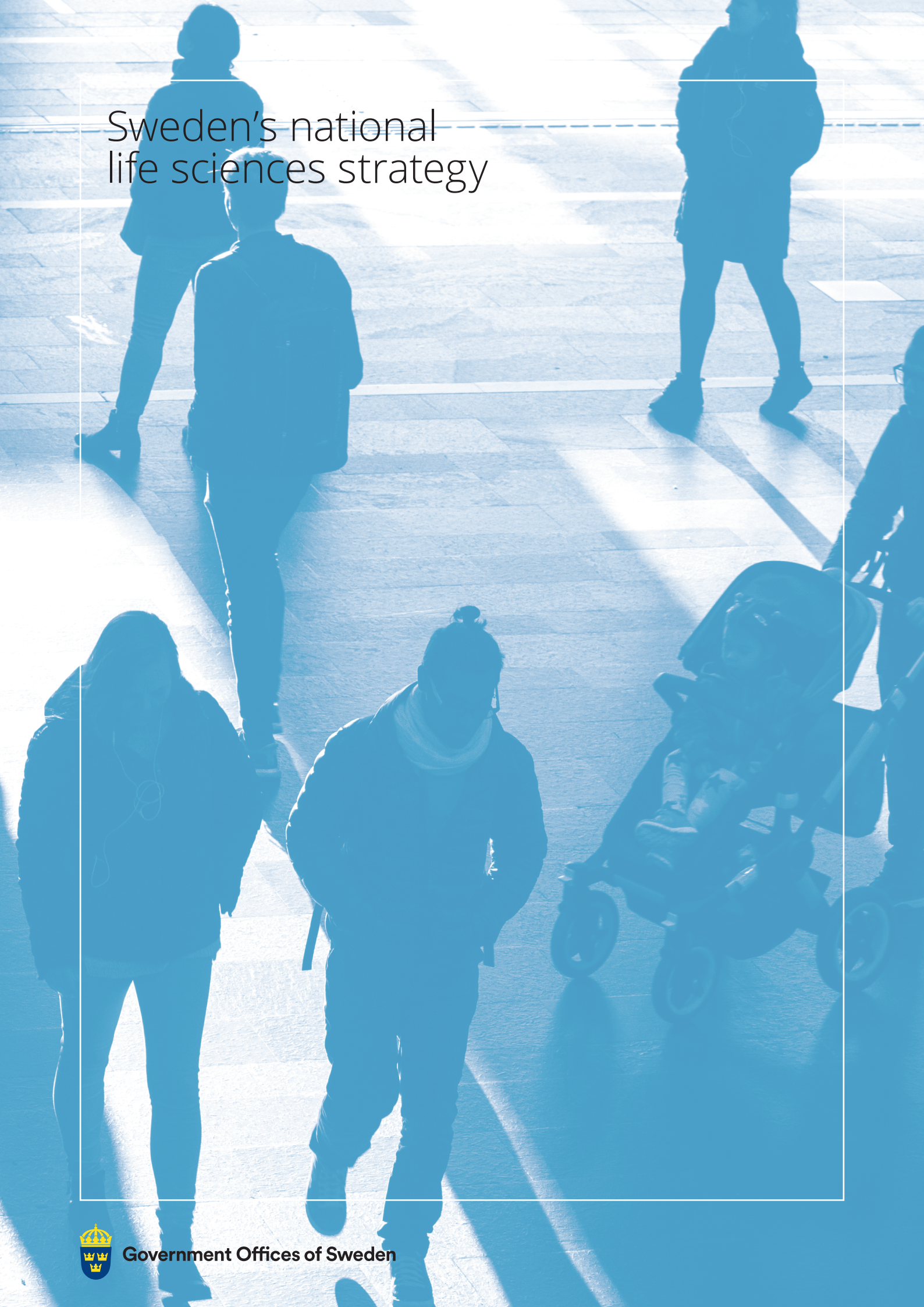
Sweden's national life sciences strategy



Government Offices of Sweden

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Foreword

Sweden is a knowledge nation that has long invested in equitable health care, research and innovation. This has benefited our economic prosperity, advanced our health care system and improved the health of our population.

Sweden aims to be a leading life sciences nation. To tackle the challenges facing Sweden's welfare, there must be greater focus on preventing ill health and disease. We need to rapidly introduce new working practices, technologies and treatments to improve the effectiveness and quality of health and social care. We can achieve this through world-leading research and innovation, favourable conditions for industry and an ecosystem of collaboration that attracts investment.

Sweden has the necessary prerequisites: world-class research and research infrastructure, a health care system of high international standard, competitive industry and world-leading innovation. The Government is firmly committed to continuing to develop these areas of strength. We want Sweden to lead the international transition to precision medicine; it is under way and the life sciences sector plays a major role in it. Ultimately, it is a matter of improving health for women and men, girls and boys, improving patient empowerment and self-management of care and treatment, and empowering care recipients and increasing their confidence.

Today's health care is yesterday's research, and today's research is tomorrow's standard health care treatments. The pace of change is accelerating; major medical breakthroughs have taken place in recent years. Several types of cancer that we were previously powerless in the face of can now be cured or treated. Advances in assistive technologies offer completely new opportunities to improve the quality and effectiveness of care services. This can make daily life easier for both care recipients and staff. Similarly, the application of

artificial intelligence creates new opportunities for using data and digital solutions in intelligent decision support systems and diagnostics. The changes taking place also call for skills development and create the need for new health professions, such as those that combine technological and medical expertise. Attracting top talent will be vital to ensure success.

Sweden's strength is collaboration between industry, academia and the public sector; through collaboration we can build a stronger society. Together with the entire life sciences sector, we will lay the foundation for continued progress – to improve the health of the population, develop our health care system and strengthen Sweden's economic prosperity.

Ibrahim Baylan
Minister for Enterprise and Innovation

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Minister for Higher Education and Research

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Minister for Health and Social Affairs

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Sweden's national life sciences strategy

Sweden aims to be a leading life sciences nation. Life sciences contribute to improving health and quality of life of the population, ensuring economic prosperity, advancing the country as a leading knowledge nation and achieving the 2030 Agenda for Sustainable Development.

This national strategy aims to strengthen the long-term competitiveness of Sweden as a life sciences nation. The Government's life sciences strategy is intended for stakeholders with a mandate and ability to change conditions for life sciences in Sweden. Sector stakeholders primarily include universities and higher education institutions, government agencies, authorities responsible for health and social care services, companies operating in the life sciences area and public and private financiers of research and innovation. Patients, care recipients, and health and social care staff are key in this context, and their experience and expertise must be harnessed in the change process – but without burdening them or similar groups with responsibility for development at national level.

To strengthen the life sciences sector in Sweden, the Government has established a life sciences coordination function[1] – the Life Sciences Office – to serve as a link between life sciences sector stakeholders and the Government's work. The Office aims to promote knowledge development, innovation and quality – in health and social care and at universities and higher education institutions – and improve conditions for the establishment and operation of life sciences companies in Sweden. The aim of the strategy is to support the initiatives and engagement to strengthen life sciences already present in society. The strategy builds on the policy direction previously adopted by the Government. In the strategy, the Government outlines objectives in priority areas in which change is considered particularly important. The strategy and its objectives are based on the current financial framework.

The role of life sciences in addressing health challenges and strengthening competitiveness

The pace of innovation is high in the life sciences sector. Data-driven innovative solutions and scientific advances will have a fundamental impact on developments in prevention, diagnostics, treatment, monitoring, habilitation and

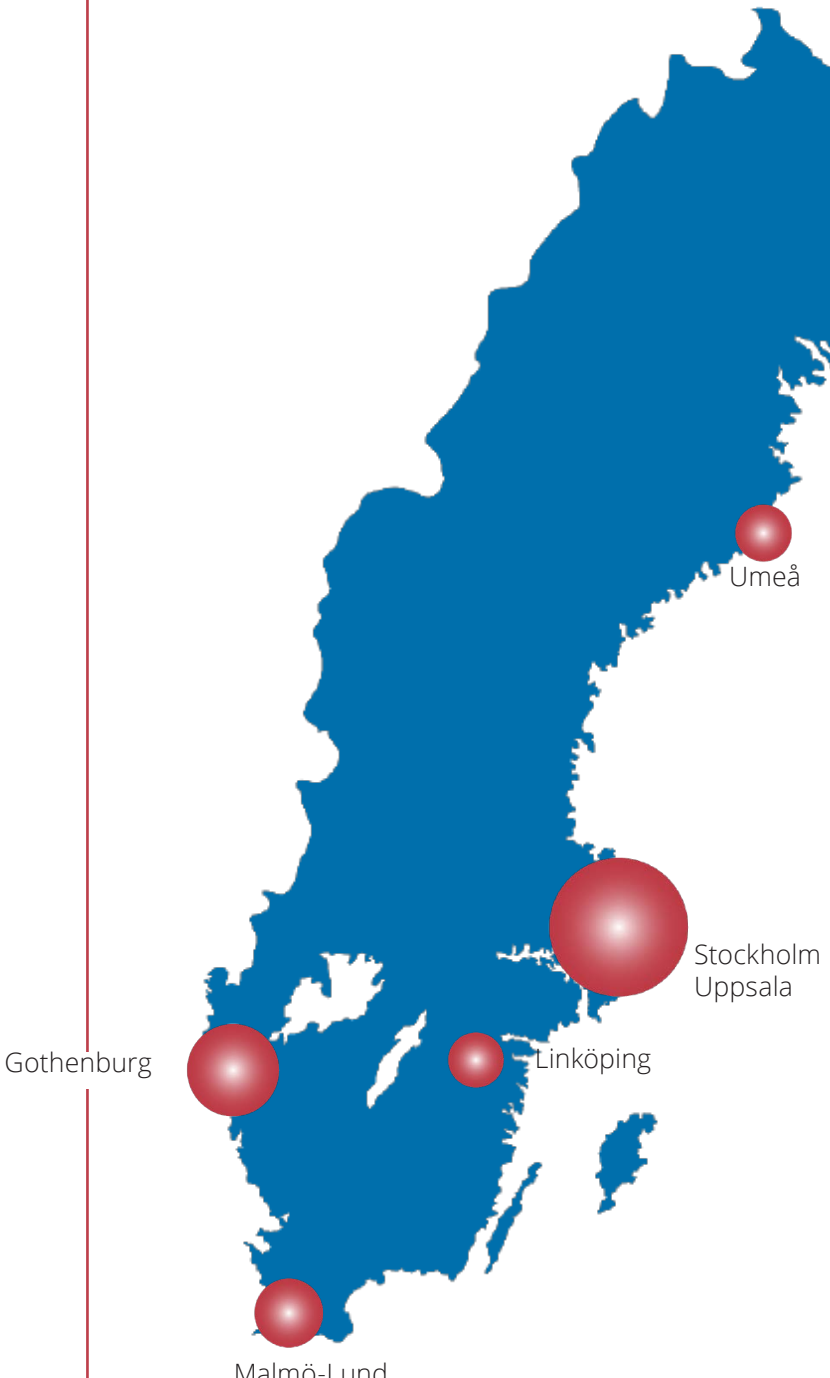
What is the life sciences sector?

The life sciences sector includes companies, higher education institutions, and public stakeholders at municipal, regional and state level whose activities contribute to promoting human health. The sector comprises research, higher education and innovation, the development of pharmaceuticals, medical devices and treatments, as well as prevention, implementation and monitoring.

[1] N2018/00814/IFK Establishing a life sciences coordination function at the Government Offices (in Swedish).

Strong life sciences clusters in Sweden

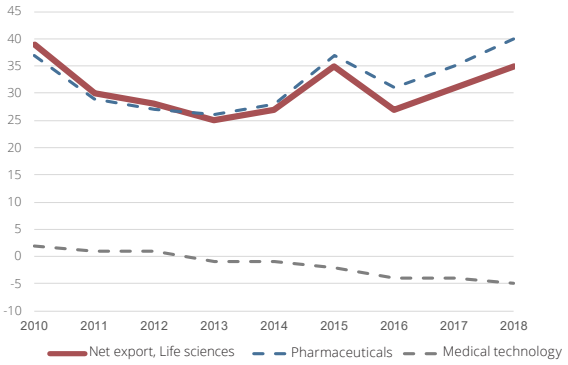
More than 42 000 employees
in almost 3 000 companies



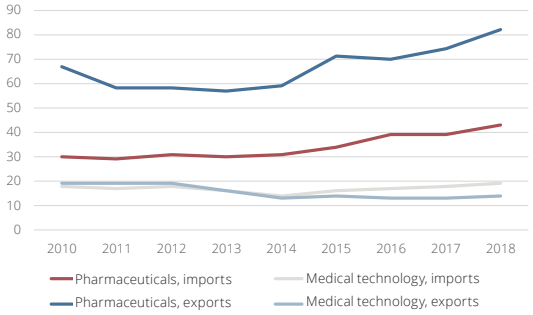
Region Skåne, which includes Malmö-Lund, is part of Medicon Valley, the bi-national cluster of the Öresund region of Skåne-Copenhagen.

Sweden's life sciences industry

Net exports



Sweden's trade in pharmaceuticals and medical technology



Sweden's foreign trade in pharmaceuticals and medical technology in SEK billions. In 2018, exports of pharmaceuticals accounted for 5.7 per cent, and medical technology 1 per cent, of Sweden's total exports.

Source: *Growth in Sweden's life science industry 2014–16*, **Swedish Agency for Growth Policy Analysis, 2018**

rehabilitation. Sweden's capacity to harness these new opportunities will have consequences for costs to society, health outcomes and competitiveness. Making such advances available should be facilitated. At the same time, all measures in the area must be implemented ethically, ensuring information security and privacy protection, as well as data protection and secrecy.

Sweden is facing major health challenges at regional, national and global level. Health inequalities across socio-economic groups are increasing, the incidence of overweight, obesity and high blood pressure is rising and conditions indicative of mental ill health are becoming increasingly common. Disability and gender also have a bearing on health. The effects of socio-economic factors, disability and gender are also mutually reinforcing. Demographics are changing and the proportion of older people is increasing. This results in a greater need for health and social care interventions. Modern health care is further challenged by growing antimicrobial resistance and global pandemics.

To address these health challenges in the long term, Sweden needs to continue to invest in research and innovation, based in part on the principle of universal design. Technological and scientific advances must be promoted and applied. OECD data[2] shows that relevant countries in 2017 invested on average only 2.8 per cent of their total health care expenditure in preventing illness and disease (3.3 per cent in Sweden). Sweden – and the rest of the world – must change approach and invest more in health promotion and prevention of both lifestyle and other diseases. Greater knowledge is needed about how ill health can be prevented, at both individual and system level, to identify the most effective measures. Shifting to early diagnostics for children and adults also increases the chances of preventing or mitigating disease.

Health care is currently being transformed through increased opportunities for personalised care – or 'precision medicine'. This transformation is challenging existing working practices, priorities and structures, and creating new needs. Sweden must now ensure that all parts of the health care system have the prerequisites to enable this system transformation to continue. This must take place in close collaboration with industry, relevant government agencies, universities and higher education institutions. It is vital for the health and quality of life of the population that conditions are favourable for implementing new technologies in the health care system. Whole-genome sequencing diagnostics is already being used today to identify the optimal treatment of certain cancers, reducing the significance of the location of the tumour in the body. Instead, the focus is on the type of cancer cells causing the disease. Other patient groups that particularly benefit from genetic diagnostics include those with rare hereditary diseases. The cause of around 250 such diseases are identified every year, and each new diagnosis may represent the launch point for developing targeted, potentially curing, therapies.

Parallel with developments towards precision medicine, a structural change is under way in the Swedish health care system. It is aimed at developing a modern, equitable, accessible and effective health care service focusing on primary care, and ensuring that care interventions in highly specialised care are allocated at the optimal level ('level structuring'), both regionally and nationally.[3,4] With the support of the Swedish Association of Local Authorities and Regions, the regions are also establishing a common health care knowledge management system.

Long-term development efforts to improve health include social, economic and ecological sustainability. The incentive for a rapid climate-smart transition is strong, because this transition is a prerequisite for our health and wellbeing in the long term. The 2030 Agenda must therefore serve as a guide.

What is precision medicine?

Precision medicine refers to diagnostic methods and therapies for personalised screening, prevention and treatment of disease, applied at individual level or to specific segments of the population. The new opportunities offered by precision medicine are based on recent advances in e.g. molecular biosciences (the 'omic' technologies) and bioinformatics, and the emergence of new high-resolution imaging technologies.

[2]OECD Health Statistics 2019 and own calculations.

[3]ToR 2017:24 Coordinated development of a modern, equitable, accessible and effective health care service, focusing on primary care (in Swedish).

[4]S2017/00506/FS Assignment to develop a procedure for level structuring of highly specialised care (in Swedish).

Illustration: AstraZeneca

Sweden is a successful research and innovation nation. The life sciences industry is one of our basic industries, but international competition is intensifying. Several comparable countries have made substantial investments in life sciences.

To harness the potential in the sector, a strategic and integrated approach, with clear objectives, is required. Broad collaboration, with clarity regarding responsibilities, is needed to reach consensus on which measures will be necessary from each stakeholder.

As a long-term framework, concrete initiatives will be regularly linked to this strategy. The strategy is based on input from sector stakeholders, such as higher education institutions, government agencies, interest organisations and companies, including the life sciences partnership group. The Government has identified eight priority areas in which change is considered particularly important:

1. Structures for collaboration
2. Unlocking the potential of health data for use in research and innovation
3. Responsible, secure and ethical policy development
4. Integration of research and innovation into care delivery
5. Assistive technologies for increased independence, participation and health
6. Research and infrastructure
7. Skills supply, talent attraction, and lifelong learning
8. International attractiveness and competitiveness

Photo: Johan Strindberg Bildhuset/TT Nyhetsbyrå

Eight priority areas and 30 objectives

1. Structures for collaboration
2. Unlocking the potential of health data for use in research and innovation
3. Responsible, secure and ethical policy development
4. Integration of research and innovation into care delivery
5. Assistive technologies for increased independence, participation and health
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8. International attractiveness and competitiveness

1. Structures for collaboration

Broad collaboration is essential to enable Sweden to be a globally competitive life sciences nation. The transition to precision medicine in health and social care will require engagement from all stakeholders in the sector. System innovation is key to harnessing new digital opportunities and data use that will enable the delivery of effective, accessible, personalised and preventive health and social care services. Stakeholders in the life sciences sector have different assignments, clients and priorities, and work towards similar but somewhat different goals. This gives the sector an inherent complexity, making collaboration and coordination more difficult. Stakeholders in the sector demonstrate strong engagement and a clear understanding that collaboration is key to achieving improvements. Collaboration is also important for achieving greater staff mobility and skills development throughout the sector.

Collaboration is particularly important in relation to the regional responsibility for planning and delivering health care, and coordinating and facilitating regional development. The regional areas of strength and specialisation need to be encouraged to act as engines to boost Sweden's life sciences internationally. Regional life sciences strategies, produced by the regions themselves, are important for developing Sweden's strengths, while also needing to be synchronised with initiatives conducted under the national strategy.

Several government agencies have assignments and responsibilities in the life sciences area, such as regulation, supervision and issuing permits. Their areas of responsibility are related from various perspectives, which is why collaboration between them is vital. They are key actors in developing the sector and Sweden's attractiveness as an international partner. A number of government agencies come together in the Council for Knowledge Management.[5] The Council's work helps ensure that the right knowledge reaches the responsible authorities and professions in health care and social services. Linked to the Council is an inter-agency group, comprising representatives from regions and municipalities, which is tasked with informing the Council of areas in which the responsible authorities need knowledge.

The Government has launched four innovation partnership programmes for the electoral period 2019–2022, one of which is in health and life sciences. A partnership group, including representatives from health care, universities and higher education institutions, industry, patients and professions, advises the life sciences innovation partnership programme and the Life Sciences Office. Through cross-sectoral mobilisation, this innovation partnership programme aims to tackle major health challenges and strengthen Sweden's global innovation capacity and competitiveness. The National Innovation Council, led by Sweden's Prime Minister, works closely with these innovation partnership programmes.

In addition to the innovation partnership programmes, the Government has undertaken a range of other initiatives to strengthen national collaboration. The Swedish Governmental Agency for Innovation Systems (Vinnova) funds strategic innovation programmes that facilitate national mobilisation and make common priorities and initiatives between

[5]Ordinance on central government knowledge management in health care and social services (2015:155, in Swedish).

sector stakeholders possible. In life sciences, the strategic innovation programmes Swelife and Medtech4Health play an important role. Moreover, the Swedish Research Council funds Clinical Studies Sweden, a network of regional nodes aimed at strengthening the conditions for conducting clinical studies in Sweden.
Nordic cooperation on policy issues would improve the possibility of using combined population and patient bases. Continued development of Nordic cooperation – including on clinical research and clinical studies, the use of biobanks and health data, patient mobility and the application of artificial intelligence – would improve the entire region's competitiveness in relation to the global life sciences sector.

Objectives

1.1 Strengthened national coordination in life sciences

The Government wants to strengthen the Swedish life sciences sector through clear national leadership. The Life Sciences Office contributes to more effective collaboration, cooperation and coordination. Collaboration between government agencies is key to ensuring that a uniform national approach is achieved for the development of life sciences in Sweden.

1.2 Partnerships for regional and national mobilisation

The Government considers it essential that developments in life sciences are conducted jointly and in a coordinated manner – at national, regional and local level – in close collaboration with industry, universities and higher education institutions. Partnership with the regions can demonstrate a shared ambition for life sciences and create conditions for realising it.

1.3 Nordic region – a world-leading life sciences hub

In the Government's assessment, broader Nordic cooperation can contribute to increased competitiveness. Joint policy development efforts can contribute to harmonised implementation of new digital solutions and precision medicine.

2. Unlocking the potential of health data for use in research and innovation

System solutions to unlock the potential of health data are essential to enable Sweden to spearhead developments in life sciences. Huge volumes of data – 'real-world data' – are generated daily in self-management, health and social care. A prerequisite for using this data to develop future care and preventive interventions is compliance with legislative requirements for protection of privacy, such as protection of natural persons with respect to processing personal data, public access to information and secrecy, information security and security protection.[6]

Technological developments mean that the volume of health data is more extensive and potentially more accessible than previously. The transition to mainly digital management of personal data in both social services and health care has taken place at the same time as these areas have undergone changes in their organisation and responsibilities. Consequently, the need for information sharing between care providers or practitioners to provide good and safe health and social care, while maintaining privacy and security, has increased in recent years. In light of this, the Government considers that a review of certain issues in the area is required and has therefore appointed an inquiry.[7] Enabling data to be used in research, innovation and development requires interoperability. This includes, for example, the technology to share data (technical interoperability), the use of the same terms/context references by those who input data to the system (semantic interoperability) and a legal basis for processing data generated in another activity (legal interoperability). Secure identification and authorisation solutions are other requirements. There are a number of areas in which existing legislation – regulating how data may be used for research and innovation – is interpreted differently by different stakeholders. This includes personal data processing carried out in health care for sample size calculation (pre-screening of potential patients ahead of clinical trials) and the regulation of research that includes acutely unconscious patients. The fact that legislation is interpreted differently may be due to varying levels of knowledge among stakeholders, but it is also due to actual ambiguities and obstacles that may need to be addressed or clarified.

At the same time, the changing use of new technology and new innovations based on data sharing and interconnected information systems makes threats more difficult to detect, risks more difficult to assess and dependencies more difficult to examine. This poses particular

What is Real-World Data?

There is no single, generally accepted definition of 'real-world data'. In this context, it refers to information on the treatment and health of individuals, found in registers and medical records, and lifestyle information collected through mobile applications and wearable technology. Such data is not collected primarily for scientific use, but it can be used for research in accordance with existing regulatory frameworks. Findings from observational studies based on data from everyday clinical practice are called 'real-world evidence'.

[6] *National strategy for society's information and cyber security* (Govt Communication 2016/17:213).

[7] ToR 2019:37 Review of certain issues relating to personal data processing in social services and health care services (in Swedish).

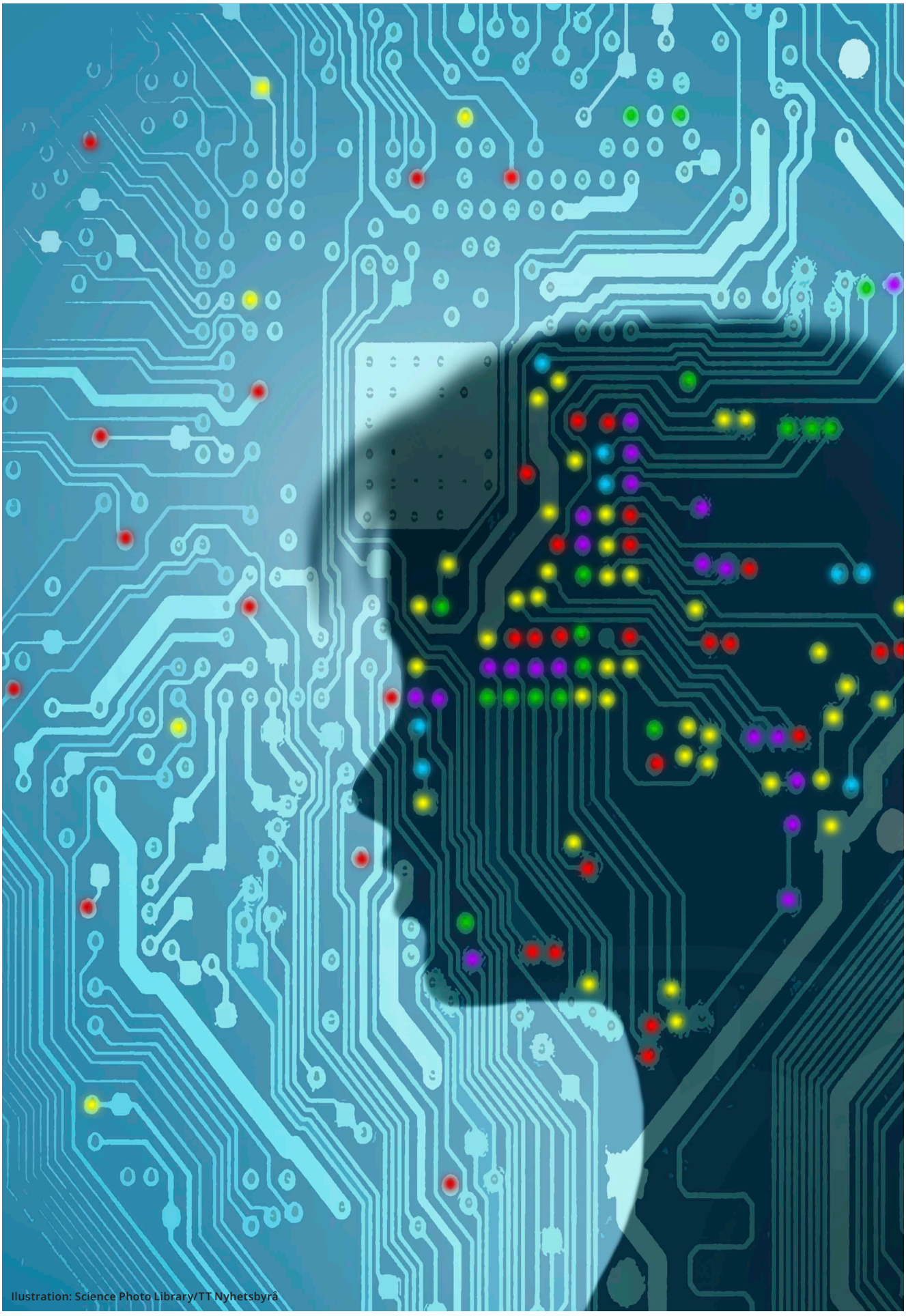


Illustration: Science Photo Library/TT Nyhetsbyrå

challenges for information management in vital public services such as health and social care. Medical records and registers contain particularly sensitive personal data, which raises questions about public access to information and secrecy, data protection and privacy protection. The sharing of patient data and access to various types of registers bring many of these issues into the limelight. The same applies to assistive technologies in health and social care, and research and infrastructure.

Data generated in health and social care is stored in a variety of systems, such as medication modules, imaging diagnostic systems, laboratory reports and medical records systems. An essential prerequisite for making data accessible is that the regions ensure that their investments in future medical information systems take international standards and open platforms into account, and that these systems are developed to conform with strict standards of information security. Making data accessible also involves enabling data analysis and eliminating the need to transfer data from various sources for use in research and innovation (e.g. federating data). The Vision for eHealth,[8] adopted by the Government and the Swedish Association of Local Authorities and Regions, states that, by 2025, Sweden will be the best in the world at using the opportunities offered by digital transformation and eHealth. This joint commitment involves, for example, clarifying and, when necessary, changing regulatory frameworks, developing a more consistent use of terms, and standardisation. The Swedish eHealth Agency has been tasked with coordinating this work.[9]

Proper access to current data is needed to monitor and improve the quality of health and social care services. It is also an important tool in making health and social care services more effective, gender-equal and equitable across the country. Certain government agencies, such as the Dental and Pharmaceutical Benefits Agency, rely on data to carry out their tasks. This requires access to quality-assured data on care interventions and outcomes at different levels and for different stakeholders. To broaden data accessibility, especially in relation to the shift to delivering more quality and local health care, the National Board of Health and Welfare has been tasked with developing the national follow-up plan for primary care.[10]

Certain health data is transferred to different types of national or regional registers. The diagnosis-specific 'quality registers' have developed over a long period of time with the aim of improving and ensuring health care quality. In recent years, central government and the regions have made joint investments in these registers. An agreement between the parties[11] states that the registers should be used as a source of knowledge for clinical research, including cooperation with the life sciences sector. Other registers include the national health data registers. These are individual-based registers, provided by the National Board of Health and Welfare, and cover inpatient and some outpatient care interventions, dental care, causes of death and prescribed drugs. There are also biobanks, which are collections of samples prepared from human biological material such as blood samples. Within the framework of Biobank Sweden, regions and higher education institutions are cooperating to build an integrated health care infrastructure for biobanks. The Biobank Inquiry[12] has submitted proposals to adapt this legislation to facilitate developments and improve conditions for using samples and information in Swedish biobanks to meet the needs of patients, health care and research. The Inquiry has also proposed establishing a national sample register (the national biobank register).[13]

The Swedish Research Council maintains the Register Utiliser Tool (RUT), a metadata tool that can be used to quickly gain a quality-assured overview of the information that is available and can be linked from different registers. RUT includes national public authority registers, national quality registers, research-generated data and biobanks. New registers are being added to optimise the use of data in research, enabling RUT to function as a national portal for sources of register data. Health data is also stored privately by individuals – in health apps to monitor personal progress and in medical device apps that

[8]https://ehalsa2025.se/in-english/.

[9]S2019/01521/FS Assignment to make available and manage common national specifications (in Swedish).

[10]S2019/03056/FS Assignment to develop the national follow-up plan for primary care (in Swedish).

[11]S2019/02385/FS Authorisation to sign an agreement on support to national quality registers in 2019 (in Swedish).

[12]The Biobank Inquiry was tasked with reviewing legislation regulating the management of human biological material in biobanks.

[13]SOU 2018:4 *Biobanks of the future*, the Inquiry's final report (in Swedish).

assist patients with self-management of chronic diseases. Surveys show that the Swedish population is generally positive about the use of their anonymised data in health care research and development,[14] but people want to be informed if they are added to a register and want to be able to opt out.[15] A group of chronic disease patients, known as 'lead user patients' (*spetspatienter*), are already contributing knowledge and data generated as they participate in self-management. Self-reported data has great potential for use in care, and in research and innovation. However, to enable such data to be shared, solutions must be developed so sharing can take place while ensuring information security and privacy protection.

Efforts around the globe to promote access to and unlock the potential of health data for use in research and innovation are currently attracting global tech companies. The driving force is potential synergies gained by partnering with life sciences stakeholders on the use of health data. However, the interest of companies in accessing and using public data generated in Sweden must be balanced against the protection of the individual's basic rights and freedoms, such as protection of privacy, including protection of natural persons with respect to processing personal data, and must observe the importance of maintaining a high level of public trust in the open society.

Objectives

2.1 Effective and secure sharing of patient data

The Government considers that regions and municipalities need better conditions for sharing patient data between different care providers. The basic premise is to strengthen these developments in data sharing while continuing to deliver safe and quality health care, and while also respecting privacy and ensuring information security requirements are met.

2.2 Increased use of health data in research and innovation

The Government would like the use of health data in research and innovation to increase, while maintaining privacy protection, to contribute to improved patient care and industry development. Ambiguities and obstacles to processing health data, and associated ethical considerations, need to be addressed. This is essential to strengthen Sweden's prominent position in digital transformation and data use. At the same time, sectoral knowledge of applicable legislation needs to be improved.

2.3 Effective, secure and ethical use of register data

The Government considers that the life sciences sector's use of register data for research and innovation should increase. It is essential that infrastructure, legislation, guidelines and other forms of support contribute to the effective, secure and ethical use of quality registers and health data registers, for example, and that a review is conducted of patient opportunities to self-report their data.

2.4 Better use of biobanks

The Inquiry on the regulation of biobanks has submitted a proposal for a new biobank act. The Government intends to consider the proposal during this electoral period. Developing the use of biobank samples should be made possible, provided that sample donor privacy is respected. Secure and stable structures are also needed for storing, searching and retrieving information and samples from biobanks.

2.5 Follow-up using real-world data

In the Government's assessment, the possibility to follow up and use real-world data needs to improve. This involves good conditions for collecting and analysing such data, including self-reported data.

[14]Research!Sweden's 2019 opinion poll.

[15]*For safety's sake*, Swedish Agency for Health and Care Services Analysis, report 2017:10 (in Swedish).

3. Responsible, secure and ethical policy development

As artificial intelligence (AI) and precision medicine are introduced in health care, the need for policy development increases. This includes adapting regulatory frameworks, approaches and working practices to be able to benefit from technological developments and new innovations. Implementation must also take into account continued rapid technological developments, including the constant need for updating, and robustness and redundancy requirements. The Government has appointed the Committee for Technological Innovation and Ethics (KOMET)[16] for coordinated and accelerated policy development. KOMET will continuously deliver input on precision medicine and other areas. Policy development to enable increased focus on both prevention and implementation requires active collaboration between government agencies.

Sweden's ambition is to be a leader in harnessing the opportunities that AI can offer, with the aim of strengthening Sweden's welfare and competitiveness.[17] This requires long-term measures for knowledge-building, skills supply, access to large volumes of high-quality data and computational capabilities, along with effective national and international frameworks to guarantee transparency, trust, security, privacy protection and an ethical approach. This ambition is well in line with the Government's Digital Strategy, with the objective that Sweden will be the world leader in harnessing the opportunities offered by digital transformation.[18] However, the use of AI in health care in Sweden is still limited.[19] National investments in cross-sectoral cooperation are being made by AI Innovation of Sweden.[20] Alongside this, private financiers have made major investments in AI research, including a billion-kronor investment by the Knut and Alice Wallenberg Foundation.

Certain new gene and cell therapies, known as advanced therapy medicinal products (ATMPs), offer potential cures and may be used for patient groups currently on lifelong treatment or without treatment options. These new medicinal products pose major challenges for financing and pricing systems, as they have a high treatment cost per patient and treatment. For traditional medicinal products, this cost may be spread over a long treatment period and, if the treatment is ineffective, it can be discontinued. Regarding ATMPs, there is considerable uncertainty at present about the long-term effects. Because such treatments are given on one occasion, this uncertainty needs to be considered in connection with pricing and decisions concerning their use. However, these new therapies could result in a lower overall cost to society, but new working practices would be required. ATMPs also challenge current working practices in terms of evaluation, regulatory approval and introduction. The clinical studies on which regulatory approval is often based include only a small number of patients, which is why introduction into health care delivery is based on limited data volumes. This places greater demands on follow-up, i.e. constant access to relevant data (see also priority area 2), and regulatory framework development based on

[16] ToR 2018:85 Coordinated and accelerated policy development linked to fourth industrial revolution technologies.

[17] N2018.14 *National approach to artificial intelligence.*

[18] N2017/03643/D *For sustainable digital transformation in Sweden – a Digital Strategy.*

[19] *Digital care services and artificial intelligence in health care,* National Board of Health and Welfare report, 2019 (in Swedish).

[20] https://www.ai.se/en.

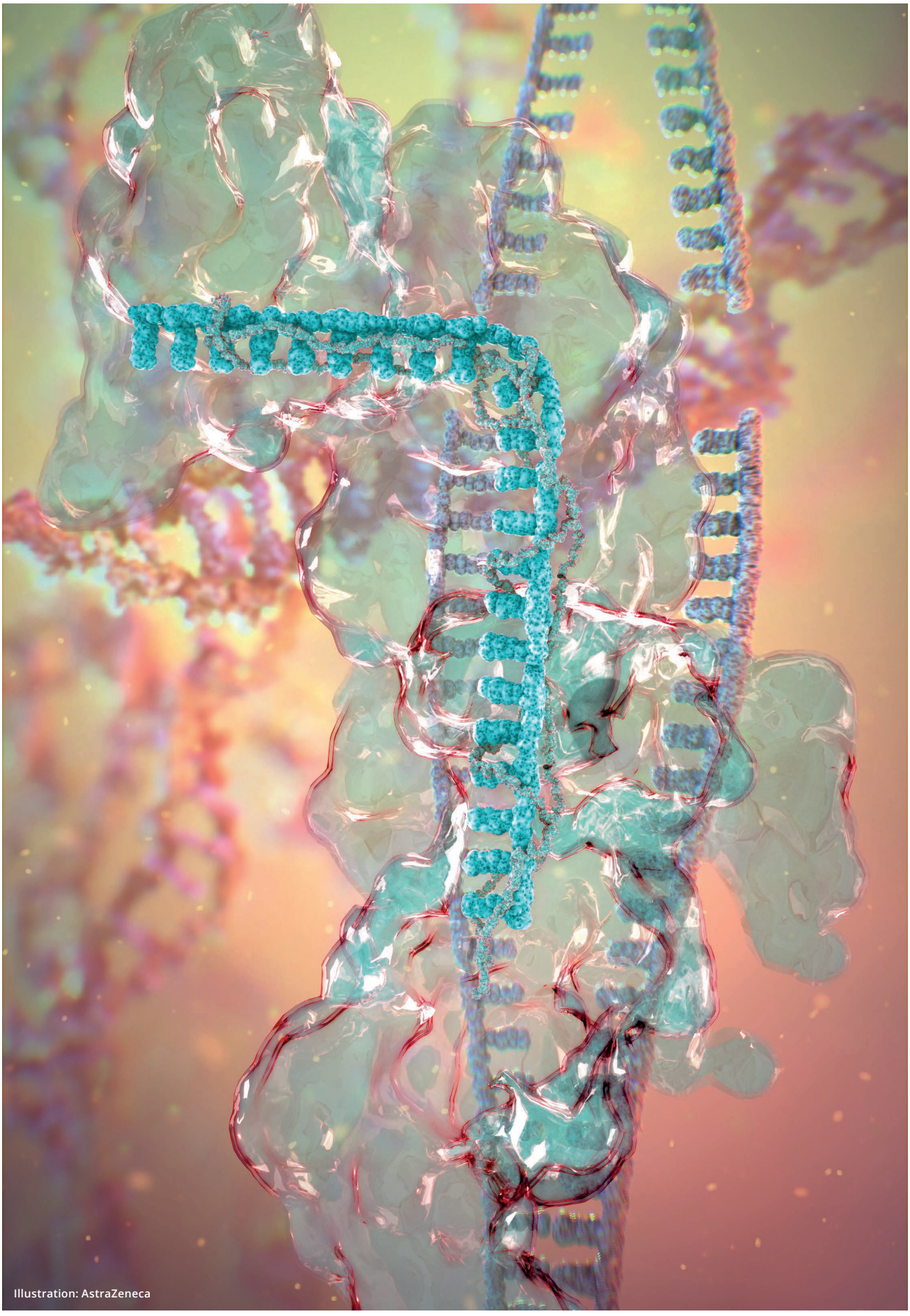


Illustration: AstraZeneca

knowledge-building through international collaboration in regulatory sciences, as conducted by the Swedish Medical Products Agency.

Research and development that is increasingly data-driven and largely based on sensitive personal data requires high security standards, both in terms of technology and privacy. The General Data Protection Regulation regulates the processing of personal data on a general level. Processing personal data in this area encompasses both general and sector-specific data protection regulations.

Using sensitive personal data for research purposes requires an ethical review. The organisation for ethical reviews in Sweden was recently changed through the establishment of the Swedish Ethical Review Authority. Moreover, from 2020 an independent board will be responsible for investigations and decisions related to research misconduct in the form of fabrication, falsification or plagiarism of data. Access to information from public registers for research purposes is regulated in the Public Access to Information and Secrecy Act (2009:400).

An ethical approach in clinical research, however, involves more elements than effective structures and legislation. It is essential that any clinical studies conducted are of high quality so that findings can be used and implemented. Anything else would be unethical treatment of patients who consent to give their time and data to these studies (see also priority area 4). In addition, equal opportunities should also exist to enable patients to take part in clinical studies, regardless of where they live in Sweden.

To better harness patients' potential and expertise, flexibility is needed with respect to where and when health care interventions are conducted. In the future, it should be possible for some of the interventions currently conducted in hospitals and health centres to take place to a greater extent at home. Perhaps this applies primarily, but not exclusively, to patients with chronic diseases who are well informed about their health condition. Enabling patients to take certain tests on their own at home, for example, can save resources while patients save time spent on travel. Providing more opportunities for patients to manage their own care can thus benefit both the health care system and the individual. This means that user needs must be considered in the development of services and products. Increased patient and user influence is therefore a key policy issue in the area of life sciences.

Collaboration between dental care and health care is important, as a large proportion of the population regularly seeks dental care. Dental examinations can potentially be used to detect diseases that are not directly related to oral health. Health screening in dental care could improve the prospects for early diagnosis and preventive interventions in primary care, for instance.

New regulatory frameworks for medical devices[21] and in vitro diagnostic medical devices[22] will apply from May 2021 and May 2022, respectively. Sweeping changes in these new regulations clarify the importance of new working practices and policy development. In several cases, the regulations require further evaluations of existing products as a result of stricter requirements. The adaptations required for this are expected to represent a major challenge for medical technology companies, particularly in view of the considerable shortage of notified bodies[23] at present. If evaluation and certification of new medical devices take a long time because of the shortage of notified bodies, there is a risk that Swedish companies and researchers will choose to look abroad to develop medical device innovations.

[21]Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[22]Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

[23]Notified bodies are independent organisations that assist and monitor manufacturers' efforts to verify that products comply with EU regulations, https://www.swedac.se/services/notified-appointed-bodies/?lang=en.

Objectives

3.1 Efficient process for implementing new therapies

The Government considers it necessary to optimise the time between the approval and implementation of new therapies. Greater knowledge is needed about how authorities responsible for health care can manage the costs and uncertainties associated with ATMPs, and what the need for new business and investment models will be. Moreover, better conditions are needed for conducting health technology assessments on medical devices in precision medicine.

3.2 Accelerated, secure and ethical policy development

The Government considers that the public sector's ability to identify and propose changes to regulatory frameworks, applications and working practices needs to be developed. The need for accelerated, secure and ethical policy development through policy labs, for example, is particularly great in terms of regulatory aspects. Sweden should be the country of choice for introducing new diagnostics and therapies, based on its excellence in regulatory issues.

3.3 Implementing new medical device regulations

The Government considers that access to notified bodies in Sweden must correspond to sector needs. It is crucial to ensure that notified bodies are in place so that the new medical device regulations can be applied.

3.4 Greater focus on preventive interventions and self-management

The Government considers that Sweden should increase its focus on health and prevention, including both preventive interventions to prevent the development of ill health and fully developed diseases, and initiatives to prevent recurrences (primary and secondary prevention). Improving capacity for early diagnosis will create better conditions for early treatment, prevention and self-management.

4. Integration of research and innovation into care delivery

New knowledge – in the form of health-promotion methods, products and treatments – is best developed and evaluated where care recipients are found, using their expertise and cooperation in the development process. Research and innovation need to be core components of health care, dental care and social care services. Collaboration with industry and academia is essential. This will require practical conditions and clear incentives. It must be organisationally and financially feasible for staff to take part, while their participation also needs to create added value for the participating patients, staff and services. The ongoing structural changes in the health care system, including increased focus on primary care and a greater degree of level structuring of highly specialised care, are changing the conditions for research and innovation in care delivery.

Photo: Sahlgrenska Universitetssjukhuset

Sweden's national cancer strategy and the structure of six collaborating regional cancer centres can be seen as a model for coordinated clinical development and implementation of new knowledge. Furthermore, the regions' health care knowledge management system, which also includes dental care, ensures that research and innovation are natural parts of these services' remit and that greater opportunities are provided for relevant implementation.

Cooperation between central government and the regions on medical training, clinical research and the development of health care is regulated by the ALF agreement.[24] When the agreement was renewed in 2015, a system was introduced to regularly evaluate the quality of health care and clinical research conducted at the university hospitals. According to the most recent ALF evaluation, Swedish clinical research is of high quality.[25] Access to quality registers and biobanks provides

What is the ALF agreement?

The ALF agreement provides almost SEK 2 billion per year in remuneration from central government to the regions for clinical research (SEK 1.89 billion in 2020).

Source: ALF, the agreement between Sweden's central government and seven regions on medical training, clinical research and the development of health care

[24]The agreement between Sweden's central government and seven regions on medical training, clinical research and the development of health care.

[25]Evaluation of the quality of clinical research in the regions covered by the ALF agreement, Swedish Research Council, 2018.

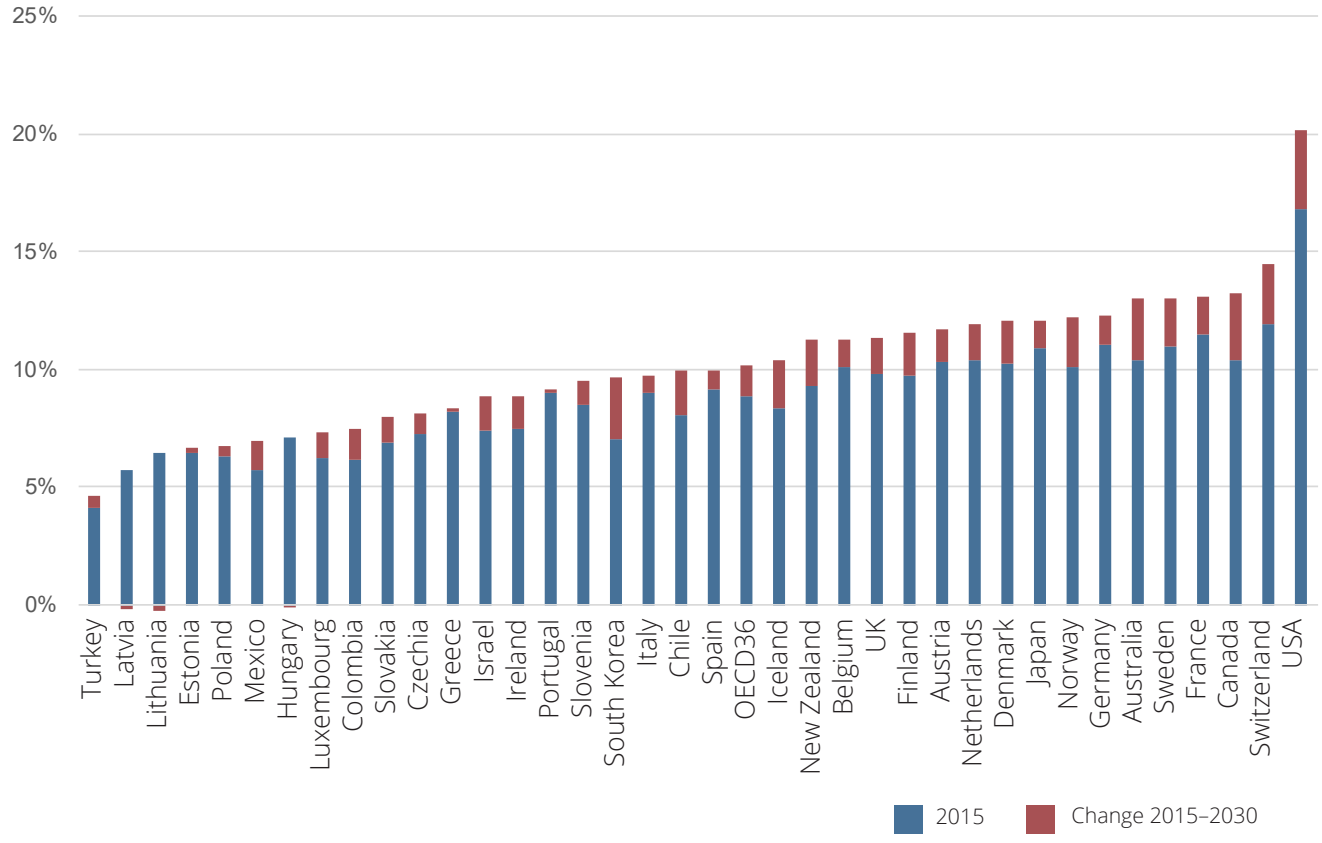
favourable conditions for conducting clinical research in Sweden. Greater coordination, based on national strategies, would further improve the quality. The evaluation also points to the need for greater internationalisation of Sweden's health care, for example through programmes for clinical practice and scientific work abroad.

Cooperation with the regions also takes place within the framework of Clinical Studies Sweden, a collaboration between Sweden's six health care regions funded and supported by the Swedish Research Council. The aim is to support and develop conditions for clinical studies in Sweden through regional nodes. In the 2000s, the number of clinical trials of medicinal products dropped in Sweden; this has often been interpreted as a reduction in clinical research in general. But this is not the case in terms of the funding of clinical research or the number of applications for ethical review.[26] Nevertheless, sector stakeholders perceive that conditions for conducting clinical research have deteriorated in recent years, as time and resources are increasingly in short supply in the health care system.

Major challenges – the need for access to digital health data, expertise and infrastructure – are expected at all levels of the health care system, as precision medicine's new, advanced diagnostics and treatment are developed and introduced. Neither highly specialised care services nor medical device and product manufacturers can develop and make these treatments available on their own.

Within the framework of Genomic Medicine Sweden, central government and the regions are collaborating to build up a national infrastructure for

Health expenditure as a percentage of GDP in 2015 and projected changes for 2015–2030



Health expenditure as a percentage of GDP in 2015 and projected changes for 2015–2030. Source: OECD *Health at a glance, 2019*

[26]The number of applications increased from 2 077 in 2010 to 2 461 in 2018 (excluding applications to make changes), figures from the Swedish Research Council, based on annual reports of the ethical review boards.

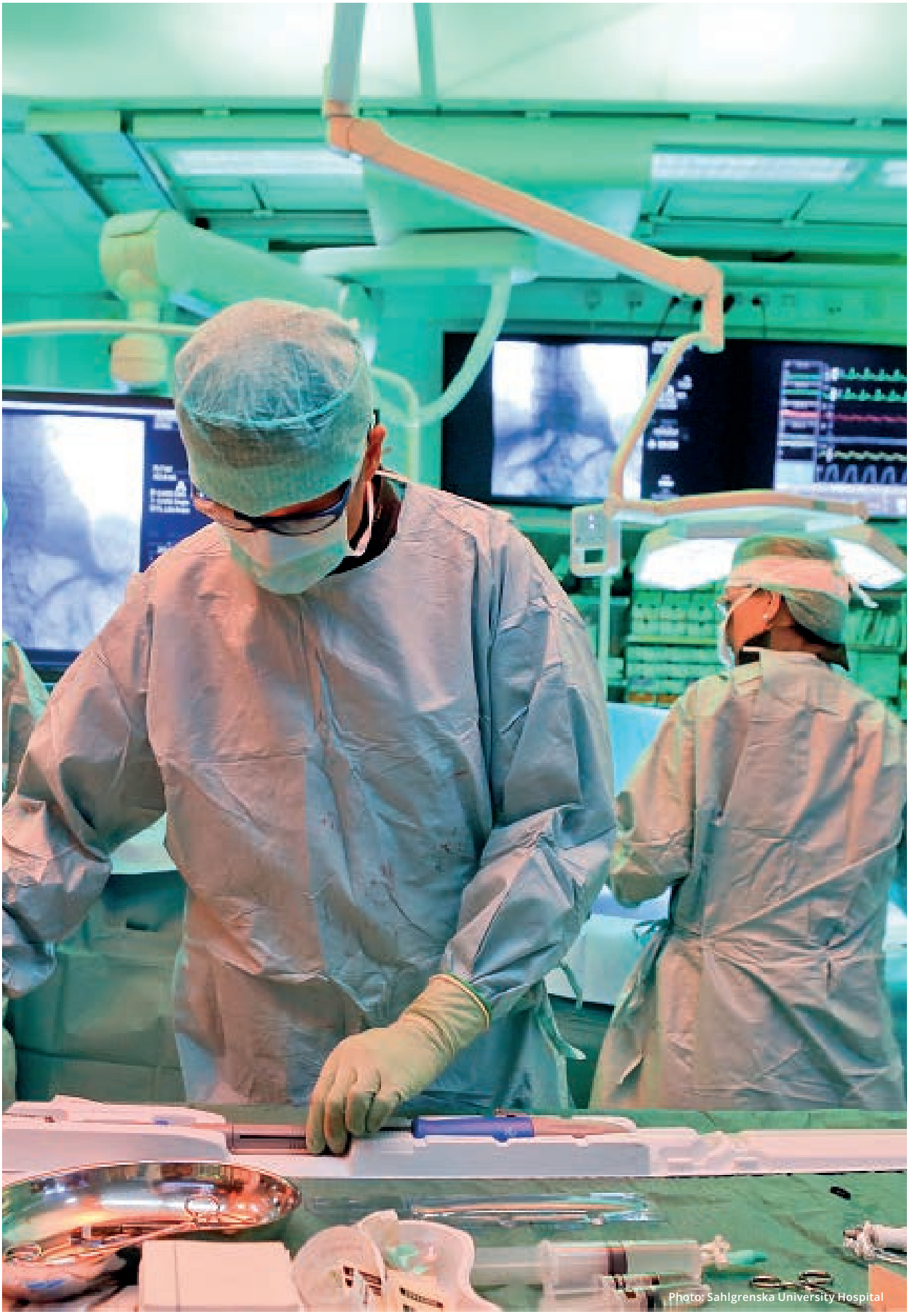


Photo: Sahlgrenska University Hospital

implementing precision medicine in Swedish health care services. The initiative originated in the Swedish Science for Life Laboratory (SciLifeLab) and is largely based on the infrastructure offered there. The goal is to make new whole-genome sequencing technologies available, cost-effectively and equitably, throughout the country and establish regional genomic medicine centres at the university hospitals.

Objectives

4.1 Incentives and good opportunities to combine clinical practice and research

The Government considers that good conditions for combining clinical practice and research throughout the health care system are essential. The combination of both clinical and research expertise is important for the continued development of Sweden's health care system. It is also important to create equivalent conditions in social care services.

4.2 More industry-initiated clinical studies in Swedish health care

The Government wants more clinical studies, conducted in collaboration with industry, to be located in Sweden. For Sweden to be able to compete for future studies, infrastructure is needed that permits rapid application in clinical use and effective evaluation of diagnostics and treatment outcomes. Ensuring that the health care system has the resources and expertise needed to take part in industry collaboration is also important.

4.3 High-quality clinical studies

The Government considers it important that clinical studies conducted in Sweden's health care system are of high quality. High quality is imperative to ensure that research findings can contribute to innovation, and be implemented and of benefit to patients and in health care.

4.4 Pioneering the introduction of precision medicine in care services

The Government wants Sweden to pioneer the implementation of precision medicine in health care services. This will require sustainable, supportive structures for diagnostics, bioinformatics and intelligent digital decision-support systems for prevention and treatment, and remuneration systems that encourage innovation and implementation of new technologies.

5. Assistive technologies for increased independence, participation and health

New digital services and health and assistive technology solutions have major potential to improve health and develop health care and social care services through prevention, habilitation and rehabilitation. The use of wearable technology and remote monitoring, for example, creates new opportunities to support individuals and provide system-level monitoring. At the same time, perspectives such as privacy protection, information security, robustness and redundancy must inform implementation. This will create conditions for more equitable health and increased quality and effectiveness in activities, while creating new business opportunities. To achieve this at system level, more effective public-private partnerships are required that include clear user involvement.

Digital technologies can increase security, confidence, participation and independence for everyone. They can help improve quality of life, particularly for older people and people with disabilities, and include wearable technology or mobile applications that provide reminders or support. Most municipalities are currently engaged in implementing assistive technology solutions in their activities, but progress is slow.[27] For example, there is a lack of knowledge about how assistive technologies can best be integrated into care services. This includes both how these products should be designed to ensure quality standards and usability, and new working practices. To increase this knowledge, public sector employees need to be involved in research work. Vinnova has co-financed several programmes aimed at more effectively identifying and harnessing existing knowledge and ideas within the public sector.

Digital health care services can, for example, improve access to initial care contacts and the ability to provide continuous monitoring. Sweden's launch of the 5G network is planned in 2020. By offering higher speeds and minimal latency, while guaranteeing a stable connection, 5G will enable the introduction of new and more advanced monitoring and remote care services. The internet of things (IoT) enables equipment with built-in sensors and connectivity to be controlled and share data via the internet. This increasing number of IoT-based solutions further reinforces the need for information security.

Technological solutions are expected to create new working practices that may increase the attractiveness of working in the welfare sector. This will also result in a broader labour market for technology and data professionals. But it will require ethical considerations and further examination of the legal framework for the use of digital technologies, and skills development initiatives for staff, especially in ethics. An important issue will be the extent to which assistive technologies can be used in health and social care for people with impaired decsion-making capacity.

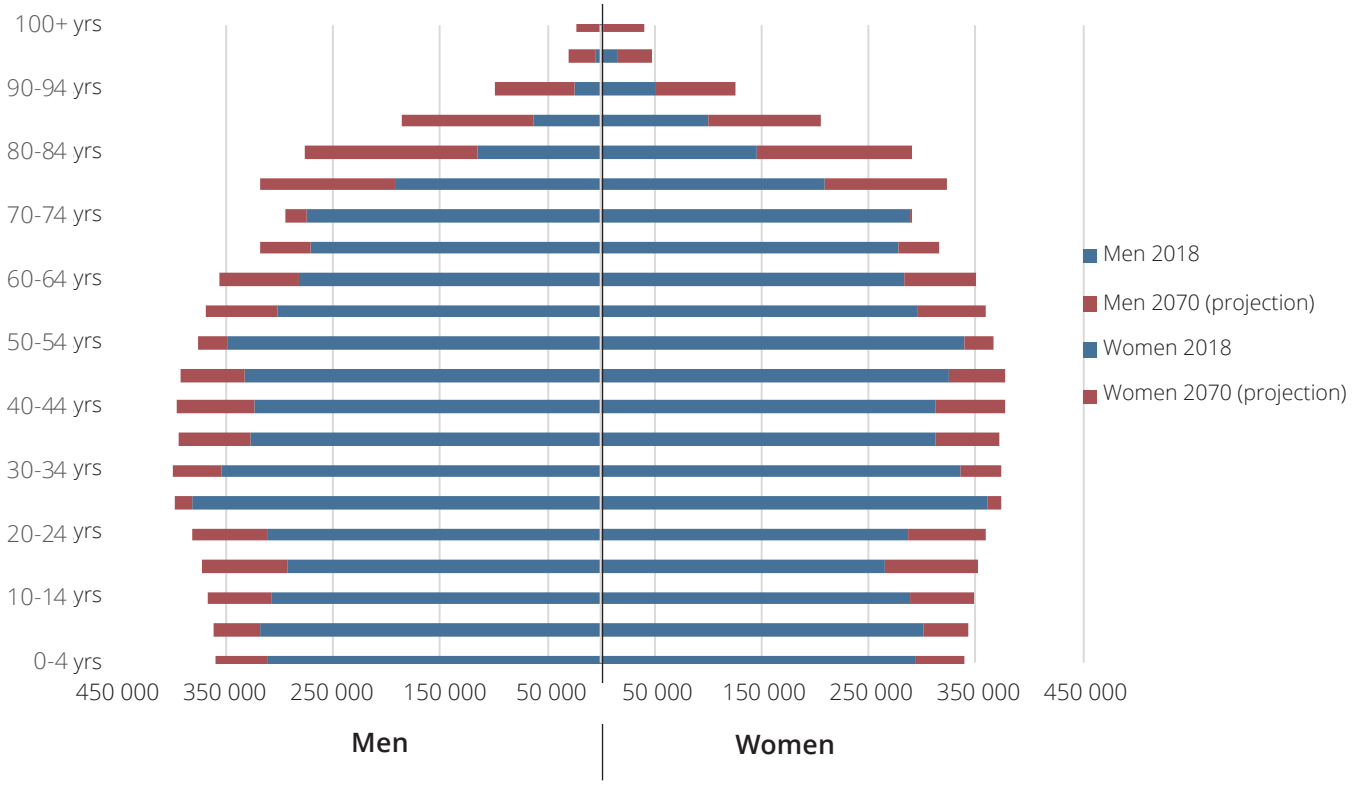
Municipal health care services comprise a large part of the total health care system. In 2016, municipal expenditure was around SEK 127 billion, equivalent to 26 per cent of total health care expenditure.[28] As many municipalities are small and have limited resources, there is a call for collaboration between municipalities, clearer national coordination and governance, and national support.

[27]Advances in eHealth and assistive technologies in the municipalities in 2019, National Board of Health and Welfare follow-up survey (in Swedish).

[28]*The state of play and advances in health, medical and dental care,* National Board of Health and Welfare status report (in Swedish).

Age distribution of Sweden's population

Population disaggregated by gender and age in 2018 and 2070 (projection)



The Government has therefore tasked the National Board of Health and Welfare with strengthening support to municipally financed health care services. The assignment is based on the action plan presented in the National Board of Health and Welfare's report, *Municipally financed health care services – pilot study* (in Swedish). Support includes both knowledge necessary for developing care services at system level and for ensuring high quality staff-patient interaction.

In the future, life expectancy is expected to increase in most countries around the world. Statistics Sweden's 2016 population projection estimates that life expectancy in Sweden in 2060 will be almost 90 years for women and almost 87 years for men. This means that the proportion of older people in the population is increasing. In 2017, almost every fifth person was over the age of 65. As the population ages, the risk of disease and multimorbidity increases. At present, people aged 80 and older account for around 5 per cent of the population, but by 2050 they are expected to account for around 9 per cent. To address the growing need for health and social care services, both systems need to be developed.

Older people in Sweden today are active well into their older years and, by international comparisons, have a high level of technology uptake.[29] This means that they have different expectations of health and social care compared with previous generations. An increasing proportion of older people with extensive and complex health and social care needs currently receive this care at home. The digital transformation in social care must be supported by technological solutions common to all public administration to provide the best conditions for good operational support for both professionals and care recipients.

There are considerable knowledge gaps in the scientific evidence for many areas within the mandate of social services. The Swedish Research Council for Health, Working Life and Welfare (Forte) is responsible for the national programme on applied welfare research, which works to improve knowledge in social services.

[29] Swedes and the Internet 2019, Swedish Internet Foundation survey.

Photo: Viktor Bjurlid /Totalskidskolan

The programme includes the PhD studies initiative, which aims to contribute to long-term knowledge-building in social services. In partnership with the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), Forte has also conducted a survey of the research needs in social services.[30] The areas assessed as most important for increased research include how social services can work on implementing, disinvesting and introducing evidence-based knowledge, what methods can be used to follow up on interventions, and how the participation of service users and their relatives can be developed within social services to improve the situation for care recipients/clients and the working practices of social services

[30] *Priorities for research on social services – perspectives from users, policy-makers and practitioners,* SBU and Forte, 2019.

Objectives

5.1 Harnessing the potential of assistive technologies
To improve quality and provide more effective working practices, the Government sees the need to accelerate digital transformation through better use of assistive technologies in care services and to promote preventive interventions, while also ensuring that privacy protection, information security, robustness and redundancy inform implementation. Assistive technology solutions need to be integrated into activities and, in some cases, linked to existing operational systems in care services to achieve the greatest possible benefit.

5.2 Development and collaboration for implementation
The Government sees the need for increased collaboration between regulatory authorities and industry. This collaboration aims to support the rapidly growing sector for health and assistive technology companies in Sweden by providing knowledge about regulatory frameworks that enable these companies to develop products and services in accordance with applicable legislation in the area. This will improve the opportunities for these companies to grow on a global market, with local ties in Sweden.

Photo: Justem Johnsson, Scandinav/ TT Nyhetsbyrån

6. Research and infrastructure

Research of the highest international standards is important for Sweden's development and prosperity in a globalised world. In contrast to those of central government, industry investments in research in Sweden have fallen for a number of years, particularly as a result of major global corporations choosing to locate a larger share of their research to international research environments outside of Sweden. This underscores the need for excellent and world-class research at Swedish universities and higher education institutions, and strong incentives for collaborating with the surrounding community.

International partnerships and contexts are needed to enable Swedish research to advance and for research quality to improve. They are also needed to tackle transnational social challenges and address the 2030 Agenda. Among international financiers, the EU is the most significant for Swedish researchers. Up to March 2019, Sweden had been granted EUR 1.4 billion in funding from the research and innovation framework programme Horizon 2020 in eighth place after countries that all have larger populations than Sweden. The next framework programme, Horizon Europe, will be the world's largest investment in research and innovation. For life sciences, the partnerships in the mission area 'Cancer' and partnership programmes will be key. The proposed Digital Europe programme for 2021–2027, which includes investments in AI and health data processing, is relevant in this context.

In recent years and in collaboration with industry and other stakeholders, the Government has invested in 'innovation hubs'. Two examples are BioVentureHub, co-located at AstraZeneca in Mölndal, and Testa Center in Uppsala. The AstraZeneca BioVentureHub offers access to

Sweden as a research and innovation nation

Sweden is one of the countries that invests the most in research, measured as a percentage of GDP. In 2018, the total expenditure for research and development conducted in Sweden amounted to approximately SEK 157 billion, corresponding to 3.3 per cent of GDP. Of this amount, public funding corresponded to 0.9 per cent of GDP.

Sweden was named the EU innovative leader in 2019. Sweden was the country that had the highest number of researchers per capita in 2015, and demonstrates a high level of scientific productivity, as measured by the number of publications per 1 000 inhabitants.

Swedish research is of high scientific standard. Sweden's share of highly cited publications is just over 11 per cent, placing Sweden 13th among the countries of the world.

The Times Higher Education World University Rankings 2020, which includes almost 1 400 universities across 92 countries, ranked five Swedish universities among the top 200: Karolinska Institutet (41), Lund University (96), Uppsala University (102), Stockholm University (175) and the University of Gothenburg (186).

Sources: Budget Bill for 2020 (Govt Bill 2019/20:1); European innovation scoreboard; Swedish Research Council, Swedish Research Barometer 2019; *Times Higher Education* World University Rankings 2020

Photo: Johan Persson, MAX IV, Lund university

the company's expertise and infrastructure for research groups from universities and higher education institutions and small enterprises in pharmaceuticals and medical technology. It has also initiated a mentoring scheme targeting university incubators and science parks. Testa Center offers environments and infrastructure for research, development and production of biopharmaceutical products, targeting companies and research groups at universities and higher education institutions. Testa Center is part of a larger billion-kronor investment in biopharmaceuticals that the Government has made in collaboration with private stakeholders. The initiative includes a national programme for protein research, method development and biopharmaceuticals production, and the Wallenberg Center for Protein Research, funded mainly by the Knut and Alice Wallenberg Foundation.

Research and innovation in life sciences are completely dependent on access to advanced research infrastructure. Important Swedish facilities in this area include SciLifeLab, MAX IV and the Swedish National Infrastructure for Computing (SNIC). SciLifeLab is a national resource centre offering infrastructure of the highest international standard for molecular biosciences focusing on health and environmental research. The centre has facilities in Stockholm and Uppsala, but involves collaborative projects with a number of universities around the country. MAX IV Laboratory, outside Lund, has the world's strongest synchrotron X-rays for materials and life sciences research. In proximity to MAX IV, the European Spallation Source (ESS) is under construction. It is currently one of the largest, highest priority research infrastructure projects in Europe, hosted by Sweden and Denmark. The ESS will be fully operational in 2025 and will be the world's most powerful neutron source, with applications in drug development, for instance. All these infrastructures generate enormous volumes of data, which must be managed effectively and efficiently. Life sciences research is becoming increasingly data-driven, requiring advanced infrastructures for data processing.

Higher education institutions that host research infrastructures generally offer access not only to equipment, but also to the staff, expertise and the


Photo: AstraZeneca

materials necessary to use the equipment. Advanced infrastructure is an important platform for cross-sectoral collaboration. The business model for using research infrastructure therefore needs to be reviewed to enable these costs to be shared by users. State funding for the construction and operation of national and international research infrastructures also needs to be reviewed to ensure the effective use of available funds to pay for both current and new investments.

Objectives

6.1 Strengthened cross-sectoral life sciences research

In the Government's view, cross-sectoral research and innovation that contribute to the sustainable development of health and wellbeing in line with the 2030 Agenda are a top priority. Free basic research is the foundation for being able to address health challenges in the long term.

6.2 Excellent life sciences research infrastructure

The Government wants Swedish life sciences researchers to have access to high-quality research infrastructure and to strengthen Sweden's position as a Big Science nation.

6.3 Increased and broader use of research infrastructure

The Government wants the use of Swedish research infrastructure to increase and wants users to represent a broad range of stakeholders to stimulate cross-sectoral collaboration.

6.4 Strengthened infrastructures for data-driven research and innovation

The Government considers that there is a need to strengthen digital infrastructure – such as computational resources for calculations and analyses, cost-effective data storage, advanced user support and increased network capacity for digital communication – to enable the processing of greater volumes of increasingly complex data.

6.5 Increased Swedish participation in EU programmes

The Government wants stakeholders in Sweden to work actively to influence the implementation of the next research and innovation framework programme, Horizon Europe, so that it addresses Swedish needs, priorities and strengths.

7. Skills supply, talent attraction and lifelong learning

Skills supply for life sciences companies and the public sector must be ensured to enable Sweden to compete as a leading life sciences nation. In a globalised world, with increasing mobility of individuals, the labour market and educational institutions are becoming more and more international and competition is intensifying for both students and people with cutting-edge expertise. Continuing digital transformation, automation and globalisation of activities results in rapid changes in the skills required. Greater need for lifelong learning – in the form of in-service training and further education of practising professionals, and career change training – requires flexible solutions.

Life sciences is a knowledge-intensive sector, often requiring specialised skills. Measures are needed both to effectively recruit internationally and to improve conditions nationally to produce the skills in demand.

Photo: Department of Philosophy, Lund University

Sweden's attractiveness as a study destination is dependent on many factors, including high-quality education, courses offered in English, gender-equal career paths, and conditions for a good study and social life for students. The Inquiry on increased internationalisation of higher education activities[31] has described factors for internationalising both education and research at universities and higher education institutions, and submitted proposals for measures to increase Sweden's attractiveness as a study destination. A special visa for highly qualified people wanting to apply for jobs or start a business will be introduced on 1 January 2021. The aim is to facilitate collaboration with internationally leading research and innovation environments, and attract and retain international cutting-edge expertise.

Skills supply is currently a particular challenge for the segment of the life sciences industry with production in Sweden.[32] This segment generates a continuous need for specialist expertise in areas such as automation, 'lean'

[31]SOU 2018:3 Internationalisation of Swedish Higher Education and Research – A Strategic Agenda.

[32]N2015/08694/IF Assignment on a national programme for protein research, method development and biopharmaceuticals production (in Swedish).

methodology, analysis, process engineering, chemical engineering and good manufacturing practices. The major pharmaceutical companies have traditionally functioned as a base for further training in drug development, but as the number of these companies have declined, skills supply in the area has become problematic. One way of managing this problem is by actively making the skills in major companies available to small enterprises.

The welfare sector is also facing major challenges in terms of future skills supply. The National Board of Health and Welfare's survey[33] of supply and demand of licensed health care staff found that the regions consider that there is a shortage of staff in several regulated professions, despite a general increase in supply of licensed staff over time. One reason for this is considered to be the increased demand for care services. Care conducted at university hospitals plays a key role in fulfilling the health care system's mandate to perform clinical research. This involves special needs in the form of research-trained staff.

It is also essential to better harness the knowledge and ideas available in health care and social services. Involving those working in the health and social care sector in product and service development increases the potential to achieve functional outcomes. This also raises skill levels, both in the health and social care sector and in the companies developing health and assistive technologies.

Objectives

7.1 Good opportunities for lifelong learning
The Government considers that there must be good opportunities for lifelong learning. This is important for the life sciences sector, where knowledge is advancing at a rapid pace and the skills required can change quickly. Cross-sectoral staff mobility is also encouraged.

7.2 Effective collaboration to ensure skills supply
The Government considers that effective collaboration and a cross-sectoral approach is necessary to ensure long-term skills supply in the life sciences sector. It is essential that future challenges are managed in collaboration with the education sector and employers in life sciences.

7.3 Offering competitive conditions to recruit internationally
The Government wants conditions in place to enable employers in Sweden to recruit international expertise in the life sciences sector.

[33] *Assessment of supply and demand of licensed staff in health and dental care,* National Board of Health and Welfare report, 2019 (in Swedish).

8. International attractiveness and competitiveness

Investments and export promotion are two fundamental components of the internationalisation of Swedish life sciences. To ensure that Sweden is an attractive investment country in a global and digital knowledge-based society, it is crucial to be able to offer an environment that includes world-leading universities and higher education institutions, an innovative and high-quality health care system, and government agencies with a clear mandate to contribute to policy development and innovation at system level. Close collaboration with our Nordic neighbours is, in some areas, a prerequisite for achieving attractive environments. Cooperation with the United Kingdom is also vital for Swedish stakeholders. In the Horizon 2020 framework programme, 'Societal Challenge 1 – Health, Demographic Change and Wellbeing', the UK is Sweden's most important partner country. With its outstanding life sciences sector, the UK will continue to be an important partner in the future too. Innovation partnerships with France, Germany and India will also create opportunities for in-depth partnership projects and policy advocacy.

Research infrastructures, test beds and incubators with links to universities and higher education institutions or global life sciences companies, higher education institutions' innovation offices and holding companies all play an important role in the innovation system supporting life sciences. A structure for long-term collaboration between the country's business incubators, with cutting-edge expertise in life sciences, is essential to ensure high international standards in the business incubator process.

Actively monitoring international developments and analysing advances in the life sciences sector in Sweden, at both national and regional level, is important to be able to market Sweden's life sciences offerings. The Offices of Science and Innovation at Sweden's embassies in Beijing, Brasilia, New Delhi, Seoul, Tokyo and Washington DC have been tasked with analysing strategic initiatives in their respective countries that are relevant for all the innovation partnership programmes, including the programme for health and life sciences. Business Sweden and Swecare are also important actors in investment and export promotion. Under the name 'Team Sweden', they work in partnership with other stakeholders in the sector to promote life sciences exports.

Sweden currently has a relatively

Photo: Erik Flyg, Karolinska Institutet

large and growing number of life sciences companies in the start-up phase. The high number of initial public offerings of such companies, particularly on active small cap equity markets, is unique in an international perspective. Yet the number of venture capitalist investors has fallen from around ten at the turn of the millennium to currently two – including Industrifonden – that specialise in life sciences. As the listing environment and stock markets can change rapidly, and the refinancing cycles for life sciences companies are becoming ever shorter, private and public venture capital is a very important source of financing.

Early investments with high or difficult-to-assess risk levels and/or delayed returns (which characterise the life sciences sector) generally have difficulty attracting private financing. Central government investments in life sciences have also sought out companies in later development phases in recent years. Saminvest AB is a wholly state-owned venture capital company that invests indirectly through privately managed funds using a 'fund of fund' structure. In partnership with private stakeholders, Saminvest has established a new venture capital fund focused on Nordic life sciences companies.

Competitive framework conditions for companies investing in research are important for the localisation of global companies. The conditions and working methods of regulatory authorities are also important. Intellectual property law is also part of the framework that is the basis for innovation, company formation, product development, collaboration and trade.

Objectives

8.1 Better business environment for research and development
The Government intends to raise the 'R&D deduction' to facilitate Swedish industry's continued investment in new technology and high-knowledge content.

8.2 Increased export and investment promotion
In line with the Government's export and investment strategy, Sweden should be positioned and marketed as a country of choice for global stakeholders when it comes to establishment, investment, and research and innovation collaboration in the life sciences sector, including in precision medicine.

8.3 World-class business incubators
The Government considers that it is important for Sweden to be able to offer competitive business incubators. Growth companies in the life sciences sector need access to world-class expertise, regardless of where in the country the company is located.

8.4 Continuous monitoring, analysis and follow-up
The Government considers that continuous analysis and follow-up of life sciences, both nationally and internationally, is essential. Knowledge about Sweden's performance in relation to comparable countries is imperative if Sweden is to market itself as a country of choice for life sciences investment.

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