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Health Sector Growth Strategy for Research and Innovation Activities

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To the reader

The Health Sector Growth Strategy for Research and Innovation Activities is a continuation of the report "Health technology and pharmaceutical research as the cornerstone of growth in Finland" ordered in 2012 by the Ministry of Employment and the Economy. The main conclusion of the report was that Finland has strong expertise in the health sector which could be used more effectively to strengthen growth and competitiveness. Private sector research activity could be increased by 2.5 times by 2020 through increased cooperation and by creating a joint action plan.

Three ministries (Ministry of Employment and the Economy, Ministry of Social Affairs and Health, Ministry of Education and Culture), Tekes - The Finnish Funding Agency for Innovation, and the Academy of Finland prepared, in cooperation with research and innovation funders and organisations in the health sector, the growth strategy that is now being announced. This is the first time when the health sector is being examined in such wide collaboration from the perspective of the growth of innovation activities and business. The ministries taking part in preparatory work are also together responsible for implementation of the strategy.

The strategy contains the key recommendations for the systematic development of research and innovation activities, as well as for increasing investments and achieving economic growth in the health sector.

The core of competitiveness is formed by university hospitals and the development of centres of expertise arising around them from the perspective of research and business partnerships. With the help of regional specialisation and nationally integrated operating models we will be able to improve our competitiveness.

Finland is considered to be in an especially good position as a leading country in the so-called personal health care research. Research and know-how are at a high level and have available globally unique comprehensive databases about national health. This potential should be utilised. The results of research and innovation activities in the health sector are also of direct benefit to clients and patients of the Finnish health care system.

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Abstract

Starting point The health sector has a strong foundation in research, product development and innovation activities, which require specialised high quality competences. Finland has invested a significant amount of public funds in health-related research and has in many sectors risen to the very top in international life sciences. However, society has not been able to benefit fully from research investment, nor has the investment produced enough added value. Finland has a unique opportunity to develop into a trendsetter of personalised medicine and health care.

Nature of the strategy The health sector research and innovation strategy is a socalled ecosystem strategy. The strategic document does not make proposals for measures to promote or emphasise any given branch of the health sector. Instead, it attempts to identify those sections in the health sector's innovative ecosystem that can be developed in order to create an international competitive advantage for Finland as a health sector research and innovation partner and a target country for investment.

Focus and objectives The pharmaceutical industry and health care technology as well as the closely related biotechnology are at the core of the strategy. Healthcare data systems and the so-called eHealth solutions form the branch of activity that is closely related to health care technology. The systematic ecosystem development work widely serves the operators in the field. The objective of the strategy is to attract health sector investments and financial growth. The national ecosystem approach emphasises the global nature of research and innovation activities. Companies play a central role in commercialisation.

Structure The first part of the document will analyse the status of the health sector research and innovation policy in Finland and internationally. Based on the analysis and the conclusions made, the second part will attempt to draw up strategic definitions of policy to correct the problem areas in the innovative health sector ecosystem and to improve Finland's position in the competitive global health sector research and innovation activities. At the end of the document, concrete proposals for measures will be made – a roadmap will be presented to promote and implement strategic definitions of policy.

Method of preparation The document can also be described as the common state of mind of central health sector operators to promote the research and innovation activity of the industry, particularly private investments. A study group with representatives from the Ministry of Education and Culture, the Ministry of Social Affairs and Health, the Ministry of Employment and the Economy, the Academy of Finland and Tekes has been in charge of managing the strategic work. The study group has been supported by an extensive expert group consisting of public and private operators. The study group has arranged several consultations, discussion forums and seminars to gather views from the sector's operators. An attempt has been made to follow the principle of extensive transparency in the preparation, and to inform relevant sector operators with the aid of stakeholders.

Key proposals for measures The strategy contains a roadmap or key measures to improve the innovative health sector ecosystem. In the recommendations for measures, an attempt has been made to consider the difficult situation in public finances. Central recommendations for measures include the development of university hospital campuses, an effective national division of labour, the development of the funding environment, the launch of innovations on the market as well as the launch of an extensive Team Finland Health cooperation.

Roadmap

- 1. Universities and cities with university hospitals will draw up action plans for developing hospital cluster research and innovation ecosystems and the related cooperation with companies.
- 2. The profiles and research foci of higher education institutions, research institutes and university hospitals will be reinforced when developing the international competitiveness of competence clusters. All policy sections will encourage skilful operators to engage in national cooperation and division of labour to improve quality.
- 3. The health sector research community formed by research institutions and higher education institutions will be assembled to maximise the impact and to create a whole that better serves decision-making and society (participation of the private sector included).
- 4. Higher education institutions and research institutions will bring their technology transfer and commercialisation operations closer together in central university cities by assembling them and particularly by reinforcing sectoral national cooperation.
- 5. With the cooperation between Tekes and the Academy of Finland, funding instruments will be developed further by taking the special features of the sector into consideration in order to make the most of research.
- 6. The state capital investment activities (Industry Investment and Tekes) will consider the needs for risk capital in the health sector.
- 7. The Academy of Finland, Tekes and other public operators will consider the development of the health sector when summarising their strategic and operational models for cooperation.
- 8. The seamless joint access to personal health data and patient documents will be enabled for research purposes. A national operations programme and rules for the application of genome data will be drawn up.
- *g.* A joint operation model will be drawn up to reinforce the work of government ministries and the business sector for exerting influence in the EU.
- 10. The implementation of innovative goods will be promoted when modernising the health technology and pharmaceutical legislation. This will also be done in the strategies and public procurement of the health sector institutions.

- 11. Proactive control of the research and innovation activities for health sector products and pharmaceuticals will be reinforced by developing company counselling activities. Training on legislation for health sector research, regulations and standards will be increased on a national level.
- 12. Systematic activities (Team Finland Health) will be initiated to attract foreign industry investments, and a decision will be made on the related division of labour.

Implementation and monitoring The strategy working groups emphasise the need to obtain approval for the strategy in a normal decision-making procedure. In order to achieve the necessary decisions and legislation, the key government ministries will establish a cooperation group (task force). Once the strategy is finished, the organisation and individuals in charge of the measures will draw up related plans and organise the necessary measures as a project. The task force will be in charge of monitoring the strategy implementation and draw up detailed indicators of the strategy's impact. An external assessment of the strategy implementation will be commissioned triennially; this will be done for the first time in 2017.



Goals and objectives

Finland's goal is to be an internationally renowned forerunner in health sector research and innovation, investment and new business activities while benefiting people's health, welfare and capacity to act.

This means that Finland is:

- **1.** The source and user of versatile and high quality scientific research and the refrom derived inventions and innovations.
- **2.** A dynamic operating environment for new companies in the field and a reliable partner for the international growth of companies.
- **3.** An attractive target country for health sector investments.
- **4.** A model country for consolidating a sustainable healthcare system with innovativone activities.



Ecosystem strategy

In Finland, healthcare industries are in need of ecosystem development. The strategy document does not assess the research done in various branches of the health sector, nor does it make proposals for measures to promote or emphasise a given section. Instead, the strategy document attempts to identify the sections in the health sector's innovative ecosystem that can be developed in order to create an international competitive advantage for Finland as a health sector research and innovation partner and a target country for investment and to support the growth of the industry business in Finland. A simplified description of the innovative health sector ecosystem can be given as follows:



Innovation Ecosystem

The pharmaceutical industry and health care technology as well as the closely related biotechnology are at the core of the strategy work. Healthcare data systems and the so-called eHealth solutions are a branch of activity that is closely related to health technology. However, the division described is only significant for the presentation of the branches; the division into branches of activity is not significant for strategic definitions of policy or recommendations for measures. The systematic ecosystem development work widely serves the operators in the field.

National ecosystem reasoning emphasises the global nature of research and innovation activities. In most branches of activity, commercially significant innovations are made in close international interaction with the researcher community and the market. The nature of the market for almost all inventions is global, particularly in the healthcare branch, and innovation activities are not national or closed. Companies play a central role in commercialisation.

Strategy objectives

The objective of the strategy is to attract health sector investments and financial growth.¹ The following criteria are among those used in an attempt to measure this:

- In the scientific health sector publications, Finland can maintain at least the current, versatile and multidisciplinary high standard and train individuals with the industry's top competences for various therapy areas and other key competence sectors.
- 2. Research activities produce health benefits, support and reinforce the population's capacity to act, and result in data to support decision-making. As a result, new innovative solutions suitable for the international market are created, enabling Finland to improve the efficiency of the social welfare and healthcare system that support the development of the entire society (a model country for a sustainable health system).
- **3.** From 2016 onwards, dozens of new knowledge-intense health sector growth companies are established in Finland each year. The goods they develop have genuine commercial potential on an international level.
- 4. In 2017, between four and seven private capital investment funds will operate in Finland, and Finland will have growing business angel activities in the field.
- 5. National and international private research investments made in the field in Finland and to Finnish operators increase on average by 20% annually. The goal is to enter into one major (private funding share between EUR 10 and 50 million), three to five significant (EUR 3 to 10 million) and ten important (EUR 300,000 to 3,000,000) research projects each year.
- 6. The development will result in a 2.5-fold increase in health sector private research investments over the next decade (currently approx. EUR 300 to 400 million). Private investments are made in basic research, translational research and applied or clinical research.
- 7. The increased turnover of health sector companies is such that when the sector is examined at five years intervals, it is observed that dozens (more than ten) of companies have grown from the category of small companies to medium-sized companies and that several (two to five) companies have grown from medium-sized companies to large companies.

Health sector statistics have been insufficiently compiled. According to estimates from different sources, there are approximately 500 companies active in the health sector, which employ 20,000 people. The turn-over of the sector is nearly EUR 5 billion, with exports of approx.. EUR 2.8 billion (in particular health tech-nology and pharmaceuticals). The starting figures of the sector will be specified during the implementation of the strategy.

1 Introduction and scope

The success of companies and regions depends on their ability to position themselves in global networks and produce, in the selected role, more added value than others. A company, region or community able to produce added value in an international operating environment is a partner to be taken seriously and will attract other operators worldwide. In order to join and position itself within global competence and value networks, Finland must actively participate and exert influence in these networks, while having internationally mobile professionals and the resolve to enhance the attractiveness of its innovation environment.

In a global economy, countries and territories are competing for investments. Investments directly create jobs, reinforce economic growth and increase tax revenue. During the last decade, competition in the field of corporate research and innovation activities has become significantly more intense. Similarly to industrial manufacturing, research and development activities are also concentrated in locations where the prerequisites for operation are best suited to private companies' strategies. This is a multisectoral operating environment related to competence and the potential to capitalise on it. The term 'innovation ecosystem' is often used.

Finland's success is based on the production of high added value, not on labour intense or mass production. The health sector has a strong foundation in research, product development and innovation activities, which require specialised high quality competences. Plenty of investments have been made in Finnish health sector competences and basic research. Purposeful investments have been made in the development of the sector's research conditions, e.g. by supporting the development of the university biocenters and developing the cooperation and division of labour of national research infrastructures. The universities' research infrastructures are already available to the private sector. It is, however, necessary to build more wide-ranged activities based on the cooperation models and to strive for more purposive application and utilisation of the research results. At best, the developing professional activity may significantly increase the potential for capitalising basic research.

The efficiency of the innovation ecosystem is also a key factor in investments related to the health sector. Social and public interest related to healthcare emphasise the role of states. In this respect, the healthcare market differs from many other commodity markets. The public sector attempts to secure equal access to health services in European and particularly Nordic healthcare systems. This means that states struggling with cost challenges play a special role as purchasers of health-related innovation and as regulators of market access in general.

According to the WHO, healthcare refers to a perfect state of physical, psychological and social welfare. However, health is a constantly evolving condition, affected by illnesses as well as the physical and social living environment, but above all, a person's individual experiences, values and attitudes. Health is one of people's most important values, but the promotion of health does not unambiguously guide their behaviour. In addition, an ageing population will result in the increase of long-term illnesses and multiple illnesses. This is when maintaining the capacity to act becomes an important value alongside general health.

Healthcare is in transition. People's role in promoting their own health and caring for themselves is increasingly emphasised. This development is accelerated by the liberalisation of health services: regardless of how much money they have, people can more freely choose where they receive treatment. An increasing desire to take responsibility for one's own health also involves challenging conventional operating models and creating a market for new technological solutions. Individuality also emphasises quality. Consumers of future health services will be increasingly aware of the solutions affecting them.

How should societies deal with this change? The change is more than likely to be very beneficial: healthy people who enjoy general well-being are the mainstay of all societies. Society should encourage people to actively try new solutions for monitoring and promoting their own health. Experiments and development work yield valuable feedback on usability and effectiveness, and the solutions produced genuinely serve citizens, professional users and society.

The most successful national economies must in all likelihood consider very radical solutions in order to develop markets related to the promotion of health. Many different tax deduction instruments affecting construction, cleaning services, accommodations, the prevention of climate change (e.g. motoring, energy taxation) etc. are used in Finland. The promotion of health also requires new incentives. Pro-research societies that gather new information and apply technology and innovations are also of interest to the industry and business activities.

The strategy document attempts to identify the sections in the health sector innovation ecosystem that should be improved to increase Finland's competitiveness; to give Finland a competitive advantage in the health sector's research and innovation divisions; and to increase business activities in the sector. The goal is to reinforce the financial growth of health-related branches of activity. The strategy document makes no comment on the solutions for modernising the Finnish healthcare system. However, the document and its recommendations for measures attempt to take into consideration the particular characteristics of the Finnish healthcare system: the exceptionally large public sector and the considerable tasks assigned to the municipalities. Sufficient evidence of achievable health benefits is a prerequisite for public funding. However, only companies can achieve sustainable financial growth and attract private investments.

The strategy document does not attempt to assess the research done in various branches of the health sector or to make proposals for measures to promote or emphasise a given branch. Furthermore, the fringes of the health sector, such as the growing welfare sector designed for promoting and maintaining health, are not examined. On the other hand, the welfare sector also benefits from the strategy's ecosystem thinking. Instead of examining the fringes of the health sector, the strategy document attempts to find solutions to the innovation ecosystem problems facing all health sector research.

The delimitation between health-related branches of activity is often difficult due to the multi-dimensional nature of the sector. Similarly, it is difficult to make a clear distinction between the health technology industry and the pharmaceutical industry. Biotechnology, the pharmaceutical industry and health technology are at the core of the strategy work. Healthcare data systems and the so-called eHealth solutions are a branch of activity that is closely related to health technology. However, this division is only significant for the presentation of the branches; the division into branches of activity is not significant for analysis, strategic policy definitions or recommendations for measures. Furthermore, the examples cited in the document are not statements on how the future contributions should be focused. Instead, they are examples intended to reveal the need for development in central research structures. It is hoped that the strategy will widely serve operators in various sectors.

One delimitation can be made by determining the actor in charge of the purchase decision for services and products. Legally, some products and services may only be purchased by order of the healthcare professional, whereas the consumer makes the decision to purchase other products and services. New inventions are very often procured by public and private healthcare operators very often purchase new inventions. Internationally, the distinction made between private and public operators varies greatly. The document does not comment on these definitions, but the role of public health care units is emphasised as testers of ideas and inventions and as innovation purchasers. Nationally, these operators therefore have a key impact on the distribution of demand in Finland.

Despite the statements made above, the strategy emphasises Finland's unique opportunity to develop into a trendsetter of personalised medicine and healthcare – also from the point of view of developing the ecosystem. Personalised healthcare is essentially based on the possibilities arising from the development of technologies for sequencing genetic resources in order to find individual solutions for treatment and for preventing illnesses. Finland is considered to have excellent potential as a trendsetter and a rapid applier of innovations, since

- Finnish genetic resources are more homogeneous than those of many other research intense countries.
- The genetic-epidemiological and clinical research is on a high level.
- We have databases on citizens' health that are uniquely comprehensive on a global level, including register data, population and illness material and biobanks combined with strong IT competences.

• Finland can reinforce clear procedures for protection of privacy and has related legislation with a sustainable foundation that guarantees the international reliability of research (e.g. the Biobank Act).

* * *

The strategy document can also be described as the common state of mind of central health sector operators to promote the research and innovation activity of the industry and particularly private investments. The first part of the document will analyse the status of the health sector research and innovation policy in Finland and internationally. In addition to the description of the health sector's central branches of activity, the national contributions to development and the development of research activities in health branches will be examined closely. Based on the analysis and the conclusions made, the second part of the document will attempt to draw up strategic definitions of policy to correct the problem areas in the health sector innovative ecosystems and to improve Finland's position in the competitive global health sector research and innovation activities.

At the end of the document, concrete proposals for measures will be made – a roadmap will be presented to promote and implement strategic definitions of policy. As for implementation, it is crucial that the strategy is connected to other operations performed at the national or EU level, such as the EU Horizon 2020 research programme, the state's strategic research funding or the national Team Finland work. The importance of Team Finland's work is central to features such as constructing Finland's image as a country.

* * *

A study group with representatives from the Ministry of Education and Culture, the Ministry of Social Affairs and Health, the Ministry of Employment and the Economy, the Academy of Finland and Tekes has been in charge of managing the strategic work. At the commission of the Ministry of Employment and the Economy, the group was chaired by attorney-at-law Mikko Alkio who also contributed to gathering the written material related to the strategy. The study group has been supported by an extensive expert group consisting of public and private operators.

The study group has arranged several consultations, discussion forums and seminars to gather views from the operators. Where possible and based on the resources available, an attempt has been made to follow the principle of extensive transparency in the preparation, and to inform various operators related to the strategy with the aid of stakeholders.

2 Operating environment

2.1 Development of the Operating Environment

According to an OECD study, life expectancy has increased on average by one year every four years since the early 1990s. The risk of becoming ill or dying prematurely has essentially decreased during the last decade, which is partly why the Finnish and European population will go through a dramatic demographic change in the decades to come. It has been estimated that 30% of the European population will be over 65 in 2060, which is more than double today's proportion of the elderly.

A higher life expectancy is a result of persistent work in public health and protection, increasingly healthy lifestyles and the general improvement in education and standard of living. However, there is evidence that 40 to 50% of the longer life expectancy is due to the improved treatment and innovative medication enabled by new technology. New innovations are enabled by significant contributions to research and product development.

Finland has contributed almost EUR 300 million of public funds to health related research annually and has internationally risen to the very top in many science sectors. In the context of strategy work, various stakeholders have largely considered that this research investment has not fully benefited society, nor has it produced enough added value. The key question related to the strategy is how to proceed in the future. Should we settle for purchasing new health sector innovations on the world market or should we also be an active partner in developing and applying innovations, and thereby obtaining the associated added value to Finland?

New technology and new innovations can help governments as they rise to the greatest challenge in healthcare: lowering costs and at the same time rendering activities more effective, therefore increasing health benefits. As governments must balance their budgets, they must also make careful decisions on how to develop their healthcare systems. This strategy also approves of the idea of collaborating with private operators and industry to create health benefits.

In the large-scale systematic application of new technologies, healthcare lags behind many other sectors. This is partly due to the nature of the health sector. Innovations can only be used once there is evidence of their effects on health. The use of digital health data serves as a good example: operating models should be created to combine patient data and the health data taken by the patients themselves. Most people are prepared to gather and use information for decisions concerning their own health and to allow the use of this information for research activities. In this context, aspects related to data protection legislation and the protection of privacy are important. In the future, legislation regulating research and innovation activities must consider in greater detail the context where the data is used, personal information included. Business activities related to welfare and health are some of the few branches of activity that have exhibited constant growth for decades. Between 10 and 15% of the gross domestic product globally is invested in the promotion of health and welfare, and the quantity of these investments is constantly increasing on the global level. On the one hand, governments aim to find ways to target public expenses in a way that increases efficiency and productivity, and on the other hand, to improve treatment outcomes with the aid of new innovations and technologies. Ultimately, innovations are used to improve the quality of life and to increase life expectancy. States with extensive health sector research and innovation activities and where the industry plays a significant role usually also fare well in the comparison of healthcare systems.

Health sector research activities in the industry are in a transitional stage as well: closed innovation models are being transformed into open models or entirely different models. There are differences between the various technological, diagnostic and pharmaceutical research operations, but cooperation with healthcare providers and, on the other hand, with the academic research community, is central to all operators. For various reasons, it is increasingly demanding to develop new innovations. This is why companies increasingly cooperate extensively with various partners. This gives Finland the opportunity to develop as a site for the sector operations.

Finland is small, but on the other hand, its size makes it suitable as a partner for domestic and international industry. The essential part of Finnish competitiveness is its ability to develop national and local operating environments or ecosystems. The development of university hospitals and scientific communities established in their surroundings are at the core of the strategy. This development will take into consideration the research and business activity partnerships. Local conditions must be developed in a new way, taking into consideration the education, research and treatment aspects. At the same time, resources should be pooled in various therapy and technology areas in order to create a sufficiently critical mass and bulk of resources to meet the requirements of internationally competitive competences. If the regions focus on competing with each other for national public research resources, we will lose our international competitiveness. Instead, if we can use the specialisation of the regions to create unified national operating models, clusters and networks to gather Finnish competences, our competitiveness will improve.

Globally, health-related branches of activity are significant for the contributions to research and product development. Our neighbouring countries Sweden and Denmark strongly invest in health-related research and the development of a research and hospital infrastructure. Many developing economies also make considerable contributions to the biotechnology field, and their pharmaceutical research and health technology sectors are exhibiting strong development. In addition to the United States, Europe, including the Nordic countries, China and Russia are significant export countries for Finnish health technology. In Russia, the pharmaceutical industry is only beginning to develop thanks to the contributions of the national Pharma 2020 programme. Russia could be a vast market area for Finnish pharmaceutical operators. Until now, it has not been sufficiently exploited.

It is also essential to consider that the majority of the regulation related to the health sector is received via the European Union. EU regulations and directives have an impact on the development and implementation of pharmaceutical and health technology innovations both directly and through national legislation. Usually a marketing authorisation for new innovative pharmaceuticals is requested throughout the EU in a so-called centralised procedure. In practice, introducing health technology products to the market requires compliance with the European harmonised standards. Current examples of legislative development on an EU level with an impact on the innovation environment include the profound modernisation of directives on clinical pharmaceutical studies, medical devices and in vitro diagnostics, as well as the transformation of directives into regulations. In addition to EU regulation, health sector export companies are faced with detailed regulation in other significant market areas, such as the United States, China, Russia and Brazil. Knowledge of pharmacovigilance and device monitoring is a competitive advantage when operating in the jungle of pharmaceutical regulations.

In the context of strategy work, it has been asked whether measures aimed at achieving growth in the sector are incompatible with the objectives of Finnish health policy. It is important to ensure that the growth strategy is acceptable from the perspective of an equal, functionally and economically sustainable healthcare system. This is why clear and transparent rules of the game must be created for research cooperation aimed at business activities.

The starting point of the strategy work has been that to achieve meaningful results, it is essential to integrate the education, research and service system structures into a more compact innovation ecosystem. However, it is most important to remember that ultimately, the ecosystem consists of skilful, creative, diligent and open-minded people with the courage to test their limits in a positive way in order to create inventions and innovations that improve people's health.

Patients and the public health sector considerably benefit from the know-how, the clinically significant outcomes and the implementation of the outcomes gathered from research activities. The countries of origin for the studies are generally in the front line for receiving such benefits. Participating in research work improves the skills of doctors and healthcare personnel and therefore brings added value for both patients and the entire society. In addition, investments into research activities have direct and positive effects on the countries in question in the form of employment and the tax revenue received.

As a whole, the health sector research and innovation activities may be a significant vitality factor, producing added value and competitive advantages for the countries that choose them as their strategic focus areas. The strategy takes into account the increasing importance of consumers and the general role of citizens in personal decisions related to their own health. The assumption is that the implementation of the strategy objectives could also be considered positive for the citizens. Research and innovations related to health and the promotion of health concerns the entire population, whereas the development of patient care only concerns a small part of it. The development of patient care and its increasingly effective implementation will lead to considerable savings for the national economy.

Typically, the new innovations in patient care require a hospital environment for testing, and the inventions and new operating model for health related research often require studies and tests performed on healthy individuals and large cohorts. It should also be noted that new operating model and data system innovations support the development of the health sector. In order to be operational, many health sector services require the ability to quickly manage and process information. For instance, the application of genomics for clinical work requires plenty of further development, resources and skills, before its benefits are widely realised.

The health care of an ageing population is a particular challenge for all developed countries. A pragmatic view should be taken of the pressure of demand, and its potential with regards to financial activity should be considered. For the sector's operating environment, the inevitable contribution to welfare may at best create an engine for continuous development (maintenance and reinforcement of the prerequisites for research) and the potential for profitable activities that also attract international investments.

2.2 Health-related branches of activity

The blurring of the divisions between traditional branches of activity is clearly visible in health-related business activities. Commercially significant innovations are increasingly made by combining various areas of expertise, technologies and services. It can be seen that biology/biomedicine, data system, measuring and imaging technologies as well as information assets and the derived analytics are coming closer together. Operators combining various areas of expertise are making significant new breakthroughs that can be capitalised on commercially.

The health sector business activities involve an extremely versatile network of operators, including companies of various sizes, ranging from small domestic PMEs to large multinational operators, and the extensive public and private sector service production system. In terms of the Finnish company structure of the sector, a relatively high number of companies are small, and there are few large research-intense companies oriented to production, which probably has contributed to the challenges for the sector's development in Finland. The establishment of new knowledge-intense service companies and the growth of international business activities for the existing companies is a positive feature in the development of the last two years. This growth is increasingly based on developed electronic services that use technologies such as cloud services and data mining.

The high research, product development and launch costs are a central challenge for the small growth companies in the sector. This often results in the sale of the semi-finished product to larger companies that have established distribution channels after the research and development stage. For instance, the pharmaceutical development costs are so high that small companies cannot launch their product on the market without the help of larger companies. This is why the development of a versatile research and innovation ecosystem is required in the sector. The further pharmaceutical development is taken, the greater the benefit to the developers and the financiers.

Good, high-quality scientific and clinical research is made in the Finnish health sector. Its foundation was laid by making significant research contributions to life sciences. Public funding has played an important role in this contribution. Finland also enjoys sufficient industrial competences in the sector and therefore has good premises for producing new innovations. In order to survive the increasingly intense global competition, companies must always be able to adapt to the constantly changing operating environment. International networking in both R&D activities and in business development is essential to growth-oriented companies. However, insufficient business competencies and the lack of networks between companies are slowing down the first steps being taken by the companies in the sector. In addition, the long-term funding of growth companies would require the development of public funding instruments and, in particular, that of the capital market. Despite these challenges, the development work objectives must be ambitious in order for the companies to succeed in their own country and on an international level.

In Finland, *health technology* is a branch consisting of various business sectors that is exhibiting strong development. In this context, health technology refers to medical devices, i.e. all devices, systems and supplies that are used for healthcare diagnostics, the prevention of illnesses, monitoring, treatment and the correction of injuries or a limited capacity to act. In addition, the concept also covers data systems and software programmes. It has been estimated that the group of health technology medical devices alone includes approx. 10,000 product families with different characteristics.

Electronic health services and welfare technology (including the healthcare ICT and eHealth, mHealth) refer to the types of tools and services based on information and communications technologies that are used for the prevention of illnesses, diagnostics and treatment as well as for monitoring patients' condition and for healthcare administration. Several start-up companies focusing particularly on the use of mobile technology for the promotion of health and healthcare have been established in Finland over recent years. A significant number of companies providing services directly to the public has already joined the Taltioni cooperative established by Sitra. In the future, Finnish healthcare data systems will have interfaces with the comparable social service systems.

Generally speaking, health technology research and development activities are long-term and expensive. At best, it can take several years to develop basic technologies and to solve new and complex technical issues. The high costs and slow progress of the research and development activities are partly due to increasing regulation. This means that in addition to the intense competition, the legislative baseline requirements for product development are strict. New products or solutions take a long time to reach the global market, which is why obtaining local product approvals, efficiency studies, the credibility of the company and the consolidation of distribution channels become increasingly important.

The pharmaceutical industry refers to a branch of industry consisting of the manufacture, importation, marketing and development of pharmaceuticals. Developing a new drug and launching it on the market is an extremely research intense and time-consuming process that lasts 10 to 15 years on average. Only one in 5,000 product ideas and one in 10,000 substances examined will become a drug that is actually commercialised.

Increasing costs and the slower pace of developing innovative drugs despite the development of the research activities and sciences is a key issue in pharmaceutical research. In Finland, the most innovative pharmaceutical development is carried out by small pharmaceutical development companies that require not only funding but also support to develop their pharmaceutical development competences. New research method, such as bioinformatics and the use of biological markers, as well as the development of pharmaceutical development closer and closer to health technology research. Many people expect that new drug innovations can be used to significantly benefit patients at a lower cost. Personalised treatment solutions are gaining an important foothold in pharmaceutical development.

The traditional innovative pharmaceutical industry is at a significant turning point, where closed research activities carried out inside companies is about to be transformed into open networks and research partnerships. It is believed that this will open up partnerships, investments and business opportunities for Finland. According to the sector industry, the Finnish merit model could consist of the following elements:

- Research competences and research-related cooperation potential between national and international operators.
- Innovations and commercialised (and patented) products derived from the research.
- Further product development where features such as national registers and biobanks are used.
- Clinical pharmaceutical research.
- Further processing and production of niche products or products requiring special competences. (Thanks to the size of the global market, niche production can be a significant industrial activity on the Finnish scale.)

Biotechnology is an extensive combination of natural sciences and technology that produces knowledge and develops research methods and tools for examining, modifying, managing and exploiting biological systems. Biotechnology applications are developed in almost all areas of industrial production. In addition to the health branch, this is done in the chemical industry as well as the food and forest industry. Some of the most significant biotechnology applications are health sector application that are used for diagnostics, the development of drugs and vaccines and for new treatments, such as gene therapy, cell therapy and tissue engineering.

2.3 Impact and transition of the health sector research and innovation activities

The starting point of the strategy work was based on the assumption that increasing research activities will also directly and indirectly benefit Finnish patients. The strategy is based on the following starting points for the sector operating environment and development.

- 1. The health sector is a significant global growth sector where a large portion of future health benefits are produced with new innovations.
- 2. Ultimately, the demand for health sector innovations is global and created by patients few inventions are limited to a given country or to a given group of people. However, health technology, pharmaceutical or health sector data system purchases are largely made as public procurements that are based on the decisions made by professional personnel. The direct role of consumers is emphasised in innovations that support the promotion of health.
- **3.** Pharmaceutical and health technology innovations are not developed in isolated conditions. Instead, the close partnership between the public and the private sector is at the core of the development. In practice, only companies can ensure the further development and commercial exploitation of the inventions.
- 4. In all branches of activity, research activities are long-term, and the development of commercial innovations often takes a long time. Some of the largest contributions to research and innovation activities are made in the health sector.
- **5.** Research activity in itself produces significant added value for health systems. Its importance and the partnership with the healthcare service system is emphasised as personalised medicine and individual service plans become more common.
- 6. The transformation of the sector's research and development activities from closed models into open or different cooperation models will give Finland a new opportunity to develop as a site for the sector operations. In many cases, Finland's size is ideal for a partnership with the companies operating in the sector.
- **7.** Though the health sector innovation ecosystem can be examined from the national point of view in the strategy, the innovation activities are not national

or closed. Instead, they are global. On the other hand, the strictly local operating environments (e.g. university hospitals and their science centres) are also very important as micro-ecosystems of the sector.

8. Finland's weaknesses can be addressed on a national level and even in a relatively short time. On the other hand, Finland has significant strengths (base of competences, databases and registers) that would take a long time for many other countries to develop - probably decades.

2.4 Finland's strengths and weaknesses

Why hasn't Finland been able to build a life science sector comparable to that of Denmark or Sweden? There are several reasons. Healthcare was only considered a cost factor in the state budget and the municipal budgets. This is a result of the 1990s economic depression and the consequential strict economical discipline and worries about how Finland will manage in the face of the ageing population. In Finnish social discussion, healthcare has largely been considered a public asset. An attempt has been made to provide healthcare (the treatment of illnesses) as cost-effectively as possible. There is nothing wrong with being cost-effective. Unfortunately, the view of healthcare as a cost factor has not allowed us to see the significant potential of healthcare from the point of view of industrial policy. The positive aspects of the industrial policy are not only limited to the diagnostics and treatment of illnesses and rehabilitation. These aspects should be considered a natural part of promoting welfare and health and the prevention of illnesses. The creation of this strategy is based on the view that "the health in all policies approach", equality aspects and growth of the health sector are not irreconcilable.

It is possible that a significant amount of knowledge and a large number of inventions have left Finland because researchers have not had enough incentives to contribute to the commercial exploitation ideas and research outcomes. However, these data and inventions that have left Finland may have been further developed and commercially exploited in other countries. We have a very different attitude towards the health sector than towards sectors such as telecommunications or energy networks and related services where we attempt to transform Finland into an advantageous development environment and a globally exceptional pilot market. Several large companies have also operated in these other sectors. These have been lacking in the health sector.

For the innovation potential, the most essential matters include the functionality and synergy of both local (university and hospital infrastructures) and national health sector innovation ecosystems (base of competences, infrastructure, funding, legislation, control and the rest of the business environment). The poor functionality of a single link in the ecosystem will easily impair the growth potential for the entire sector.

The critical mass of organisations carrying out research activities and sufficient and persistent resourcing are essential, regardless of whether these organisations are specialised research institutions, universities or healthcare operating units. In recent years, the constant decrease in the funding base (e.g. the old EVO funding, currently the state research funding) for research carried out in the service system has caused particular problems. In addition, the amount of municipal funding allocated for research has remained very small. The key question related to the objectives of this strategy is how the municipalities and hospital districts in charge of organisation envisage the position and importance of research activities, including the direct and indirect health benefits that developing research activities will ideally have for the inhabitants of the area.

Finland's reputation as a pro-innovation country should also not be undermined. If Finland is willing, the global health sector transition and the continuing growth will create the potential for significantly increasing Finland's share of the investment and for developing goods that are competitive on the world market. However, it must be considered that the research activities in the sector require long-term contributions. Long leaps ahead are rarely made; small steps forward are much more common.

In the pharmaceutical industry, the trend among international companies is to centralise global operations, which means that instead of comprehensive country-specific organisations, small markets will be covered by large geographic entities. In this case, there is a risk that the Finnish organisation be attached to foreign subsidiary, such as a Swedish company, resulting in the emphasis of sales and marketing in the Finnish operations, and research and innovation activities play a minor role. On the other hand, the pharmaceutical research paradigm has changed: whereas international pharmaceutical companies previously carried out research activities at their own research centres, today research is increasingly carried out in strategic partnership with researcher communities and companies of various sizes. Finland has the potential to form financially and scientifically significant partnerships. If international companies have no other activities in Finland apart from sales, it is difficult for them to form strategic partnerships. The operating requirements for international companies therefore have an impact on the creation of strategic partnerships.

It is essential to bear in mind that competition between different countries is not comparable to the Olympics, where only the winners count. Achieving a level such as that of Sweden and Denmark is likely to produce significant economic growth and benefits for Finnish citizens. On the other hand, the better the national ecosystem we create in Finland, the better we are as a partner to the other Nordic countries enabling Finland to compete for international investments etc. Other European countries that are pioneering and successful in the health sector include e.g. Switzerland and Austria.

The potential and challenges of the Finnish health sector can be presented in various ways. On the one hand, Finland can be seen as a country that has invested in health sector research for decades, gathering sample collections and registers and training professional personnel that are at the top of their field globally. It seems that investments are finally paying off. The growth of health technology has been particularly strong, and the investment made in biotechnology and the pharmaceutical industry are beginning to result in individual success stories.

The development can also be seen in another light. The hundreds of millions of euros contributed to research and product development have not produced the expected outcomes or positive cash flow. Employee cooperation negotiations are carried out in many "subsidiaries" (research institutions); the role of research is decreasing in hospital infrastructures; innovations are not adequately implemented; and the "company" does not have a consistent or functional management that understands the need for structural modernisation and reassessment. Furthermore, the resources for research are rapidly decreasing.

Half of the picture is true in both presentations. It is clear that many companies in the sector are successful regardless of state measures. However, state measures can be used to share risks, encourage companies to grow and to create general research and piloting environments via partnerships. At the same time, the public innovation ecosystem is a cause for concern, and this concern is very topical. In Finland, the significant contributions made to health over the last decades are at risk of being wasted, if legislation and structures are not resolutely developed from the point of view of commercialising research and its outcomes.

As the international assessment of the Finnish innovation system commissioned by the Ministry of Employment and the Economy stated in 2009, the Finnish innovation ecosystem is indented and fragmented. This is also true for the health sector. The fragmentation particularly affects the ability of companies to carry out longterm research cooperation with various operators of the public sector. The predictability of the operating environment has a similar effect. Inversely, the features mentioned above are seen as limiting the potential of companies, particularly foreign research-intense companies, for becoming attached to the Finnish research and innovation system and for carrying out long-term cooperation with the healthcare service system. Healthcare requires treatments based on evidence as well as thoroughly examined devices and pharmaceuticals. It is essential for their effects and benefits to be proven through research.

In the view of companies, the fact that market access is slow for innovations is Finland's considerable weakness. Generally, the interest of companies lies particularly in markets with a demand for their products. This problem concerns both health technology and pharmaceutical research, and it affects the desire on the part of both small and large companies to invest in research in Finland. On the other hand, Finland has often made contributions based on the "technology push" in situations where the needs and demands of public operators and private individuals should have been much better known.

For Finland, it is essential to develop funding to aid companies in their growth. It is extremely important to health sector operators that the ecosystem for capital acquisition also be developed. This includes the stock market, capital investors, private investors, institutional investors, investment funds, industrial investors and family businesses. Together, they provide companies with the best possible conditions for funding their growth and creating jobs in Finland. For instance, few companies have begun trading on the stock exchange in Finland over the past decade in comparison to countries such as Sweden. In Sweden, 153 companies have been added to the First North market place for small growth companies since 2005. In Finland, there are five such companies. In Sweden, as many as 31 of these companies haves moved from this list to the main stock exchange. In Finland, this has not happened for any of the companies. It must be noted that many of the above-mentioned Swedish companies operate in the health sector.

Summarizing, facts such as the following support the growth of the Finnish health sector branches:

- Significant base of competences: high scientific level in several globally significant therapy areas and strong technological competences.
- Strongly developing application of data systems and mobile technology in the promotion of health and welfare.
- A comprehensive sector of higher education institutions and higher education based on research on all educational platforms; the strategies of several universities focused on health.
- Key researchers are closely networked in the framework of both Nordic research (Nordic EMBL Partnership in Molecular Medicine) and research carried out in the EU (ESFRI and EMBL).
- Statistics, extremely competitive registers and measures promoting the openness of research data as well as the new legislation on biobanks.
- A good price-quality relationship of the research activities and patients who are committed to research studies.
- Considerable and long-term public contributions to the health sector research and innovation activities, including the biological sensors operating in the framework of universities.
- The long-term reinforcement of the health technology sector, a developing PME sector and game industry.
- High-quality competences in conceptualisation and architecture related hospital infrastructures.
- Good connections and close cooperation with developing countries with rapidly growing health markets.
- Rising public and private sector demand for increasingly effective and cost-efficient products and processes.

Finland is considered to be in a pretty good position, particularly as a leading country in the research for personalised healthcare. Finland has top research competences in many therapy areas and versatile competences in health technology, such as diagnostics and imaging. Finland also has solid ICT competences and a strong technology industry.

3 Starting points for the strategy

3.1 Importance of the ecosystem functionality

In most sectors, research and innovation activities are carried out in close global interaction with both the researcher community and the market. The market for almost all inventions is global in nature, particularly in the health sector. Innovation activities are not national or closed. Companies play a central role in commercialisation.

Traditionally, the commercial development activities for medicine and health technology have mainly consisted of internal company activities. However, the sectors are in a major transition both geographically and where forms of cooperation are concerned. Cooperation with universities and research institutions has mainly been based on the basic research of the initial stage carried out by these parties and to the licensing of intellectual property rights related to the derived innovations. After the intellectual property rights are licensed, the company has developed services for the market as internal company operations or as outsourced activities. This traditional operating model can be called a closed and internal innovation model.

Over recent years, health sector research has increasingly moved on to the use of different cooperation models. The Finnish operating environment has also come to be used as a platform for research, development and pilot activities. Pilot activities also produce reference data for international trade. The goal of cooperation is to maximise the innovation potential and to exploit the broader base of competences between higher education institutions and companies. This innovation model is characterised by features such as a close cooperation among companies, between companies and universities or among universities, the exchange of competences, shared and jointly owned intellectual property rights and shared benefits. The creation of cooperation models has been promoted before and is promoted today by features such as Tekes programmes (such as Lääke 2000, Diagnostiikka 2000 and Finnwell), the OSKE (Health and Well-being Cluster Programme) activities (Lääkeklusteri and HealthBIO), the SHOK (Strategic Centres for Science, Technology and Innovation) activities (SalWe and DIGILE) and the future INKA (Innovative Cities programme) activities (Future Health). An integrating innovation ecosystem is also a goal of the national cancer centre planned for the future. A close partnership and common goals to improve health and welfare are central to the new activities.

The examples of Sweden and Denmark indicate that even small countries have the potential to profile themselves as forerunners of health sector research and innovation activities. It is essential to achieve a common state of mind to improve the innovation ecosystem and to link it to the service system as well as to commit to the development of the sector's research and innovation requirements. The strategy process has proven that Finnish innovation environment operators are willing to collaborate to create ecosystems, but lack the appropriate incentives to speed up the development. A jointly approved coordinating umbrella operator of the health sector is also lacking. It is important to create such an operator with strong government backing.

In international competition, Finland has a good opportunity to become one of the leading countries in the sector by repairing the broken pieces of the ecosystem. The national innovation ecosystem is important when assessing how Finland can attract more research and innovation investments. The innovation ecosystem can be divided and outlined in various ways. One common way is to divide the ecosystem and its operators as follows:

- Base of competences (education and research in polytechnic institutions and universities and in various research institutions).
- Funding for research and innovation activities (the Academy of Finland, Tekes, Sitra, Finnvera, Industry Investment, state research funding (formerly research EVO), international or EU research funding (including IMI, EIT), foundations, private investors, capital investors and industrial funding).
- Infrastructures and networks (universities, Biocenter Finland, university hospitals, other healthcare operating units carrying out research activities, sectoral organisations, INKA, SHOK activities (in the future, Team Health Finland and specialised areas of responsibility related to social affairs and health).
- Definitions of policy, legislation and the attitudes of public operators (STM, TEM, OKM, Fimea, Valvira, the National Institute for Health and Welfare, hospital districts, Tekes, the Academy of Finland).
- Markets and demand (public and private healthcare operators as purchasers, patients and individuals working to promote health).

As previously stated, innovations are central engines of growth. During the last decade, it was believed that small and medium-sized companies inparticular are the source of innovations and are therefore significant in achieving growth. Finland made strong contributions to growth companies, for instance via various funding and service entities. In health-related research, the role of small and medium-sized companies is also significant in creating new innovations.

However, it is important to note that commercially successful innovations are often created in versatile cooperation structures involving long-term basic research and various companies of various sizes. These are referred to as open innovation activities. It is the opposite of closed research activities carried out within companies. However, open innovation activities do not mean that anyone can freely benefit from the inventions. On the contrary; the ability to effectively protect the inventions is generally very important to open innovation activities. This particularly applies to the health technology and pharmaceutical research sector. On the other hand, it cannot be assumed that just any new product or service will become the object of publicly financed procurements. New innovations compete for resources available in society with products already in use and with other products attempting to access the market.

In the future, choices must be made in the health sector as well. This strategy does not advocate for any specific focus areas, but it does recognise that the importance of selectiveness has already been emphasised in previous Finnish research and innovation strategies. The relevance of science in the future is difficult to predict. Sufficient resources should be left for open 'bottom up' funding in the future. At the same time, we must have the courage to make centralisation decisions in specific areas of competence that are believed to generate future demand for inventions and derived innovations. Here, the planned research institution reform and the strategic research funding instrument to be established at the Academy of Finland play a special role.

For the past decades, the health sector has been strongly assessed from the point of view of costs, which means that the development of activities, the improvement of quality and efficiency as well as the potential of economic policies have remained on the back burner even in government measures. It is essential to establish a dialogue on combining the goals of health, science and industrial policies and to secure the commitment of the government to promote them in the same direction.

3.2 Current shortcomings and fragmentation in the Finnish health sector innovation ecosystem

The shortcomings and fragmentation of the health sector innovation ecosystem as identified during the strategy work are listed below.

- 1. The insufficient development of university hospital clusters and other leading hospital clusters as well as regional ecosystems from the point of view of research and innovation infrastructures. Insufficient systematic health technology training and mobility of the sector personnel among various operators.
- 2. Insufficient cooperation among universities and general institution-centered thinking that prevents the formation of large, thematic entities and projects. This is why the resources are dispersed, Finland's global interests are unclear and the ability to compete for private and EU funding is decreasing.
- **3.** The insufficient coordination of research institutions; by tightening the coordination, an attempt would also be made to commercialise the created ideas, inventions and technology conjunction with the private sector.
- Poor quality and lack of scale advantages for the technology transfer operations of public research institutions and universities.

- **5.** The fragmented path of growth funding that in many cases leads to the premature transfer abroad of commercially significant inventions and competences.
- 6. The fragmentation of research and innovation funding.
- 7. The poor use of personal health data and patient data.
- **8.** The scattered health-related influencing work in the EU, including the management of various regulations and standards.
- **9.** The poor market access for innovations related to health technology and pharmaceuticals, the lack of pilot activity and testing environments and the general lack of innovation friendliness in public procurement activities and a reimbursement policies.
- **10.** The lack of systematic health sector competences and marketing activities for investment possibilities.

At the end of the strategy, measures will be presented; an attempt will be made to correct the shortcomings identified below with a roadmap. The goal of the roadmap is to help decision-makers to address the fragmentation of the innovation ecosystem. This is how Finland can be turned into a country that is increasingly competitive in terms of attracting investments, which lays a good foundation for growth entrepreneurship in the health sector.

It is also essential that the dialogue and increasingly close cooperation between various operators continue in practice after the approval of the strategy. The negative effects of the excessive compartmentalisation that often follows the boundaries of government ministries can be eliminated by forming a joint view of the importance of health sector growth to Finland and by agreeing on synergistic methods for implementing the strategy.

4 Health sector innovation ecosystem and strategic definitions of policy

4.1 Base of competences

With the help of new information, Finland must achieve new growth based on competences and exploit the possibilities of internationalisation. Higher education institutions play a significant role in creating prerequisites for growth. The university reform carried out in 2010 gave Finnish universities facilities similar to those of leading foreign universities. International visibility and the ability to form partnerships with leading international experts require that resources be combined on a national level in order to improve the quality of research and to render its effects more versatile.

In the framework of their administrative and financial autonomy, higher education institutions can make more independent decisions on the measures required for implementing their strategies and profiles. The Ministry of Education and Culture plays the role of a national assembler in guiding higher education institutions, but the definition of policy made in many other policy areas will affect the operation of higher education institutions. Horizontal cooperation must ensure that the choices made in individual higher education institutions result in a nationally significant entity and that cooperation and the division of labour is created between operators by using the organisations' own starting points.

The ongoing polytechnic reform has similar goals for quality, efficiency and international orientation though features such as legal personality have been dealt with differently. (For international visibility, the high standard of Finnish research and competences plays a central role that requires cooperation e.g. between higher education institutions and research institutions carrying out health sector research and organising health sector training.)

In Finland, health sector research has been distributed among various universities and polytechnic institutions (approx. 10), research institutions (the National Institute for Health and Welfare, the Finnish Institute of Occupational Health, Kela and VTT Technical Research Centre of Finland) and hospital districts. In particular, five medical faculties (Helsinki, Turku, Tampere, Oulu and Kuopio) and university hospitals and adjacent scientific centres will form national junctions in the field of health-related research. Universities and polytechnic institutions carrying out technical health sector research and providing this type of training also operate in the same cities. However, Finland has plenty of small research units, independent researchers and research groups. Unlike some European countries, Finland does not have a single leading research institution in the sector with an objective such as the development of competences and the production of high-grade science from the point of view of inventions and commercial potential.

Finland has world-class top competences in several therapy sectors. In addition, the competences and the reliability of healthcare professionals are of a very high standard. Finland also has patients who take a positive view of studies, which significantly promotes clinical research activities.

Strategic definitions of policy

- An extensive, comprehensive and multidisciplinary medical and health technology base of competences for the health sector is maintained, and in selected areas of competence, an attempt is made to become a leading country. The interaction between researchers and the industry is increased, and the circulation of personnel in various duties is enabled in order to achieve competences that include knowledge of the requirements of businesses.
- The goals are to create clearly larger entities and a close, multidisciplinary and multisectoral cooperation and coordination between the operators.
- Decisions on the structures of public research and innovation activities and their main content-based policies are made in close cooperation with the government ministries (MSAH, MEC, MEE), public funders and research units.
- With the backing of government ministries, the creation of significant partnership agreements among companies able to engage in the further development and commercialisation of researchers, the service system (university hospital districts; and in the future, specialized areas of responsibility) and innovations.
- Entrepreneurship and industry cooperation are included as a better option in the curricula of all central higher education institutions providing health education and technical studies.

4.2 Support and funding for health sector research and innovation activities

The most important public funders of the health sector research activities include Tekes and the Academy of Finland. In international competition, the reliable and transparent activity of the public research and innovation funders is one of Finland's strengths.

A significant amount of the sector's public funding is channelled through applications (the so-called bottom up model). Today, the various support programmes of Tekes and the Academy of Finland are the most important instruments for the strategic orientation of research funding in the sector. It should be noted that from a national perspective, funding is relatively short-term; it is project-specific and is broken up every year between thousands of individual research projects. This is the most extensive coordination for channelling the funding between research and innovation funders and research institutions. Strong public resourcing should be allocated for high-grade units so that they would not have to spend such a significant amount of time on fundraising. In Finland, general social and healthcare financing has been arranged according to the so-called multichannel model, where the most important funders include the municipalities, the state, households, Kela, employers and private insurance companies. As for the research activities carried out in the service system, the most important financiers have been the research commissions for specialised areas of responsibility that distribute state research funding, and the most important research environments have consisted of hospital districts, particularly university hospital districts. For research activities, funding allocated for the general hospital infrastructure and ways to integrate research activities into the general infrastructure that is administered in conjunction with the university will all play a central role in the future.

A significant amount of the research resources in the health sector's research institutions (the National Institute for Health and Welfare, the Finnish Institute of Occupational Health, Kela and VTT Technical Research Centre of Finland) are used for general reporting and development activities carried out to support political decision-making. These activities are often carried out quite rapidly. However, only a small part of the research and innovation resources spent annually by research institutions is used for the types of entities with the international high-grade science and significant commercial growth potential that could enable the sector to grow financially in Finland. For the growth strategy, a more precise channelling of annual contributions to reporting and research activities and their separation from contributions made to international high-grade research would be a necessary reform in these research institutions.

Compared to other sectors, the characteristics of the sector involve a long stage between coming up with an idea and accessing the market. This stage must be financed somehow. Impatience often leads to commercially significant inventions and competences being prematurely sold abroad. Finnish health sector companies face particularly intense international competition with many other countries which support their companies with various financing instruments (e.g. subsidised loans).

Finland still has a relatively undeveloped market for capital investment. This makes it considerably more difficult to finance ideas, inventions and the growth companies that may be established as a result of their creation.

Strategic definitions of policy

- Funding is used to support the development of a versatile base of companies in the sector and the systematic development of an ecosystem that takes the private sector into consideration.
- The cooperation between research and innovation funders will become even tighter, and for public operators, funding will be allocated to high-grade units and larger entities that are successful in reviews and assessments.
- The allocation of public funding for research and innovation activities should be reformed. The resources are allocated more efficiently to international highgrade science and major entities with commercial growth potential.
- The transparency of the research investments made in research institutions will be increased.

4.3 Research infrastructures, networks and partnerships

In Finland, dozens of public operators are involved in health sector research and its funding. The fragmentation of the operator field makes it considerably more difficult to coordinate the research activities and secure an effective outcome. This is also reflected in the little attention research activities get when developing the physical operating environment such as hospital infrastructures. The fragmentation of the infrastructure and the financial instruments as well as the shortcomings in competences related to regulation and agreements make it particularly difficult for companies to carry out long-term research cooperation with various public sector operators. Inversely, the features mentioned above are seen as limiting the possibility that companies, particularly foreign research-intense companies, will become attached to the Finnish research and innovation system and for these companies to cooperate with the Finnish social and healthcare service system.

Through features such as the Biocenter Finland concept, Finland has made significant investments in health sector research. Biocenter Finland is a national research infrastructure network. Biocenters form a national cluster of competences where various research and competence profiles complement each other. The strategic toplevel competence clusters (SHOK), SalWe Ltd. and Digile Oy attempt to provide an opportunity for close and long-term cooperation between research units and companies. The planned national cancer centre is an example of a new type of operation model where the use of the service system resources is also coordinated more effectively for research and experimental treatment.

On an international level, Finnish researchers and research groups are well networked and held in high esteem. Despite this and the high-grade base of competences, it has traditionally been difficult to attract international professionals to Finland. This is partly due to Finland's geographical location, but relatively few efforts have been made to market our core competences and to create international partnerships beyond the researcher and research group level.

In recent years, the strong development of small and medium-sized companies (PMEs) has been one of the significant positive developments in the sector. PMEs make the sector more versatile and significantly support the modernisation of health-related branches of activity. Finland has a few international top companies in the health technology sector. In other health-related branches of activity, leader companies such as these have not been established. The establishment of this type of beacon companies would increase the possibilities to internationalise and exploit the commercial potential of the core competences in that sector.

Strategic definitions of policy

• The distribution of labour and specialisation among university hospitals, research organisations and various research infrastructures will be clarified.

- Cooperation among university hospitals, the adjacent research clusters and various partners will be developed; the objective will be to reinforce needs-based research that meets the prerequisites for business activities.
- The systematic gathering of core competences and the marketing of competences will be accelerated. The goal is to make Finland attractive to significant international and Finnish investments.
- Research organisations will build long-term strategic partnerships with Finnish and international companies. They will support the production of added value for Finnish competences and for the derived inventions.

4.4 State policy choices, legislation and its implementation

A frictionless operating environment is a key element to global research and innovation competition. It is influenced by national and long-term policy choices and legislation. This will enable us to improve Finland's reputation as a site for health sector research.

Finland's public research and innovation system has not opened up or become international as hoped. Finland does not attract sufficient research and innovation professionals or international investments. In the health sector, Finland is not profiled as a country attempting to rapidly implement or create testing platforms for new pharmaceutical or health technology innovations. The difficulty in obtaining reference clients in Finland is also making it more difficult for new innovations to access international markets. Often the issue is also too careful an approach (fear of conflicts of interest), which particularly prevents the partnerships between the private and public sector that are vital to the health sector. In the future, Finland will need multisectoral local communities that encourage operators to think broad-mindedly and to engage in multisectoral cooperation.

There is a considerable number of regulations and standards related to the health sector, and they are constantly changing in the EU and globally. The insufficient knowledge of regulations and standards is making it more difficult for innovations to access the markets and causes delays of several months, even years. This is also financially costly. The possibility for new products to access public funding has been restricted to pharmaceuticals available for outpatient care up until now. The Health Care Act provision on the national service selection and on the council to establish to support its definition which came into force in early 2014 will clarify the processes and decisions made to include new innovative products as part of the publicly funded national service selection.

Finland has suffered from a poor understanding of the dynamics of open innovation activities and a poor ability to protect inventions. When assessing legislation that is central to research and innovation activities, the protection of inventions and the development of income distribution models related to the commercialisation of various types of public and private research must be particularly emphasised. Finland should make a strong contribution to developing models in order to ensure the legitimacy of the health sector growth strategy from the point of view of all parties. The Finnish national economy and Finnish patients must also be able to benefit from the international research activities and product development that are aimed at commercialising innovations. Few companies are prepared to transfer their strategic (and generally, highly confidential) top research to a cooperation structure where the results of research activities are shared by various operators. This is why sustainable development and growth require clear legislation and instructions from the authorities, a commitment to good research practices and the consideration of the economic interests and business secrets of companies in various stages of the process.

The new Biobank Act that came into force in September 2013 is a noteworthy example of legislation that significantly promotes research activities and whose evolution conforms to the principles described above. Together with Finland's unique healthcare statistics and patient registers, the biobanks will enable the simultaneous use of research material that is exceptionally large even on a global level. In Finland, so-called biobank expert centres are planned around the biobank activities to build cooperation between the public and the private sector. The initiation of biobank activities in Finland is an important step for medical research and for Finland's attractiveness to foreign investors. In addition, biobank activities may promote the networking of the industry and Finnish PMEs and the creation of strategic partnerships, if biobanks are linked as part of research clusters in a natural way.

Strategic definitions of policy

- A conscious attempt is made to develop Finland's reputation as a pro-innovation country on the level of attitude strategies and legislation; our reputation is a key factor for attracting private sector investments.
- The implementation of innovative goods and innovative public procurements is promoted when reforming the health technology and pharmaceutical legislation and in drawing up strategies for the sector institutions.
- The development of innovative comprehensive service products where technological solutions are applied will be reinforced in the strategies of the sector institutions. The cooperation between higher education institutions and the public, private and third sectors are used to integrate various types of competencies.
- The companies' awareness of regulations and standards will be improved with additional training. The patient regulation competences of companies must be one of the criteria for public funding granted for product development. The authorities and certification bodies will commit to more fluid communication with manufacturers.
- A willingness to develop inventions and innovations will be required of the healthcare system; the role of the system as a testing environment will be recognized, and prerequisites for operation will be created for it. Particular attention should be paid to efficiency studies. The efficient implementation of innovations often requires further development as experience is acquired and understanding increases.
- Clear rules are drawn up for experimental treatment, the documentation of its outcomes and its inclusion in the publicly funded service selection.
- The systematic register-based research carried out after the implementation of inventions will be reinforced.

5 Roadmap: key recommendations for measures

- 1. Universities and cities with university hospitals will draw up action plans for developing hospital cluster research and innovation ecosystems and the related cooperation with companies. The development of the local operating environment and support mechanisms from the point of view of the creative and innovative individuals operating within them is at the core of the plans. Fragmentation 1; responsibility: operators in university hospitals, government ministries)
- 2. The profiles and research foci of higher education institutions, research institutes and university hospitals will be reinforced when developing the international competitiveness of competence clusters. All policy sections will encourage skilful operators to engage in national cooperation and division of labour to improve quality. Forming international partnerships and attractiveness require high-quality research. One of the topical tools is the Innovative Cities (INKA) programme. Fragmentation 1 and 2; responsibility: metropolitan area operators, government ministries, higher education institutions, research institutions)
- 3. The health sector research community formed by research institutions and higher education institutions will be assembled to maximise the impact and to create a whole that better serves decision-making and society (participation of the private sector included). The ongoing international assessment process of the National Institute for Health and Welfare and the Finnish Institute of Occupational Health is linked to this. Research institutions should operate in close cooperation with university hospital campuses and biobanks and ensure that particularly personalised medicine solutions are developed in Finland and that they are integrated to basic healthcare and specialised healthcare. (Fragmentation 3; responsibility: government ministries)
- 4. Higher education institutions and research institutions will bring their technology transfer and commercialisation operations closer together in central university cities by assembling them and particularly by reinforcing sectoral national cooperation. When inventions are processed into products and services, contributions are made particularly to the identification of ideas and inventions, development work and the search for suitable partnerships. This operation is a significant junction in the ecosystem, and its goal is to network internationally with private and public operators and to acquire the necessary patenting competences and other substance competences case by case. (Fragmentation 4; responsibility: MEC, higher education institutions, MEE

- **5.** With the cooperation between Tekes and the Academy of Finland, funding instruments will be developed further by taking the special features of the sector into consideration in order to make the most of research. Researchers and research groups are encouraged to further develop ideas with international growth potential into commercially exploitable inventions. (Fragmentation 4)
- 6. The state capital investment activities (Industry Investment and Tekes) will consider the needs for risk capital in the health sector. An attempt is made to primarily activate private risk investors to invest in health sector companies in order to promote their growth and internationalisation. If the establishment of new health sector growth companies continues at the current rate, the goal is to establish between four and seven health sector capital investment funds in Finland. Public funding will be developed, taking into consideration the need for long-term market-based funding in the sector to promote stock exchange listing and the development of the so-called First North market place. Instruments related to granting export credits will be developed. (Fragmentation 5; responsibility: MEE)
- 7. The Academy of Finland, Tekes and other public operators will consider the development of the health sector when summarising their strategic and operational models for cooperation. Tekes and the Academy of Finland will cooperate particularly in programme activities, research assessment and in exerting influence in the EU. (Fragmentation 6)
- 8. The seamless joint access to personal health data and patient documents will be enabled for research purposes. A national operations programme and rules for the application of genome data will be drawn up. (Fragmentation 7; responsibility: MSAH, Sitra)
- **9.** A joint operation model will be drawn up to reinforce the work of government ministries and the business sector for exerting influence in the EU. (Fragmentation 8; responsibility: government ministries, business sector organisations)
- 10. The implementation of innovative commodities will be promoted when modernising the health technology and pharmaceutical legislation. This will also be done in the strategies and public procurement of the health sector institutions. It will be ensured that university hospitals have practical opportunities to act as partners to companies in experimental treatment and product pilot activities and other types of development work. (Fragmentation 9; responsibility: MSAH, MEE)

- 11. Proactive control of the research and innovation activities for health sector products and pharmaceuticals will be reinforced by developing company counselling activities. Training on legislation for health sector research, regulations and standards will be increased on a national level. The Fimea scientific counselling and pharmaceutical counselling activities can be used as a model. Information on the phenomena observed in the monitoring and control of the social and health sector activities will be capitalised. Public funders will serve as a link for counselling and promote the understanding of companies of relevant regulation. (Fragmentation 9; responsibility: MSAH, MEE)
- 12. Systematic activities will be initiated to attract foreign industry investments, and a decision will be made on the related division of labour. (Fragmentation 10; responsibility: MEE and Sitra)
- **13.** A Team Finland Health network will be established and in conjunction with sectoral unions and competence clusters, an annual marketing plan for the sector will be drawn up. In conjunction with sectoral unions and the organisers of the Slush event, an annual health sector growth event will be organised to bring together the sector's researchers, entrepreneurs, funders, the national and international industry as well as the central public sector operators. The activities will be planned and restart to meet the objectives set. (Fragmentation 10; responsibility: Ministry of Employment and the Economy, Ministry of Social Affairs and Health, Sitra)



6 Implementation and monitoring

It is essential to the implementation of the strategy that Finland be committed to its implementation and that an attempt be made to follow through on the strategy. As emphasized above, shortcomings in a single part of the ecosystem may result in Finland's inability to obtain the competitive advantage aspired to in the strategy. A mere gradual improvement of competitiveness is not sufficient. Slow decisionmaking is also highly detrimental to the competitive advantage.

- The strategy will be presented to the Research and Innovation Council, and the necessary decisions will be made on its implementation. Where necessary, an attempt is made to include the measures needed to complete the strategy in the following Government Programme.
- 2. The need to inform and consult Parliament and its key committees will be assessed separately. It is essential that the strategy also be approved according to the normal decision-making process.
- 3. In order to achieve the necessary decisions and legislation, the key government ministries will establish a cooperation group (Task Force). Once the strategy is finished, the organisation and individuals in charge of the measures will draw up related plans and organise the necessary measures as a project.
- 4. The Task Force will be in charge of monitoring the implementation of the strategy, and it will draw up detailed efficiency indicators for the strategy in conjunction with the sector's public research and innovation funders, sectoral unions and Statistics Finland.
- 5. An external assessment of the strategy implementation will be commissioned triennially; this will be done for the first time in 2017. The assessment will take into account the turnover, the personnel, the contribution to research and product development as well as other economical and social impacts of the operators in the sector.

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Health sector growth strategy working group configuration

Study Group

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The study group has held a total of ten meetings.

Expert Group

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Katariina Raij	Laurea University of Applied Sciences	Director
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Timo Veromaa	Suomen Bioteollisuus FIB (Biotie Therapies Corp.)	President, CEO
Antti Viitanen	Novartis Finland Oy (Lääketeollisuus Oy)	Managing Director

The expert group has held a total of six meetings.











TYÖ- JA ELINKEINOMINISTERIÖ ARBETS- OCH NÄRINGSMINISTERIET MINISTRY OF EMPLOYMENT AND THE ECONOMY