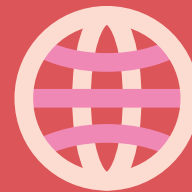


ROADMAP

The health industry



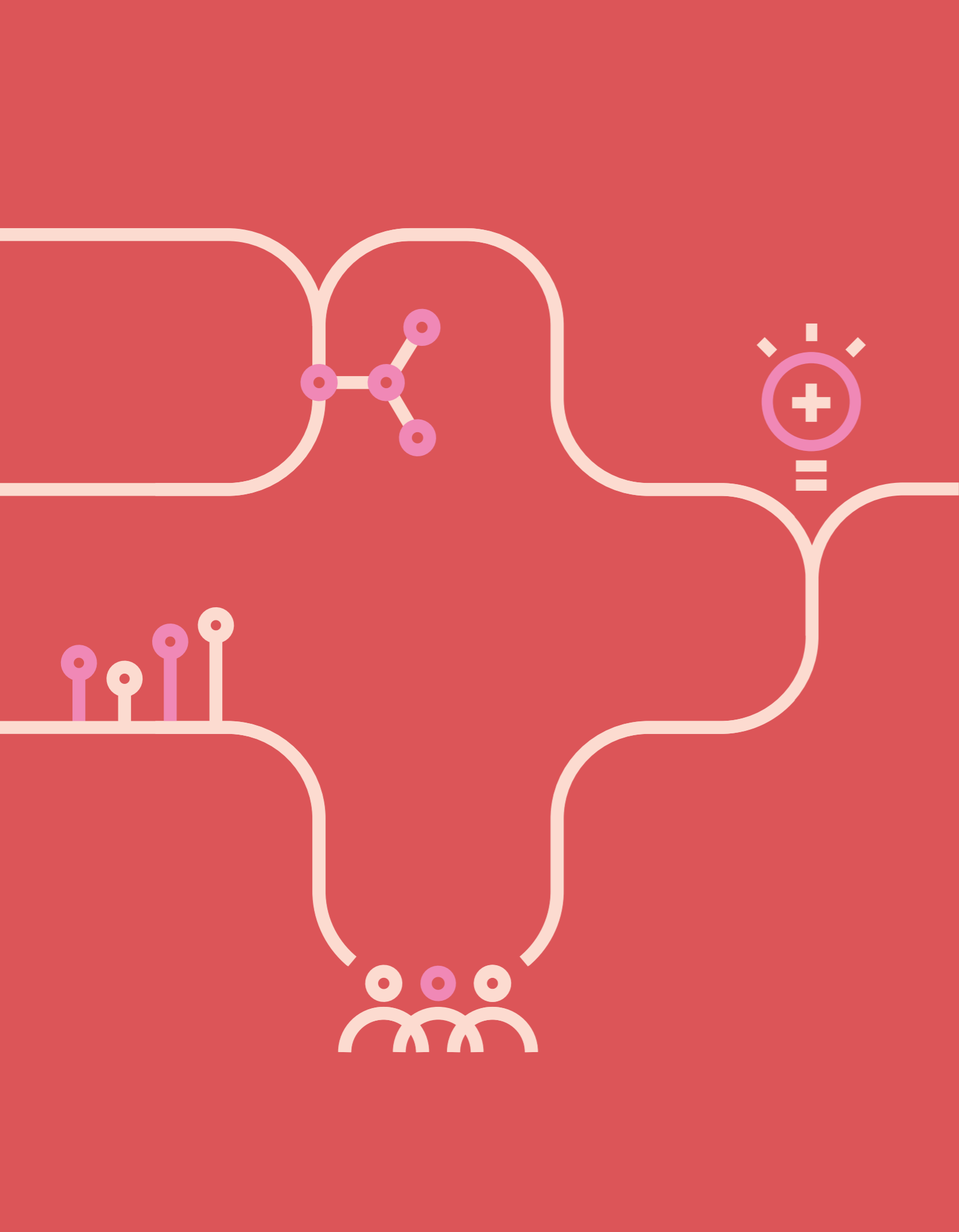
Norwegian Ministry of Trade,
Industry and Fisheries

Norwegian Ministry
of Health and Care Services

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(Please note that the term «industry» throughout this document encompasses all health and care businesses except those that provide services.)



Preface

Norway shall be an attractive country for business activities, also including the health industry. The interplay of a successful private sector with the public sector provides the basis for economic growth and a strong and sustainable welfare state. Industry plays an important role in achieving our health policy goals related to prevention, treatment and care.

The Norwegian welfare system shall be maintained and further developed. Most countries are experiencing numerous challenges during these times characterised by war, demographic change, shortage of skilled labour, energy and climate crisis, as well as increased international competition. The recent report by the Health Personnel Commission underscores the importance of adopting new technology to meet the challenges in health and care services. Industry will have an important role in solving these challenges, and it will be up to them to seize the opportunities.

Acknowledging that industry has an important role in achieving our health policy goals was one of the primary messages in the White Paper “The Health Industry” (2019), which came about on the initiative of the Labour Party. It was presented by the previous government and received broad support in Parliament.

This roadmap is aimed at industry that develop pharmaceuticals, medical devices and digital tools, and provides their professionals with a larger tool kit thereby contributing to increased profitability and value creation in the health industry. We have had a close dialogue with stakeholders in the health industry. In autumn 2022, we met with stakeholders from the health industry and the health and care sector. Based on this the Government identified several topics that are particularly relevant for the health industry to succeed in its initiatives. These topics are highlighted in this roadmap.

A well-functioning health and care sector is important for each and every one of us, and for society as a whole. The sector is vital for the sustainable society of the future. This provides the business sector great opportunities to establish profitable jobs and create value, not only in and for Norway, but also on the global market.

Several ministries and several levels of government are responsible in dealing with the framework conditions for the Norwegian health industry. The purpose of this roadmap is to show the great breadth of the Government’s policies to promote and strengthen the health industry in Norway, and charts out the best course for the future thereby paving the way for the health industry.

Jan Christian Vestre
Minister of Trade and Industry

Ingvild Kjerkol
Minister of Health and Care services

The business sector's place in health policy



Public health services provide security in everyday life, and the Government's goal is to create a health-promoting society by ensuring:

- sustainable and equitable use of resources
- good health and coping skills in the population, regardless of social background
- good patient pathways and rapid access to services throughout Norway
- a sector that is prepared in the face of crises and disasters
- a sector that is an attractive place to work in a lifelong career

The business sector plays an important role in the work of realising these goals. New technological solutions can help elderly and people with illness to live longer at home, and it can contribute to solutions that require less personnel. This will alleviate the burden on the health and care services. Important contributions from the business sector can include technology and solutions that take into account different health literacy levels in population groups and that promote a healthier lifestyle or insight into own health. The health industry has a role in developing solutions in diagnostics, treatment and prevention of disease and ailment.

The Government's health policy is and will be presented in several reports, strategies and studies in 2023 and 2024, and highlights the business sector as an important contributor to our common health service.

Report No 15 to the Storting (2022–2023) Folkehelsemeldinga – nasjonal strategi for utjamning av sosiale helseforskjeller (Public Health Report (White Paper) – National Strategy for reducing social inequalities in health' – in Norwegian only) emphasises that preventive and health-promoting work must take place in all areas of society, including in and in collaboration with the business sector.

A new *National plan for the health and care services (White Paper)* will be presented in 2023. The plan will address the framework for the further development of both the municipal health and care services and the specialist health services in addition to the interaction between them. Key goals include good patient pathways and good services throughout Norway.

A lack of healthcare professionals is a challenge for health systems in the vast majority of comparable countries. The Health Personnel Commission's report *Tid for handling* ('Time for action' – in Norwegian only) (Norwegian Official Report (NOU) 2023:4) points, among other things, to the need for innovations that reduce the need for personnel throughout the health and care services. Solutions that can contribute to changes in the organisation and division of responsibilities and free up time for healthcare professionals can reach a large market, including internationally. Among other things, the work will be followed up in the *National Health and Interaction Plan*.

The role of municipalities and county authorities

As independent, elected and self-governing bodies with a great responsibility for safe and satisfactory health and care services, the role of municipalities and county authorities must be emphasised. They are tasked with providing services under the Health and Care Services Act. Municipalities are free to decide how they carry out their procurements within the framework of the procurement regulations, and whether they want to participate in innovation projects based on local conditions and needs. This also applies to municipalities' responsibilities in the health and care sector. The business sector must approach the municipalities directly to discuss possible cooperation. Prior to this, the business partners should familiarise themselves well with the Norwegian health system and build up a good understanding of the municipalities' role, schemes, etc.

The HealthCare21 Advisory Board has prepared a report on the *Norwegian Association of Local and Regional Authorities' strategic research agency (KSF)*. KSF will be a collaboration and funding model that helps create a structure for a systematic knowledge boost and innovation in municipal services.

NOU 2023:9 Generalistkommunesystemet ('The system of general competence municipalities' – in Norwegian only) confirms that health and care services are among the most important tasks the municipalities are responsible for, with over a third of their total resources being used in this particular area. The committee of examining and analyzing the system of general competence municipalities has mapped out how they fulfil their tasks, mainly by looking at legal compliance, including within welfare services. The committee found that small rural municipalities have a lower degree of legal compliance than larger municipalities, mainly due to a lack of capacity and expertise.



White Paper No 24 to the Storting (2022–2023) Fellesskap og meistring – Bu trygt heime ('Community and mastery – Living safely at home' – in Norwegian only) was presented on 16 June this year. The proportion of older people will increase in the future. This development will have a big impact on society and requires a new and sustainable policy. Increased demand for age-friendly solutions, both from the health and care services and from consumers, represents market opportunities for the business sector.

In addition, a *White Paper on health preparedness* will be published in 2023. This will provide direction on how Norway should be prepared to protect the lives and health of the population in crises and disasters.

In 2024, the Government will present a new *priority setting White Paper*. Among other things, this will assess personalised medicine and ensure transparency and verifiability in relation to priorities in the health service.

Nasjonal strategi for persontilpasset medisin (2023–2030) ('The National Strategy for Personalised Medicine 2023–2030' – in Norwegian only) presents the Government's vision of personalised medicine as an integral part of prevention, diagnostics, treatment and follow-up in the health service, with the goal of improving health and coping throughout life. The business sector plays an important role in achieving the goals of the strategy as a supplier and development partner. Several health industry stakeholders

have personalised medicine as a focus area that can increase value creation. Good models have been developed for public-private cooperation in the field.

In the autumn of 2021, the Directorate of eHealth submitted the report *Samarbeid med næringslivet på e-helseområdet* ('Cooperation with the business sector in the field of eHealth' – in Norwegian only), with recommendations on the use of research, innovation and business development to strengthen implementation capacity. The report proposes several measures for better cooperation between the public and private sectors in the area of ehealth. A plan has been prepared to strengthen cooperation between industry clusters, the municipal sector and the specialist health service, where one of the measures is regular contact meetings with select industry organisations and associations.

The HealthCare21 Advisory Board facilitates better coordination through dialogue, cooperation and forums across the public, private and voluntary sectors. Appointed by the Ministry of Health and Care Services (abbreviated HOD) in collaboration with relevant ministries, the Advisory Board is the only permanent national arena where representatives from health trusts, the higher education sector, user organisations, the health industry and the municipal sector meet. In the follow-up to the White Paper on the Health Industry, it aims to contribute to good public health, efficient and high-quality health and care services, value creation and business development.



«A well-functioning health and care sector is important for each and every one of us, and for society as a whole. The sector is vital for the sustainable society of the future. This provides the business sector great opportunities to establish profitable jobs and create value, not only in and for Norway, but also on the global market.»

Policy for health industry development



The Government shall strengthen Norwegian competitiveness through good overall framework conditions. We need a more diversified economy going forwards to safeguard our welfare society through more profitable jobs and increased value creation. As a knowledge-intensive and growing industry, a well-equipped and efficient health industry will contribute to the development of sustainable services for the population.

The health industry has many of the same needs as the rest of business sector. Good general framework conditions for the business sector means good framework conditions for the health industry. The sum of the framework conditions is decisive for establishing a value-creating and adaptable business sector. The Norwegian business sector enjoys good terms overall, with an effective tax system, sound infrastructure and political stability. However, our relatively open economy requires us to adapt and readjust.

Value creation in the health industry

According to figures from Menon Economics (2023), the Norwegian health industry accounted for a total turnover of NOK 65 billion in 2021 (excluding the distribution link), of which approx. NOK 22 billion was export revenues.

Municipalities and health trusts are an important market for the health industry and are often referred to as the 'domestic market'. The health industry meets the authorities as regulator, research funder, owner of universities and hospitals, manager of health registries and biobanks. Often, the public sector is the only customer. For many companies, the domestic market is also an important testing ground for new products and solutions.

Many areas of the health industry are characterised by long research and development cycles that need advanced infrastructure and production capacities. These are strictly regulated and require access to patients and data from public health and care services. This means that there is a lot of cooperation in the research and development process, across sectors and national borders. Commercialisation processes are long, expensive and risky, and require long-term and risk-bearing capital with knowledge of the health and care sector and the health industry. In addition, the value chains are long and complicated, requiring a large number of input factors that are often produced by one global manufacturer alone.

The value and supply chains have faced challenges that have increased over time, especially during the pandemic, and currently as a result of the geopolitical situation. Some challenges have arisen through market mechanisms and historical structures, others have been created through business and security policies in certain states.

A robust health industry is part of the foundation for society's resilience in crisis. A good industrial and business policy, which prioritises sustainability, restructuring, efficiency and profitability, can also have positive ripple effects for preparedness. It is about using society's overall resources efficiently.

To ensure access to pharmaceuticals and medical devices, we need to cooperate with our closest partners in the Nordic region and the rest of Europe. The EU is investing in the health industry to build resilience through both regulatory and non-regulatory measures. The Norwegian health industry must participate in this European initiative.

It is important to the Government that the business sector has a significant role in the interaction required to solve the challenges in the health and care sector, and it will work to facilitate good interaction between the health and care services and various private stakeholders in the health innovation ecosystem.

In 2022, the Government presented a *Roadmap for the Green Industrial Initiative*. It includes several key focus areas for the entire breadth of the business community, such as access to capital, research, technology development, digitalisation, expertise and export. The health industry is a green, low-emission industry, and the Government therefore believes it should have the best growth and development opportunities. The Government aims to present an updated Roadmap for the Green Industrial Initiative in the autumn of 2023.

We have received input from industry stakeholders, the public administration and research communities in areas which they consider particularly important for the development of the health industry in Norway. We have divided this under twelve topics in this road-map, where we describe what the Government is doing and outline how it will handle these topics in the time ahead. Within the twelve topics, policies that fall under the remit of several ministries are discussed. The responsible ministry(-ies) is shown in brackets in 'the road ahead' sections.

Industrial partnerships

The Government is working to establish strategic industrial partnerships with particularly important countries, including the EU. The purpose is to systematise cooperation between the countries to facilitate the green transition, the development of common value chains and stronger export work targeting key markets. Depending on the country and market the partnerships encompass, the health industry may be a relevant sector to incorporate. One of the industrial partnerships is with Germany, which covers several sectors, and the ambition is that this can be expanded in the long term.



The Government's prioritised areas



1. Testing and piloting

Stringent requirements apply to pharmaceuticals and medical devices. Testing and verification are required to demonstrate efficacy and safety. Technological solutions for use in patient treatment or solutions for the health and care sector must also be safe. Different parts of the health industry need access to different types of test facilities, and this often includes costly infrastructure both in terms of investments and operations.

Norwegian hospitals, universities and university colleges have laboratory capacity and other infrastructure that is suitable for testing and piloting. A new life science centre is under construction at the University of Oslo, which will provide us with world-class research infrastructure (see page 24). There are no obstacles in the regulations to leasing laboratories etc. at Norwegian hospitals as long as it does not affect normal operations. Only the actual costs must be covered. The White Paper on the Health Industry showed an unused residual capacity that the health industry should be able to benefit from.

The Norwegian Catapult Programme supports multi-purpose centres for testing, simulating and piloting new products and processes. The scheme's main target group is small and medium-sized enterprises and it helps companies without sufficient resources to access expensive equipment and test solutions. The scheme is managed by Siva, in collaboration with the Research Council of Norway and Innovation Norway. In 2023, NOK 148.3 million has been allocated to the scheme, and funds will also be allocated under the Green Platform Initiative, the purpose of which is to create sustainable businesses that contribute to the green transition. In autumn 2022, Siva announced a call for pilot projects for the establishment of nodes under the Norwegian Catapult Programme. The purpose of the catapult nodes is to give companies

across the Norway easier access to test facilities and industry know-how, thereby contributing to a more sustainable transition of the Norwegian business sector.

To date, five centres have been established under the Norwegian Catapult Programme covering production technology, materials technology, digitalisation, ocean and marine technology, as well as renewable energy. As of today, there is no dedicated catapult centre for health, but the health industry can use existing catapults. Health was among four priority areas in pre-projects carried out in 2019/2020 for a new call for proposals for the programme. The Government will request Siva, in collaboration with the Research Council and Innovation Norway, to investigate how the health industry can benefit more from the Norwegian Catapult Programme; see also section 6 on the production of pharmaceuticals.

See also section 6 on production.

LINKEN eHealth Lab

LINKEN is an innovation arena at Nordland Hospital Trust and was opened by Minister of Health and Care Services Kjerkol in September 2022. Its purpose is to create an arena for collaboration where healthcare professionals, the business sector, research communities, patients and others can develop new solutions for the health sector. This is done through advisory services, project facilitation and building bridges. The focus is on the development and realisation of technologies that enable more health services in patients' homes.

The road ahead

- ☀️ Contribute to increased use of test, pilot and upscale facilities at hospitals, universities and university colleges. (Ministry of Health and Care Services – abbreviated HOD / Ministry of Education and Research – abbreviated KD)
- ☀️ Further develop the Norwegian Catapult Programme within the current public policy instrument system. (Ministry of Trade, Industry and Fisheries – abbreviated NFD)
- ☀️ Contribute to extensive cooperation for testing and development, including through the new Life Science Building at the University of Oslo. (KD)

2. Clinical trials

Clinical trials are a prerequisite for the development of pharmaceuticals and medical devices. They contribute to more knowledge and competence-building within the health services, and can give patients access to new methods with improved effect compared to standard treatment. In Norway and many other countries, the number of clinical trials on pharmaceuticals funded by the industry has declined in recent years. The reasons for this include capacity constraints among healthcare professionals, inadequate infrastructure, and a lack of incentives to conduct clinical trials. In some cases, there may be a conflict of priorities between industry-funded trials and trials initiated by the health care service itself.

The Government is following up the *Nasjonale handlingsplan for kliniske studier (2021–2025)* ('National

Action Plan For Clinical Trials (2021–2025)' – in Norwegian only). Clear instructions have been provided to the regional health authorities and underlying agencies that clinical research must be an integral part of patient care. The ambitious goal of increasing the number of clinical trials in the health trusts by 15 per cent annually continues to apply. To achieve this goal, more companies must conduct their trials in Norway. The implementation of the plan requires that relevant stakeholder contribute their expertise and resources to a comprehensive infrastructure for clinical trials in Norway. The opportunities that exist for conducting clinical trials in Norway, including future clinical trials, need to be highlighted. According to the Norwegian Medicines Agency, the number of applications for pharmaceutical trials from the industry increased by 57 per cent from 2020 to 2022.

The Government has increased the Norwegian Medicines Agency's budgets to increase its capacity to provide good and effective regulatory guidance on clinical trials of pharmaceuticals and medical devices.

The road ahead

- ☀️ Follow up the National Action Plan for Clinical Trials, among other things by facilitating the establishment and improvement of common national services for clinical trials such as digital consent. (HOD)
- ☀️ Ensure that research communities in both the private and public sectors receive timely and relevant high-quality guidance when conducting clinical trials in Norway. (HOD)

NorTrials

NorTrials is the flagship in the effort to bring more clinical trials initiated by the industry to Norway and receives dedicated funding of NOK 30 million annually over the national budget. This is a binding partnership between the specialist health service and the health industry. The Association of the Pharmaceutical Industry and Melanor (industry organisation for medical devices) sit on the board together with CEOs of the regional health authorities. Six NorTrials centres in the fields of cancer, inflammation, brain health, cardiovascular diseases, medical devices and gastrointestinal diseases have been established at the university hospitals. These will serve as hubs in national networks, and will contribute to ensuring that patients across the country participate in trials.

3. Clusters

The collaboration between the business sector, knowledge environments and the public sector is important to promote knowledge-sharing, transition and innovation. In the Norwegian health industry, there are many different networks and clusters that contribute to collaboration between the business sector and knowledge environments. These facilitate, among other things, knowledge-sharing between large and small enterprises and research communities. Participating in a cluster can give enterprises access to knowledge and expertise about possible national and international sources of funding, infrastructure and participation in international research and innovation work. Linking Norwegian stakeholders to international clusters and networks can often help strengthen Norwegian results.

The cluster programme under the auspices of Innovation Norway, Siva and the Research Council helps support innovation stakeholders. The cluster programme comprises three levels: Arena, Arena Pro and GCE (Global Centres of Expertise). The mature cluster sub-programme helps clusters that are qualified under a common European certification scheme to apply for funding for the implementation of development projects that have value for a sector, value chain or technology area beyond the cluster's own members.

The cluster programme has played a particularly important role in establishing new clusters. Operating aid for economic activity is prohibited in the state aid regulations, but an exception is made for operating aid for immature clusters, limited in time to a maximum of ten years. After that, the cluster is expected to finance its own operations. Innovation Norway has supported the establishment of several health clusters through this programme.

Innovation Norway is working to further develop the cluster programme. The aim is a more efficient programme that is adapted to the level of funding. The programme will continue to help strengthen cooperation and expertise in Norwegian industry clusters.

The road ahead

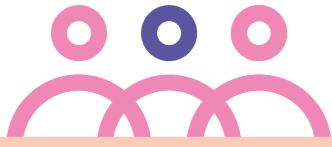
- ☀️ Ensure a concrete approach for the revised cluster programme. (NFD)

Norwegian clusters

In Norway, we have several strong health clusters, such as the three NCEs Norway Health Tech, Oslo Cancer Cluster and Norwegian Smart Care Cluster, and the Life Science Cluster, which is part of the Arena cluster programme. These clusters support and develop private and public partnerships and have strong international networks. The clusters are cooperating well and are considering forming a complete 'super cluster'.

Oslo Cancer Cluster has a world-class research environment in cancer immunotherapy and a growing pipeline of preclinical and clinical stage assets. The presence of several pharma, technology and IT companies strengthen the cluster's position as an international knowledge and innovation hub in the cancer field.





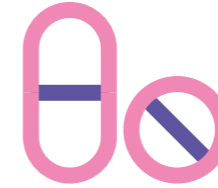
4. Health technology and personalised medicine

Digital solutions will support the Government's goals of good patient pathways and rapid access to health care services, as well as sustainable and equitable use of resources. In order to provide the best possible health care, relevant and necessary information about a patient's medical history and use of medication must always follow the patient. Such solutions are also intended to support employees in their day-to-day work and contribute to effective problem-solving. The Government will prioritise measures that promote interaction between health service levels and focus on technology and digitalisation contributing to reduced growth in the need for personnel to meet future sustainability challenges. In the National Health and Interaction Plan, the Government will present its digitalisation policy for the health and care services.

Digitalisation is changing how goods and services are produced and used and encompasses a range of technologies. A good ecosystem for business-oriented digitalisation heralds new market opportunities and creates more jobs. This should include a targeted research system for both basic and applied research on key digital technologies, combined with mechanisms for disseminating and making use of research results, facilities for testing and verifying new technologies, and adequate access to advanced digital skills and expertise on digital security.

There is a significant potential for business development through the use of artificial intelligence (AI) in many disciplines, not least in health. Internationally, AI has already contributed to better diagnostics for several years. In Norway, we have a good starting point for developing and adopting AI in the health field. We have good health registries and large amounts of data that are particularly valuable for the development of AI. The Norwegian Board of Health Supervision, the Norwegian Directorate of eHealth, the Norwegian Medicines Agency, the Norwegian Digitalisation Agency and the Norwegian Directorate of Health have published extensive information about AI, including guides and information about relevant regulations and ethical issues related to the use of this technology. In addition, an interagency regulatory guidance service has been established where institutions that develop or are about to introduce AI solutions can seek guidance.

Joint and coordinated supplier dialogue in high-priority areas in the municipal sector is important to ensure good supplier follow-up in dialogue with the health industry. This is a role that the Norwegian Association of Local and Regional Authorities (KS) is working to facilitate, in collaboration with other stakeholders. The sector relies on suppliers that develop good solutions, patient record systems and welfare technology solutions in particular. Joint and coordinated supplier dialogue can give municipalities the tools to strengthen their position



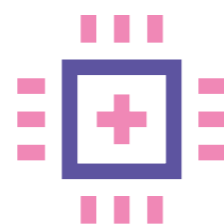
as buyers and increase predictability in relation to procurement by, among other things, developing common standards and frameworks that support their needs. Coordinated requirements and expectations from municipalities and county authorities can also contribute to predictability for suppliers, lay the foundation for developing municipal systems in a direction that meets the needs of the municipal sector – and that also facilitates innovation, testing, and scaling of solutions.

The establishment of a health technology scheme will support the introduction of new technology in the health and care services and encourage municipalities to invest in health technology, including improved patient record solutions and welfare technology. The health technology scheme can be developed gradually, and the state's general policy instruments for innovation and business development should be used as a frame of reference.

See also section 8 on international research and innovation cooperation and section 12 on export.

The road ahead

- ✦ Establish a health technology scheme that supports the introduction of new health technology in the health and care services. (HOD)
- ✦ Establish the Norwegian Directorate for Medical Products, with overall responsibility for health technology assessments of pharmaceuticals and medical devices. (HOD)
- ✦ Emphasise standardisation and guidance to help municipalities acquire patient record systems that meet the necessary requirements for security, functionality and interaction, as well as improve predictability for suppliers and give them a better basis to improve their performance. (HOD)
- ✦ Follow up the National Strategy for Personalised Medicine (2023–2030). (HOD)



5. Access to and use of data

Norway has extensive health registries that have been built up over a long period of time and that are based on mutual trust between patients, researchers, the health and care services and the registry administrators. Access to and management of such data will become increasingly important for the development and use of services, medical devices and pharmaceuticals. Among other things, it will contribute to quality improvement of the health and care services in addition to the development of new and more effective forms of treatment. This will contribute to commercialisation and increased value creation. Health data is a key tool in the development of pharmaceuticals, products and solutions in health and welfare technology.

Faster and easier access to health data could also allow more public-private partnerships where the use of health data is a prerequisite. The Health Data Service was established in 2021 to facilitate access to and contribute to increased use of health data. From 15 March 2023, the Health Data Service has become the decision-making authority for applications for access to data from the Cancer Registry of Norway, the Norwegian Health Archives Registry and the national health registries managed by the Directorate of Health and the Norwegian Institute of

Public Health. The Health Data Service will be further developed with an emphasis on extracting added value from the solutions that have already been established. This applies to the further introduction of joint application and case management services, an overview of the content of the registries (metadata) and other services. Reducing the case processing time for applications for access to health data is a priority. Information about this is available on the Health Data Service's website.

In recent years, changes have also been made to the regulations to facilitate access to health data. The terms for disclosing and compiling health data were coordinated and collected in the Personal Health Data Filing System Act through a legislative amendment in 2020. Furthermore, regulations on a national solution for the disclosure of health data were adopted in January 2023 to establish the Health Data Service in the Directorate of eHealth to provide infrastructure for secondary use of electronic health data. HOD will assess whether there is a need for further amendments to the regulations.

In order to facilitate better use of health data, the health registries in the Directorate of Health and the Cancer Registry of Norway will be moved to the Norwegian Institute of Public Health on 1 January

2024. The Health Data Service will also be moved from the Directorate of eHealth to the Norwegian Institute of Public Health.

In parallel, work is underway to streamline and increase the use of existing data and analytics infrastructures, including in the higher education sector. The Directorate of eHealth cooperates with the sector on the use of the analytics infrastructures TSD at the University of Oslo, SAFE at the University of Bergen and HUNT Cloud at the Norwegian University of Science and Technology (NTNU). The Directorate also cooperates with Statistics Norway and Sikt – Norwegian Agency for Shared Services in Education and Research on the use of the analysis service microdata.no. The goal is to realise as many benefits as possible of the Health Data Service as a national access manager without a joint data platform. Work on establishing the Health Analysis Platform in a general cloud solution has been discontinued as a result of changes in the legal framework after the Schrems II judgment from the European Court of Justice. As the situation stands, the assessment is that the reuse of existing data and analytics services and distributed data provides the greatest benefit to users in the short term and that there are still significant legal and financial risks associated with alternatives involving a common data platform.

A health data council and a user council have been established to help users influence the development of measures to facilitate access to health data. Participants in the Health Data Council come from the business sector, regional health authorities, the higher education sector and the institute sector, the Research Council, the municipal sector, Statistics Norway, the public administration and patient and user organisations. Cooperation between the business sector and the other stakeholders is crucial for successful development in this area.

See also section 8 on international research and innovation collaboration.

The road ahead

- ✧ Facilitate access to public health data for the business sector. (HOD)
- ✧ Collect central health registries and the Health Data Service under the Norwegian Institute of Public Health to contribute to better utilisation of health data. (HOD)



6. Production of pharmaceuticals

There are currently eleven companies that produce medicines with a marketing authorisation in Norway. Several of the major pharmaceutical companies have production and/or research activities in Norway, while others are mainly engaged in sales and distribution. The pharmaceutical market is global with highly complex value and supply chains. The Norwegian pharmaceutical industry must therefore function in an international market to be sustainable. Some pharmaceutical manufacturers in Norway export almost their entire production, such as GE HealthCare's production of X-ray contrast agents. The development of pharmaceuticals is research-intensive, demanding in terms of capital and expertise and entails great risk. Pharmaceutical production is very resource and cost-intensive, but there is a possibility of high returns for those who succeed. An increased pace of innovation means production is in many cases more closely linked to research and innovation.

One of the issues the pandemic has put on the national agenda is whether drug preparedness can be improved by producing vaccines and pharmaceuticals in Norway. A distinction must be made between measures for health preparedness (including pharmaceuticals) and measures for profitable business development, but sustainable business development can have positive ripple effects for health preparedness. From a business policy perspective, the development and production of vaccines and

pharmaceuticals must be carried out wherever the business stakeholders find it profitable.

Siva, the Research Council and Innovation Norway have been tasked with assessing possible approaches, arrangements and measures to follow up the points in the Government's policy platform, the Hurdal Platform, on facilitating the production of critically important drugs in Norway, such as vaccines, biopharmaceuticals and pharmaceutical raw material. The assignment also included an assessment of possible measures that could contribute to profitable production of pharmaceuticals in Norway, including the establishment of a centre. The report was submitted in Spring 2023 and outlined three alternatives: 1) a joint physical centre for the production of biopharmaceuticals, with a strategic spearhead, 2) a decentralised centre of expertise utilising a virtual centre structure and 3) a national initiative linked to the Nordic region, where a national centre for pharmaceutical production is built through various sub-initiatives. This can be done by establishing a decentralised competence hub, quickly followed by an escalation where several projects are connected to the hub, for example a national catapult centre. The report concludes that a centre for the production of biopharmaceuticals could be an important step towards potentially increasing the production of pharmaceuticals in Norway, but it ultimately finds that a centre developed through sub-initiatives is the best approach and recommends alternative

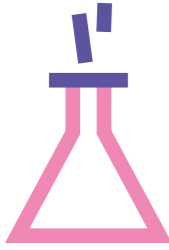
three. Such an approach will ensure the gradual realisation of new Norwegian pharmaceutical production, while at the same time developing capacity and expertise that will ensure companies' presence in Norway. This also includes close coordination with the other Nordic countries, where there is significant complementary infrastructure and expertise that a Norwegian initiative can benefit from.

The Government considers that such a broad national strategic initiative could support cooperation between stakeholders and relevant institutions to facilitate pharmaceutical production. Furthermore, this will constitute a positive Norwegian contribution to international cooperation, for example in the Nordic region and in the EU. The initiative involves gradually developing new environments based on existing ones, looking at the value chain from research to production in context and applying measures as needed. Such an initiative will also mean that different technology areas are included, and that the initiative can be developed over time in line with the needs of the business community and society at large, and have international influence. This will be done through dialogue between the funding agencies, the health and care sector and the authorities. How the health industry can benefit to a greater extent from the Norwegian Catapult Programme is also a measure that the Government will investigate further. Measures with budgetary consequences must be assessed in the ordinary budget processes.

The Government has decided that Norway will negotiate with the EU to achieve an agreement on Norwegian affiliation to the strengthened European cooperation on health preparedness, including the European Health Emergency Preparedness and Response Authority (HERA). Efforts will be made to find a solution that gives Norway the greatest possible influence through full participation rights. The EU aims to reduce global dependencies and secure regional capacities. The White Paper on health preparedness that the Government will present in 2023 will provide political and strategic direction for health preparedness in Norway.

The road ahead

- ✦ Siva is requested, in collaboration with the Research Council of Norway and Innovation Norway to establish a national initiative on pharmaceutical production within existing frameworks and instruments (NFD).
- ✦ Siva is requested, in collaboration with the Research Council of Norway and Innovation Norway, to look into how the health industry can benefit to a greater extent from the Catapult Programme, including assessing whether a separate centre should be established for the industry or whether this can be done at current centres.



7. Research, education, innovation and commercialisation

Knowledge is essential to promoting innovation and increased value creation in the health industry. The Government invests broadly in research and education and is committed to the targeted use of the significant funds invested. It is also a goal that publicly funded research benefits society. Through the policy instrument systems, measures are made available to support research and innovation projects in the business sector.

In Autumn 2022, *the White Paper No 5 to the Storting (2022–2023)* Long-term plan for research and higher education 2023–2032 was presented. The goal is a democratic and sustainable society with high value creation, fair distribution, widespread trust among the population and good public services throughout the country. The main message is that more research-based knowledge and expertise are needed to solve the many challenges we face and that this new knowledge must be applied. Health is highlighted as one of six thematic priorities. For this priority, the report addresses the knowledge needs related to public health challenges, the One Health approach, sustainable services, integration of research in the services, better use of health data and more value creation based on investments in life sciences and health research.

Access to a workforce with the right skills will be a major challenge going forward. The Health Personnel Commission's report *Time for action* (NOU 2023:4) shows that access to human resources in the health and care sector is under considerable pressure. The report also shows that access to labour is becoming a bottleneck and that other solutions must be considered, such as technologies that require less personnel and can ensure good health and care services in the future. Going forward, the efforts of personnel in the health and care sector must be directed towards municipal care in order to cope with the increasing number of elderly people. At the same time, the municipalities and the specialist health service must take measures to reduce the growth in the need for personnel, such as better division of responsibilities and increased use of technology.

Good access to expertise is crucial for the health industry to create increased value and new profitable jobs, innovate and realise new business opportunities in the market. There is not unlimited access to expertise in Norway, and priorities must be made. A lack of expertise can hamper the emergence of new profitable businesses in the health industry, delay innovation in working life and slow productivity growth. Structural labour shortages and an unmet demand for several key critical competencies mean that it is necessary to carefully consider which areas to prioritise. Part of the solution is to attract more international research and innovation expertise to Norway.

R&D in health-related publicly funded research

In total, Norwegian companies, research institutions, educational institutions and health trusts spent NOK 81.6 billion on R&D in 2021, and there is little growth in total R&D expenditure. In the medicine and health disciplines, the health trusts' and the higher education sector's use of resources for research amounted to almost NOK 5.3 billion and NOK 8.4 billion, respectively. This is mainly financed via the block grants from HOD to the specialist health service and from KD to the higher education sector. A proportion of funding is earmarked for specific budget purposes in the Research Council and to hospitals, mainly through HOD's budgets.

Universities and university colleges

The sector has a key function in several areas, including through its responsibility for basic research, education and innovation activities. Curiosity-driven basic research is an important part of the value chains in the development of pharmaceuticals, diagnostics and vaccines, medical technical equipment and digital health. In addition, the sector contributes to business-oriented, applied and interdisciplinary research. It offers important research infrastructure and is a partner and supplier of R&D services for the business sector and the public sector. It is part of the social mission of universities, university colleges and tertiary vocational colleges to educate candidates in accordance with the needs in a labour market that is constantly changing due to technological developments, changes in business structures or acute, intervening events.

Institutes

The institute sector is a partner and supplier of R&D services to the business sector and the public sector. It comprises almost 50 institutes with different objectives, where the proportion of R&D activities varies, as well as how much of the core activities comprise R&D. Some institutes are also responsible for statutory administrative tasks, such as the Norwegian Institute of Public Health.

The Life Science Centre at UiO

The Life Science Building is a historical initiative at the University of Oslo (UiO). It is scheduled for completion in 2026 and will be Norway's largest university and hospital building, as well as a joint building for leading university and hospital environments in life science. Extensive interdisciplinary co-operation will help solve major societal challenges in health and sustainability and ensure Norway's competitiveness internationally. The building will also be central to cooperation with the business sector and the sharing of expertise and infrastructure.



White Paper No 14 to the Storting (2022–2023) Utsyn over kompetansebehovet i Norge (Utsynsmeldingen) ('Out-look on the skills needs in Norway' needs in Norway – in Norwegian only) was presented in spring 2023. Its goal is to contribute to a high employment rate and meet the most important skills needs in the labour market and society at large. The Government prioritises:

- skills for a highly productive and competitive business sector
- skills to implement the green transition
- skills for good welfare services throughout Norway and for managing demographic developments
- qualifying and mobilising people outside the labour force.

The Government has appointed a committee of representatives of the social partners to work on a skills reform for the labour market. A comprehensive and targeted skills policy is central to achieving the goals of high productivity and as relevant skills as

possible in the labour market. This is also linked to the goal that as few people as possible should be excluded from the labour market. It is crucial that the skills policy is developed together with and supported by the social partners. The committee will submit its report in October 2024.

Education is important for good health and care services. The dimensioning of vocational education must be in line with the needs of society and the labour market. The Government is working on simplifying the funding system for universities and university colleges to give this sector greater autonomy and flexibility to adapt its study programmes to the needs of society and the labour market. In the management dialogue with the institutions, the emphasis is on business relevance and innovation activities, in addition to cooperation and dialogue with the business sector. Interaction between the higher education sector and the health industry is important to promote industrial and business development.

Good cooperation with the institute sector is needed to realise research and innovation's potential for many health industry enterprises. In 2020, the Research Council conducted a survey of the potential for interaction between the health industry and relevant parts of the institute sector. This helped to highlight the importance of the institutes for the development of the Norwegian health industry. The report showed that the health industry has little cooperation with parts of the institute sector, and that there is a potential for increased cooperation. One of the things the Research Council points out is that the institutes must be more active in promoting their own expertise to the health industry, and that dialogue and meeting places are important. The Research Council follows up the report in dialogue with the stakeholders.

A culture of innovation, invention and commercialisation must be created in the higher education sector and the health trusts. The Government will take steps to ensure that more publicly funded research strengthens value creation through increased

commercial use of research. This will help ensure that the results of publicly funded research benefit all of society.

In the annual assignment documents from The Ministry of Health and Care Services to the regional health authorities, the health authorities are required to increase their innovation activity and strengthen cooperation with the business sector. A special indicator for measuring innovation in the specialist health service has been introduced, which confers points for benefit and dissemination.

Technology Transfer Offices (TTOs) help mobilise and ensure professional management of commercialisation of publicly funded research. The TTOs are organised as separate companies outside the higher education institutions and the health trusts. Some are owned by one institution, while others are owned jointly by several. Half of the TTOs are owned by universities and university colleges, university hospitals and the regional health authorities. In order to manage the institutions' commercialisation work,



the TTOs are developed and organised to facilitate the early stage of the technology transfer process, the so-called TTO function. The TTO function includes further work on evaluation, securing rights and developing ideas and knowledge, including the possible establishment of new companies.

Funding is available to public research institutions through the Research Council's FORNY programme, which can help fund the early stage of the TTO function.

The policy instrument system for research and innovation mainly consists of general programmes that are also open to the health industry. At the national level, these are managed by funding agencies such as the Research Council of Norway and Innovation Norway. Overall, the health industry uses public policy instruments actively, and has good projects that succeed in the competition for funding.

In the Research Council's overall funding for and in the business sector in 2022, the health industry is the fifth largest industry with total funding of around NOK 750 million. Of this amount, NOK 396 million was awarded to the business sector directly. The remaining funds went to the institutes, universities, university colleges and health trusts to develop new and improved products, processes and services in cooperation with the business community.

The health industry is an active user of the Skattefunn tax relief scheme. In 2022, the number of approved Skattefunn applications accounted for a total of NOK 603 million, divided between 550 different projects.

Research and development are fundamental input factors when it comes to producing and translating knowledge into innovation and higher productivity. The Norwegian business sector has experienced strong growth in R&D investments over the past decade. The Government believes that a further strengthening of R&D in the business sector will lead to increased value creation in the future and has initiated work on a strategy for increased research and development in the sector.

Innovation Norway also has a large number of projects aimed at health. In 2022, NOK 170 million was allocated in loans and grants to health projects. This included NOK 21 million in public research and development contracts to health, which represented 43 per cent of the scheme.

Even though the policy instrument system works well, many companies find it generally unpredictable, which makes it difficult to know which stakeholder or scheme can meet their needs. The Government is in the process of simplifying the system and making it greener through its work on The Policy Instrument System 2.0.

Innovation Norway, together with Export Finance Norway (Eksfin), Siva and the Research Council, is developing 'Én vei inn' – 'the one-stop shop' a digital gateway to the policy instrument system where users can get quick answers and guidance for further contact with the business-oriented policy instruments. This will be an important step towards simplifying and making the policy instrument system more accessible, among other things by reducing the amount of time



and resources the business sector uses to search for information about relevant schemes.

The emergence of innovative growth companies in the health industry can contribute to new products and services in the sector. These companies also contribute to the dissemination of new knowledge, new concepts and new ways of solving issues. Innovation Norway offers policy instruments for start-ups that are also relevant to entrepreneurs with growth ambitions in the health industry. The policy instruments include capital, expertise, advisory services and networks. The start-up schemes are intended to fund early market orientation and commercialisation until the companies are competitive in the market. In spring 2023, the policy instruments have been adjusted with a view to facilitating more coherent start-up funding divided into phases. These phases will be tailored to needs and have clear milestones, linked to the gradual development of the product and marketing efforts, with expertise and network services. In 2023, a pilot will also be launched for a third phase tailored specifically to the needs of growth-oriented start-ups, particularly related to longer development cycles and capital needs. Innovation Norway's start-up funding schemes apply to

companies for up to five years and can largely be combined with other general schemes for grants, loans and guarantees.

It is important that projects funded through the business-oriented policy instruments contribute to a low-emission society and a green business sector.

R&D in the health industry

In 2021, the Norwegian business sector invested a total of nearly NOK 38.3 billion in their own R&D activities and purchased R&D services for NOK 8.9 billion. The Norwegian health industry is research-intensive and invests heavily in R&D. Health-related R&D was carried out for almost NOK 2.8 billion in 2020, an increase of NOK 367 million from 2019 (source: Statistics Norway).



IPCEI

IPCEI (Important Projects of Common European Interest) is an exemption provision in the EU state aid rules that allows national authorities to provide more funding than is normally allowed for projects that are considered to be of strategic importance for the EU. In June 2022, the Government decided that steps should be taken to facilitate indirect participation in IPCEI Health. As a result of a recent revision of the EU state aid rules in response to the US Inflation Reduction Act (IRA), it is now possible to use simpler procedures for funding IPCEI-related projects.

The road ahead

- ☼ Give universities and university colleges greater freedom to set their own priorities within the scope of the current framework conditions. (KD)
- ☼ Expect universities, university colleges, health trusts and research institutes that receive basic allocations or basic funding from the state to follow up on the thematic priority areas for health in the Long-Term Plan for Research and Higher Education, and also expect that they contribute to meeting the knowledge and skills needs described in the plan based on their prerequisites and responsibilities. (KD/HOD)
- ☼ Prioritise the skills necessary for a highly productive and competitive business sector and the skills necessary to implement the green transition.
- ☼ Prioritise the skills necessary to ensure good welfare services throughout Norway and to manage demographic developments, weighed against the need for labour in other sectors of society.
- ☼ In future allocations to higher vocational education, the government will prioritise study places in technical subjects, health care, and areas important for the green transition, and facilitate dialogue with the county authorities on how they can follow up these priorities in their management of the sector.
- ☼ Align FORNY so that the R&D institutions themselves take responsibility for commercialisation at an early stage. (NFD/KD)
- ☼ Present a strategy to increase research funding from the business sector. (NFD/KD)
- ☼ Pursue broad, open policy instruments for research and innovation in areas where the health industry has performed well. (NFD)
- ☼ Follow up indirect participation in IPCEI Health. (HOD/NFD)
- ☼ Further develop the policy instrument system through *The Policy Instrument System 2.0*, which will make it easier to navigate the system and simplify it to enable the business sector to get help to become greener and meet a comprehensive and coordinated policy instrument system. (NFD)

8. International research and innovation collaboration

Norway has skilled researchers and a good international reputation in several areas, but the best knowledge environments and the most ground-breaking ideas are developed through international cooperation on research and innovation. Through international cooperation, Norwegian stakeholders gain access to considerable knowledge, international research networks and global markets. The authorities facilitate international cooperation through Norway's full participation in the European research and innovation cooperation, in addition to Nordic and bilateral cooperation with selected countries. The business sector should think about the big picture when investing internationally and consider both the bilateral and multilateral possibilities for funding projects and cooperation constellations.

The EU

Norwegian participation in EU programmes provides great opportunities for cooperation and funding for Norwegian actors, also within the health industry. The EU places increasing emphasis on developing its open strategic autonomy. It wishes to reduce dependencies and vulnerabilities in supply lines

in strategically important areas for society and the economy. Measures in a number of policy areas have been implemented to diversify access to raw materials, increase own production capacity and ensure a well-functioning internal market. This work also includes strengthening the European health industry as a strategically important area.

Norway participates in Horizon Europe, The Framework Program that aims at strengthening Europe's innovation capacity and competitiveness, as well as create jobs. The total contribution to Norway's participation in Horizon Europe is estimated at around NOK 25 billion. Through the programme, businesses can apply for funding for projects together with partners in other countries. Health is a priority. The innovation dimension is strengthened through a separate programme pillar for innovation. This initiative aims to make Europe a leader in market-creating innovation and SME growth through the European Innovation Council, whose primary focus is developing and scaling up breakthrough technologies and ground-breaking innovations, as well as supporting the overall development of the innovation ecosystem in Europe.



Health partnerships through Horizon Europe

Norway participates in all the health partnerships in Horizon Europe. The partnerships with the highest relevance to the business sector are:

- The Innovative Health Initiative supports the health industry and contributes to health innovation that enables cross-sectoral technologies, knowledge, products and services for a patient-centred health system.
- Transforming Health and Care Systems aims to contribute to the transition towards more sustainable and people-centred health and care systems with an emphasis on quality, efficiency and accessibility.
- Personalised Medicine will help health systems to optimise personalised medicine by, among other things sharing data, demonstrating solutions and supporting policy development.
- Pandemic Preparedness and Response aims to improve Europe's preparedness to predict, prevent and respond to emerging infectious health threats by better coordinating funding for research and innovation.

So far, Norwegian research and innovation communities have seen a very good financial return from Horizon Europe compared with previous framework programmes. So far this year, Norwegian stakeholders have received 3.35 per cent of the competition-based funds, and are leading among the Nordic countries. The projects in which Norway is involved have an estimated value of EUR 3.5 billion, and if this trend continues, Norway's return will exceed our total contribution. So far (2023) the Norwegian success rate for health calls under Pillar 2 is 5.1 per cent. Several of the partnerships will also be relevant for Norwegian innovation and business environments, and Norway participates in all new health partnerships. These are large consortiums with many stakeholders in different disciplines, sectors and industries. The European Commission enters into agreements through the partnerships to the effect that funds from the framework programme will be used in conjunction with funds from the Member States or from the business sector.

Norway participates in the EU's two major initiatives on cancer. Europe's Beating Cancer Plan addresses prevention, early detection, treatment, care, cancer patients' quality of life and carers. The EU Mission on Cancer is the second major initiative, where research communities, governments, industry, user organisations and health trusts work closely together. The Norwegian Cancer Society and the Research Council have taken the initiative to establish a national hub where the Oslo Cancer Cluster plays an important role. The goal is to mobilise stakeholders to collaborate and jointly apply for calls across disciplines and

sectors, and ensure consistency with local, regional and national initiatives.

The EU health programme EU4Health will contribute to improving the health of the population and protecting the population from cross-border health threats. The programme is implemented through the EU's contribution to financing and facilitating development initiatives through cooperation between countries in Europe. The programme's calls for proposals target government actors, non-profit organisations, academia and the business sector, among others. The European Commission makes major strategic acquisitions in the health field through the programme, and also uses it to invite tenders for the operation and development of various services. Norwegian business can compete for the tender contracts on an equal footing with companies in EU countries. The Norwegian Directorate of Health provides information about calls for proposals, analyses of the EU's strategy and policy in the field of health, as well as advice on participation in the programme, and they will mobilise the Norwegian business sector to participate in calls for proposals that are designed as tenders.

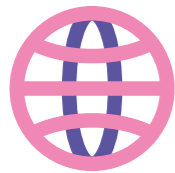
The investment and capacity-building programme DIGITAL will contribute to increasing the business sector's competitiveness. This is Europe's most important tool for building digital capacity and infrastructure and securing digital sovereignty in six areas: high performance computing, artificial intelligence and data, cybersecurity, advanced digital skills, enhanced use of technologies and

own investment in semiconductor production (The European Chips Act). Good capacity in DIGITAL's focus areas is important for the future development of the health industry, and test facilities are now being established that focus on health. High performance computing infrastructure, where a large number of computing processors work in parallel to process huge amounts of data in real time, is also essential for this capacity.

Nordic cooperation

Our Nordic neighbours have strong environments and stakeholders affiliated to the health and care field. The Nordic countries have a total population of 27 million people and very good register data. Nordic cooperation is thus particularly relevant to clinical trials and the use of health data.

The Nordic Council of Ministers for Health and Social Affairs coordinates Nordic cooperation on health and welfare, for example through the establishment of an e-health group in 2011. This in turn has subgroups for research and standardisation. In the period 2021–2024, one of the goals is for the Council of Ministers to contribute to good, equitable and safe health services and welfare for all. For the period 2021–2024, the Nordic ministers of trade and industry adopted eight intersectoral programmes to follow up Vision 2030, for the Nordic region to become the world's most sustainable and integrated region by 2030. One of these programmes is implemented and followed up by Nordic Innovation and focuses on 'the Nordics as a leading region within life science and health technology'. The purpose is to facilitate



a world-leading ecosystem for research, innovation and business development in the areas of sustainable life science and health technology. The programme includes measures such as Nordic testbeds and clinical trials, joint marketing, easier access to health data in the Nordic region and student and researcher exchanges.

The health industry should look more closely at existing bilateral opportunities and study the work that takes place in the Nordic Council of Ministers.

In spring 2023, the Government presented *White Paper No 16 to the Storting (2022–2023) Nordisk samarbeid* ('Nordic cooperation' – in Norwegian only), which, among other things, highlights initiatives in health preparedness, sharing of health data increased, knowledge after the pandemic and pharmaceuticals for children.

In April 2021, Innovation Norway and its sister organisations in Finland and Sweden signed a collaboration agreement on health technology. This is followed up through knowledge sharing and joint market positioning.

See also section 12 on export.

Bilateral cooperation

Norway engages in bilateral cooperation with eight countries outside Europe, which are considered our most important research, innovation and education partners. The Panorama Strategy for 2021–2027 for

the prioritised countries Brazil, Canada, China, India, Japan, South Africa, South Korea and the USA aims to increase cooperation on research, innovation and higher education. These countries are far from homogeneous, but several of them have world-leading environments in health research and innovation. Norwegian companies looking for international partners should consider the great potential these environments represent.

The road ahead

- ✧ Continue Norwegian participation in EU programmes and initiatives (in particular Horizon Europe and DIGITAL), by assessing the alignment of national policy instruments with European ones in order to maximise the impact of combined policy instruments.
- ✧ Participate in the EU Cancer Mission. (HOD)
- ✧ Contribute to mobilising Norwegian applicants from the health industry to EU programmes and schemes.
- ✧ Continue to invest in Nordic health cooperation. (HOD)

9. Intellectual property rights

All businesses – both public and private – have various forms of intellectual property rights. The scope and importance of these assets have increased over time and now account for over 80 per cent of corporate assets on a global basis. For the health industry, it is more important than in many other industries to secure IPR, because innovations in this industry often have the world as their market. They also typically

require large investments in development, but are easy to copy so that the risks are high unless a good IPR strategy is in place.

Every year, 300,000–400,000 patent applications in technologies related to the health industry are filed with patent authorities worldwide. The largest share tends to be in the medical technology category, where almost as many applications are submitted as in pharmaceuticals and biotechnology combined. In Norway, most patent applications are submitted in the pharmaceuticals and biotechnology categories. More than 300 active design rights have been registered in the health industry in Norway, especially in the field of medical devices. There are just over 42,000 active trademark rights in the health industry, which are important marketing tools. In trademark and design, foreign businesses dominate as rights holders, owning around 90 per cent of registered rights in Norway.

Digital health is an area of rapid growth where other forms of IPR than those that can be registered are particularly important. This includes trade secrets, databases, copyrights and agreements.

The road ahead

- ✧ Work to ensure that companies in the health industry ensure professional identification, safeguarding, handling and utilisation of their IPR. (NFD)
- ✧ Consider measures to strengthen IPR expertise in the health industry. (NFD)

10. Capital

Norwegian authorities must have effective policy instruments, but the health industry must itself endeavour to take advantage of the commercial opportunities that exist in the market, both at the national and international levels. To succeed, the industry needs a well-functioning capital market for the financing of potentially profitable projects, research and innovation. This applies in particular to those parts of the industry that are characterised by long and risky development cycles that involve investments with limited secondary value, for example R&D in pharmaceuticals and diagnostics, but also solutions that require shorter and capital-intensive development cycles such as medical technology and digital health.

The Government gave its assessment of access to capital in Norway in the 2023 White Paper on financial markets, which was presented in spring 2023. It states that, overall, the Norwegian financial market functions well, that most companies and individuals meet their capital needs in the market and that public schemes complement the private funding schemes.

Public capital is mainly geared towards projects related to research, entrepreneurship and innovation, as well as early-stage projects, where it is assumed that value creation will increase if the capital market is supplemented with policy instruments. Over time, several state policy instruments have intended to both develop expertise in the investor environments and provide promising companies with capital.



In the policy instrument system, Investinor is the main provider of equity to early-stage projects. The company manages a total of seven mandates on behalf of the state, and provides capital to companies either through direct investments from Investinor or investments in funds. At the end of 2021, approximately 17 per cent of Investinor's funds were invested in the health sector. Through investments in funds, Investinor can help develop specialised management environments that can, among other things, benefit the health industry. Examples of funds in Investinor's portfolio that involve a considerable amount of health investments include Sarsia Seed in Bergen, Norinnova in Tromsø, Sintef in Trondheim and Startuplab, Inven2 and Hadean Ventures in Oslo.

These investments have paid off – several companies have managed to enter the stock market, and a number of early-stage companies have been able to attract both Norwegian and foreign capital and expertise. Other schemes in the policy instrument system are also relevant; for example, loans from Innovation Norway can be used to partly finance investment projects that concern start-ups, innovation, restructuring and development. The loans are intended to stimulate the development of innovative growth companies.

The final formal agreements are in place for Norwegian companies to participate in the European programme InvestEU. This opens up great opportunities

in Europe for Norway. InvestEU brings together financial instruments across different policy areas in the EU. The programme consists of funding schemes such as loans, guarantees and equity investments. This is probably the most important EU programme for the breadth of Norwegian business and industry as regards access to funding. The programme has strong synergies with Horizon Europe, EU4Health and other EU programmes, and it is a key part of the European Green Deal. The business sector will have access to the instruments directly through the Nordic Investment Bank (NIB) and the European Investment Bank (EIB) or indirectly through private investment funds and banks that have received funds from the European Investment Fund (EIF). Innovation Norway and Investinor also have mandates to cooperate with the EIF on InvestEU instruments in Norway. The health industry is one of InvestEU's main focus areas. Several Norwegian fund managers are already in dialogue with the EIF about investments.

The road ahead

- ☀️ Maintain a well-functioning capital market for the further development of the health industry in Norway. (NFD/Ministry of Finance)
- ☀️ Instruments such as Investinor, the various loan arrangements in Innovation Norway and Norwegian participation in InvestEU can stimulate the development of competent investment communities and access to capital

for profitable projects in the health industry. (NFD)

- ☀️ Adopt an proactive business policy that contributes to good overall framework conditions that facilitate private investment and further growth. (NFD)

11. Public procurement

Public procurement amounts to about NOK 743 billion a year (Statistics Norway 2022), and is an important strategic instrument for stimulating innovation and new solutions. The Norwegian procurement rules facilitate innovation, while fundamental principles of procurement law, such as the principles of competition and equal treatment, guide the implementation of public procurement. The Government expects the health and care services to use their purchasing power wisely, and to use their freedom of action for dialogue with the market. At the same time, the business sector must be aware of these services' needs, the documentation requirements and regulatory framework.

In the specialist health service, the four health regions jointly own the Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF). In the period 2020–2022, the trust delivered 2,700 procurements with a total value of approximately NOK 71 billion. Eighty per cent of the procurements were for a health trust. In terms of value, national procurements accounted for two-thirds.

The Norwegian Agency for Public and Financial Management (DFØ)

DFØ is the Government's expert agency for public procurement. It plays an important role as a driving force and centre of expertise for sustainable and innovative procurement. Some of the key aspects of the Directorate's work include the development of methods and guidance on procedures and implementation models for procurement that facilitates innovation. The agency's website contains guidance and templates for contracts and tender documents for various innovative procurements. DFØ actively contributes to innovation projects by providing guidance on the implementation and contract follow-up of this type of procurement, and it is also responsible for measuring and reporting on the use of innovative procurement as an instrument.

In most major procurements, the Norwegian Hospital Procurement Trust issues an indicative announcement encouraging suppliers to provide input. Pipeline meetings, dialogue conferences or other supplier meetings are organised as needed. The type of meeting/conference chosen depends on the complexity, market situation and scope of the procurement. In minor procurements, market



surveys are often carried out and dialogue meetings or dialogue conferences are held if necessary, if, for example, the procurement involves innovative products, services or solutions that are not common in the market, or in cases where the requirements or specifications in the procurement are complex or unique.

The Norwegian Hospital Procurement Trust annually conducts about 300 dialogue meetings related to pharmaceuticals alone. These are conducted with a pharmaceutical company about a specific procurement or a specific drug. In addition, an annual supplier meeting is held where the whole supplier market is invited to participate. The Norwegian Hospital Procurement Trust also has regular meetings with relevant industry associations, including the Association of the Pharmaceutical Industry in Norway and Melanor, where innovation and innovative procurements are on the meeting agenda.

The White Paper *Smartere innkjøp – effektive og profesjonelle offentlige anskaffelser*, ('Smarter purchasing – efficient and professional public procurement' – in Norwegian only) which was presented by the previous government, reviews measures to promote innovation in public procurement. Innovative procurement includes both procedures for purchasing innovation and procurement methodology and activities that promote innovation. The goal is to develop a supplier market for solutions that result in a new or significantly improved product, service or process.

The Government has appointed a public committee to review the procurement regulations and present

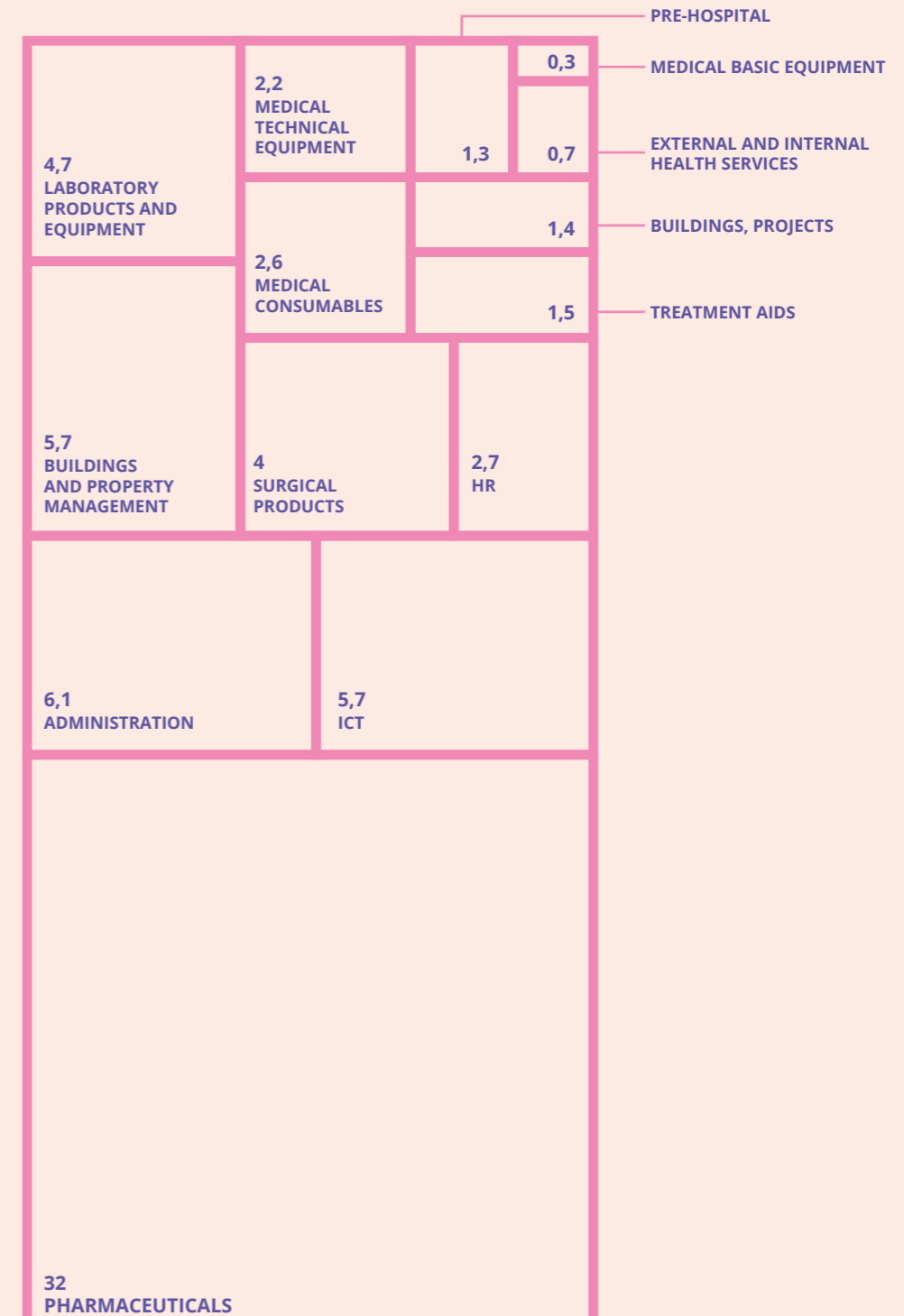
proposals for amendments. The purpose is to make the regulations simpler and more accessible, among other things through changes in the structure, material changes and a review of the regulations relating to societal considerations. The committee is tasked with proposing changes that strengthen climate and environmental considerations and combat social dumping and work-related crime. It will also investigate how the public sector can promote innovation in procurement, especially innovation that promotes the green transition. The submission of the first interim report is expected in November 2023, and the second in May 2024.

The National Programme for Supplier Development helps municipalities, county authorities and state-owned enterprises carry out innovative procurements. They provide advice on how to carry out innovative procurements from the preparation phase to project implementation.

The road ahead

- ☀ Ensure increased awareness of procurement responsibilities in the public sector. (Ministry of Local Government and Regional Development – abbreviated KDD)
- ☀ The Norwegian Agency for Public and Financial Management (DFØ) will continue to promote innovative public procurement. (KDD)
- ☀ Follow up the work of the official committee that reviews the procurement regulations. (NFD)

The value of the Norwegian Hospital Procurement Trust's procurements broken down by category in 2020–2022, in NOK billion





12. Exports

Particularly in areas where we excel and have strong research/business communities, we will promote Norwegian business and industry. The Government continuously considers a number of strategic measures to strengthen our international competitiveness. International cooperation should be an integral component of the health industry's assessment of markets, strategies and initiatives. This includes clusters and networks. The COVID-19 pandemic showed how vulnerable we are, and that international cooperation is necessary to ensure access to, among other things, medical countermeasures. Such cooperation must therefore be embraced at several levels: multilaterally, bilaterally and in the Nordic context. Strengthening our exports will develop the breadth of the Norwegian economy and contribute to the green transition and increased value creation.

In 2021, the health industry's exports amounted to NOK 22 billion and it created 11,000 jobs across Norway (Menon). Seventy per cent of exports in 2021 went to the United States and Canada, but Asia and the Nordic region are also important markets. The health industry is a diverse industry, but in this context it is limited to pharmaceuticals, medical devices and digital devices. The majority of exports

come from pharmaceuticals and medical devices. Figures from 2021 show that 71 per cent of export revenue comes from the sale of pharmaceuticals, 28 per cent from the sale of medical devices, and 1 per cent from the sale of digital solutions.

Many of the Norwegian health technology companies operating in the municipal sector are small in an international context. They operate in a small domestic market and will need entry into an international market in order to succeed. Both municipalities and county authorities depend on health technology companies having a larger market than just the domestic market in order to develop sustainable and innovative solutions that meet the needs of the health sector.

The Norwegian Association of Local and Regional Authorities (KS) has emphasised that health technology companies need support to reach an international market. It is important to use the arenas and meeting places that the Foreign Service and Innovation Norway can provide. Networks and collaboration between companies can help them learn from each other and see that they can be stronger together. KS also points to the need for good incentive schemes that help the Norwegian health industry enter international markets. Product

development is expensive in Norway, which can be an obstacle. Health technology companies must be guided and supported to adopt European and international standards in their solutions, so that they are relevant internationally.

Norway's Export Strategy

The Minister of Trade and Industry launched Norway's Export Strategy (Hele Norge eksporterer) in March 2022. This is both a new way of organising how we develop our national export promotion strategies as well as a programme to build a Norwegian 'export culture'. The Norwegian Ministry of Trade, Industry and Fisheries is responsible for analysing, prioritising and deciding these strategic initiatives. In order to ensure participation and co-funding from the business sector, the Export Advisory Council has been established comprising representatives of the business sector and the social partners, which will propose and develop specific export promotion initiatives and advise the Government on the strategic direction of the export work. The model assumes that it is the business sector itself, through the Export Advisory Council, that will propose new national initiatives, while the Ministry decides how the initiatives will be implemented, including the Government's contribution to funding and allocation of funds. Innovation Norway will implement the

initiatives in close cooperation with the other policy instrument agencies, the Foreign Service and the industry business sector. The first two initiatives are in offshore wind and the maritime sector.

The Export Advisory Council has proposed to the Minister of Trade and Industry that one of the next sectors to be designated as a strategic export promotion initiative should be within the health industry. In June, the Minister of Trade and Industry and the Minister of Health and Care Services announced that the advice from the Export Advisory Council will be followed up, which means that the health industry will be one of the special export promotion initiatives under Norway's Export Strategy. The Export Advisory Council is now drafting proposals for the content of such a future export initiative, in close cooperation with other relevant stakeholders and companies in the health industry. A report with proposals from the Export Advisory Council is expected in autumn 2023.

Export Finance Norway

Eksfin is part of the public policy instrument system. Eksfin offers loans and guarantees to foreign buyers of Norwegian exports. In 2022, Eksfin also received an expanded mandate to furnish loans and guarantees for export-oriented investments in Norway. Eksfin's services were also recently expanded to



include guarantees for loans for working capital to Norwegian companies. As of 18 January 2022, Eksfin had approximately NOK 129 million in outstanding loans and guarantees in the health industry. Most of this was guarantees.

Marketing Norway in the health industry in specific countries

Innovation Norway has several activities aimed at relevant markets for the internationalisation of the Norwegian health technology such as the EU and the US. Within the EU, the Nordic region, and Denmark and Sweden in particular, is a priority, in addition to Germany and the UK. Efforts are also being made to target other markets such as Asia and North America.

Innovation Norway implements initiatives based on the maturity of the markets. Investments are made, for example, via company presentations online and articles on the health technology aimed at the relevant market.

In 2022, the governments of Norway and Sweden agreed to work more closely together to facilitate greater business cooperation, among other things by making it easier for companies to scale up their business by providing easier access to a Nordic market. As a follow-up to this work, Innovation Norway's office in Sweden has established an export programme (Global Growth) for Norwegian health companies. Furthermore, in May 2023, Team Norway participated with a Norwegian pavilion at the Nordic region's largest trade fair for eHealth, Vitalis, in Gothenburg,

where around fifteen Norwegian companies participated. The Swedish and Norwegian markets share many of the same challenges, which provides opportunities for more cooperation, as well as for the export of Norwegian solutions. In Denmark, a Global Growth programme was implemented, which led to a joint collaboration project with the Danish Export Association in the field of health technology. In the US, plans are under way for a major initiative, HPO HealthCare USA, which will focus on both medical technology and biotechnology.

The road ahead

- ✧ Invest in export promotion. The Hurdal Platform aims for a 50 per cent increase in Norwegian exports by 2030 (excluding the oil and gas sector). (NFD)
- ✧ Work to ensure that the entire breadth of the Norwegian business sector can realise its overall export potential, seen in the context of Norway's Export Strategy and the development of major national strategic export initiatives. (NFD)
- ✧ Together with relevant businesses, develop and initiate a separate export promotion initiative within the health industry as part of Norway's Export Strategy. (NFD)
- ✧ Use various forums with relevant countries – both bilaterally and multilaterally – to emphasise the potential inherent in strengthened cooperation between Norwegian and international stakeholders.

Summary and the road ahead

The Government's policy platform flags our ambitions for the Norwegian health industry. These ambitions are specified in more detail in this roadmap. Measures to develop the Norwegian health industry and following up the roadmap are the responsibility of several ministries. We wish to see a close and constructive dialogue with industry, the policy instrument system and the health and care sector about how well measures and other framework conditions respond to their needs.

In that regard we are establishing an arena for a strategic dialogue between the authorities and the health industry. The purpose of such an arena is for relevant ministries and the health industry to be able to discuss the roadmap's prioritised areas and other framework conditions. It is meant to facilitate a better mutual understanding of the challenges we face and contribute to a comprehensive follow-up of the roadmap. At the same time, it is of course important that the stakeholders interact well with each other, for example through the HealthCare21 Advisory Board.

There is a great potential for industrial development in health and life sciences. The development of products and services is important when we evolve future health services, as well as understand both current and future challenges and crises. At the same time, the health industry can provide new and beneficial knowledge-based jobs across Norway, as well as contribute to value creation in the Norwegian economy. It is therefore important for all of us that we succeed in this area.



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