the National Authority of Medico-legal Affairs (TEO), which was merged with Valvira in 2009 www.valvira.fi.

The pharmaceutical wholesaler must keep records of the imported medicines, submitting the respective reports to the authorities without delay. The accountability also extends to the sales of the pharmaceuticals, which are reported to the authorities twice a year. The wholesaler must also inform FIMEA about any availability problems, while the responsibilities of the pharmaceutical wholesalers (importers) also include the obligation to maintain stocks. In view of crisis situations, they need to maintain stocks of certain medicines defined in legislation, with the demands imposed on the pharmaceuticals manufacturers contained within the legislation. The introduction of the generic substitution regime brought about great variation in sales, and therefore the system of stock keeping obligations is now being reconsidered.

The EU has not come up with a joint decision regarding the postal or Internet sales of pharmaceuticals, with the decision left to each member state. Contrary to several other EU countries, Finland allows neither postal sales of pharmaceuticals nor their distribution through the Internet. For

security reasons, the authorities warn the public of possible fake drugs distributed through these trading channels.

5. Patents and trademarks

5.1. Patents in Finland

5.1.1.What is a patent?

As Finland is part of the European Union, the definition of a patent is the same: an exclusive right accorded by society to an inventor who in exchange of it has to permit the publication of his or her invention.

5.1.2.The geographical validity of a patent

A patent granted in Finland only protects the invention in Finland. You need not file your patent applications in foreign countries on the same day as they are filed in Finland, but you cannot leave the filing until you have the Finnish patent in your hand. There is no such thing as a worldwide patent. The application process can, however, be started by a single application: an international application, a PCT application.

5.1.3.European patents

By filing a single application for a European patent it is possible to obtain a patent for 40 European countries. The European patent is not a supranational patent, but a bundle of national ones; the application is processed and the patent granted by the European Patent Office. The application shall designate the states and extension states in which the applicant wishes to obtain a patent. Application forms are available at the website of the European Patent Office.

The application may be drawn up in the English language, which is one of the processing languages of the European Patent Office. However, all member states (except Monaco and Luxembourg) demand that, to take effect, the patent must be translated into the official language of that state.

NB: If the market of the invention is merely, for example, in the Nordic countries, the most favourable solution in an economic sense may be to file a national application in each of those countries.

5.1.4.The validity period of a patent

A granted patent may be maintained for 20 years from the date on which the application was filed,

and a patent is maintained by paying renewal fees. The fee shall be paid annually by the end of the first month of a new application year. If the renewal fees are not paid, the patent lapses and the invention becomes available for others, provided that it does not enjoy other types of protection, such as a utility model, design right or copyright.

5.2. Medical patents in Finland

The time of validity of patents concerning medicinal products can be prolonged by a maximum of five (5) years through an SPC (Supplementary Protection Certificate).
A patent in itself doesn't give the right to sell a medicine to consumers. The inventor of the new molecule must show extensive research results assuring that the medicine is indeed useful for the purpose, safe and of high quality.
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Different types of patents and protection for new medical products in Finland are:
• A **product patent** gives the exclusive rights to a new medicine regardless of its method of fabrication
• A **fabrication method patent** gives exclusive rights only to a specific fabrication method, not the end product
Documentation coverage
During the documentation coverage time of six years, the medical authorities cannot use the results concerning the safety and functionality of a medicine (found by its developer in order to get selling rights) to judge the safety and functionality of another medicine with the goal of giving it selling rights. By European standards the documentation coverage time is short in Finland, and this often leads to competing drugs coming to market quite quickly, which in turn may result in low prices.

5.2.1.General guidelines for applying for a patent in Finland

Patent applications are filed with the NBPR (National Board of Patents and Registration of Finland). Before applying, it is advisable to study patent publications from the same field. Such publications can be found, for example, at the esp@cenet database on the Internet.
The application form is available from the Internet. The form has to be filed in two copies and be accompanied by three copies of the following items:
• a description of the invention, preferably with a drawing if the invention can be illustrated
• patent claims
• an abstract
As well as:
• a statement concerning the right to the invention, if the applicant is a person other than the inventor, or the inventor is not the sole applicant; the statement may also be an assignment by which the inventor transfers his or her right to the invention to the applicant
• a power of attorney, if the applicant has appointed a representative
The patent application may be mailed to the physical address:
National Board of Patents and Registration
P. O. Box 1160, FI-00101 Helsinki
Or sent electronically through the Epoline Online Filing (eOLF) programme, which can be downloaded for free from the NBPR website http://patent.prh.fi.
The application may be drafted in the English language or in another language. However, the application has to be translated into Finnish or Swedish before it is made available to the public. It will not be examined before it has been translated into Finnish or Swedish.
If an application is rejected, the applicant has the opportunity to appeal the decision from the NBPR's Board of Appeal and see if the members of that Board disagree with the examiner. The appeal has to be lodged within 60 days from the date the applicant is notified of the rejection.
The Patent filling process at the NBPR takes approximately 2 – 2.5 years to be completed.
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5.3. Trademarks in Finland

There are three ways to apply for a trademark, by:
1) the official NBPR application form (printable from the website)
2) an NBPR online application form
3) a written letter of application (no form)
The application must include the applicant's name or company name, domicile or registered office and address. A trademark can be applied for by a company, an organisation or a private person. The application must be signed by the applicant or his/her representative.
Private traders applying for a trademark
A foreign applicant with neither domicile nor registered office in Finland must appoint a

representative, who is obliged to represent the applicant in all matters concerning the mark. If you have a representative, you must also give their name, domicile or registered office and address. Furthermore, you must enclose a power of attorney with your application.

List of goods and services

The application fees must be paid for the application to become pending. A copy of the receipt should also be attached. Similarly, an online application will only be registered in the system after the payment of the application fee through the applicant's online bank; the person who pays the fee is considered to have signed the application. The NBPR does not refund application fees if the application is rejected or dismissed, even if it is the applicant who withdraws the application.

Fees for trademark matters

The validity of registration is limited. The protection of a registered trademark begins on the date on which the application is filed. The registration is valid for 10 years from the registration date, and it can be renewed every 10 years.

6. Market Authorisation for Pharmaceutical Products

6.1. EMA – the European Medicines Agency and the European network

The objective of the agency when it was set up was to speed up the assessment process for new medicines, so that valuable new products would not be unnecessarily delayed in reaching the European market. The agency was also created to improve safety and provide the industry with a harmonised and reliable European regulatory framework.

The EMA operates in partnership with the national competent authorities for human and veterinary medicinal products in the Member States, and the EEA-EFTA countries Iceland, Liechtenstein and Norway. The authorities make scientific resources available in the form of a network of more than 3 500 European experts who assist the agency in performing its scientific tasks.

The European medicines network – a partnership between the European Medicines Agency, the European Commission and more than 40 medicines regulatory authorities in the European Union (EU) and the European Economic Area (EEA) – is the basis of the agency. The network gives the agency access to a pool of experts who participate in the work of the agency as members of the scientific committees, working parties and scientific advisory groups.

A medicinal product may only be placed on the market in the European Union when a marketing authorisation has been issued by the competent authority of one Member State for its own territory (national authorisation procedure), or when an authorisation has been granted at European level pursuant to Regulation 2309/93 (Community authorisation procedure).

The harmonisation of pharmaceutical products in Europe, although heavily regulated, has never reached 'total harmonisation' status. In Europe there are two routes for marketing medicinal products:

• the centralised, European level authorisation procedure by EMA – the agency located in London, UK

• the decentralised, national authorisation procedures of each European country's own agency responsible for marketing authorisations

6.1.1.The centralised procedure

The centralised procedure is compulsory for all medicinal products for human and animal use derived from biotechnology processes. The same applies to all human medicines intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative disorders and for all designated orphan medicines intended for the treatment of rare diseases. Similarly, all veterinary medicines intended for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals have to go through the centralised procedure. For medicinal products that do not fall under any of the abovementioned categories companies can submit an application for a centralised marketing authorisation to the EMA, provided the medicinal product constitutes a significant therapeutic, scientific or technical innovation or the product is in any other respect in the interest of patient or animal health. Applications are submitted directly to the EMA in London.

The main objective pursued by the centralised procedure is the improvement of the functioning of the single market for medicinal products, the avoidance of duplication of scientific evaluation and the

reduction of administrative burden.
Fig. 6.1. EMA applications 2009
Fig 6.2. Centralised procedure times (EMA)

6.1.2.The national procedures

The decentralised procedure and the mutual recognition procedure apply to the majority of conventional medicinal products and are based on the principle of 'mutual recognition' of national authorisations. In brief, the system provides for the extension of a marketing authorisation granted by one Member State to one or more other Member States identified by the applicant. Where the original national authorisation cannot be recognised, the points in dispute are submitted to the EMA for arbitration.

The European Commission adopts the final decision in both cases with the assistance of the scientific committee. The opinion of the scientific committee is transmitted to the European Commission.
Clinical trials conducted with patients in the EU area is a positive factor in the market authorisation decision, but the location of the company is not an evaluation criteria.
As the market authorisation procedures are relatively complicated and vary from country to country, there are a number of service companies that provide market authorisation and regulatory services to companies who want to register their product in the country. These contract research organisations (CROs) have particular expertise in market authorisation procedures with local authorities (Fimea in Finland). See more about CROs in Finland in chapter one.

6.1.3.Mutual-recognition agreements

Mutual-recognition agreements (MRAs) between the European Community and partner (third) countries include specific annexes relating to medicinal products and GMP. These allow EU Member States and the MRA partner to mutually recognise conclusions of inspections of manufacturers carried out by the respective inspection services of the other party, and to mutually recognise the manufacturer's certification of conformity to specifications for each batch without re-control at import. The agency is responsible for the implementation and operational aspects of these MRAs. MRAs with Australia, New Zealand, Switzerland, Canada and Japan are currently operational, but with slightly different provisions as to scope and applicability.

6.1.4.ATMP - Advanced therapies and other emerging therapies

The agency's Committee for Advanced Therapies (CAT) was inaugurated in January 2009. The committee deals with advanced therapy medicinal products (ATMPs) for human use that are based on gene therapy, somatic cell therapy or tissue engineering. These innovative medicines offer groundbreaking new treatment opportunities for diseases and injuries of the human body. The CAT is a multidisciplinary committee, and a large part of its work in 2009 was dedicated to implementing and further developing the regulatory framework for ATMPs. It achieved this by drafting procedural and scientific guidelines for public consultation and helping applicants to prepare their applications for the procedures introduced by the new legislation.

6.1.5.EMA's international strategy

Since 2009, the EMA has started to implement a global international strategy: an International Liaison Officer has been appointed and bilateral relations with the US FDA and the Japanese and Canadian authorities have been increased.
During the same year, the agency also participated in two meetings with the Chinese State Food and Drug Administration, with particular focus on good manufacturing practice (GMP) and issues relating to clinical trials. A specific action plan on inspections is under development.
The agency also supported the European Commission in discussions with India, within the framework of the working group on pharmaceuticals, and with Russia in the EU-Russian dialogue sub-group on pharmaceuticals.
The Committee on Herbal Medicinal Products (HMPC) provided input to the European Commission on the establishment of draft herbal monographs for several Indian medicinal plants, having considered the extent of their traditional use in the EU Member States.

7. Sources

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