The Danish Life Science Council

Recommendations for a European Life Science Strategy

March 2025

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Preface

The life science industry is one of the most valuable and strategically important sectors in Europe's economy and is essential for ensuring the health and well-being of all Europeans. However, as outlined by Mario Draghi in his report on The future of European competitiveness, Europe's growth has slowed and the European life science sector is losing ground to other major economies.

Innovative treatments, including innovative medicines and medical devices, is critical not only for improving the health and quality of life for all Europeans, but also for responding to demographic changes and the growing burden of chronic diseases. Achieving these goals requires research, innovation, and medical breakthroughs within Europe.

Global competition in the life science sector is intense, with other regions outpacing Europe. Despite its strong science and research base and its history as a life science innovation hub, the EU is gradually losing ground to the US and China. The EU faces a declining number of R&D investments, clinical trials, sales and tax revenues, jobs and societal impact. Between 2002 and 2022, the investment gap with the US increased from €2B to €25B. The Draghi report highlights the root causes of this competitive gap, including lower private and public investment in R&D, a weaker innovation ecosystem compared to the US, and a slow, complex regulatory framework.

Regaining Europe's competitive edge while enhancing its economic security and resilience will require a vibrant and innovative industrial landscape characterised by innovation friendly regulation, high productivity, investments and a strong focus on public-private partnerships to accelerate the adoption of new technologies within healthcare. Europe does possess significant strengths and we must leverage our values of sustainable competitiveness, open strategic autonomy, and fair competition. These core values provide a solid foundation for future growth and innovation.

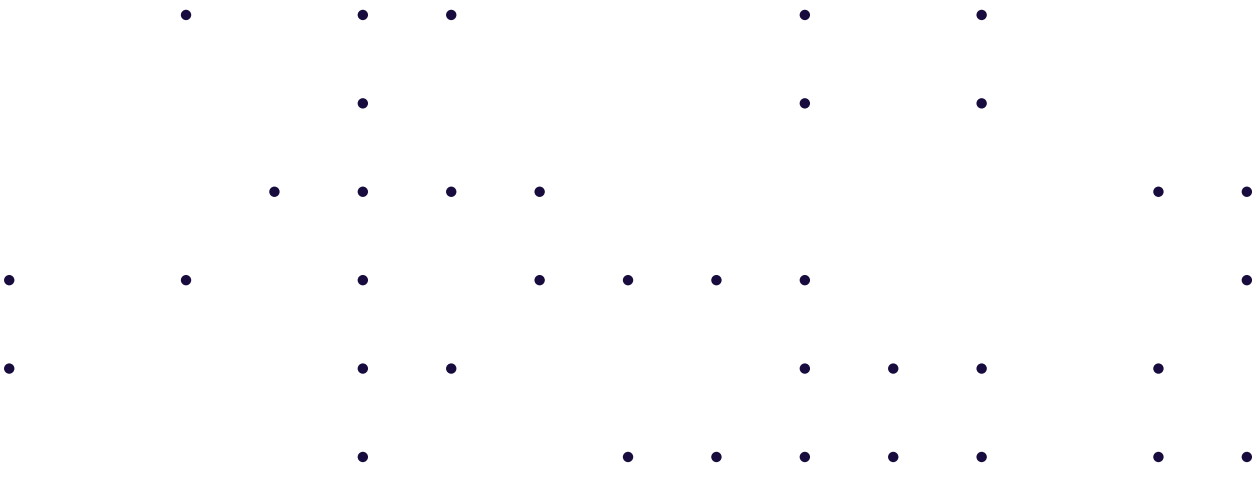
In November 2024, the Danish Government and a broad majority in the Danish Parliament agreed on a new Danish life science strategy. The strategy puts the needs of patients at the centre and outlines concrete initiatives to provide a framework that can deliver on these needs, with the entire value chain for life science as the main focal point. It highlights the interdependence between the public and private sectors and emphasises the linkage between a strong industry and research ecosystem and a robust healthcare system with good access to medicines and treatments.

The Danish Life Science Council welcomes the initiative of a European Life Science Strategy. Drawing upon the experiences from the Danish Life Science Strategy, the Council has prepared its recommendations for the European Life Science Strategy.

We hope that the European Commission will prioritise efforts to enhance European competitiveness and transforming ambitions into action, to realise the vision of Europe as an internationally competitive life science ecosystem that fosters growth, attracts researchers and clinical trials to transform research into innovative treatments and supports European manufacturing as a core industrial strength. The European Life Science strategy represents the intersection of the interests of patients, healthcare systems, society, and European resilience and economic growth. A strong strategy can ensure the necessary innovative breakthroughs that provides opportunities for European patients to have access to the latest and most effective treatments and medicines.

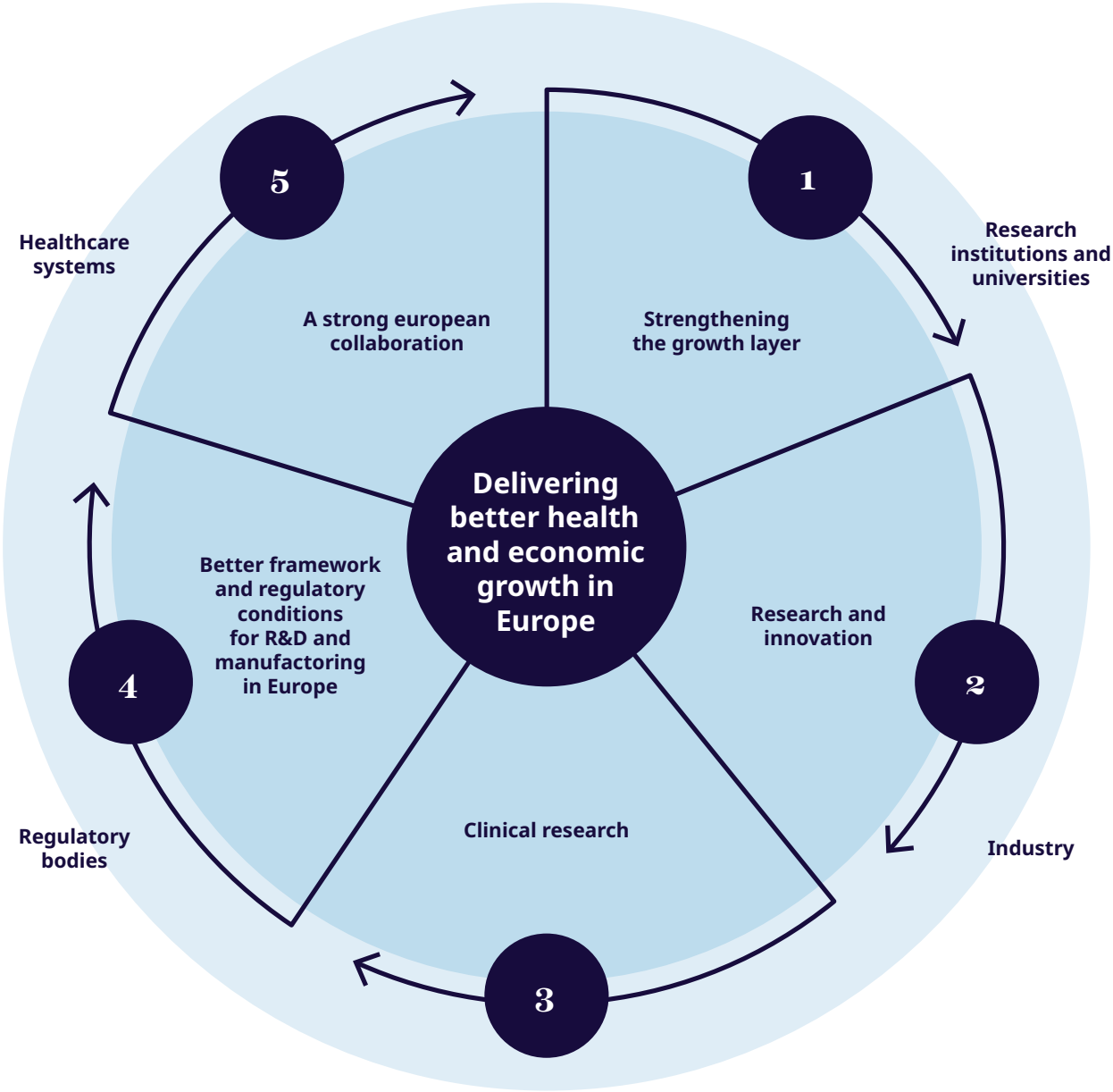
A thriving European life sciences sector is crucial for delivering life-changing treatments that improve the lives of patients and enhance the health and well-being of citizens across Europe.

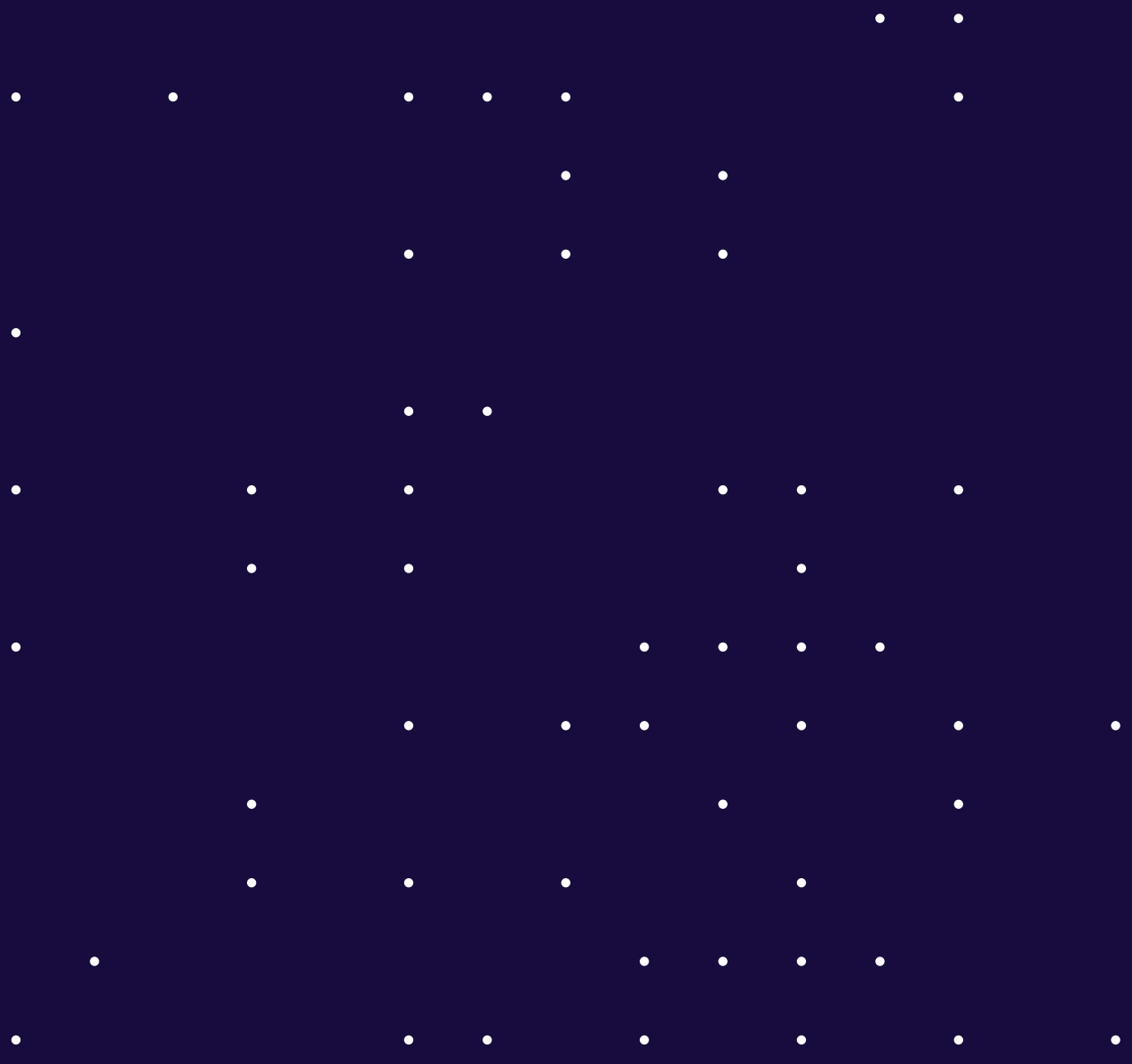
Lars Rasmussen
Chair for the Danish Life science Council



The life science ecosystem

The life science ecosystem consists of key players and components that create the innovative, competitive and well-functioning life science-system with a twofold purpose: to deliver better health and ensure economic growth.





Recommendations from the Danish life science council

The European life science sector is crucial to the European economy, growth and employment.

However, it is facing increasing international competition and a number of challenges. The Draghi report points to different factors including lower spending on R&I and innovation; a slow and complex regulatory framework; slower approval time for new medicines and medical devices by regulatory agencies; and fragmented access to health data, etc. Hence, the EU is no longer the dynamic hub for innovation in life science technologies it once was.

A European Life Science Strategy should address all these issues. Prompt action is essential to prevent the emerging gap from widening further. The strategy should adopt a holistic approach, encompassing and promoting all facets of the life science ecosystem, including initial growth layer, research and innovation, clinical research and framework conditions for manufacturing and launching within the EU.

The European life science sector is crucial to the European economy, growth and employment.

Themes

01 **Strengthening the growth layer**

02 **Research and innovation**

03 **Clinical research**

04 **Better framework and regulatory conditions for R&D and manufacturing in Europe**

05 **A strong European collaboration**

Strengthening the growth layer

01

The life science sector, especially the pharmaceutical industry, is often mistakenly characterised as being made up of a few large companies with the capacity and financial strength to develop new medicines. In reality, the sector also includes numerous start-ups and SMEs, encompassing the medical devices industry, that are essential for innovation but are facing significant challenges in accessing venture capital in Europe.

As a result, successful European companies, particularly unicorns, are increasingly turning to the US to attract capital. This trend has led to lower R&D investments within Europe and the relocation of innovative European companies to the US.

As the Draghi report outlines, access to venture capital is crucial for the growth of start-ups and SMEs, and yet Europe lags behind the US. The growth segment, encompassing life science start-ups and SMEs, is under significant pressure. On average, between 2020 and 2024, start-ups in the EU were just 29 % of the total number of start-ups in the US. In other words, for every European life science start-up established between 2020-2024, three start-ups were established in the US. During the same period, annual funding for EU start-ups represented just 5% of the total funding available in the US, with a sharp decline from 11% in 2020 to only 2% in 2024.

An enabling framework needs to be created for the private capital market through market-driven initiatives and stronger collaborations with private investors.

Recommendations:

- Analyse possible models for a European life science investment fund, with the goal of establishing the fund through the European Investment Fund (EIF) in order to attract institutional investors that primarily invest in local venture funds and secondly include syndication investments in life science companies. Additionally, new large European late-stage venture funds should be created to address the need for scaling of companies. This will accelerate the growth of life science-companies and make it easier to retain them in Europe.
- Enlarge the mandate of the EIB in order to allow for direct equity investment in EU strategic high-tech priority sectors such as AI, semiconductors, medtech, life sciences/ bio-medical etc., also enabling the option of providing contingent capital to National Promotion Banks (NPB) to co-invest with the EIB in such projects when desirable.
- Prioritise soft funding through The European Innovation Council (EIC) to strengthen Europe's life science innovation ecosystem in the future. The EIC stands as a prime example of a successful program under Horizon Europe, providing crucial funding to start-ups and SMEs through a combination of grants and investments. The EIC plays a vital role in retaining talented researchers and entrepreneurs by ensuring access to soft funding, particularly during the critical stage of translating innovations into commercialization.

Research and innovation

02

Research and innovation are crucial for the development of new, innovative medicines, therapies, and medical devices and the general development of the European healthcare systems. Global competition is increasing, and it is essential that Europe establish world leading framework conditions to stimulate, support and foster an innovative ecosystem with all relevant key players, to remain competitive in a global market.

Building on the strong European science and research base, a key factor is the ability to transform fundamental research into innovation and entrepreneurship and to enhance collaboration between industry and academia. The US has established attractive innovation hubs (such as Kendall Square in Boston) for the global life science industry and research environment by providing the right framework conditions, targeted financing, and a pool of talent and skills based around world class universities.

Improved possibilities for collaboration between academia, healthcare systems and industry are necessary to support the conversion of research into commercial solutions addressing concrete health problems. Additionally, supporting world-leading research and technology infrastructures that serve as knowledge and innovation hubs will attract high-level expertise and foster innovation.

As highlighted in the Draghi report, Intellectual Property Rights (IPR) drive medical development by stimulating research and innovation of novel medicines. A coherent and predicable framework that protects IPR is vital for incentivising innovation in the EU, attracting investments, and ensuring that the benefits of innovation remain within the EU. This includes supporting related protection schemes such as regulatory market and data protection, and supplementary protection certificates (SPC).

To enhance its competitiveness in life sciences, Europe should also focus on enabling technologies such as artificial intelligence (AI) and quantum technologies, which can transform and revolutionise the discovery of new medicines, technologies, clinical trials, patient treatments, diagnostics and manufacturing processes. The EU must develop responsible, transparent, and fair AI that aligns with its values, while investing in secure AI infrastructure within Europe. In quantum technologies, the EU has strong potential for applications in drug discovery and treatment. To seize these opportunities, Europe needs to advance these technologies with long-term investment, expecting significant results in about five years.

Recommendations:

- Create and invest in a limited number of European world-class innovation hubs to gain critical mass to rival the size, appeal and impact of major US hubs. Prominent examples are BioValley in France, GoCo Health Innovation City in Sweden and the current Danish effort in developing a major innovation hub for life science and quantum technology located in central Copenhagen.
- Increase EU-funded investments in life science research, including in Horizon Europe and future framework programs. In continuation, EU should support selected, specialised clusters of biotech and pharmaceutical excellence.
- Benchmark and align the IP regulatory framework for life sciences with the US, to ensure that conditions for investing in the life science industry and patient access to prevention, early diagnosis and treatment in Europe, are globally competitive.
- The EU should leverage its influence in international organisations such as the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) to promote robust IP standards – and ensure that strong IP protection and enforcement provisions are included in all new Free Trade Agreements (FTAs) with third countries.
- Promote AI sandboxes from laboratory to the market, including the possibility to exempt businesses from existing legislation under regulatory supervision, to foster innovation and competitiveness.
- To remain at the forefront of AI and quantum technology advancements in health tech, EU should establish centers of excellence that bring together experts from AI, quantum technologies, and life sciences to work on interdisciplinary cutting-edge research and improve access to health data.
- Invest in establishing AI compute processing power and maturing quantum technologies within Europe. This includes developing a robust AI infrastructure with seamless access and advancing quantum computing and sensing technologies for use in life sciences. It is important to protect European technology and IP and to secure access to the latest quantum computing resources for the life science sector.

Clinical research

Clinical research is essential for advancing medical knowledge and improving patient care. It involves systematically testing new treatments, interventions and diagnostic tools to determine their safety and effectiveness.

By conducting clinical trials, researchers can identify high-value care and eliminate low-value practices, ensuring that patients receive the best possible treatment. Access to and sharing of health data across member states is one of the foundations for timely and personalized diagnostics. Prioritising and engaging the life science industry in the implementation of the European Health Data Space (EHDS) is crucial for boosting research, developing new medicines.

Early patient access to the most effective and safe treatments is crucial for the health of European citizens. As healthcare systems across Europe face increasing pressure due to rising costs, demographic changes, and changing clinical practices, it becomes more important than ever to ensure that innovations are rapidly integrated into patient car, and the sharing of best practice.

The Covid-pandemic was the breakthrough for platform trials. The method establish lasting clinical trials for perpetual testing of many interventions simultaneously and over time within a disease. Embedded in clinical practice, platform trials can assess the value of any interventions or processes and, therefore, facilitate valid removal of any type of low-value care. Platform trials constitute adaptive, lasting clinical trial structures for valid and cost-effective removal of healthcare and facilitate implementation of new treatments.

International clinical trials or multi-country clinical trials are important in advancing medical research, as they provide the ability to enhance equity by enabling patients from a wider range of genomic, biological, ethnic, and socio-cultural backgrounds to take part, as well as help expedite recruitment as it allows access to much larger patient populations. Multi-country clinical trials within the EU also have the potential to spread the benefits of a robust European life science ecosystem throughout the Union. There is also a close correlation between hosting clinical trials and access to new treatments.

Recommendations:

- Facilitate models testing both the administrative, digital, clinical and academic embedding of platform trials across several member states. Funding of platform trials could be through the current Horizon Europe and the future FP10 through bottom-up or impact-driven calls.
- Establish a harmonized, agile clinical trials ecosystem in EU that supports multi-country clinical trials in order to deliver on the full potential of the EU Clinical Trials Regulation (CTR), thereby promoting simplification and flexibility. The ecosystem should support harmonized dossier reviews by National Competent Authorities and Ethics Committees across Europe, ensuring streamlined approval for multi-country clinical trials.
- Prioritize a smooth and simple implementation of the European Health Data Space (EHDS) with timely involvement of the life science industry and increase efforts to standardise existing data sources to a common data model building on the work initiated by the European Health Data Evidence Network (EHDEN).

Better framework and regulatory conditions for R&D and manufacturing in Europe

04

Ensuring the supply of high-quality medicines in the EU is a key objective of the European Health Union and essential if European patients are to have access to new and effective treatments. As outlined in the Commission's communication on biotechnology and biomanufacturing, stimulating local production and creating a balanced regulatory framework are essential for safeguarding the EU's supply security and maintain manufacturing within Europe.

To ensure that Europe remains competitive, it is vital to simplify the regulatory framework, remove barriers to innovation, and create conditions that encourage manufacturing within the EU.

The regulations of Medical Devices (MDR) and In Vitro Medical Devices (IVDR) are examples of how introducing significant bureaucracy can hinder both patients' access to innovative medical technologies, patient safety and innovation in the EU. From 2015 to 2023, the EU's market share of medical devices dropped from 39% to 26%, while the US grew from 42% to 47%. This shift highlights the impact of EU regulations and the more supportive environment for innovation and market access in the US. The EU must learn from these experiences.

Another pressing issue is the regulation of combination products, which now account for up to 25% of the pharmaceutical pipeline. However, the EU regulatory system remains fragmented with separate authorities for pharmaceuticals, medical devices, and diagnostics. There is a need for a more effective coordination across authorities involved in certifying combination products, both in relation to the device part and the medicine part, ensuring that time-to-market becomes significantly more streamlined than today.

Recommendations:

- Revision of the MDR/IVDR regulation to increase predictability, proportionate surveillance and fostering innovation and to make the EU more competitive, by 1) Removal of the mandatory re-certification process for medical devices every five years across all risk classes, 2) A higher level of transparency and predictability for companies in the certification process, 3) Establishing a fast track procedure for innovative medical devices in EU, and 4) Rethink the certification process concerning product updates.
- Streamline regulatory processes for combination products by 1) Clarifying the roles and responsibilities of notified bodies, national health authorities (National Competent Authorities - NCAs), and the European Medicines Agency (EMA), and 2) Establishing a ”one-product” approach for combination products, ensuring that the right authority support is in place.
- Implementing a ”competitiveness check” as outlined in the Mission Letters for all regulatory actions to ensure that they contribute to enhance the EU’s competitiveness, including costs of compliance and administrative burden on the overall competitiveness of the EU’s life sciences sector.
- Yearly blueprint of the competitiveness of the European life science industry and development of a ‘tracker’ on key competitiveness sector-specific indicators. Examples of indicators include time to market, global share of R&D investments, patent applications, use of expedited pathways, free trade agreements securing a level playing field.

A strong european collaboration

05

The geopolitical tensions and the Covid-19 pandemic have exposed vulnerabilities in global supply chains, underscoring the need for Europe to ensure the security and resilience of its supply chains, particularly in critical sectors such as healthcare, pharmaceuticals, and medical technologies.

EU must keep a strong global position to remain competitive. A unified and cooperative European approach is crucial for enhancing Europe's global competitiveness in life sciences, ultimately improving growth, health outcomes and ensuring a resilient future for all citizens.

EU must secure Europe's patients access to state-of-the-art prevention and treatment. One approach is for example to generate knowledge models on the positive ripple effects of investments in new healthcare initiatives. The EU must be prepared to embrace emerging technologies, such as personalized medicine, advanced therapies, and AI-driven digital solutions. This requires the EU's framework legislation and data infrastructure to be adaptable to these new advancements, while also facilitating the sharing of successful national experiences and cooperation models that promote innovation. Additionally, the EU must provide leadership in areas where coordinated efforts are crucial, such as addressing the needs of patients with rare diseases and tackling antimicrobial resistance (AMR).

Diversifying value chains and securing new trade agreements will reduce reliance on a limited number of countries, thereby strengthening the industry's resilience and reducing fragility. At the same time, it is vital to promote free trade and fair competition, with all parties adhering to the same rules and standards.

One of the key lessons learned from the process in developing the Danish Life Science Strategy is the importance of focusing on the entire value chain for life science, supporting all interconnected elements that affect the sector. Moreover, close involvement and collaboration among all relevant stakeholders in the development of the strategy is crucial to achieving long-term success.

Recommendations:

- A European life science strategy should take a holistic approach and cover the entire life science ecosystem with an aim to develop framework conditions that allow the life science ecosystem to deliver the innovation and technology needed to provide the best possible health care for all Europeans and growth.
- The development of the strategy should take a cross-sectoral approach and organization across DGs in the Commission, for example through the establishment of an interdisciplinary Life Science Office.
- Establish a European Life Science Council, to bring together representatives from key European institutions, authorities, academia, patient organizations, and industry, to enhance the competitiveness of the EU's life sciences industry, support research and innovation, and address key challenges such as patient access to health, security of supply, and health crisis preparedness. This forum should provide input to the European Commission on new policy and regulation relevant for the life science industry, as well as identify the most burdensome existing legislation for companies, patients, and researchers in Europe.

The Danish Life Science Council

The Danish Life Science Council is appointed by the Danish government with the purpose to strengthen the public and private partnership, focusing on the framework conditions for the life science industry in Denmark and globally.

Members of the Danish Life Science Council:

- **Lars Rasmussen**, Chairman of the Board, Coloplast, Lundbeck and WSA (Chairman)
- **Lars Fruergaard Jørgensen**, CEO, Novo Nordisk
- **Britt Meelby Jensen**, CEO, Ambu
- **Julie Enevold Brooker**, Country Manager, Johnson & Johnson Innovative Medicine
- **Mai-Britt Zocca**, CEO, IO Biotech
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- **Ann Leistiko**, Danish Patients, CEO, Danish Lung Association
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- **Dorte Bech Vizard**, Head of Department, Danish Ministry of the Interior and Health
- **Nils Agerhus**, Head of Department, Ministry of Higher Education and Science
- **Jens Brøchner**, Permanent Secretary of State for Industry, Business and Financial Affairs

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Danish Ministry of Industry,
Business and Financial Affairs
Slotsholmsgade 10-12
DK-1216 København K, Denmark

Tlf.: +45 33 92 33 50
E-mail: em@em.dk

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