The Danish National Life Science Council's recommendations

for the Government's upcoming strategy for life science

DECEMBER 2023

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December 2023

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Preface

The life science sector is crucial to our society. Pharmaceutical, medtech and biotech companies contribute massively to the Danish economy. At the same time, the partnership between public and private stakeholders in the healthcare sector is a cornerstone in the development and future-proofing of our healthcare system and welfare.

Today, life science is one of Denmark's biggest export industries. Since 2008, exports have more than tripled and in 2022, the life science industry exported for DKK 175 billion, equivalent to 20 percent of the total Danish goods exports. In addition, life science companies in Denmark employ over 50,000 full-time equivalents (FTEs).

At the same time, innovative healthcare solutions and treatments are making a tangible difference every day for citizens, patients and employees in our healthcare system and around the world. In other words, life science shines a light on Denmark. The sector is generating a great deal of activity and demand, and the potential towards 2030 is huge.

However, international competition is intensifying. For example, global competition to attract clinical trials and investigations is increasing, and several countries are actively working to attract greater investment in life science. Additionally, global supply chains are under pressure. These factors place great demand on the life science industry's competitiveness and framework conditions if Denmark is to maintain and expand its international position of strength.

At the same time, the Danish healtcare system faces a future involving demographic developments, challenges with recruitment and retention of staff, new treatment options and higher expectations, which will put the system under considerable pressure.

For this reason, the upcoming strategy needs to take Danish life science to the next level, not only by aiming high, but also by generating real action and momentum.

In the Danish National Life Science Council, we have taken a closer look at what it will take for Denmark to become Europe's leading life science nation. Our recommendations are organised under four aspirations for the sector and our society. These aspirations and the specific recommendations and proposed solutions can help us realise the great potential of the life science sector.

Firstly, we need to bring more innovation into the healthcare system. Innovation must be a prioritised core task throughout the healthcare system, enabling us to offer better health and value for citizens and staff while ensuring that the public sector becomes a springboard for the growth and export of Danish healthcare solutions. Through the development, testing, implementation and scaling of efficient and labour-saving healthcare solutions, the life science sector must contribute to freeing up 10,000 FTEs in the healthcare system by 2030. This is ambitious and requires us to successfully scale many more innovative solutions in our healthcare system. We must therefore all commit to disseminating the solutions that have proven their worth across the Danish healthcare system. This will result in innovative medicines and healthcare solutions not only being developed but also being deployed where they can make a difference, both for patients and in terms of freeing up labour in our healthcare system.

Secondly, we must create a stronger and broader foundation for the future of life science in Denmark. We must strengthen our ecosystem, both by ensuring that more new life science entrepreneurs succeed and by attracting outside investments. This requires us to maintain our leading position in clinical research. It requires us to succeed in realising the potential of our unique health data and to

ensure that research and knowledge at our universities are translated into entrepreneurship and new companies to a greater extent. We must therefore create entrepreneurial and innovative environments in public-private partnerships with access to consistent funding so that we can incubate and develop more life science companies. This is the foundation for Denmark's position of strength, now and in the future.

Thirdly, Denmark must assume a stronger international leadership role to ensure competitive framework conditions for the life science industry. International competition is increasing, and at the same time, the international frameworks in the EU and globally are becoming increasingly crucial for the industry's competitiveness. This calls for Denmark to take greater responsibility when it comes to solving global health challenges. Therefore, we need a more strategic and targeted public-private partnership on export promotion and advocacy for the sector's framework conditions in the EU and globally.

Fourthly, we must position Denmark as one of Europe's most attractive countries for life science manufacturing and foreign investment. We have a unique opportunity to double exports by 2030, but this requires making it easier to establish and expand manufacturing facilities in Denmark. At the same time, it is a basic condition that the industry has access to the right employees and skills.

These four tracks form the framework for our recommendations. For each recommendation, specific solutions have been proposed that can develop and improve the framework conditions in the life science area and contribute to future growth and prosperity in Denmark by 2030.

It has been crucial for our work to provide few, but ambitious recommendations with a great impact. We wanted to emphasise efforts that create real, structural change – across both public and private stakeholders.

The work of the Danish National Life Science Council has been characterised by an impressive level of commitment, ideas generation and cooperativeness. And in our work, we have involved a wide range of stakeholders from the life science ares who have provided input for the recommendations while offering support to ensure that the recommendations have the best possible conditions for being realised.

The process has highlighted how much there is to gain when public and private stakeholders across the life science area come together, set common goals and work in a spirit of trust, dedication and dialogue to identify the best solutions.

It is now a matter of realising the ambitions and turning the specific recommendations into action. The Danish National Life Science Council welcomes the fact that, in addition to a new life science strategy, the Government has announced an entrepreneurship strategy, a strategy for personalised medicine and a globalisation strategy, as well as launching the healthcare structure commission.

Our hope is that our aspirations and recommendations can help stregthen life science in Denmark and make the industry a leader in global markets. This will ensure that the sector can continue to create jobs, growth and value – for the benefit of patients, the healthcare system, companies, the Danish economy and the society we all share.

Lars Rasmussen
Chairman of the Danish National Life Science Council

The importance of the Life Science industry for Denmark

EXPORT

175

billion DKK in 2022

More than tripled since 2008, accounting for 19.7% of total Danish export.

FULL-TIME EQUIVALENTS

50,000

Denmark has more than 50,000 FTEs in the life science sector in 2020. This corresponds to a 25% increase from 2008 to 2020.

A RESEARCH-HEAVY INDUSTRY

Research and development in the life science industry account for:

37%

of the total amount of R&D (2020)

Source: Life science-industriens økonomiske fodaftryk (Erhvervsministeriet 2023)
(Economic footprint of the life science industry (Danish Ministry of Industry, Business and Financial Affairs 2023))

Overall vision for Danish life science by 2030

Denmark must be Europe's leading life science nation

1 ASPIRATION

Denmark must secure a world-class patient care and healthcare system by focusing intensely on the development, testing, implementation and scaling of efficient and labour-saving healthcare solutions in close collaboration with companies. The ambition is to free up 10,000 FTEs in the healthcare system by 2030.

ASPIRATION 2

Through a cohesive innovation environment, Denmark must be the country in Europe that incubates and develops the largest number of viable life science startups for the benefit of human and planetary health.

3 ASPIRATION

Denmark must be a strong player in the EU and globally when it comes to providing solutions to global health challenges and working for export promotions and for competitive framework conditions for life science that benefit patients, healthcare systems and growth.

ASPIRATION 4

Denmark must be among the top 3 manufacturing and investment countries for life science in Europe.

Overview of recommendations

Recommendation 1:

Innovation must be a prioritised core task in the Danish healthcare system. Patients must have access to innovative medicines and medical devices, and systematic development, testing, implementation and scaling of labour-saving healthcare solutions in close collaboration with private companies.

- Development and implementation of new healthcare solutions as a prioritised core task throughout the healthcare system
- Establishment of a Health Partnership to run innovation programmes for selected areas of the healthcare system with potential to free up labour
- Establishment of a Danish innovation index
- Fast and efficient uptake of medicines
- Establishment of incentive models that support healthcare professionals in engaging in the development, testing, implementation and scaling of healthcare solutions in collaboration with private companies
- Establishment of a common evaluation paradigm for impact assessments of new healthcare solutions
- Better tools for procurement and tendering
- Investigation of the possibility of establishing a National Centre for Patient Collaboration

Recommendation 2:

Denmark must prioritise and conduct more clinical research as an integrated part of patient care.

- Implementation of recommendations from the working group on better frameworks for clinical research in Denmark
- Continued support from the clinical trials association Trial Nation for further clinical research in Denmark

Recommendation 3:

The potential of Danish health data must be realised.

- Realisation of the Vision for Health Data and follow-up on the recommendations from the National Partnership for Health Data for research, quality development and innovation regarding e.g. national health data infrastructure
- Rapid and incremental development and realisation of national health data infrastructure
- Flexible legal frameworks and national practice for health data utilisation

Recommendation 4:

Better technology transfer from universities and hospitals to entrepreneurs and companies must be ensured.

- Harmonisation of principles for managing intellectual property rights at Danish universities in connection with spinouts
- Increase in technology transfer opportunities at hospitals and universities through more business developers and more funding for patenting
- Creation of a national legal unit to manage technology transfer at universities

Recommendation 5:

Companies must have access to consistent funding throughout the value chain.

- Better early funding opportunities for promising life science entrepreneurs via Innovation Fund Denmark and the Export and Investment Fund of Denmark (EIFO)
- Danish effort to establish European "Late-stage Ventures" to scale up companies
- Intensified efforts to attract venture capital funds to Denmark
- Abolition of the taxes on phantom income

Recommendation 6:

There must be better frameworks for collaboration between research environments, the healthcare system and companies.

- Establishment of more laboratory facilities, more business development support and increased translational capacity
- Creation of a Danish 'Kendall Square'
- Greater incentives and a financial framework for innovation at universities and hospitals

Recommendation 7:

Strategic efforts to promote exports of Danish healthcare solutions must be strengthened.

- Strengthening of Healthcare Denmark in line with the life science industry's potential and international position of strength
- Ability for health authorities and the healthcare system to prioritise export promotion activities

Recommendation 8:

Advocacy for Danish interests in the EU must be strengthened to support Europe as an attractive life science region through competitive regulatory framework conditions and international market access.

- Reinforcing advocacy for Danish interests in the EU through the permanent Danish EU representation in Brussels in order to boost the framework conditions for life science
- Reinforcing the Danish Business Authority and the Danish Medicines Agency to build sector-specific expertise in life science to support the permanent Danish EU representation in Brussels
- Prioritising life science before and during the Danish EU presidency in 2025 through a coordinated effort

Recommendation 9:

Health diplomacy and international official cooperation must be strengthened and targeted to support the Danish life science sector and attract international life science companies to Denmark.

- Establishment of a public-private contact forum to contribute to strategy and prioritisation in the international work in the life science field
- Customisation of the mandate and focus of the health advisors deployed based on the two to three key priorities for authorities and companies in each market
- Maintaining and intensifying the focus of Danish health authorities' involvement in official cooperation
- Boosting efforts regarding intellectual property rights in e.g. China

Recommendation 10:

The framework for Denmark as a life science manufacturing country must be strengthened, including through the designation of industrial zones suitable for life science manufacturing and smoother administrative approval processes for licences.

- Designation of new industrial zones that create space for growth in life science manufacturing close to existing life science clusters, key infrastructure and strong knowledge environments
- Well-functioning business infrastructure to support life science manufacturing expansion and investment
- Faster and smoother licensing processes through the creation of a 'one-stop-shop' for establishing or expanding life science manufacturing and attracting foreign companies

Recommendation 11:

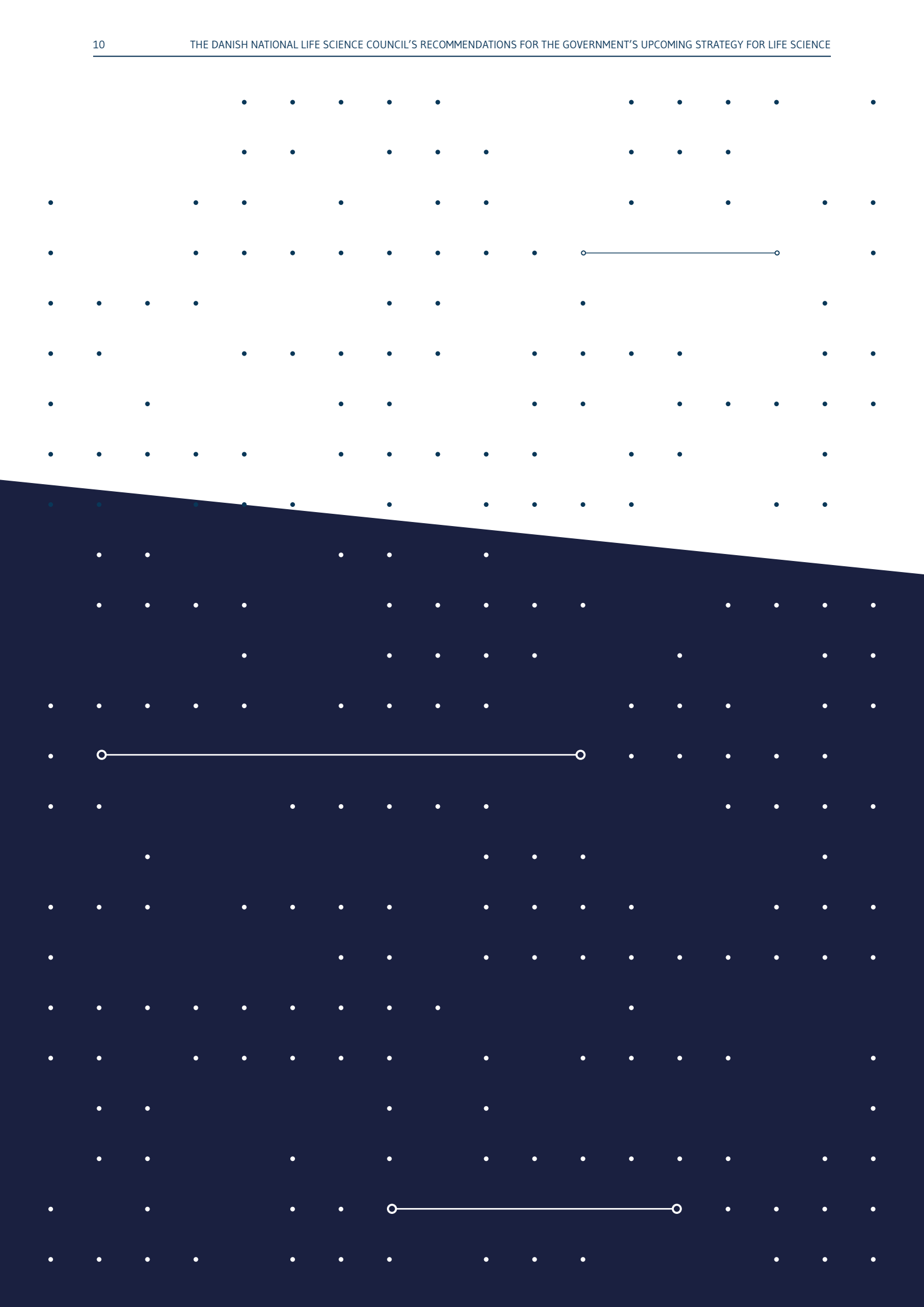
The frameworks for educating future employees and attracting them to the life science industry must support the realisation of growth ambitions.

- Expansion of industrial PhDs and industrial post-doctoral programmes
- Creating specialised biopharmaceutical research and training centres and identifying skills requirements in the life science industry by 2030
- A greater number of targeted, binding partnerships to create more study places aimed at life science manufacturing
- Better frameworks for attracting and retaining international labour, research talent and international students

Recommendation 12:

The focus on the sector's framework conditions must be maintained in order to realise growth ambitions.

- Establishment in the life science strategy of key performance indicators in key areas such as innovation, new business development, exports and manufacturing to support the strategic development of the life science sector in Denmark by 2030
- Continuation of the operations of the Danish National Life Science Council and the life science units at the Danish Ministry of Industry, Business and Financial Affairs and the Danish Ministry of the Interior and Health



CHAPTER 1:

Better uptake of innovation in the healthcare system through public-private partnerships

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Better uptake of innovation in the healthcare system through public-private partnerships

The healthcare system is currently facing one main challenge, which is often referred to as the demographic 'double whammy'. On the one hand, the healthcare system is facing challenges in recruiting and retaining healthcare professionals. At the same time, demographic devolments indicate that we will have more elderly people and more people with chronic diseases in the future. This puts pressure on the healthcare system and can have a significant impact on patient care and the future capacity and performance of the healthcare system.

Innovation in the healthcare sector has long been in the spotlight, and for good reason. Through public-private partnerships, the development of innovative healthcare solutions – i.e. both medical devices and pharmaceuticals – has helped to provide Danish patients and the healthcare system to create more value and better health. At the same time, innovation and public-private partnerships have boosted the Danish life science industry's growth opportunities and thus the Danish economy.

Innovative solutions developed by companies or in collaboration between companies, research environments and the healthcare system can help meet the healthcare system's need for labour-saving healthcare solutions while contributing to prevention and solutions that can help people manage their own illnesses close to home.

This applies to labour-saving solutions in the healthcare system as well as citizen-centric treatments and solutions that have proven that they can free up resources. At the same time, new, innovative medicines can, for example, make it possible to treat patients who previously had no treatment options, or create greater treatment effects and fewer side effects for the individual patient.

However, realising the great potential of deploying innovative healthcare solutions does not come without its challenges. Both the healthcare system and companies are experiencing a slow uptake of new healthcare solutions across the healthcare system, despite the fact that they have already demonstrated significant impact.

In the field of pharmaceuticals, the Reimbursement Committee and the Danish Medicines Council have a major impact on the use of new medicines across the healthcare system. New innovative medicines may run the risk of challenging the current evaluation methods in institutions and thus create dilemmas in terms of striking a balance between patients having access to the most effective and safe treatments while ensuring the best possible health for the money. For example, new gene therapies are often associated with higher initial costs and greater uncertainty about their clinical and adverse effects for the public healthcare system – especially the long-term effects.

This has a number of unfortunate consequences for our society. Citizens and patients miss out on the most innovative healthcare solutions and treatments and thus the best possible patient care or citizen-centric solution that can contribute to prevention, early detection and a higher quality of life. The healthcare system and healthcare professionals miss out on labour-saving solutions that can ensure more efficient workflows and thus help generate more value and time for the patient, along with a better work environment.

Denmark must secure patient care and a world-class healthcare system through a targeted focus on the development, testing, implementation and scaling of efficient and labour-saving healthcare solutions in close collaboration with companies. The ambition is to free up 10,000 FTEs in the healthcare system by 2030.

In addition, companies miss out on the opportunity to enter the Danish market and at the same time experience major challenges in scaling their innovative solutions once they have gained market access. Furthermore, the failure to adopt the latest innovative medicines can lead to companies avoiding Denmark as a country in which to conduct clinical trials.

Action is needed now to strengthen the healthcare system's incentives to implement and scale proven, existing healthcare solutions and enter into public-private partnerships that can boost innovation and labour-saving healthcare solutions. This includes, among other things, a more value-based approach that supports a focus on life cycle costs and the derived effects of innovative treatments and healthcare solutions.

Clear frameworks must be created for public-private partnership and the development of new innovative solutions, and a better and more systematic structure must be established to drive the development, testing, scaling and implementation of existing solutions. This must be done based on a needs- and challenge-driven approach that focuses on unlocking resources in a broad sense. A targeted public demand for labour-saving solutions will focus and strengthen the innovation power of Danish companies and the industry's efforts to develop medical devices and pharmaceuticals that support and future-proof the healthcare system.

Recommendation 1:

Innovation must be a prioritised core task in the Danish healthcare system. Patients must have access to innovative medicines and medical devices, and labour-saving healthcare solutions must be systematically developed, tested, implemented and scaled in close cooperation with private companies

Through collaboration with life science companies and knowledge institutions, the healthcare system has great potential to both develop and scale healthcare solutions that can improve patient care and help free up staff resources in the healthcare system. It is therefore essential to promote innovation and collaboration as a core task in the healthcare system to ensure that there are sufficiently robust incentives or structures in place that support the prioritisation of scaling and implementing existing innovative solutions and developing new healthcare solutions.

Today, the healthcare system has three core tasks on which it is measured and assessed: treatment, education and research. However, there are no fixed frameworks for assessing quality, setting national targets, etc. for innovation processes, including the development, implementation and scaling of healthcare solutions. At the same time, frameworks and rules in this area are often unclear.

The task of innovation needs to be a prioritised core task to ensure that the healthcare system maintains a stable and high demand for innovation and to ensure that collaboration with companies and other players in the life science environment is enhanced, including the skills to take part in the collaboration – as has been the case for the other three core tasks. At the same time, there is a need for more systematic demand for solutions that are not currently in demand, such as interdisciplinary and preventive solutions that can make the citizen more self-reliant and improve individuals' quality of life.

When it comes to medicines, there is a need to continue and to increase the dialogue on the frameworks for evaluating medicines in the Reimbursement Committee and the Danish Medicines Council. This is to ensure that patients have rapid access to the most effective and safe medicines while supporting a financially sustainable healthcare system and Denmark's position as a leading life science nation. The dialogue between the industry and the public healthcare system on risk sharing and other innovative contractual models should be intensified in order for more innovative medicines to be adopted in the Danish healthcare system in a financially sustainable manner.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Development and implementation of new healthcare solutions as a prioritised core task throughout the healthcare system.** Development and implementation of new healthcare solutions as a prioritised core task throughout the healthcare system. Developing and implementing new healthcare solutions should be a prioritised core task throughout the healthcare system. The experiences gained during the Health Partnership's innovation programmes will provide a basis for assessing what further measures are required to realise this.

- **Establishment of a Health Partnership** that runs innovation programmes for selected areas of the healthcare system in which there is potential for freeing up labour and increasing value for the individual and for the healthcare system. An important aspect of the Health Partnership's work is that binding agreements should apply for broad scaling of the solutions in the innovation programmes, which are developed, tested and matured and then, on this basis, assessed to be ready for implementation. The success of the Health Partnership should be measured by the extent to which the activities succeed in helping to realise the goal of freeing up resources corresponding to 10,000 FTEs in the healthcare system by 2030. The health partnership is described in more detail in Box 1.

- **Establishment of a Danish innovation index** that, on the basis of the relevant indicators, can create the frameworks for actively working with and systematically monitoring the level of innovation in the healthcare system and in patient care.

- **Rapid and efficient uptake of medicines.** Targeted collaboration between companies and public authorities on the development and increased use of innovative agreement models, especially risk-sharing agreements and confidential discount agreements. This includes both primary and secondary care and should be integrated in the work of the Danish Medicines Council, the Reimbursement Committee and the procurement organisation Amgros. Risk-sharing agreements can also be useful in the field of medical devices.

- **Establishment of incentive models** that support healthcare professionals in engaging in development, testing, implementation and scaling of healthcare solutions in collaboration with private companies.

- **Establishing a common evaluation paradigm for impact assessment of new healthcare solutions.** Today, there is no common, widely recognised standard and process for the testing and investigation of medical devices.

- **Better tools for procurement and tenders.** Further development of tools for public procurement departments that support a focus on life cycle cost in procurement. The Danish Government and Danish Regions should allocate funds to further develop the data-driven model for value-based procurement initiated with the latest life science strategy. There should also be a more uniform interpretation of public procurement rules and state subsidy rules across the healthcare system.

- **Investigation of the possibilities of a National Nentre for Patient Collaboration.** Involving patients and their needs in the development process of new solutions is crucial. Understanding patients' wishes, challenges and preferences can guide the development of more effective solutions. Research and development of medicines and medical devices should therefore address the needs of patients to support the improvement of their care, daily life and quality of life. For this reason, the possibility of establishing a National Centre for Patient Collaboration should be investigated, the aim of the centre being to ensure a strong professional environment surrounding the work on collaboration with patients and relatives. The Centre should also ensure that the collaboration is relevant for organisations, researchers, clinicians, patients and patient representatives. Organisations must have access to guidance, facilitation and assistance in recruiting patients and patient representatives, and it must be ensured that patients and relatives can contribute to relevant collaborations and develop their skills.

Box 1:

The Health Partnership

The purpose of the Health Partnership is to accelerate the development, procurement, testing, implementation and scaling of efficient and labour-saving healthcare solutions and increase value for citizens, patients, healthcare professionals and the healthcare system through innovative healthcare solutions from – or developed in partnership with – the life science industry. An important aspect of the Health Partnership's work is that binding agreements apply for the broad scaling of the solutions in the innovation programmes, which are developed, tested and matured and then, on this basis, assessed as being ready for implementation. At the same time, the Health Partnership should support the development of relevant skills for the innovation task in the healthcare system. Health Partnerships should select specific areas of action within two types of innovation programmes:

1 Maturation and nationwide scaling of existing and proven labour-saving solutions: This type of innovation programme should focus on mature and well-known solutions that need support for further maturation on a larger scale, with a view to nationwide roll-out and scaling. Solutions should be past the pilot stage, i.e. have demonstrated labour-saving and clinical outcomes. Focus should be on areas characterised by relatively high technological maturity and low organisational complexity.

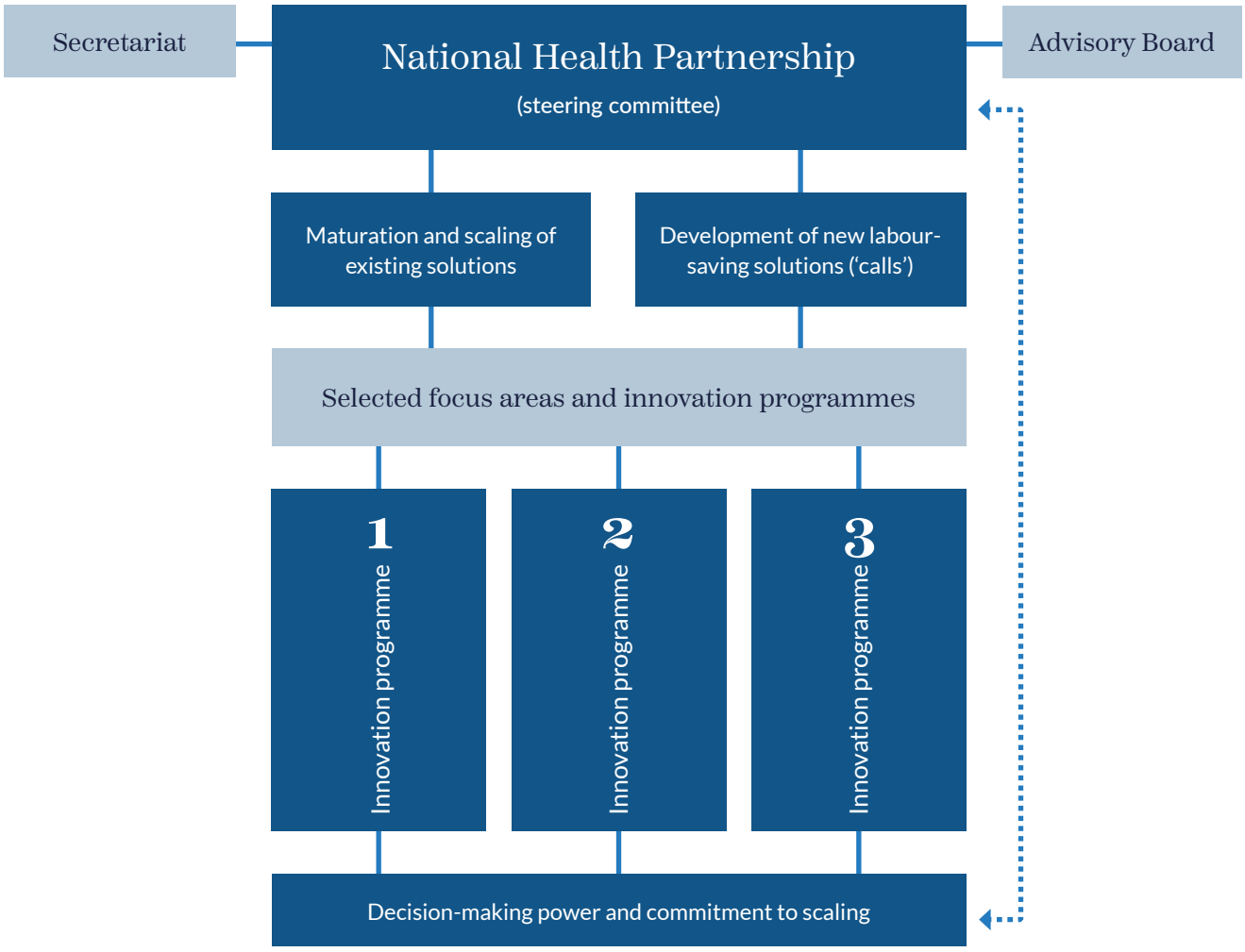
2 Development of new labour-saving solutions (challenge-based 'calls'):
In this type of innovation programme, specific health challenges are identified and tendering procedures are initiated so that relevant parties across the public and private sectors can submit a bid for contracts in public-private innovation partnerships and jointly develop new labour-saving solutions. This may include intersectoral solutions that ease the pressure on the healthcare system as a whole.

The Health Partnership must determine which specific innovation programmes will be initiated, and this should be based on a challenge-driven and needs-driven approach.

It is a prerequisite that the Health Partnership has the financial resources to drive the development, testing, implementation and scaling of innovative healthcare solutions. The work of the Health Partnership will therefore require significant financial prioritisation, including funding through venture capital and funding of the innovation programmes and the subsequent nationwide scaling, which extend beyond the framework of the life science strategy.

A strong governance structure is required for the Health Partnership to succeed. Among other things, this will require that the Health Partnership is rooted from both a clinical and a managerial perspective in the healthcare system, but also that it is set up with 'external expertise' in terms of knowledge and experience of innovation processes, technological development and scaling, e.g. from the private sector. A successful Health Partnership will also require a strong secretariat.

Figure 1: Organisation of the Health Partnership



Recommendation 2:

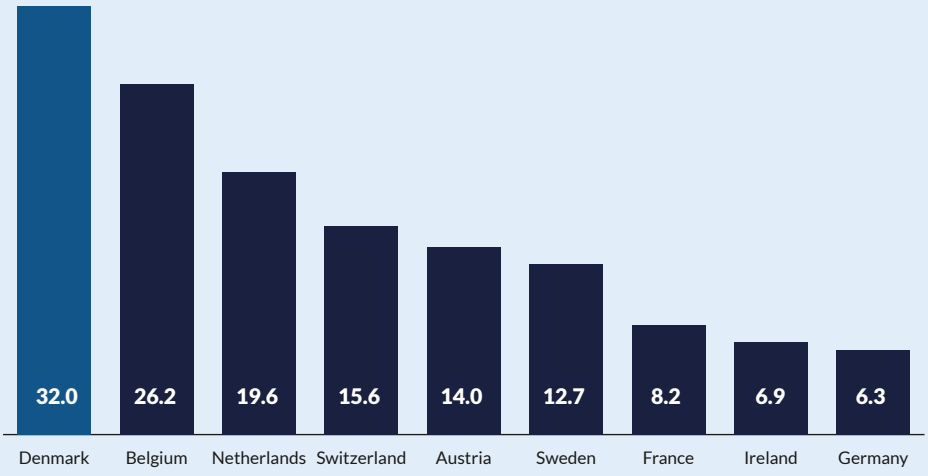
Denmark must prioritise and conduct more clinical research as an integral part of patient care.

Denmark is an international pioneer when it comes to conducting clinical research. Through public-private partnership on clinical research, patients gain access to the latest medicines and technology. It is a legal requirement for new medicines and technologies to be tested on patients through clinical trials or investigations before the authorities grant marketing authorisation. At the same time, clinical research helps to dertermine whether one healthcare intervention is better than another, and thus which treatments to select and reject. This provides the basis for the healthcare system to prepare the most effective treatment regimen from both a patient and a health economics perspective. Clinical research is also a factor in recruitment, helping to develop and retain environments characterised by professional expertise in hospitals across Denmark. In total, these are prerequisites for good patient care and health equity.

From 2010 to 2019, the total amount of clinical research conducted at the hospitals almost doubled – from DKK 2.9 billion in 2010 to almost DKK 5.6 billion in 2019. Danish and foreign companies' funding for research activities increased from around DKK 247 million in 2010 to around DKK 495 million in 2019, with the majority of the increase coming from foreign companies.

Taking a deeper dive into the figures, Denmark is particularly strong in clinical trials of pharmaceuticals. There has thus been an increase in the number of applications for clinical trials of pharmaceuticals for use in humans since 2010 – from 226 in 2010 to 345 in 2022. Denmark is currently one of the countries in Europe with the highest number of clinical trials of pharmaceuticals per million inhabitants.

Figure 2: Number of clinical trials in selected countries per million inhabitants, 2022



Source: Life science-industriens økonomiske fodaftryk (Erhvervsministeriet 2023)
(Economic footprint of the life science industry (Danish Ministry of Industry, Business and Financial Affairs 2023)).

The trend fluctuates more when it comes to the development in the number of clinical investigations of medical devices. For example, the number of clinical investigations of medical devices decreased from 34 investigations in 2020 to 24 in 2022.

Clinical research is an important prerequisite for a strong ecosystem for future growth in Danish life science and for the sector's significant impact on the Danish economy. In addition, clinical trials of medicines and clinical investigations of medical devices contribute to better patient care and cohesion in the Danish healthcare system.

The global competition for attracting clinical trials and investigations is increasing. Today, several countries have built up the knowledge and infrastructure to conduct high-quality clinical research. This puts Denmark's leading position under pressure. The frameworks, for example, should be strengthened so that the healthcare system can test existing and new solutions and enter into public-private partnerships with the life science industry. If Denmark is to remain competitive on the international stage and contribute to better health for citizens in the future, there is therefore a need to continuously strengthen the frameworks for clinical research.

As a consequence of the recommendation, As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Recommendations from the working group on better frameworks for clinical research in Denmark must be implemented.** This will significantly increase the opportunities for Denmark to maintain and develop its internationally recognised position within clinical research. Clinical research, including an implementation plan for the recommendations from the working group, should be actively integrated in the upcoming life science strategy. At the same time, strengthened frameworks for clinical research are crucial for Denmark to establish itself as the country in Europe that incubates and develops the largest number of new healthcare solutions and startups in the field of life science.

- **Trial Nation must continue to support further clinical research in Denmark.** Trial Nation must continue to work to make it easier and more attractive for life science companies to conduct clinical trials and clinical investigations in Denmark. Specifically, Trial Nation must bridge the gap between relevant stakeholders in clinical research and act as a single point of entry for researchers and companies looking to find suitable sites and patients.

Recommendation 3:

The potential for using Danish health data must be realised.

Health data is at the heart of health research, and if Denmark is to remain a leading life science nation, the potential for using Danish health data must be realised.

In Denmark, we have unique health data, but there are a number of barriers to realising its potential. It must be easier and quicker to access data in a safe and secure manner, it must be possible to link health data across the entire healthcare system, and there must be access to advanced data analysis in a secure environment that utilises the great innovation capacity in Danish life science.

By breaking down these barriers, Danish health data holds potential for conducting research results and innovation that cannot be conducted elsewhere, as we can link data between authorities. For this reason, solid frameworks for health research can contribute to growth and exports in the life science industry and give Denmark a competitive advantage globally when it comes to attracting foreign investment.

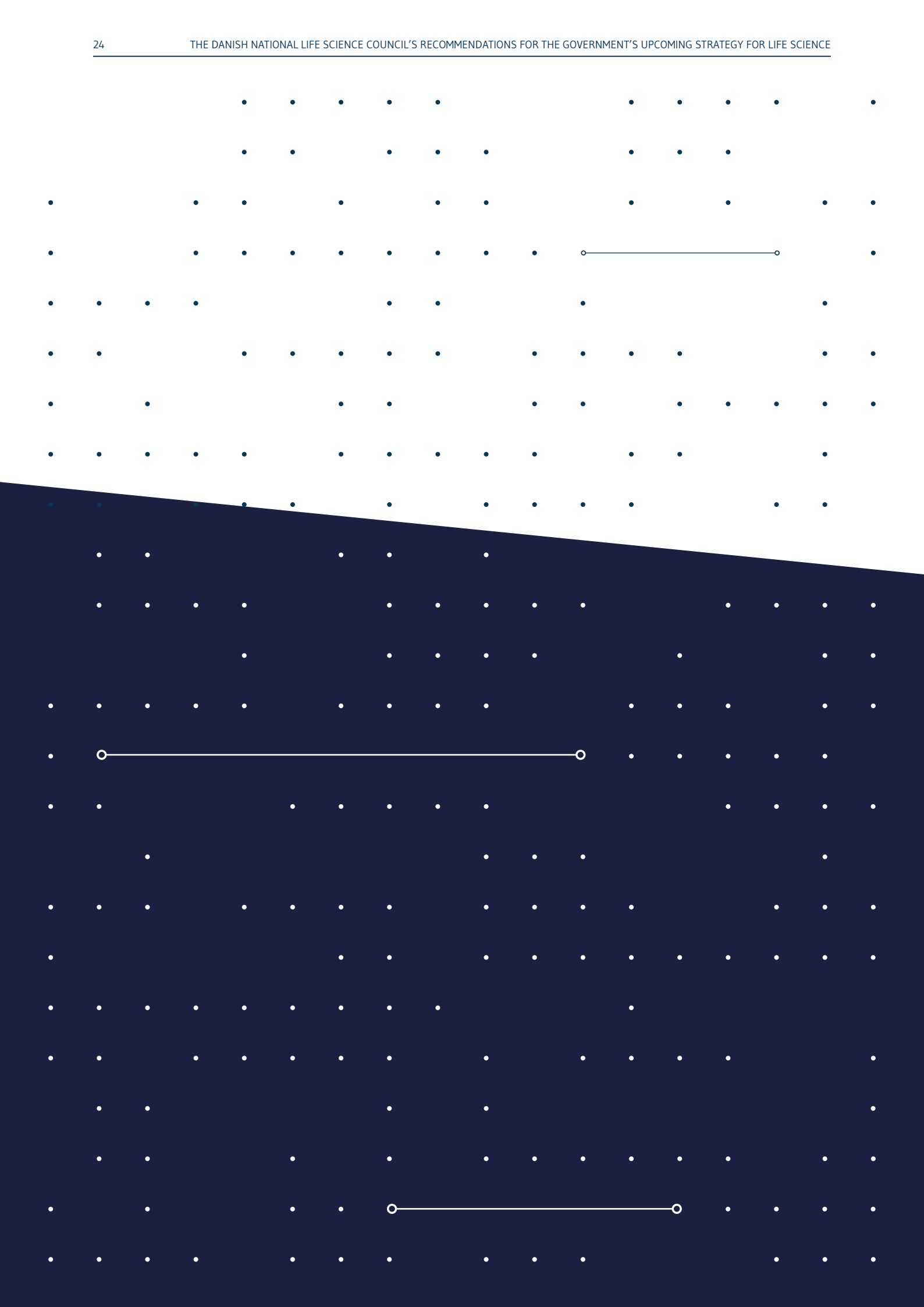
With broad support from the authorities responsible for the data and from the National Partnership for Health Data, there is now potential to realise the goals of the Vision for health data. In the near future, decisions must be made that will lead to the establishment of a new health data infrastructure.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Realisation of the Vision for health data and follow-up on the recommendations from the National Partnership for Health Data for research, quality development and innovation regarding national health data infrastructure.** It is crucial to follow up on the development of a cohesive infrastructure for health data and the establishment of an efficient and transparent organisation across the healthcare system that ensures rapid, uniform and efficient case management of access to health data for healthcare professionals, universities and life science companies. In this regard, it is important that national health data infrastructure is realised as soon as possible.

- **Rapid and phased development and realisation of national health data infrastructure.** In the latest life science strategy, funds were allocated to the Vision for health data. The analytical work is complete, and there is now a need to implement a new health data infrastructure.

- **Agile legal frameworks and national practice for the use of health data.** There is a need to increase opportunities for utilising health data, partly through national health data infrastructure, in order to better harness the potential of new technologies. In addition, there is a need for agile, nationwide processes for GDPR compliance.



CHAPTER 2:

A stronger growth layer in the life science industry

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A stronger growth layer in the life science industry

Denmark's life science industry is and has been undergoing rapid development. However, growth in life science is primarily driven by a few large MedTech and pharmaceutical companies. If Denmark's position of strength in life science is to be maintained and developed, we must continue to stimulate the development of the ecosystem. Only in this way can we increase the chances of incubating innovative startups and developing viable companies that can eventually grow into large international companies.

This requires that we strengthen the framework conditions for the growth layer within life science. The journey from research collaboration or idea at the university and with the clinician to patent application and company spinoff, and finally scale-up so that the specific healthcare solution can be manufactured and distributed globally, must be far more agile and cohesive than it is today.

Many countries and regions are working hard to offer the most optimal framework for the life science ecosystem. For this reason, it is crucial that we in Denmark also maintain constant focus on ensuring that the Danish framework conditions are attractive and comparable to those of our competitors, so that we can continue to benefit from the life science industry's crucial contribution to society in the future.

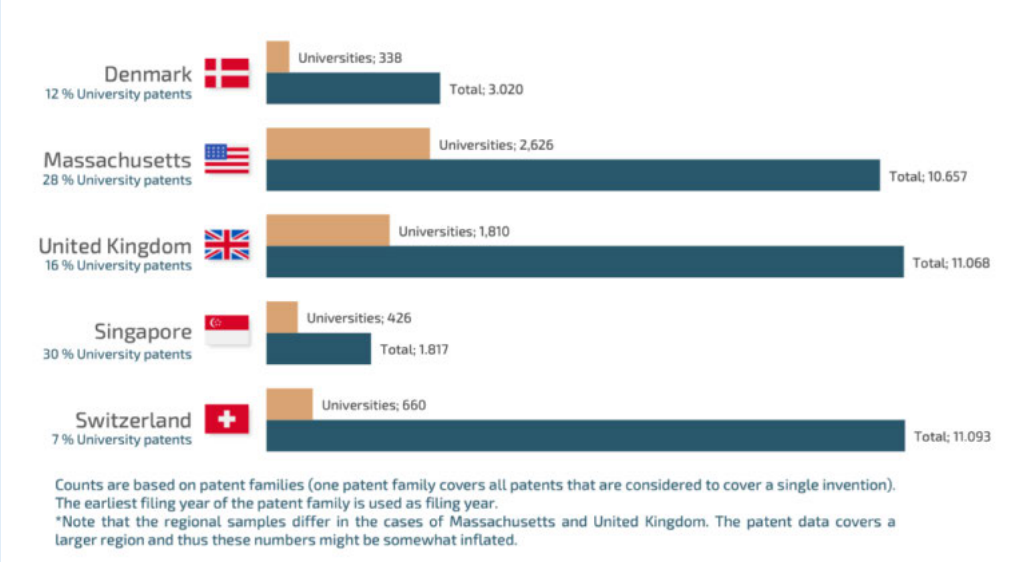
A high prioritisation of research and development in general is a basic prerequisite for innovation. Denmark has a very strong foundation in terms of research and scientific performance, but we can and must become better at translating knowledge into innovation, growth and better human health. Good ideas and real solutions must be brought to life, and they must be anchored in, for example, startups and small and medium-sized enterprises.

Moreover, a direct comparison of Denmark with four of the other leading life science regions in the world – Cambridge-Oxford, Massachusetts, Switzerland and Singapore – shows that Denmark is falling behind on several parameters. This is true when it comes to university rankings, scientific productivity and quality, patent activity, the number of startups and access to startup funding. At the same time, the number of life science-related patents coming out of Danish universities is too low compared to the leading life science regions.[1].

[1] https://bii.dk/wp-content/uploads/Damvad-BII-NNF-Startup-ecosystem-review-Final-report-22-March-2022-003.pdf

Through a cohesive innovation environment, Denmark must be the country in Europe that incubates and develops the largest number of viable life science startups for the benefit of human and planetary health.

Figure 3: Number of patents coming out of universities in selected life science nations



Source: Untap the Startup Potential: A comparative review of the Danish life science startup ecosystem (Damvad 2022)

The crucial success criterion is that we strengthen the quality and number of value-creating patents and successful spinouts that remain viable companies after a number of years and go on to make a positive difference to society and generate better health. There is a need to bring the life science ecosystem closer together and to establish greater agility and flexibility in the future so that researchers, clinicians, patients, the healthcare system and companies can more easily engage in close dialogue on inventions, collaborations, barriers and scaling opportunities. This is to ensure that the healthcare solutions of the future are created in Denmark and reach patients faster.

In Denmark, we have all the prerequisites and potential to create more new, successful life science companies and thereby ensure a stronger and broader foundation for Danish life science in the future. A stronger growth layer will not only increase prosperity in Denmark, but also contribute to more research being translated into real solutions that benefit healthcare systems, patient health and the quality of life of citizens around the world. The Danish Government should therefore lead the way by aiming for Denmark to be the country in Europe that incubates and develops the largest number of viable startups within the field of life science.

Recommendation 4:

Better technology transfer from universities and hospitals to entrepreneurs and companies must be ensured.

In recent years, the Danish life science ecosystem has seen significant increases in the number of publications and clinical trials and in the amount of national and international investments. However, there is still untapped potential to increase the number and improve the quality of new inventions, patents and new companies that can deliver genuine healthcare solutions for the benefit of citizens and the healthcare system.

Since 2013, the number of patent applications and invention disclosures has decreased, despite increased commercialisation activity in the patent portfolios of Danish universities. The number of patents granted remains fairly stable at around 40 per year.[2] At the same time, there is great potential for much more technology transfer, as research-based innovation provides knowledge-intensive companies with a solid foundation for developing high-tech products that perform well in the global market and benefit patients worldwide.[3]

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Harmonisation of the principles for managing intellectual property rights at Danish universities in connection with spinouts.** Institutions currently have different strategies for managing the transfer of intellectual property rights, which is reflected in different choices of commercialisation models and terms. By harmonising the principles across all universities within each of the specific life science fields when transferring intellectual property to startups, everyone will have the same mandate and basis to succeed. This process could be based on the models utilised by MIT, Cornell or the Universities of the Netherlands, for example, which include precise definitions of valuation in the form of a value ladder model. If deferring valuation, it is recommended that a framework for royalties be agreed upon, e.g. a maximum defined percentage of revenue for up to ten years. This recommendation will ensure a clear distribution scale and a transparent agreement model that is known by the inventor, institution and investors. There must be room to adapt the agreement model to the specific business area because the longer time to market makes performing valuation of healthcare solutions more difficult compared to other areas, for example.

- **Strengthening the opportunities for technology transfer in hospitals and universities through more business developers and more funding for patenting.** The Danish National Life Science Council assesses that business developers working with researchers and performing valuation of their discoveries are few in number and find it difficult to prioritise maintaining close contact with researchers and clinicians. Increasing the number of business developers at the individual institutions will contribute to more

[2] https://dkuni.dk/wp-content/uploads/2023/06/noegletal-for-kommercialiseringsstatistikken-2022.pdf
[3] https://bii.dk/wp-content/uploads/Damvad-BII-NNF-Startup-ecosystem-review-Final-report-22-March-2022-003.pdf

researchers making invention disclosures, which is a crucial initial step in technology transfer. Another key element of the translational process is that institutions have the ability to file the right patents based on validated and thorough proof of concept studies. Patent activity is declining, partly due to a lack of resources, and therefore more earmarked funds should be allocated to filing and maintaining patents as well as to proof of concept, which is crucial for strengthening the possibilities of developing inventions and improving the quality of patents.

- **Establishment of a national legal unit to manage technology transfer at universities.** Legal and specialist expertise should be brought together, strengthened, harmonised and shared across Denmark. The unit must ensure that intellectual property is transferred quickly and frictionlessly and, in more complex situations, provide support when intellectual property rights are co-owned by Danish universities and/or international universities. Ownership of rights will, as today, be based on an assessment of whether it is commissioned research, co-funded research, etc.
  It is essential to continue to ensure close collaboration between the central, national legal unit and researchers and business developers at the individual institutions. By setting clearly defined targets, the national unit will establish and manage how much intellectual property and technology is transferred annually and set ambitious targets for how quickly agreements and contracts are to be finalised. The unit must involve relevant stakeholders from the life science ecosystem and set key performance indicators for the technology transfer offices. These may include job creation, the number of viable startups that continue to exist, for example, five years after being founded, and capital attracted.

Recommendation 5:

Companies must have access to consistent funding throughout the value chain.

Danish life science maintains a high standard internationally and has huge potential, thanks to a strong research and innovation environment with many skilled researchers, clinicians, companies and talented individuals with new ideas. However, there is a major challenge in turning these ideas into startups and subsequently viable companies that can bring their products to market for the benefit of the individual citizen, the healthcare system and Denmark. One of the biggest impediments is a lack of funding and capital.

This can be seen, for example, in the number of IPOs of new life science companies, where Denmark has lagged significantly behind the other Nordic countries and other comparable countries in recent years.[4] Analyses show that the Nordic countries are leaders in the biotech sector when it comes to innovation, but lag behind globally when it comes to the translation and development of startups and viable companies.

The Nordic countries publish about three times more research articles per citizen than the EU, US and China averages. However, the Nordic countries lag significantly behind when it comes to attracting capital, both early-stage and late-stage funding. Here, Nordic biotech companies attract on average 20–50 percent less funding than in the US and China, because there is not the same access to capital from, for example, public funds and venture capital funds[5].

In Denmark, there is a lack of grant funding and venture capital to support the entire value chain, from early research and emerging untested ideas to the translation and spinout of new life science companies at various levels of maturity. The lack of venture capital may mean that some healthcare solutions never make it out of the laboratory and reach patients, just as Danish start-ups risk relocating to the US, UK or other European countries with better access to capital.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Better early-stage funding opportunities for promising life science entrepreneurs via Innovation Fund Denmark and the Export and Investment Fund of Denmark**, for example in the form of explorer grants, seed funding and match funding. This will provide researchers with better access to early-stage funding, enabling the development of a project to reach a more mature stage and providing better proof of concept in less time, and it will ensure a sufficiently strong connection between funding in the very early stage and fully market-based venture capital funds. According to an assessment from Innovation Fund Denmark, only 49 percent of all applications to the fund's InnoExplorer programme are successful funding. Similarly, in the Export and Investment Fund of Denmark's match funding scheme, there is significantly more demand for funding than the scheme can currently accommodate. This means that the demand for early-stage funding is significantly higher than what is currently available. New funding should be allocated to the InnoExplorer programme and the match funding scheme, bringing them to approximately double the amount.

- **Denmark must work to establish European late-stage ventures to scale up companies.** In order to retain more life science companies in Europe and attract the capital that can take companies to the next level, a dedicated unit should be created - for example within the Export and Investment Fund of Denmark - which, in co-operation with other European sovereign funds, the European Investment Bank, the European Innovation Council, pension companies and others, establishes two to three new funds in the pharma, MedTech and biosolutions area. Inspiration for this can be drawn from the recently

[4] danmark-er-fortsat-bagud-med-risikovillig-kapital-og-investeringer-til-ivarksattere.pdf (danskerhverv.dk)
[5] McKinsey & Company 2021. Nordic Biotech: assessing and unleashing the innovation engine

established NATO Innovation Fund, for example. As an alternative to establishing new funds, strengthening existing managers and creating a 'Growth Fund' may be considered within the existing framework of the Export and Investment Fund of Denmark – as Sofinnova and Forbion, among others, have succeeded in doing.

- **Intensified efforts to attract venture capital funds to Denmark.** The limited number of startups and the small size of the market means that attention from venture capital funds targeting Danish startups is limited. There is therefore a need for more venture capital from the state to attract further venture capital funds to Denmark, e.g. in the form of funds earmarked in the Export and Investment Fund of Denmark for the life science area. However, opportunities for attracting venture capital funds and expertise also depend on the general economic framework conditions, including tax incentives.

- **Abolition of the taxes on phantom income.** Denmark has a number of tax barriers that prevent venture capital funds from establishing themselves and making investments. Competitive tax incentives are needed so that tax rules do not unnecessarily hinder the Danish life science ecosystem. In particular, the taxes on 'phantom income' can result in investors being left with a loss at the time of sale in the worst-case scenario, as the tax on milestone payments can exceed the profit on the sale amount. It is therefore recommended that the taxes on phantom income be abolished.

Recommendation 6:

There must be better frameworks for collaboration between research environments, the healthcare system and companies.

The strongest life science innovation environments are characterised by close collaboration between universities, companies and clinical researchers in the healthcare sector. In concrete terms, this means that researchers, clinicians and companies can work side by side and have easy access to developing and investigating their solutions in the laboratory and in clinical trials and investigations. In addition, patient involvement can help ensure that the development of new solutions is driven by patient needs.

The interaction between students, researchers, clinicians, patients, companies and academia is in itself a key parameter for further innovation of the highest quality. This applies to both university researchers and clinical researchers. But if we are to reap the benefits of these interactions in a Danish context, it must be easier and more attractive to transition from a research career to employment in industry – and back again. At the same time, there is a big difference between whether and for how long startups are allowed to use university facilities and at what cost, which limits their further development.

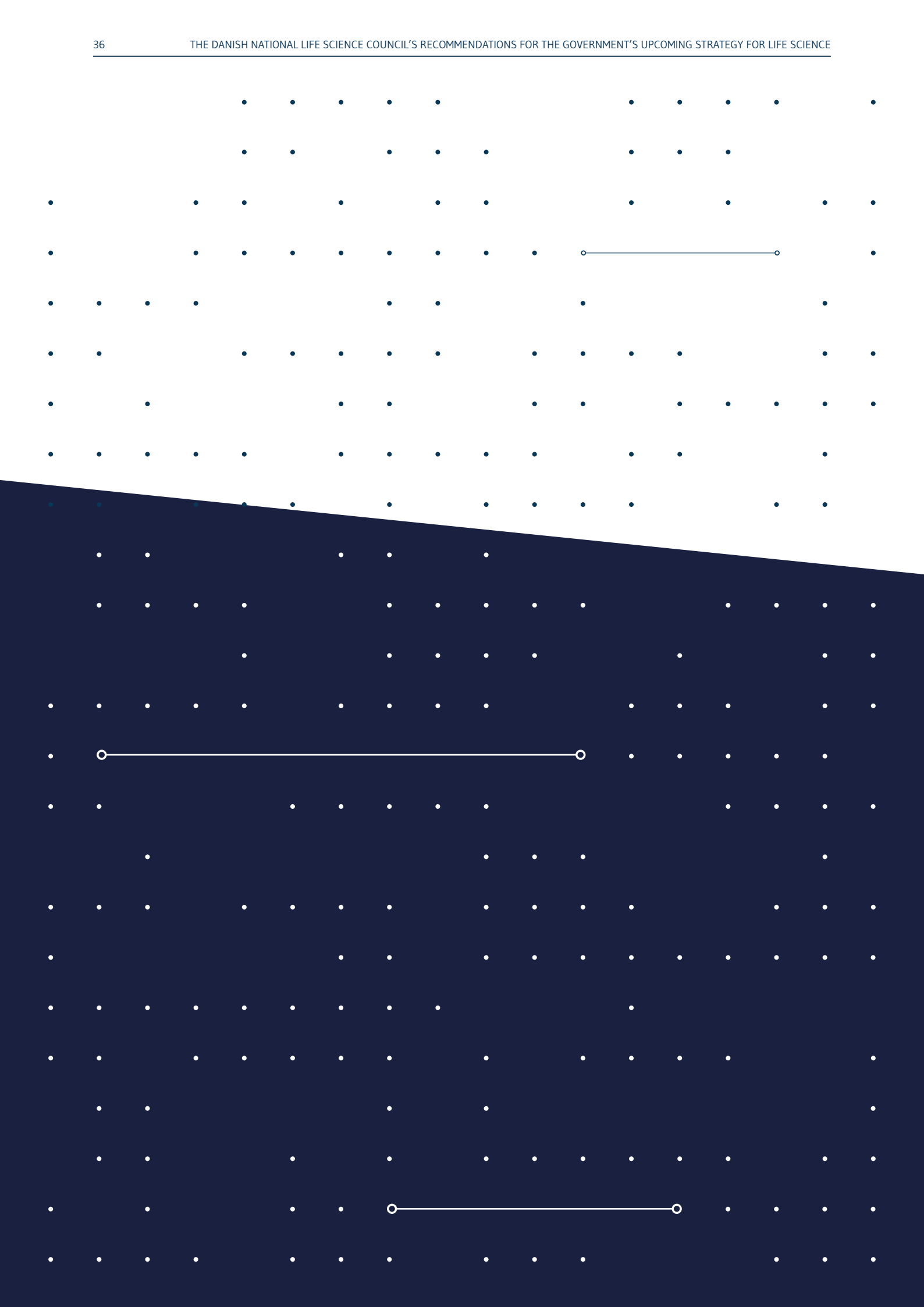
There is therefore a need to create better frameworks for public-private partnership between research environments and the life science industry regarding the development of entrepreneurial environments. At the same time, there is a need for a strong interdisciplinary environment in which different specialisations can meet and collaborate.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Establishment of more laboratory facilities, more business development support and increased translational capacity.** Additional physical infrastructure with associated specialised translational expertise should be established in existing innovative environments. There is also a need for companies to be allowed to remain at universities until they have matured sufficiently. Public buildings and areas should be made available for this purpose, as private investors are expected to be willing to set up and run the facilities. In this connection, changes may be needed to the Executive Order on the Danish Act on Public Research Institutions' Commercial Activities and Cooperation with Foundations (the Tech Trans Act).

- **Establishment of a Danish 'Kendall Square'.** Denmark should establish an internationally leading innovation district for life science based in Copenhagen Science City and inspired by the well-renowned area around Kendall Square in Boston, USA. In this district, companies and researchers will be able to work side by side, which will significantly boost the possibilities of attracting the necessary resources, including capital and skills, to Denmark. At the same time, the various startups will have better access to knowledge sharing and sparring for establishing proof of concept, translation, clinical studies and the regulatory area, attracting capital, etc. The district must function as a knowledge hub for life science, where researchers and both large and small companies can share knowledge across the entire value chain, from a budding idea to an international healthcare solution that benefits patients and citizens.

- **Strengthened incentives and a financial framework for innovation at universities and hospitals.** A paradigm shift is needed at universities and in hospitals to ensure that innovation and translation are at least as prestigious and supported to the same degree as, for example, the publication of research articles. For this reason, a separate financial framework must be created in addition to the existing funding and be earmarked for new investments in innovation. The financial framework can, for example, be realised as a new innovation taximeter grant or other distribution scale that supports innovation and ensures that universities and hospitals are incentivised and measured on innovation. This should be seen in the context of the proposal for a national innovation index to focus efforts. In addition, universities should be rewarded to a greater extent for attracting and securing external funding, and there should be a focus on requiring commitment to scaling for projects and solutions that receive public development funds and can subsequently demonstrate documented clinical and/or labour-saving effects.



CHAPTER 3:

International cooperation and health diplomacy

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International cooperation and health diplomacy

Danish life science companies and the Danish healthcare system are in an international position of strength that helps to solve global health challenges. For years, many Danish life science companies have been researching, developing and marketing healthcare solutions with great success. Danish health authorities are also an internationally recognised partner when it comes to sharing healthcare challenges and solutions.

At the same time, life science accounts for more of Danish exports than ever before, with an export value of DKK 175 billion in 2022, corresponding to around 20 percent of total Danish goods exports. Based on the development in exports over the past 10–15 years, and in light of the global demographic development with an increasing number of citizens with lifestyle and chronic diseases and an increased demand for healthcare solutions, the sector is estimated to reach exports of up to DKK 350 billion in 2030 in a high-growth scenario.

However, Denmark's international position of strength should not be taken for granted. This is especially true in a time of greater international competition within life science, in which global supply chains are under pressure, markets are becoming increasingly isolationist and countries are focusing on industrial policy initiatives to promote their positions of strength. In addition, there is an increasing connection between trade policy, health policy and industrial policy, as well as increased legal and regulatory complexity. This calls for a more active international effort regarding the life science industry's framework conditions.

A strengthened, more strategic and targeted public-private partnership on export promotion and advocacy for the sector's framework conditions in the EU and globally is crucial to maintaining and further developing the Danish position of strength and realising the life science industry's significant export potential.

At the same time, strong Danish health diplomacy and international governmental cooperation are important prerequisites for promoting Danish exports and ensuring that Danish healthcare solutions contribute to making a difference for patients around the world. It will also contribute to making Denmark attractive to foreign companies and investments, which is crucial if Denmark is to fulfil its growth potential by 2030.

For this reason, the Danish Government should lead the way by aiming for Denmark to be a strong player in both the EU and the world when it comes to delivering solutions to global health challenges, as well as work for export promotion and competitive framework conditions for life science that benefit patients, healthcare systems and growth.

Denmark must be a strong player in the EU and globally when it comes to providing solutions to global health challenges and working to promote exports and for competitive framework conditions for life science that benefit patients, healthcare systems and growth.

Recommendation 7:

The strategic effort to promote exports of Danish healthcare solutions must be strengthened.

More export promotion activities, authority-level cooperation and visits from foreign delegations are crucial if the life science industry's great export and growth potential is to be realised and Danish healthcare solutions are to contribute to solving global healthcare challenges. The demand from companies is increasing, and there is therefore a great need to strengthen the resources of the relevant actors to carry out export promotion activities.

The task of creating a showcase for Danish healthcare solutions with stronger roots is a joint public-private responsibility, currently managed by the public-private marketing consortium Healthcare Denmark in close collaboration with healthcare authorities and the healthcare system. Today, the financial framework for Healthcare Denmark is not commensurate with the importance of the sector and the ambition to realise the great potential of Danish life science.

Moreover, a stronger showcase for Danish healthcare solutions requires that health authorities, regions and hospitals participate in export promotion activities. Today, the opportunities are limited, as there is neither the time nor the necessary resources in the busy daily routine at hospitals and clinics. A commitment from the regions to participate in more inbound and outbound delegation visits and export promotion campaigns could therefore help strengthen strategic export promotion efforts.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Healthcare Denmark must be strengthened in line with the life science industry's potential and international position of strength.** This must improve the management of more incoming visits by foreign delegations and, for example, the development of communication and marketing campaigns that can be used by Danish delegations around the world.

- **Health authorities and the healthcare system must be able to prioritise export promotion activities.** The regions must actively participate in export promotion activities, as well as international authority-level cooperation and partnerships. This must provide greater opportunities to showcase Danish healthcare solutions in practice during international visits, and to reap the benefits of foreign experience, e.g. by introducing new technologies that can relieve the burden on the healthcare system. The regions must also help promote innovative healthcare solutions that can be showcased to foreign delegations, ensuring that the Danish market becomes a showcase for the rest of the world.

Recommendation 8:

Advocacy for Danish interests in the EU must be strengthened to support Europe as an attractive life science region through competitive regulatory framework conditions and international market access.

The international competitiveness of the life science industry is closely linked to legislation and the regulation of the sector, which largely takes place at EU level. Specifically, the sector is facing increasing regulation from the EU. This applies, for example, to the European Commission's proposal to revise the EU's pharmaceutical legislation, which includes a proposal for reducing the regulatory data protection period for new medicines, as well as a proposal to revise patent legislation, which, among other things, includes expanded opportunities for compulsory licences. In addition, EU regulations on medical devices (MDR) and in vitro diagnostic medical devices (IVDR) are being implemented, as well as proposals for the European Health Data Space (EHDS), which will impact regulation and access to health data. The adjustments to the EU's pharmaceutical legislation and the implementation challenges of the MDR and IVDR risk significantly weakening the international competitiveness of European life science companies, which could clearly reduce investment in new innovation, research and product development to the detriment of European patients.

At the same time, there is increased EU regulation in areas such as digitalisation, artificial intelligence, the environment and sustainability. Developments in the EU mean that life science companies must increasingly navigate a regulatory complexity that imposes new requirements and has a significant impact on both innovation activity and patients' access to healthcare solutions. For this reason, before and during the upcoming Danish EU presidency, it will be important to prioritise European advocacy and international competitiveness in the life science sector.

In addition, the current geopolitical and trade policy situation places greater demands on companies to operate in shifting circumstances with an increasing degree of technical trade barriers and generally increased protectionism in export markets. This has also meant that the WTO's power to act has been severely narrowed. Denmark should actively engage – both nationally and in the EU – in efforts to reform the WTO.

If Denmark is to succeed in future-proofing life science as a Danish position of strength, this will require an enhanced effort in the EU and internationally. There is thus a need to further reinforce advocacy for Danish interests in key framework conditions for life science in the Permanent Representation of Denmark to the EU and in supporting functions in Denmark. Denmark should prioritise that the revision of EU's pharmaceutical legislation is implemented with European competitiveness in mind.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Reinforcing advocacy for Danish interests in the EU through the Permanent Representation of Denmark to the EU in Brussels in order to strengthen the framework conditions for life science.** Active efforts should be made to support Danish life science within sector regulation as well as EU industrial policy and trade and competitiveness policy, including with a view to ensuring a link between industrial policy and health policy.

- **Strengthening the Danish Business Authority and the Danish Medicines Agency to build sector-specific expertise in life science to support the Permanent Representation of Denmark to the EU in Brussels.** Denmark should take the lead and actively promote focusing in the EU on the life science sector's European framework conditions.

- **Prioritising life science before and during the Danish EU presidency in 2025 through a coordinated effort.** Health and life science should be prioritised during the Danish EU presidency, including emphasising the importance, challenges and international competitiveness of the life science industry.

Recommendation 9:

Health diplomacy and international governmental cooperation must be strengthened and targeted to support the Danish life science sector and attract international life science companies to Denmark.

The strategic health diplomacy and authority-level cooperation generates value for the Danish life science industry and health authorities' access to international best practices. Cooperation between Danish health authorities and other nations' counterparts in strategic markets creates national goodwill and lends crucial legitimacy to Danish healthcare solutions. At the same time, the authorities' efforts secure platforms, networks and knowledge of the local market and Danish solutions for the benefit of Danish life science companies.

Efforts to share this knowledge and local insights must become more systematised towards 2030. This applies to capturing and sharing the most important knowledge regarding framework conditions, market insights, regulations and political currents that affect Danish life science companies in the relevant country.

At the same time, it is crucial that the authority-level cooperation is able to cover a broader scope to tackle the challenges that the life science industry faces in key areas of industrial policy in important export markets, such as intellectual property rights in China and Brazil. Health policy and business policy should be more closely linked.

As part of the implementation of the current life science strategy, the Danish Ministry of the Interior and Health and Danish Ministry of Foreign Affairs have established official cooperation with the high-income countries, such as the US, Japan, South Korea, France, Germany, Norway, the UK and Canada.

No Danish company can on its own resolve the issue of market barriers or establish the necessary dialogue with local authorities around the world that Danish official cooperation and health diplomacy is paving the way for today. It should therefore be a priority to further develop and strengthen this area and ensure greater cohesion between health diplomacy and authority-level cooperation towards 2030.

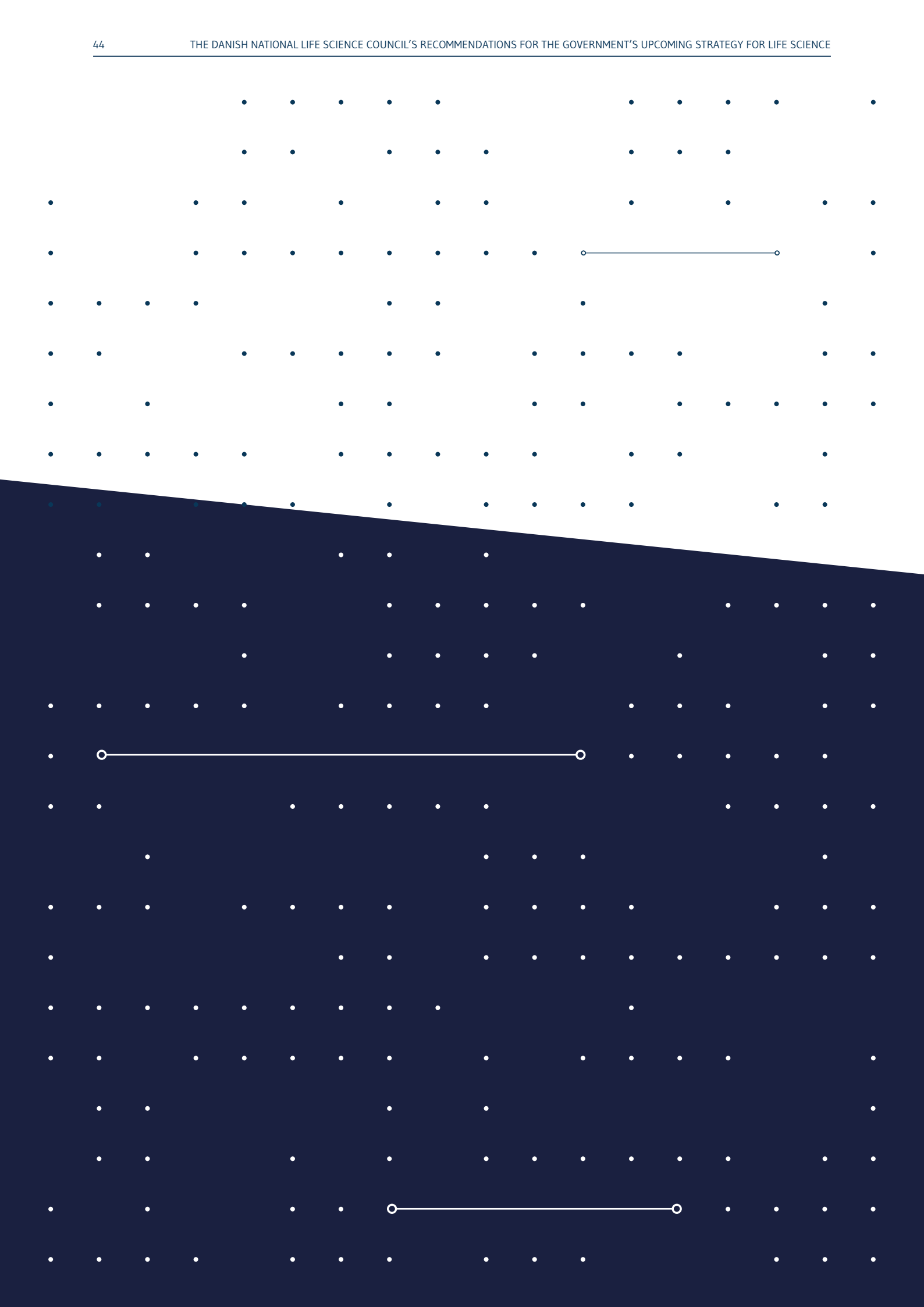
As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Establishment of a public-private contact forum** that will contribute to strategy and prioritisation in the international work within the life science sector. Specific goals should be set for export promotion activities and international efforts. The forum must help ensure that efforts to capture and share knowledge and local insights regarding framework conditions, market insights, regulations and political currents are more systematised and targeted to the needs of the life science industry.

- **Adjustment of the mandate and focus of the posted health advisors based on the two to three key priorities for authorities and companies in each market.** Adjustment must ensure that the posted advisors focus more on addressing the challenges that Danish companies face in the country in question. Depending on the region and country, companies face very different challenges, and this should be better reflected in the deployed advisor's mandate and priorities. This may include revisiting the geographical focus, especially in relation to the selected European countries.

- **Maintaining and further sharpening the focus of the Danish health authorities' involvement in authority-level cooperation.** To an even greater extent than today, efforts must be targeted at Danish positions of strength and contribute to addressing the life science industry's framework conditions in the individual countries.

- **Strengthening intellectual property rights efforts in e.g. China.** The international protection of intellectual property rights is a cornerstone of the life science sector and a crucial framework condition for companies. China is the second largest purchaser of Danish life science products. However, there is a need for greater proximity to the Chinese patent authorities and easier access to advice for Danish companies in China.



CHAPTER 4:

Framework conditions for life science manufacturing and investments in Denmark

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Framework conditions for life science manufacturing and investments in Denmark

Denmark's life science industry is a driver of growth for the country's overall economy. Danish industrial manufacturing is currently performing significantly better than in many other Western countries, which is mainly due to Danish pharmaceutical manufacturing.[6] This progress is, amon other things, driven by the fact that both Danish and foreign life science companies have invested in manufacturing facilities in Denmark. These facilities are modern and high-tech, which has also helped to decouple the life science industry's growth from CO_2 emissions.

International competition for attracting life science manufacturing is high. Other European countries such as Ireland, Switzerland and Sweden are taking a keen interest in the life science industry and have stated their ambition to make it easier and more attractive for companies to locate their manufacturing facilities in those countries. And it is not just our European neighbours we have to compete with. The US and China in particular are at the forefront when it comes to attracting life science investments and labour. Just 20 years ago, the difference between life science investments in research and development made in the US and Europe was around DKK 15 billion. Today, the difference has approached around DKK 185 billion, illustrating that Europe is losing ground.[7].

There are a number of crucial competitive parameters that apply when Danish and foreign life science companies are to decide where to make new investments. This includes access to skilled labour, a good and stable supply of electricity and water, well-functioning infrastructure, smooth approval processes for licences, existing manufacturing, opportunities for green symbiosis and the value of a strong market that rewards innovation and secures market access for new innovative products.[8].

Successful Danish life science also relies heavily on knowledge, skills and a highly skilled labour force. However, more than half of life science companies report that they are currently experiencing recruitment challenges, and the demand for labour is only expected to increase further in the coming years.

In addition to finding the right employees, access to suitable premises is an important prerequisite if Denmark is to be an attractive location for life science manufacturing companies. There are currently challenges in securing sufficient land with good and stable access to the electricity grid, water supply and infrastructure connections. In addition, the fast and efficient establishment of manufacturing facilities in Denmark is challenged by the fact that up to 20 different permits are currently required from both municipalities and government agencies, with long processing times. In many cases, the authority to make decisions regarding the necessary permits for manufacturing companies currently lies with the municipalities, which have varying degrees of competence and capacity. Several companies experience the long processing times as an obstacle to their investments in locating manufacturing capacity in Denmark. At the same time, a flexible authorisation setup is crucial for attracting foreign manufacturing investments.

If Denmark is to be a competitive country in terms of retaining existing life science manufacturing facilities and attracting new investments, it is crucial to formulate clear, strategic ambitions and strengthen the framework conditions that can further boost the industry's manufacturing and enhance our position of strength in the life science field. For this reason, the government should lead the way by aiming for Denmark to be among the top three manufacturing and investment countries for life science in Europe.

[6] NYT: Medicine is sustaining industrial manufacturing – Statistics Denmark (dst.dk)
[7] Charles River Associate for EFPIA, 2022: Factors affecting the location of biopharmaceutical investments and implications for European policy priorities.
[8] Damvad Analytics, 2020: *Dansk Life Science frem mod 2030*, p. 8.

Denmark must be among the top three manufacturing and investment countries for life science in Europe.

Recommendation 10:

The framework for Denmark as a life science manufacturing country must be strengthened, including through the designation of industrial zones suitable for life science manufacturing and smoother administrative approval processes for licences.

Life science manufacturing in Denmark is on the rise. However, several companies face significant challenges in the form of a lack of suitable sites for manufacturing facilities, a sufficient and stable supply of resources such as electricity and water, and traffic congestion challenges and long processing times for licences. These bottlenecks will not only delay or prevent the expansion of manufacturing at existing life science companies in Denmark – they will also constitute a concrete barrier for new companies, including foreign ones, establishing manufacturing operations in Denmark.

When Danish and foreign life science companies are planning new investments in manufacturing capacity, access to critical infrastructure forms a central part of the considerations. A good and stable supply of green power and water plays a crucial role in the geographical location of new investments, and life science manufacturing is particularly vulnerable to power outages. This is why political plans are needed to address the uncertainty regarding adequate power. In countries such as France and the UK, the authorities state that they will exempt vulnerable companies from power outages, and this should also be made possible in Denmark.

Life science companies derive great value from being located in clusters with other companies, which can ensure the circulation of employees and ensure opportunities for sustainable resource utilisation through symbiosis and the recycling of residual products and resources across manufacturing facilities. The expansion of life science manufacturing in Denmark should therefore be based on areas with existing life science manufacturing and strive to incorporate the symbiosis model from the start, paving the way for the exchange of heat, cooling, water and materials across companies, municipalities, private actors, etc. Several of the existing life science clusters in Denmark are increasingly experiencing challenges with congestion. Addressing congestion challenges is central to the possibility of expanding life science manufacturing and investment in Denmark.

Info box:

Examples of major existing life science clusters in Denmark

- Hillerød has established itself as a strong life science cluster with facilities for manufacturing pharmaceuticals and for contract manufacturing.
- Ballerup, Gladsaxe and Copenhagen are home to some of Denmark's largest life science companies across the MedTech and pharmaceutical industries, employing more than 5,000 people in each of the municipalities.
- Kalundborg is home to one of the world's leading industrial symbioses in the fields of life science and biosolutions, focusing on public-private partnership on the utilisation of green resources.
- Odense has a high concentration of life science companies in areas such as robotics and welfare technology.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **Designation of new industrial zones that create space for growth in life science manufacturing close to existing life science clusters, central infrastructure and strong knowledge environments.** The sites should be geared in advance towards sustainable life science manufacturing that can be scaled, and designed in advance as symbioses to reuse waste streams. In this context, the Danish Government should prioritise funds to establish and expand critical infrastructure, especially transport infrastructure, energy supply and water supply. In these zones, there should also be a fast-track application process for the most important licences for manufacturing expansion, e.g. expansion of the transmission network, environmental approvals, urban development plans, etc. in order to shorten the processing time. It is recommended that the areas around existing life science clusters, such as Hillerød, Odense and Kalundborg, be expanded, and that new industrial zones be established to create more manufacturing capacity in more parts of the country.

- **Well-functioning business infrastructure to support life science manufacturing expansion and investment.** Specifically, the Danish National Life Science Council points out that the use of water other than groundwater in pharmaceutical manufacturing is authorised in connection with the revision of the Danish Water Supply Act and associated executive orders, e.g. the Executive Order on Drinking Water. In order to ensure a stable supply of electricity, national critical functions must be made more resilient to power outages and secured in the event of brownouts, and more pilot projects should be initiated with the aim of shortening the processing time for the power grid roll-out. In addition, an ambitious national strategy for utilising surplus heat should be drawn up, and the price cap on heat should be removed so that, for example, costs for transmission lines are not included.

- **Faster and smoother licensing processes through the creation of a 'one-stop shop' for establishing or expanding life science manufacturing and attracting foreign companies.** Both Danish and foreign companies should only have to turn to one place regarding manufacturing projects. The one-stop shop must ensure that procedures are as smooth as possible and that investment projects of national strategic importance are prioritised. The new one-stop shop must thus be responsible for ensuring the quickest possible implementation of the specific projects and coordination with other relevant authorities, from national to local level.

Recommendation 11:

The frameworks for educating future employees and attracting them to the life science industry must support the realisation of growth ambitions.

Employees with the right skills form a fundamental part of a well-functioning life science sector. At the same time, highly skilled labour is crucial for establishing and expanding manufacturing and attracting investments in and to Denmark. This is evidenced by the fact that labour is identified as the second most important factor determining the location of pharmaceutical investments in the EU.[9] However, in Denmark and across national borders, labour supply cannot keep up with demand in the life science industry.

Access to the right employees requires Denmark to ensure more balanced dimensioning of places on educational programmes that supports the needs and demands of the life science industry, but this is not enough. In order to keep up with the demand and need for labour, more study places for international students are required, and there is a need to actively identify and break down barriers prohibiting international students from coming to Denmark to study. At the same time, it is essential that we succeed to a greater extent in retaining foreign students after graduation so that their skills and expertise can be applied in the life science industry in Denmark.

In order to support and drive the development of the life science industry, it is also important that there are good opportunities for employees to continuously receive further training to ensure they have the right skills. At the same time, it must be easier to bring foreign employees into the country, including helping partners and families settle in well in their new environment, as this increases the likelihood of retention.

Analyses estimate that in a high-growth scenario, there will be up to 30,000 more FTEs in life science in 2030 compared to 2020. This means that the life science industry will be short of up to 10,000 FTEs by 2030.[10]
There is therefore a need for a dedicated and targeted effort now to enable us to secure the workforce in the life science industry by 2030 and realise the potential for attracting manufacturing and investment in Denmark.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **The expansion of industrial PhDs and industrial post-doctoral schemes,** so that more researchers from academia choose to take a job in industry and later return to academia. This creates value for the researcher themselves, but also for public independent research and the private equivalent. By zigzagging between the different worlds of research throughout their careers, researchers bring with them knowledge, perspectives and experience that can enrich both sectors.

- **Establishing specialised biopharmaceutical research and training centres and identifying skills requirements in the life science industry towards 2030.** Biopharmaceutical research and training centres must attract, support and develop employees with the right skills to work in manufacturing across the life science industry. Inspiration should preferably be drawn from other countries, including Ireland, where investments have been made in similar training and development centres aimed at life science manufacturing. Consideration can also be given to whether to focus on specific manufacturing techniques that give Denmark a competitive edge. It is proposed that a working group be set up to identify the future need for labour in the life science industry as soon as possible across vocational education and training, professional education and long-term higher education, including Master's degree programmes, with the aim of upgrading the relevant programmes as soon as possible.

[9] CRA 2022: Factors affecting location of biopharmaceutical investments and implication.
[10] Damvad Analytics 2020: Dansk Life science frem mod 2030, p. 27

- **More targeted, binding collaborations to create more places in educational programmes aimed at life science manufacturing** and strengthening cooperation between companies and educational institutions. Targeted educational programmes in pharmaceutical manufacturing must be designed so that the programmes qualify students for further studies at the next level, e.g. from operator to production technologist or from production technology to BSc. In addition, the modules in the individual programmes should be organised so that they include regular full-time studies as well as continuing and further education to upskill employees in pharmaceutical manufacturing. In this context, the green transition should be included as an important academic component. A number of these programmes should preferably be located in the vicinity of the life science companies' physical premises. This will allow more companies to join forces to create strong educational alliances locally, as seen with Campus Kalundborg. The creation of more places for education and training aimed at life science manufacturing, including the creation of specific English-language programmes, should be an active element of the ongoing educational reform.
- **Better framework for attracting and retaining international labour, research talent and international students.** It must be possible to offer foreign employees salary packages equivalent to those of Danish employees, tailored to the individual's needs within the scope of the Pay Limit Scheme, without the requirement that the salary can only be paid in cash and only to a Danish bank account. In addition, when employees from third countries apply for work or residence permits, the processing times at the authorities should be shortened, and it is essential that the fast-track scheme is made available to very small companies. Furthermore, changes are proposed to the rules for spouses of foreign employees, e.g. that spouses may not work for the same group without separate authorisation, and that work permits only apply to full-time positions.

Recommendation 12:

The focus on the sector's framework conditions must be maintained in order to realise growth ambitions.

If the Danish position of strength in the life science sector and the ambitious development goals are to be realised for the benefit of patients, growth and jobs, there is a need to continuously focus on the framework conditions of the Danish life science sector. At the same time, a sustained focus is necessary to realise the potential of increased collaboration and coordination of efforts between the public and private sectors to generate increased growth, prosperity and better patient care.

In this context, establishing key performance indicators (KPIs) is an effective way to continuously monitor the progress and development of the life science sector in Denmark towards 2030 based on the strategic milestones and ambitions.

As a consequence of the recommendation, the Danish National Life Science Council has identified the following concrete solutions:

- **The life science strategy should establish KPIs in key areas such as innovation, new business development, exports and manufacturing.** The KPIs must support the strategic development of the life science sector in Denmark towards 2030. The Danish National Life Science Council will regularly discuss developments in the KPIs.

- **The Danish National Life Science Council and the life science units in the Danish Ministry of Industry, Business and Financial Affairs and the Danish Ministry of the Interior and Health must continue operations.** In an international context, the Danish National Life Science Council is considered to be a unique forum for strengthening the public-private dialogue and promoting efforts across the areas of business policy, health policy and research and education policy within life science. The life science units in the Danish Ministry of Industry, Business and Financial Affairs and the Danish Ministry of the Interior and Health are also crucial framework conditions for ensuring a sustained, focused and coordinated effort in the life science area in Denmark.

Mission of the Danish National Life Science Council

In April 2023, the Danish Government asked the Danish National Life Science Council to provide recommendations for a new strategy for life science.

The framework for the Council's work has been that with the new strategy, the Government wishes to support favourable framework conditions for the life science sector to unlock further potential for both the industry and the healthcare system.

The strategy aims to address the life science sector's key challenges and ensure a long-term focus towards 2030. The Government's proposal for a new life science strategy is expected to be launched in spring 2024.

The Danish National Life Science Council has prioritised developing a few specific and ambitious recommendations in order for the upcoming life science strategy to be focused on the most important challenges and potential for the sector.

In 2023, the Danish National Life Science Council held four meetings – in April, June, October and December.

The Council's work has been organised around four overarching themes:

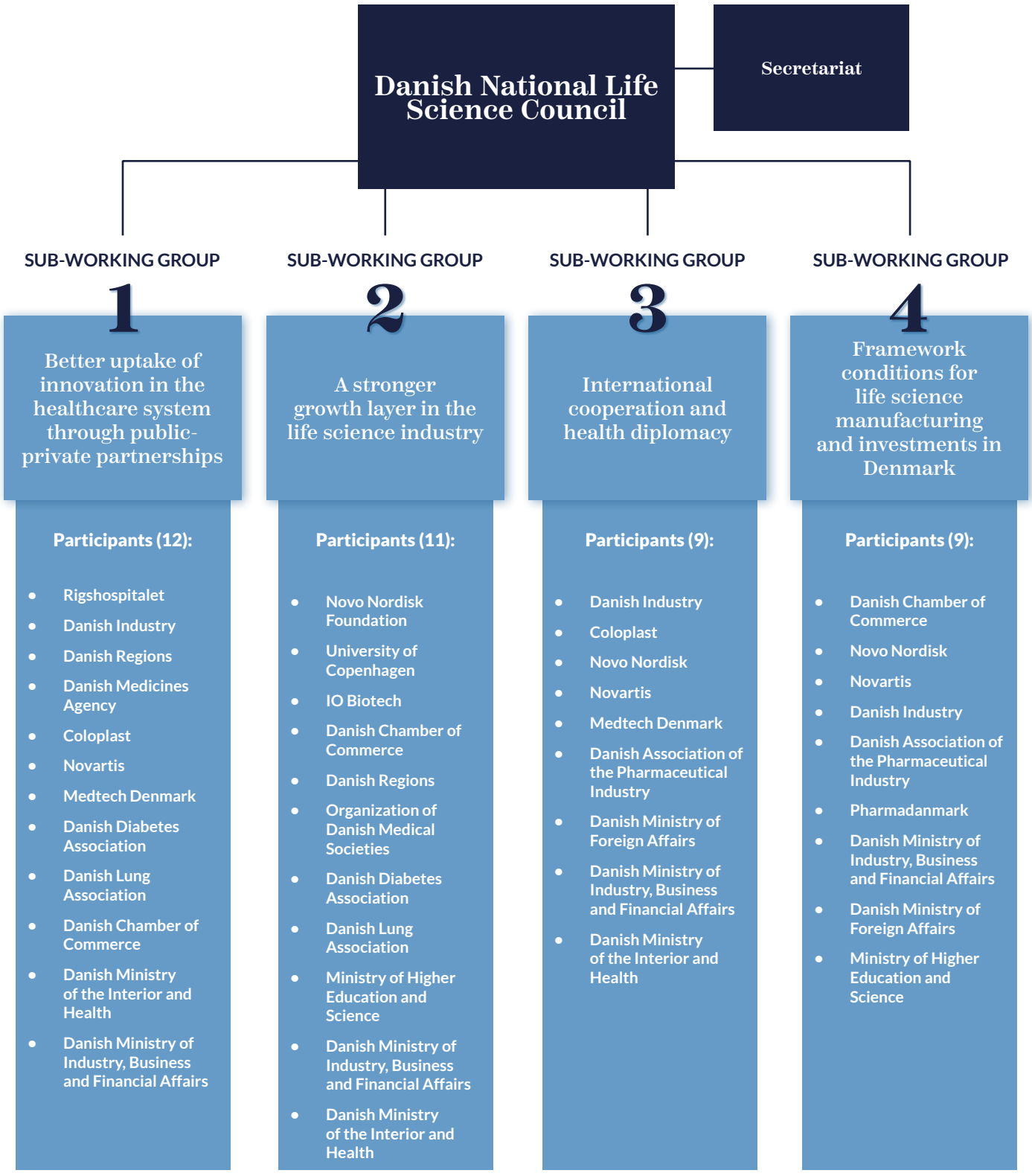
1. Better uptake of innovation in the healthcare system through public-private partnerships
2. A stronger growth layer in the life science industry
3. International cooperation and health diplomacy
4. Framework conditions for life science manufacturing and investment in Denmark

Four sub-working groups have been set up under the Danish National Life Science Council, which, based on the four themes, have been tasked with drafting recommendations for discussion and prioritisation in the Council. During the process, each sub-working group organised a theme day where a wide range of stakeholders in the life science sector were invited to provide input for the work of the Danish National Life Science Council. The broad involvement has helped lend support to the Council's recommendations and ensure they are rooted across the sector.

In September 2022, the Danish National Life Science Council published a set of recommendations for research and innovation efforts, which should be seen as a supplement to the present recommendations.

The relevant ministries have participated in the work of the sub-working groups. Among other things, the ministries have provided guidance and professional sparring on ongoing political efforts with relevant interfaces with the work of the Danish National Life Science Council, including the health structure commission, the robustness commission and the Government's upcoming entrepreneurship strategy. The ministries are not the co-authors of the Danish National Life Science Council's recommendations, as these are addressed to the Danish Government.

Organisation of sub-working groups



Members of the Danish National Life Science Council

Council members:

- Lars Rasmussen, Chairman of the Board, Coloplast and Lundbeck (Chairman)
- Lars Fruergaard Jørgensen, CEO, Novo Nordisk
- Kristian Villumsen, CEO, Coloplast
- Peter Drøidal, Country Manager, Novartis
- Mai-Britt Zocca, CEO, IO Biotech
- Mads Krogsgaard Thomsen, CEO, Novo Nordisk Foundation
- Lars Bo Nielsen, CEO, Danish Medicines Agency
- Rasmus Møgelvang, Director, Rigshospitalet
- Brian Mikkelsen, CEO, Danish Chamber of Commerce
- Emil Fannikke Kiær, Political Director, Danish Industry
- Peter Huntley, CEO, Medtech Denmark
- Ida Sofie Jensen, CEO, Lif – Danish Association of the Pharmaceutical Industry
- Adam Wolf, CEO, Danish Regions
- Susanne Axelsen, Consultant, Senior Clinical Lecturer, Chair, Organization of Danish Medical Societies
- Susie Stærk Ekstrand, CEO, Pharmadanmark
- Claus Richter, Danish Patients, CEO, Danish Diabetes Association
- Ann Leistiko, Danish Patients, CEO, Danish Lung Association
- Trine Winterø, Vice Dean, Innovation and External Relations, Faculty of Health and Medical Sciences, University of Copenhagen
- Dorte Bech Vizard, Head of Department, Danish Ministry of the Interior and Health
- Nils Agerhus, Head of Department, Ministry of Higher Education and Science
- Michael Dithmer, Permanent Secretary of State for Industry, Business and Financial Affairs

THE DANISH NATIONAL LIFE SCIENCE COUNCIL'S RECOMMENDATIONS
for the Government's upcoming strategy for life science

December 2023

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