

MAY 2021

Agreement on a strategy for life science

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Introduction

The COVID-19 crisis has shown the importance of the life science industry and a world-class healthcare system. A strong healthcare system and a strong life science industry can ensure the best possible treatment for patients. But it also benefits the welfare society, companies and the Danish economy.

Life science puts Denmark in a position of strength. This is also reflected in the industry's economic footprint on the Danish economy. The industry's goods exports have risen sharply over just a few years and amounted to DKK 151 billion in 2020, corresponding to 22 per cent of all Danish goods exports. This is almost a tripling compared to 2008 and means that life science is one of Denmark's largest export industries. However, the potential for Danish exports related to life science is much greater. If exports related to life science increase by the same average annual growth rate as from 2008-2020, exports will reach DKK 345 billion in 2030, cf. Figure 1.

The life science industry in Denmark has experienced massive growth. The number of companies and employees in the industry is increasing, and the same applies to the volume of foreign investment, the companies' investments in their own research and development, and the industry's added value.

At the same time, life science is one of the industries that is at an advanced stage in the green transition. The industry delivers green growth and has managed to decouple greenhouse gas emissions from production. Thus, greenhouse gas emissions in the life science industry have halved since 1990, while value added growth has increased nearly tenfold in the same period.

Life science is a research-heavy industry based on knowledge and a highly skilled workforce. The industry employs approximately 50,000 people, corresponding to 2.2 per cent of the total employment in Denmark, of which the majority of those employed are in pharmaceuticals and biotech.



Figure 1

Potential for Danish exports related to life science towards 2030

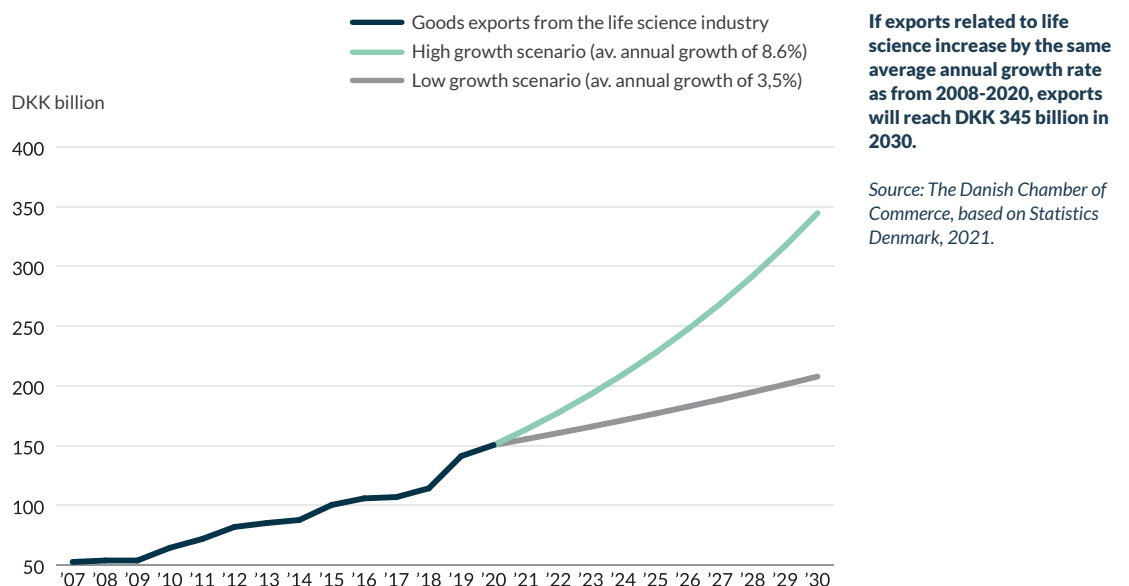
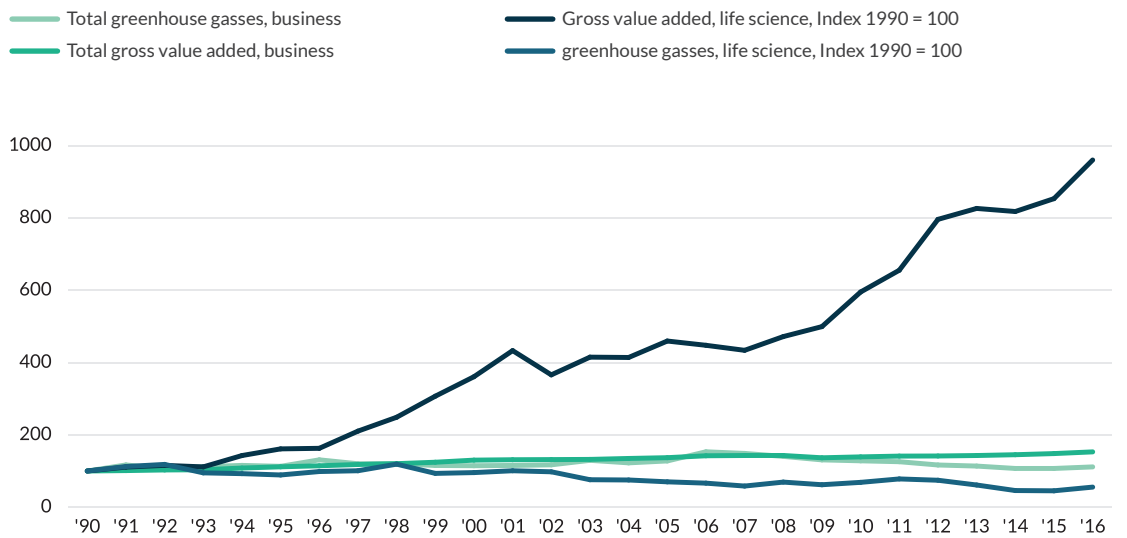




Figure 2

Development in gross value added and greenhouse gas emissions compared to 1990

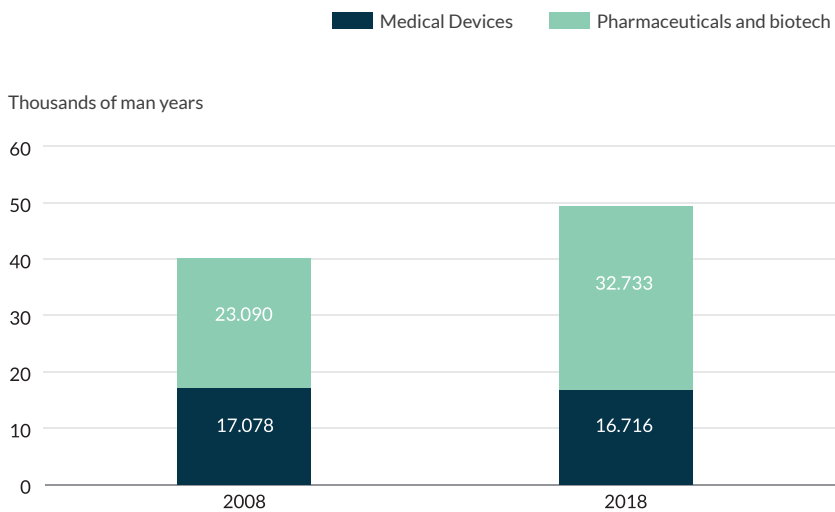


Extensive decoupling between growth and emissions in life science.
 Source: Ministry of Industry, Business and Financial Affairs, 2020, Life science industry's economic footprint



Figure 3

Employment in the life science industry 2008-2018



The life science industry was responsible for 49,449 man-years in 2018. That is 2.2 per cent of total private employment in Denmark.

Source: Ministry of Industry, Business and Financial Affairs based on Statistics Denmark

Agreement on a strategy for life science

Between the Danish Government (Social Democrats), the Liberal Party of Denmark, the Danish Social Liberal Party and the Socialist People's Party, Unity List, The Conservative People's Party and the Alternative Party

OF MAY 20, 2021

The COVID-19 crisis has shown us the importance of a life science industry and a world-class healthcare system – and the importance of them being able to interact. We must therefore secure the foundation for a strong healthcare system and a strong life science industry, which in interaction with each other, contribute to better patient care whilst benefitting our welfare society, companies and the Danish economy. The aim is to make Denmark stronger.

Denmark has a strong life science industry. This is partly due to the public and private sector investing massively in research within life science. Denmark is, for example, the OECD country in which the public sector conducts the most life science research in as a percentage of GDP, and life science accounts for a significant share with 31% of total public investment in research and development.

In close collaboration with the healthcare system, the life science industry can also help us create an even stronger welfare society in Denmark with new, innovative forms of treatment. To the benefit of patients and public health.

Good framework conditions must continue to be provided for the cyclically robust life science industry, which leads the way in sustainable and innovative solutions, and is in rapid development. We must support this, as there is still a large untapped growth potential. However, competition is fierce, and many countries are strengthening the framework conditions to support the life science industry. Therefore, we need a new national strategy for life science, able to significantly strengthen input and framework conditions for Danish life science. The strategy reflects

the wishes of the industry, and therefore implements the majority of the long-term recommendations from the Restart Team for life science and biotech.

The parties to the agreement agree to allocate funds for a total of 38 initiatives within seven main areas:

- Better framework for research and development
- Better use of health data
- Denmark as a showcase
- Highly qualified workforce
- Targeted internationalisation and government cooperation
- Healthy and green growth
- Knowledge-sharing and collaboration

The parties to the agreement note that the Danish Government is actively working to ensure a stable supply of vaccines for the country – including in the event of the need for revaccination as well as contributing to global vaccine collaboration. The parties behind the reopening agreement have thus agreed that the government has initiated a market research on possible production of COVID-19 vaccines in Denmark based on the best available technology.

The parties to the agreement note that they will receive annual status reports on the implementation of the initiatives in the agreement.

The parties to the agreement agree on the following initiatives:





Better framework for research and development

We must provide good opportunities to utilise the development of life science products and solutions for the benefit of patients, growth and welfare in Denmark. We must therefore create the best conditions for research and development, including clinical research, and ensure close public-private partnerships. These are the prerequisites

for increasing value creation. The parties to the agreement will initiate initiatives that will support the best framework conditions for research and development in the health area, and ensure that Denmark continues to have a strong foundation for development and innovation.

Initiative 1 Extended increase in deductions for R&D expenditure

The life science industry accounts for more than a third of private investments in research and development in Denmark. Therefore, higher tax deduction on research and development activities is an important framework condition for strengthening the life science industry. Investments in research and development strengthen the productivity of the companies making those investments, and have a positive knock-on effect on the productivity of other companies. In June 2020, the R&D deduction was increased for 2020 and 2021. The parties to the agreement note that the Finance Act for 2021 decided to extend the R&D deduction of 130% to 2022.

Initiative 2 Continuation of Trial Nation, the national association for the provision of clinical research in Denmark

In 2018, the Trial Nation association was established to ensure stronger national coordination of clinical research in Denmark, so that Denmark remains one of the leading countries in Europe in the field. The parties to the agreement generally want to strengthen clinical research in Denmark for the benefit of patients, the healthcare system and companies. Therefore, the grant of a total of DKK 4.5 million annually will be continued in 2022 and 2023 for Trial Nation until the end of 2023. Trial Nation must build on the unique collaboration between the state, regions and life science companies to promote clinical research in Denmark. Trial Nation will also continue to strengthen the ecosystem and help make it more attractive for Danish and foreign companies to place clinical trials in Denmark.

Initiative 3 Establishment of a working group to support a better framework for clinical research in Denmark

If Denmark is to be a leader in clinical research and attract foreign investment, the conditions for clinical research must be reviewed. In collaboration with Danish Regions, a working group will therefore be set up, which will identify barriers to clinical research in Denmark, and make suggestions on how conditions can be improved. This process is envisaged to the relevant extent together with identifying the extent of clinical research in Denmark and its funding, which has been initiated under the auspices of the Agreement on A Research Reserve, etc. for 2021. DKK 0.3 million has been allocated for the initiative in 2021.

Initiative 4 Establishment of a national digital platform for clinical trials

It can be difficult to recruit subjects for clinical trials, because there is no national information source where the public, patients and healthcare professionals can find information about open trials. Nor is there a national solution that supports contact between trial principles and relevant trial subjects at this time. In collaboration with Trial Nation, the establishment of a national overview of clinical trials in Denmark and a national digital platform has been initiated, where patients and citizens can register as interested in participating in future clinical trials. This should make it easier and faster to recruit trial subjects and give patients access to participate in clinical trials. The agreement allocates DKK 2 million in 2022 and 2.4 million in 2023 for operation of the digital platform.

Initiative 5 Fee relief for commercial undertakings in connection with clinical trials

Clinical trials are important as treatment options for patients, and for the development of new innovative treatments in life science. To make Denmark an attractive place to conduct clinical research, the fees for commercial clinical trials were dropped in 2018. Thus, the Danish Medicines Agency has exempted commercial sponsors from all fees for phase I trials. The agreement continues the initiative with DKK 1 million annually in 2022 and 2023.

Initiative 6 Support for efficient case processing of applications for clinical trials with drugs, etc.

With the EU regulation on clinical trials of medicinal products, the scientific ethics assessment of applications for drug trials will have to be transferred from the regional scientific ethics committees to national biomedical research ethics committees. The parties to the agreement will allocate DKK 4.8 million in 2021 to ensure a timely and smooth adjustment process for the implementation of the new regulatory setup, along with more efficient case processing by the science ethics committees for the Capital Region until transition to the new setup.

Initiative 7 Establishment of an IT system to support national biomedical research ethics committees

To support Denmark's readiness to handle regulatory work within the forthcoming new regulatory setup as a result of the EU Clinical Trial Regulation, a digital IT system will be established to support regulatory management in the national biomedical research ethics committees. DKK 2.0 million will be allocated in 2021, and 0.6 million annually in 2022 and 2023 for the initiative.

Initiative 8 Pilot scheme with virtual clinical trials

The conduct of clinical trials is hampered by the fact that the recruitment of subjects in clinical trials requires physical attendance. This can make it difficult for relevant subjects to participate. In order to make clinical trials accessible and relevant to a wider range of subjects, the parties to the agreement will explore the possibilities of establishing a pilot scheme with virtual clinical trials, where information is primarily provided digitally. The pilot scheme will be established for a two-year period, with DKK 0.3 million allocated in 2021, 0.6 million in 2022 and 0.3 million in 2023.

Initiative 9 Development of the Danish Medicines Agency's skills within new technologies, methods, etc. concerning clinical trials

In the future, the countries that offer the best environment to deal with new needs and technologies will be the most attractive for clinical trials, as technologies, methods and regulatory conditions within clinical trials are constantly evolving. Achieving a strong European positioning in relation to future methods and innovation in clinical research is therefore important. The parties to the agreement will therefore strengthen the Danish Medicines Agency's ability to translate national knowledge and challenges into solutions under the auspices of the EU, to find solutions in the regulatory system in the EU. DKK 1.4 million will be allocated annually in 2021-2023.

Initiative 10 Better opportunities for healthcare professionals to research – support for shared positions

It can be difficult for healthcare professionals to find time to prioritise research. Managerial focus on ensuring time and space for conducting clinical research is also important. The parties to the agreement want to support the possibility of prioritising research as part of work, e.g. by supporting sharing positions that enable sharing work between clinic and research. DKK 10 million annually in 2021-2023 has been allocated for this initiative.

Initiative 11 Continuation of Open Entrepreneurship

There is considerable untapped potential in translating the innovative research results created at Danish universities into more start-ups and innovative companies in Denmark. Initiatives that increase the number of start-ups and innovative collaborations between researchers and entrepreneurs with a view to increased commercialisation and dissemination of Danish research results and inventions to the benefit of society are therefore needed. The pilot project "Open Entrepreneurship" has succeeded in creating a stronger culture of entrepreneurship by increasing entrepreneurship and commercialisation among researchers. The parties to the agreement agree to join forces with the Danish Industry Foundation and continue the Open Entrepreneurship project until and including 2023, with a view to greater commercialisation of Danish research results, which will ensure new growth companies and jobs, better patient care and better health. DKK 3.5 million has been allocated annually in 2022 and 2023 for continuation.

Initiative 12 Access for research-based start-ups and SMEs to scientific literature

Life science companies, and start-ups in particular, benefit greatly from the latest knowledge and research in the healthcare field to ensure that their life science products and solutions are based on the latest available knowledge. The parties to the agreement want to allocate DKK 0.5 million in 2021 for an analysis to identify the demand for research literature among start-ups and SMEs in Denmark, and to identify barriers and opportunities to give such companies free access to license-based scientific literature. The analysis must result in grounds for a decision in relation to a possible initiative in the area.

Initiative 13 Gathering experience on handling rules for the transfer of patents regarding forms of treatment and medicines for private companies from public research in Denmark and selected countries

A study will be commissioned into how the ownership of intellectual property rights, patents, etc. relating to forms of treatment and medicines has been handled in Denmark and certain comparable countries, as well as in the EU. The results will include an overview of the current requirements for the sale of intellectual property rights from public research institutions to private companies. The study will also identify the competition law framework for the sale of intellectual property rights from public research institutions to private companies. It will form the basis for the Life Science Council to discuss and – if relevant – make recommendations in this area. The Ministry of Higher Education and Science is preparing the study in collaboration with the Ministry of Industry, Business and Financial Affairs in 2021, and the parties to the agreement have agreed to allocate DKK 0.5 million in 2021 for this purpose.





Better use of health data

The Danish healthcare system has a long tradition of collecting and using health data for the benefit of patient treatment and research. Danish health data is completely unique internationally, because many health registers and databases cover the entire population over many years and can be linked across data sources. It provides good opportunities for valuable research, quality development and the development of new innovative solutions for the benefit of patients. It can also contribute to growth and exports in the life science industry and help attract international investment in health research. It is therefore crucial to seize the considerable opportunities that health data offers us in research and innovation. This is an area where Denmark is strong internationally, and where there are good opportunities for us to become a leader. The parties to the agreement therefore want an ambitious vision for the use of health data, where strengthened and flexible

use of health data goes hand in hand with data security and confidentiality. At the same time, it is absolutely crucial to ensure high data security and transparency, so that the public can be confident that health data is used safely and ethically. The parties to the agreement therefore want patient associations, the National Science Ethics Committee and the Data Ethics Council are involved in working with health data, e.g. under the auspices of the national partnership for better use of health data (initiative 14).

It is essential that initiatives on health data in the strategy for life science and the national strategy for personal medicine support each other, so as to ensure a coherent and efficient infrastructure for better use of different types of health data to ensure world class targeted treatment of the individual patient and health research.

Initiative 14 Establishment of a national partnership for better use of Danish health data for research, quality development and innovation

A national partnership for better use of Danish health data for research, quality development and innovation will be established. The partnership must be a forum for the exchange of knowledge and experience concerning the use of health data as well as a discussion of needs, challenges and possible initiatives with a focus on respecting public rights to confidentiality and data protection. The partnership must bring together all relevant players within the health data area, including e.g. patient associations, and supported by secretarial services in the Ministry of Health together with the Ministry of Industry, Business and Financial Affairs, for which DKK 0.5 million has been allocated annually in 2021-2023. The partnership will follow the implementation of the life science strategy's initiatives on health data.

Initiative 15 Realisation of vision for better use of health data

The parties to the agreement agree that Denmark must be an international leader in using health data for research, development and public authority tasks in an up-to-date, innovative and safe manner. In collaboration with the relevant parties in the health data area, the vision for better use of health data must be realised by ensuring coherent service functions and data infrastructure, able to improve the opportunities to use and make use of the potential of Danish health data for both public and private research, health professionals and health authorities. The parties to the agreement agree to develop a single common point of entry to data overview, guidance and application for access to health data (initiative 16). In addition, in collaboration with the central authorities and stakeholders, the potential for establishing a common national analysis platform for health data with supercomputer facilities, flexible approval processes and data services must be explored (initiative 17).

Initiative 16 A single point of entry for data overview, guidance and application for access to health data

The government and the regions have initiated the establishment of a single point of entry to health data, which will make it more manageable and flexible for researchers to apply for access to health data for research. The point of entry will consist of three functions – a data map, a guidance function and an application portal – accessed via a single website. The parties to the agreement have agreed to allocate DKK 4.0 million in 2021 and 3.7 million annually in 2022 and 2023 for the establishment of the data map and the guidance function.

Initiative 17 Establishment of secure national analysis platform for health data

It can be administratively cumbersome and technically difficult to combine health data from authorities as well as other data, e.g. on social issues. In addition, there is no common national data infrastructure.

To support these needs, the parties to the agreement will allocate DKK 4.0 million in 2021 and 3.0 million annually in 2022 and 2023 to investigate the potential of establishing a common national analysis platform in collaboration between the central authorities and stakeholders in the field, able to support data user access to health data and other relevant data from various data controllers in a secure analysis environment, with extensive storage and computing capacity (supercomputer facilities). It is important to ensure fast and smooth access to data on the analysis platform, which is why approval of applications for data access should be coordinated or gathered across data controllers, and common data services should be offered to data users. The parties to the agreement agree that a preliminary analysis must be carried out of the essential aspects for the establishment of a common national analysis platform with flexible approval processes and data services.

Initiative 18 Improved investment in health data in the Ministry of Health

Technological developments in the field of health data give rise to new questions, needs and challenges in relation to the use of health data for research, innovation and the work of the public authorities. The parties to the agreement will therefore prioritise DKK 1.5 million in 2021 and 2.0 million annually in 2022 and 2023 for a strengthened health policy and strategic effort in the Ministry of Health, which will launch new efforts to ensure a good administrative, technical and legal framework for the use of health data.

Initiative 19 International provision of opportunities for the use of Danish health data for research and development

In order to attract international partners and investment in health research in Denmark, the plentiful opportunities for research in Danish health data must be clearly communicated. The parties to the agreement will allocate DKK 0.5 million in 2021 to the Danish Health Data Authority, in collaboration with Invest in Denmark, to implement enhanced investment in international provision of opportunities through the use of Danish health data for research and development.

Initiative 20 Statistics service at the Danish Health Data Authority

Researchers can access pseudonymised data at the Danish Health Data Authority via remote access to a secure analysis environment (Forskermaskinen – the research machine). In addition to Forskerservice (research service), the Danish Health Data Authority will establish Statistics Service, from where companies, patient associations and journalists, for example, can order smaller, tailor-made statistical extracts and, in the long term, smaller analyses of data from the national health registers prepared by the Danish Health Data Authority.





Denmark as a showcase

The Danish domestic market plays an important role in how well Danish products and solutions perform on the export markets. This is because rapid commissioning of products and widespread use in Denmark act as a seal of quality, which foreign health authorities refer to when they make purchases. An innovative domestic market is a competitive parameter in terms of attracting international life science companies. A high degree of openness to innovative solutions can thus mean that companies will prioritise

Denmark when it comes to launching new treatment options. The Danish healthcare system therefore functions to a large extent as a showcase for the global markets. In addition, the parties to the agreement agree on the need to strengthen the quality of prevention, treatment and rehabilitation of chronic diseases, support coherence across sectors and reduce inequality in chronic disease.

Initiative 21 Strengthened focus on innovative purchasing and new billing models

Development and commissioning of innovative technologies and medical equipment, value-based payment and new treatment options in the healthcare system often provide better patient care for the individual, and are to the benefit of society as a whole. Innovative procurement, however, requires more resources for both the purchaser and the company to complete due to higher complexity. Therefore, the parties to the agreement agree to boost investment by DKK 2.0 million in 2021, 0.5 million in 2022 and 1.5 million in 2023 to strengthen the innovation-promoting range of innovative health technologies and medical equipment, e.g. by initiating work to develop a prototype of a data-driven model for value-based procurement, develop innovation criteria, ensure competence development among purchasers and develop innovative contract paradigms.

Initiative 22 Pool for innovative purchasing

It must be more attractive for the public sector and companies to enter into innovative collaborations to support the adoption of innovative solutions in the health care system. Innovative procurement often requires different preparation compared to traditional procurement. The parties to the agreement therefore agree to allocate a pool of DKK 9.0 million in 2021, 4.0 million in 2022 and 5.0 million in 2023 to support innovative public procurement of innovative technologies and medical equipment. The pool will make it easier for public institutions to seek and procure new innovative solutions, which will help companies to target their innovation. It will be revealed whether the pool can also support procurement in the pharmaceutical field.

Initiative 23 Task force for initiatives targeted at chronic disease, and inequality in health

The parties to the agreement have agreed to allocate DKK 4.0 million in 2021 and 2022, and DKK 3.9 million in 2023 for a task force for initiatives targeted at chronic diseases and inequality in health. The task force will create a basis for strengthening the quality of prevention, treatment and rehabilitation, supporting coherence across sectors and reducing inequality in chronic disease. Its work will also focus on people with several chronic diseases, i.e. multiple chronic conditions (MCC).

An important part of its work will be to support the development of systematic collection, use and sharing of data in the municipal efforts and in processes across municipalities, general practice sector and hospitals. It will also be tasked with conducting framework analysis of where new technologies can support good treatment of patients as well as increased involvement of health professionals.

Initiative 24 Providing health apps and encouraging Nordic co-operation on a better framework for accreditation

The market for healthcare apps is developing rapidly and is helping to expand the toolbox in healthcare. However, it is difficult to get an overview of available health apps, including assessing their effect. There is also demand for a structured use of health apps, where standards for and quality assurance of selected apps contribute to a “quality stamp” of health apps and market access. The parties to the agreement therefore agree to allocate DKK 5.0 million in 2021, 4.0 million in 2022 and 1.0 million in 2023 for the development of a technical solution that can be integrated into the MinLæge (MyDoctor) app, via which a doctor can easily and efficiently “prescribe” apps for patients based on a catalogue, when it can benefit the patient’s course of treatment. The technical solution is envisaged under the Nordic co-operation, which is underway on a model for accreditation of health apps in the Nordic countries.





Highly qualified workforce

New technology is changing the jobs of the future, and the way in which many jobs are performed will be affected by investments in new technology. It requires new skills and innovative employees that can help create new opportunities for the companies. A prerequisite for strengthening Danish life science and keeping Denmark in the absolute elite is a highly qualified workforce. Companies are also

looking for innovative and specialised employees who can contribute new knowledge, help promote our health and strengthen the life science industry. Ongoing demand for continuing and further education of employees in the healthcare system and in the life science industry is required.

Initiative 25 Pool for digital competencies in the healthcare system

Strategic focus on supporting patients, staff and management in the healthcare system in using new technologies, e.g. telemedicine, AI technology for decision support, healthcare apps, etc., is crucial to promote the introduction of innovative technologies and medical equipment in the healthcare system. It is also an important element for the Danish healthcare system to be able to continue to function as a strong showcase for Danish life science companies. A pool of DKK 3.3 million is therefore allocated in 2021 and 2.0 million annually in 2022 and 2023 to support the work of strengthening digital competencies in the health care system.

Initiative 26 Strengthened focus on skills development and continuing education in life science

If Denmark is to realise the potential of its life science industry as well as create and maintain high-quality production jobs, it requires a workforce that continuously develops the right professional skills. The parties to the agreement will set up a working group to analyse the need for skills development within the life science industry. Therefore, DKK 2 million will be allocated annually in 2021 and 2022, and 4 million in 2023 to initiate and implement initiatives within, for example, educational development and capacity-building for educational programmes targeted at life science with a view to enhanced quality.



Targeted internationalisation and government cooperation

The life science industry is a strong export industry in growth. Life science goods exports accounted for just over 9% of total Danish goods exports in 2008, while in 2020 it amounted to 22% corresponding to DKK 151 billion. Foreign companies are showing great interest in Denmark, and the volume of foreign investments in life science accounted for almost half of the total foreign investments in Danish industry in 2018.

However, global development trends affect conditions for Danish companies that are experiencing increasing competition, increased regulatory complexity and barriers to market access. Therefore, it is important to break down market barriers, spread awareness of efficient and innovative Danish solutions and purposefully work to ensure the best possible conditions for the export of Danish products, services and solutions.

Initiative 27 Enhanced international collaboration between authorities to promote Danish exports

In order to gain access to the relevant decision-makers and authorities abroad, it is crucial that Denmark can offer dialogue and cooperation at a high professional level with relevant Danish health authorities. Collaboration between the authorities is based on long-term and health-based collaborative relationships and requires strategic and long-term effort by the Danish health authorities, as well as building the necessary capacity with these authorities. There is still great potential in spreading Danish solutions in the field of health and life sciences, as well as increasing demand from strategically important countries for these solutions. The parties to the agreement will therefore allocate DKK 4.7 million in 2021 and 16.8 million annually in 2022 and 2023 to upgrade the international cooperation between the authorities significantly within the Ministry of Health's department.

Initiative 28 Strengthened global health diplomacy and government cooperation

There is global and growing potential in marketing health and life science solutions for Danish exports. As new market opportunities arise, competition for market shares for life science companies in a highly regulated industry increases. Therefore, Danish authorities, nationally and internationally, must work to ensure clear and equal framework conditions for export companies and work for sustainable exports.

Further developing and strengthening targeted and sector-focused export campaigns is needed. Due to the export potential and market opportunities for the life science industry, the parties to the agreement want to strengthen cooperation with foreign authorities in both regulatory and trade policy areas and

promote the access of small and medium-sized enterprises in particular to exports on high-value markets through a significant strengthening of seconded health sector experts. This will be targeted at the strengths of Danish life science companies. DKK 5.6 million will be allocated in 2021 and 16.8 million in 2022 and 2023 for this campaign.

Initiative 29 Danish influence in the European HMA network, and enhancing drug safety

In 2018, the Danish Medicines Agency's participation in HMA (The Heads of Medicines Agencies) was strengthened. The Danish Medicines Agency has played a central role in HMA, including through the chairmanship of the former director of the Danish Medicines Agency of the HMA board, his participation and dialogue with the broad European stakeholder environment as well as participation in key working groups. The Danish Medicines Agency has become the spokesperson for HMA-related work and has played a central role in the implementation of new European legislation for clinical trials, etc. The parties to the agreement agree to continue the initiative with DKK 1.0 million annually in 2022 and 2023, thereby ensuring a strong pharmaceutical authority that provides fertile ground for a strong life science industry.

Initiative 30 The Danish Medicines Agency's involvement in the European Medicines Agency (EMA)

The European Medicines Agency (EMA) is a coordination agency that draws on the professional staff and expertise of the national medicines authorities. The significant contribution to the EMA of the UK authorities is being phased out as a result of Brexit. As part of the strengthening of the Danish Medicines Agency (DMA), new expertise is being recruited in relation to unfinanced work within the EMA, which the UK formerly bore a large share of. Strengthening Denmark's position in the EMA is of vital importance for Denmark as a life science nation, as several companies will seek scientific advice from the DMA, and its influence on future medical products will be enhanced. The parties to the agreement will allocate DKK 2.7 million annually in 2022 and 2023 to this end.

Initiative 31 Increased efforts to attract specialist life science investment to Denmark

The strengthening of Invest in Denmark (IDK) has contributed to attracting billion-dollar construction investments and increased the total number of foreign life science investments in Denmark. With the global economic crisis, and the consequent increasing global competition for retaining and attracting foreign investment, further strengthening is needed. The parties to the agreement will continue the current strengthening and add additional funds to investment advisers in two of IDK's main markets. DKK 1.7 million will be allocated in 2021 and 2.5 million annually in 2022 and 2023.

Initiative 32 Continuation of grants to Healthcare Denmark

There is great potential in marketing innovative Danish healthcare solutions, which is a task that Healthcare Denmark handles today. Healthcare Denmark has built up an activity catalogue that supports the marketing of Danish healthcare solutions and the Danish healthcare system – including during the period with COVID-19. The parties to the agreement will continue financing Healthcare Denmark with DKK 2.0 million annually until the end of 2023.

Initiative 33 Continuation of the Danish Innovation Center in Boston

Boston and the surrounding area is a world-leading epicentre of life science. In 2018, a Danish innovation centre was established in Boston. The centre builds bridges and promotes Danish companies and researchers' collaboration with Boston's strong life science ecosystem. The centre is well established, and has built up a strong local network with significantly increased visibility for Denmark and Danish players. The parties to the agreement will ensure continued financing for the innovation centre, by allocating DKK 2.5 million annually in 2022 and 2023.

Initiative 34 Reserve for preliminary investigation regarding Danish candidacy for HERA

In the second half of 2021, the Commission is expected to make proposals for the establishment of a European Health Emergency Response Authority (HERA), which aims to strengthen the EU's crisis preparedness for future health crises. Neither the location of HERA nor the process for this has been determined at present. The government supports the establishment of the agency, but no decision has been made on a Danish candidacy. If, following the publication of the Commission's proposal, it is deemed appropriate to consider a Danish candidacy for hosting HERA, an analysis of the advantages and disadvantages will be needed, including the probability that a possible Danish candidacy will be successful. The parties to the agreement therefore agree to set aside a reserve of DKK 1.5 million in 2021 for a possible feasibility study.





Healthy and green growth

Denmark has set an ambitious climate target to reduce greenhouse gas emissions by 70% in 2030 compared to 1990. The business community has an important role in the effort to realise that target.

Between 1990-2017, the life science industry experienced strong economic growth measured by gross value. During the same period, the life science industry succeeded in reducing its absolute greenhouse gas emissions, while this remained unchanged for the Danish business sector. The life science industry is actively working to reduce CO₂ emissions from its production processes and products. It is also researching and testing new climate-friendly

solutions that can reduce CO₂ emissions in other sectors. The sector's work within green solutions must continue to be supported.

Within climate-related biosolutions, Denmark has a position of strength with leading global companies as well as an undergrowth of SMEs and start-ups working with the green solutions of the future. The parties to the agreement will initiate new initiatives that will continue to contribute to the life science industry having the right framework conditions to deliver green growth, decouple CO₂ emissions and value growth, as well as contribute to the development of new climate-friendly solutions.

Initiative 35 Collaborative project on biosolutions

Innovation and development of green technology are absolutely central to solving the global climate challenge. The Danish biotech industry can play a crucial role here, as it is already among the best in the world in the development of biosolutions that solve climate challenges. In order to create coherence and unleash the biotech industry's business and climate potential, the parties to the agreement will establish a collaborative project under the auspices of the Green Business Forum. The project's aims will include bringing together relevant private and state actors across sectors in order to create a common focal point for dialogue on how the potential of biosolutions can be realised. DKK 1,0 million has been allocated for the project in 2022.

Initiative 36 Partnership for Intelligent Waste Management

Products from the life science industry today generate large amounts of (plastic) waste in the healthcare sector, which is sent for disposal. Less use of plastic and increased recycling can help reduce Denmark's total CO₂ emissions and support the green transition. The Climate plan for a green waste sector and circular economy of 16 June 2020, established a Partnership for Intelligent Waste Management, which will support the use of new technologies and digital solutions that can increase waste recycling. The parties to the agreement want a separate track to be established in the partnership, which focuses on supporting increased recycling of medicine packaging and used medical equipment, taking into account patient safety and safe handling in the waste phase. DKK 0.4 million has been allocated for the initiative in 2021.



Knowledge-sharing and collaboration

The COVID-19 crisis has underlined the importance of strong, effective and trustworthy public-private partnerships in the health and life science field for our society. Crisis management under COVID-19 has required joint efforts among a wide range of public and private actors across multiple sectors.

Over time, Denmark has built up a strong and well-functioning ecosystem around life science, which includes the entire value chain from early research and development to the marketing of Danish life science products in global markets. The parties to the agreement want to strengthen this, so that together we can realise Denmark's enormous potential in life science.

Initiative 37 Establishment of a National Life Science Council

If Denmark is to continue to be a leading life science nation, sustained focus on adapting the framework conditions for life science is necessary, so that the potential for Danish life science can be fully utilised for the benefit of patients, the healthcare system and companies. The purpose includes ensuring the framework for an even stronger welfare society with a focus on job creation, increased health and better treatment for the benefit of patients. Therefore, the parties to the agreement have agreed to establish a national Life Science Council with high-level participation of e.g. life science companies, foundations, industry organisations, employee organisations, patient associations, universities and representatives from the health service, which can strengthen the dialogue between the public and private sectors and discuss the industry's national priorities and general framework conditions. Among other things, the Council will continuously be updated on the implementation of the life science strategy and discuss a number of interdisciplinary themes, including, for example, looking at how the framework conditions for entrepreneurship and venture capital within life science can be further strengthened. The Council will also discuss and make recommendations on possible future priorities in research and innovation efforts within life science.

Initiative 38 Continuation of the life science unit under the Ministry of Industry, Business and Financial Affairs and a full-time post for coordination in the Ministry of Health

In order to strengthen business policy within life science, a life science unit was established in the Ministry of Industry, Business and Financial Affairs with the previous growth plan for life science. The unit works to ensure the best possible growth conditions for the industry, including contributing to the

implementation of the growth plan as well as other life science-related initiatives. The need for business-oriented focus on the health agenda will continue, so that the life science industry has a unified single point of entry to the many ministries that are in contact with the industry. Therefore, the parties to the agreement agreed to continue the life science unit under the Ministry of Industry, Business and Financial Affairs, for which DKK 5.0 million is allocated for 2022 and 2023. The parties to the agreement also agreed to allocate DKK 0.5 million in 2021 and 0.8 million annually in 2022 and 2023 to the Ministry of Health, so that focused and coordinated effort is ensured.



Financial table

Overview of initiatives in the Agreement on a strategy for life science (DKK million)

No.	Initiative	2021	2022	2023
Better framework for research and development		19.8	23.6	23.7
1	Extended increase in deductions for R&D expenditure	-	-	-
2	Continuation of Trial Nation, the national association for the promotion of clinical research in Denmark*	-	4.5	4.5
3	Establishment of a working group to support a better framework for clinical research in Denmark	0.3	-	-
4	Development and establishment of a platform for recruiting subjects for clinical trials*	-	2.0	2.4
5	Fee relief for commercial undertakings in connection with clinical trials*	-	1.0	1.0
6	Support for efficient case processing of applications for clinical trials with drugs, etc.	4.8	-	-
7	Establishment of IT system to support medical committees	2.0	0.6	0.6
8	Pilot scheme with virtual clinical trials	0.3	0.6	0.3
9	Development of the Danish Medicines Agency's skills within new technologies, methods, etc. concerning clinical trials	1.4	1.4	1.4
10	Better opportunities for healthcare professionals to research - support for shared positions	10.0	10.0	10.0
11	Continuation of Open Entrepreneurship	-	3.5	3.5
12	Access for research-based start-ups and SMEs to scientific literature	0.5	-	-
13	Gathering experience on handling patents from public research	0.5	-	-

Better use of health data		10.5	9.2	9.2
14	Establishment of a national partnership for better use of Danish health data for research, quality development and innovation	0.5	0.5	0.5
15	Realisation of vision for better use of health data	-	-	-
16	A single point of entry for data overview, guidance and application for access to health data	4.0	3.7	3.7
17	Establishment of secure national analysis platform for health data	4.0	3.0	3.0
18	Improved investment in health data in the Ministry of Health	1.5	2.0	2.0
19	International promotion of opportunities for the use of Danish health data for research and development	0.5	-	-
20	Statistics service at the Danish Health and Medicines Authority	-	-	-

* Initiative 2, 4, 5, 29, 30, 32, 33 and partially 38 (Continuation of life science unit in the Ministry of Industry, Business and Financial Affairs) are funded in 2021

Overview of initiatives in the Agreement on a strategy for life science (DKK million)

(continued)

No.	Initiative	2021	2022	2023
Denmark as a showcase		20.0	12.5	11.4
21	Strengthened focus on innovative purchasing and new billing models	2.0	0.5	1.5
22	Pool for innovative procurement in healthcare	9.0	4.0	5.0
23	Task force for investment targeted at chronic disease, and inequality in health	4.0	4.0	3.9
24	Promotion of health apps	5.0	4.0	1.0
Highly qualified workforce		5.3	4.0	6.0
25	Pool for digital competencies in the healthcare system	3.3	2.0	2.0
26	Strengthened focus on competence development and continuing education in life science	2.0	2.0	4.0
Targeted internationalisation and government cooperation		13.5	44.3	44.3
27	Enhanced international collaboration between authorities to promote Danish exports	4.7	16.8	16.8
28	Strengthened global health diplomacy and government cooperation	5.6	16.8	16.8
29	Danish influence in the European HMA network, and enhancing drug safety*	-	1.0	1.0
30	The Danish Medicines Agency's involvement in the European Medicines Agency (EMA)*	-	2.7	2.7
31	Increased efforts to attract specialist life science investment to Denmark	1.7	2.5	2.5
32	Continuation of grants to Healthcare Denmark*	-	2.0	2.0
33	Boston Innovation Center*	-	2.5	2.5
34	Reserve for preliminary investigation regarding Danish attraction of HERA	1.5	-	-
Healthy and green growth		0.4	1.0	0.0
35	Collaborative project on biosolutions	-	1.0	-
36	Partnership for Intelligent Waste Management	0.4	-	-

* Initiative 2, 4, 5, 29, 30, 32, 33 and partially 38 (Continuation of life science unit in the Ministry of Industry, Business and Financial Affairs) are funded in 2021

Overview of initiatives in the Agreement on a strategy for life science (DKK million)

(continued)

No.	Initiative	2021	2022	2023
Knowledge-sharing and collaboration		0.5	5.8	5.8
37	Establishment of a National Life Science Council	-	-	-
38	Continuation of life science unit in the Ministry of Industry, Business and Financial Affairs* and life science efforts in the Ministry of Health	0,5	5,8	5,8
Total (DKK million)		70,0	100,4	100,4

As part of the Agreement on payment of the remaining two weeks of frozen holiday funds, export package and reserve for extension of assistance packages of 2 December 2020, DKK 70 million has been allocated annually in 2021-2023 for the development of a new life science strategy. In addition, in connection with FL21, a reserve for a growth plan for life science of DKK 30.4 million for 2022-2024 was allocated.

* Initiative 2, 4, 5, 29, 30, 32, 33 and partially 38 (Continuation of life science unit in the Ministry of Industry, Business and Financial Affairs) are funded in 2021

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