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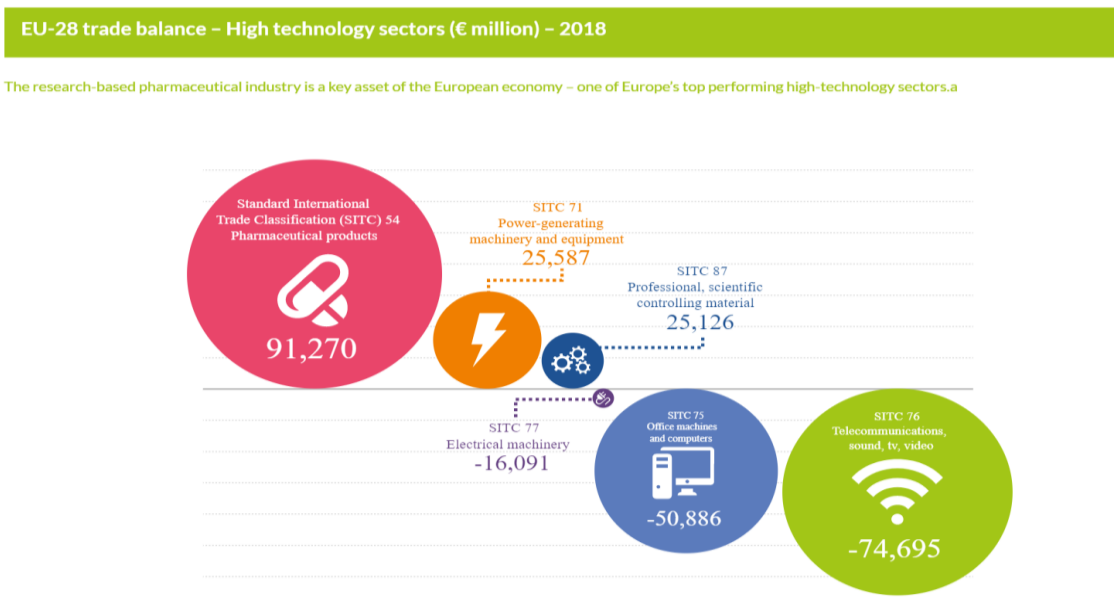
Høringssvar til Roadmap om en kommende lægemiddelstrategi, Timely patient access to affordable medicines.

Lægemiddelindustriforeningen (Lif) har med tak modtaget ovennævnte høring. Lif har følgende bemærkninger til høringen som vi håber, vil indgå i regeringens høringssvar til Kommissionen.

Background

Research, development and production of pharmaceuticals is one of Denmark's core business strengths. Pharmaceuticals make up 17% of all Danish exports, worth 17 billion EUR in 2019 (127 billion DDK) and contributing more than 100% of total surplus on the Danish trade balance. The industry directly employs 28,000 people and underpins more than 90,000 jobs through its subcontractors, etc. The foundation for the success of the Danish pharmaceutical export is that the industry is globally competitive and has strong and stable framework conditions.

The European pharmaceutical industry also contributes significantly to the trade surplus, worth 91 billion EUR in 2018 to the European trade surplus. See below. And the pharmaceutical sector is a major contributor to the EU economy as a knowledge-intensive sector with 842,000 direct jobs and generates about four times more employment indirectly – upstream and downstream – than it does directly. The global pharmaceutical market is estimated to grow in the next years, offering a growth potential for EU industry.



Source: Eurostat, Comext

General remarks
Lif welcomes the European Commission roadmap for a new pharmaceutical strategy. We also very much welcome the overall goal of the initiative to support the European pharmaceutical industry to remain an innovator and world leader. And we are committed to finding joint solutions to achieving faster, more equitable access for patients in Europe.

Ensuring that patients in Europe get access to the medicines they need
The industry is fully committed to finding joint solutions to achieving faster, more equitable access for patients in Europe and in working together to secure sustainable healthcare systems in the EU countries.

One way to achieve this is to secure a sound functioning market for generics and biosimilars in the EU countries. Strong competition and use of generics and biosimilars and faster access to innovative medicines will contribute to securing a sustainable development of the healthcare sector across the EU. The Danish healthcare sector has long experience with generic competition and use of biosimilars.

We advocate for the swift adoption of a robust EU HTA Regulation that will strengthen alignment on evidence and speed up patient access across the region. The access to new medicines could be enhanced by securing a direct line from the EMA approval of new medicines to a joint EU evaluation of the value of new medicines in a EU HTA process. While at the same time respecting that decisions on pricing and reimbursement policies must remain a national competence taking into account the many different healthcare systems across the EU region.

To further the fast access for patients to new medicines, the EU countries could also work to share knowledge on the use of innovative procurement particularly concerning medicines with contingent approval from EMA and the following process to gather data (RWD) and information on the effect of the medicines.

In parallel, we call for a comprehensive analysis of the main reasons and drivers of access, supply and shortage issues to ensure common understanding of the multi-factorial challenges Europe faces, and to help develop meaningful solutions. A High-Level Forum on Better Access to Health Innovation can provide such a platform for stakeholders to jointly identify, analyse and address challenges in the area of access and availability and co-create solutions.

A strong IP framework and incentives structure for pharmaceuticals are crucial for investments in innovation and development of new innovative therapies
In order to secure investments in innovation in Europe and make Europe an attractive and competitive region for industrial development we must secure a world-class IP system to protect R&D. To be a world leader requires ensuring parity with the US and China's incentives framework.
Research and development of new therapies is a costly and long process, with significant commercial risks for the companies involved. It typically takes 10-12 years and costs 1,3-1,6 billion EUR (10-12 billion DKK) to develop a new medicine. With a globally competitive incentives and IP framework, Europe can attract investment into the development of future innovation for the benefit of patients and secure highly productive jobs and a significant trade surplus.

Europe needs a new – and more simple - regulatory framework that is stable, fast, effective, and globally competitive to maintain leadership in medical innovation

A strong regulatory framework is essential to achieving Europe's ambition to be a world leader in medical innovation. The current EU Pharmaceutical Framework provides a strong framework that should be maintained. However, the forthcoming Pharmaceutical Strategy provides opportunities to improve Europe's research infrastructure by developing clinical trial networks and building a European health data space. From a regulatory perspective, the new Pharmaceutical Strategy could improve the use of real-world data, AI and evidence, embrace innovative clinical trial approaches, create a dynamic regulatory assessment process and introduce a clear assessment pathway for drug/device combinations. The variations framework should be modernized to ensure it embraces innovation, enables efficiency gains and paves the way for international alignment. From a regulatory point of view the new technologies also gives the possibility to bring a simpler regulatory and administrative system, also in regard to more practical things such as for example electronic package leaflet and the possibility to use multilingual packs.

The Danish Life Science Strategy

As noted, we very much welcome the overall goal of the initiative to support the European pharmaceutical industry to remain an innovator and world leader. However, the Roadmap does not contain the necessary drivers of innovation to realize its own ambition. Europe needs a research infrastructure that delivers the next generation of vaccines and treatments. That means developing clinical trial networks, biobanks and data banks, building a European health data space and delivering public-private collaboration mechanisms to accelerate bringing health solutions to patients. It is built on an intellectual property and incentives framework that protects investment in medical research, especially for orphan and pediatric medicines. Aligning incentives with unmet medical need and advances in science is critical in tackling health challenges of the future and to make Europe a world leader.

In Denmark, we have launched a national strategy for the life sciences industry, which in a close public-private partnership contributes to strengthening the framework conditions for life science companies throughout the value chain for research into the market, so that the life science industry can become an international leader in innovation. It will be obvious to the work on the upcoming pharma strategy.

Green growth and competitiveness should go hand in hand

Lif fully supports the Commission's objectives to reduce use of resources, emissions, degradation and pollution throughout the whole life cycle of pharmaceuticals. The Danish life science industry has proven to be highly competitive with very high growth rates - 900% since 1990 - and at the same time been able to reduce CO2 emissions with 55%. An EU Pharma Strategy should strengthen the basis for continuing green growth. This should be done by easing implementation of new energy-saving technologies, equipment and processes within the GMP framework, supporting research and development of green biotechnological solutions, paving the way for circular economy initiatives and incorporating climate footprints in HTA developments. We strongly support an ambitious implementation of EU Green Deal.

We look forward to continuing to be a leader in this area and encourage the European Commission to ensure that green growth and competitiveness go hand in hand and hope that the Danish government will be an active voice and convey our positions in the upcoming negotiations on a Pharma strategy.

Venlig hilsen

Thomas Klit Christensen
Head of Foreign Trade Policy