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Permanent Representation of Sweden to
the EU, Square de Meeûs 30, 1000 Brussels

Nordic Seminar on the EU Life Sciences Strategy – Recommendations from the Nordic Pharma Associations

The research-based pharmaceutical industry

The Danish Association of the Pharmaceutical Industry

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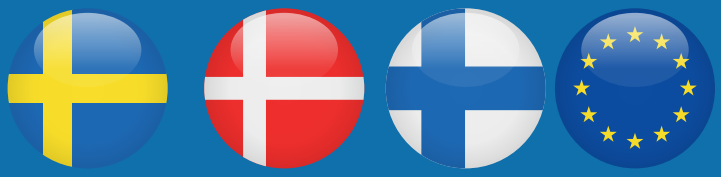
efpia



Nordic Seminar on the EU Life Sciences Strategy

On 1 October, a seminar on the future life sciences strategy was organized in Brussels by the Nordic pharmaceutical industry associations Lif Sweden, Lif Denmark and Pif Finland, bringing together participants from the European Parliament, the European Commission, and the business sector. The participants agreed that the life sciences sector represents a key industry for the future and will be crucial for strengthening the EU's global competitiveness. Currently, the sector directly employs over 900,000 people across Europe and is the largest contributor to the EU's trade balance. Moreover, the life sciences sector drives the development of groundbreaking technologies and medicines through intensive research efforts.

However, the industry faces fierce competition, particularly from the U.S. and China. According to Mario Draghi's recently published competitiveness report, Europe has lost 25% of its global share of R&D investments to other regions over the past two decades. Similarly, the EU's share of global clinical trials has declined from 25.6% to 19.3% during this period.

During the seminar, it was emphasized that a new life sciences strategy is urgently needed, as it has been 22 years since the last one was developed. A coordinated EU-wide strategy is essential to create the right conditions for the industry to regain its leadership position. The Nordic countries have valuable experience in working with national life sciences strategies in a triple helix model, much of which could be scaled up to the European level.

Following the discussion at the seminar, the three pharmaceutical industry associations in the Nordic countries, recommend the following:

1. Develop a holistic and focused life sciences strategy

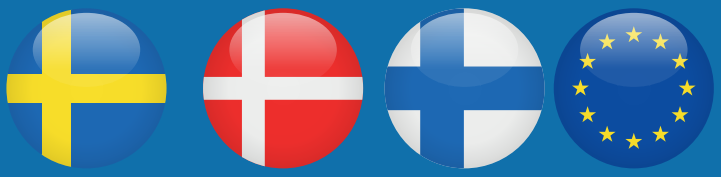
There is a need for a life sciences strategy that addresses prevention, diagnostics and patients' early access to innovative therapies through sustainable healthcare systems, resilience, competitiveness, research and innovation. A clear and targeted strategy is essential for setting achievable ambitions and ensuring coordinated efforts. The experiences of the Nordic countries, where the national strategies have resulted in better regulation, increased structural efficiencies and public-private partnerships offer valuable insights for comparison and best practices.

2. Establish a Life Sciences Office

There is a pressing need for efficient coordination, which can be achieved through a dedicated life sciences office within the European Commission to coordinate the directorates responsible for legislation impacting the life sciences sector. A unified approach with clear accountability is needed to ensure that all stakeholders are aligned on the necessary actions. In addition, an EU Life Sciences Forum could bring together representatives from key European institutions, authorities, academia, patient organizations, and industry, will create a strong foundation for collaboration and dialogue. This forum could play a key role in developing common solutions to support the European ambitions in the life science sector.

3. Secure Europe's patients access to state-of-the-art prevention and treatment

Europe must invest in health by developing joint, systematic evaluation models and generating knowledge on the positive ripple effects of 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. The proposed EU Life Sciences Forum should enhance patients' access to health innovations. 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).



4. Improve framework conditions

The upcoming life sciences strategy must focus on strengthening framework conditions across Europe. Instead of increasing state aid or supporting individual projects, the emphasis should be on creating an environment where all companies, including SMEs and start-ups, can thrive. Key priorities include improving access to capital, developing talent, enhancing education, ensuring a well-functioning internal market, minimizing administrative burdens and creating future proof regulatory frameworks. A concrete step in this direction would be the full transition to electronic Product Information Leaflets for medicines (ePIL) across Member States, which will represent a move towards a more integrated and harmonized Single Market.

Strengthening STEM education and addressing skill shortages by integrating the life sciences sector into the European skills agenda is critical. Facilitating the acquisition of advanced digital and transversal skills in the R&D and manufacturing workforce, with an emphasis on continuous learning and adaptability, will be essential for driving growth and innovation.

To further minimize regulatory burdens, the Commission should introduce an SME and Competitiveness Check, ensuring that new and existing regulations do not negatively impact EU competitiveness. Additionally, the Commission should monitor long-term investment trends in R&D and manufacturing, benchmarking against leading life science markets like the US, China, and Japan, and take corrective actions when necessary. This includes evaluating regulatory frameworks, funding structures, and market conditions to ensure the EU remains a global leader in life sciences.

5. Enhance EU research and innovation policy

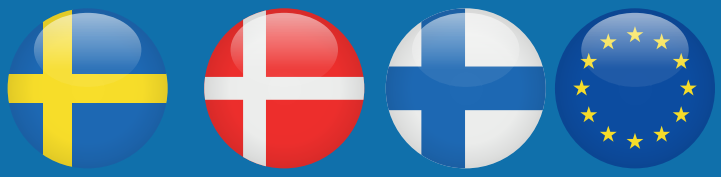
It is encouraging that the new European Commission will place a stronger emphasis on innovation. The EU needs a more focused innovation policy to make it easier for companies to move from ideas to marketable products. Both the next Multiannual Financial Framework (MFF) and upcoming framework programs should allocate more resources to the life sciences sector, and the framework programs should specifically update to include a new ambition for life sciences and regulations that attract businesses to Europe. Additionally, the EU should enhance its focus on clusters, providing targeted support to specialized biotechnology and pharmaceutical clusters through strategic use of EU funds, including Horizon Europe and future framework programs.

6. Facilitate data sharing

The swift implementation of the European Health Data Space (EHDS) is crucial for the EU's life sciences industry. EHDS will enhance access to and sharing of electronic health records. This will boost research and the development of new medicines, enhance the use of AI in healthcare, improve the conditions for clinical trials. Furthermore, it will provide a stronger foundation for regulatory and policy decisions.

7. Reinforce internationally competitive IP rights

Recent proposals to shorten regulatory data protection (RDP) and orphan market exclusivity (OME), along with the expansion of the Bolar exemption, have reduced investor confidence in the EU IP framework. Such changes could negatively impact innovation by destabilizing the investment environment. EU must re-establish a predictable and enforceable IP system to provide legal certainty and encourage innovation and investment. Critical incentives, including Supplementary Protection Certificates (SPCs), patents, regulatory data protection, and Market Protection must not only be granted efficiently but also in a predictable manner to ensure continued growth in the sector.



8. Harmonize EU clinical trials

The EU should establish a harmonized, agile clinical trials ecosystem that supports multi-country clinical trials. To achieve this, the EU should deliver on the full potential of the EU Clinical Trials Regulation (CTR) by promoting simplification and flexibility. It should support harmonized dossier reviews by National Competent Authorities and Ethics Committees across Europe, ensuring streamlined approval for multi-country clinical trials. Additionally, integrated processes should be developed for studies involving both medicinal products and medical devices or in-vitro diagnostics, ensuring a cohesive and efficient regulatory approach.

9. Promote free trade and fair competition

The EU's pharmaceutical industry operates on a global scale, relying on international value chains. It is essential for the EU to remain open and committed to cooperation with global partners. Diversifying value chains and securing new trade agreements will reduce the EU's over-reliance on a limited number of countries, thereby strengthening the industry's resilience. At the same time, it is vital to ensure that trade remains fair, with all parties adhering to the same rules and standards.

For more information:

Lif – the research-based pharmaceutical industry

Lægemiddelindustriforeningen

Pharma Industry Finland (PIF)

Efpia

The research-based pharmaceutical industry

The Danish Association of the Pharmaceutical Industry

LääketeollisuusPharma Industry Finland

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