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Important Factors for the EU Life Sciences Strategy

The life sciences sector—encompassing pharmaceuticals, medical devices, in vitro diagnostics, medical software, and biotechnology—is one of Sweden's most strategic industries. With over 52,000 employees, it is a key driver of job creation and accounts for 10% of Sweden's total goods exports. The Swedish and European life sciences sectors invest a significant share of their revenue in research and development, driving progress in groundbreaking technologies such as biotechnology, AI, and digital health. The sector also holds substantial geostrategic importance, as demonstrated during the pandemic, when the rapid development and production of vaccines proved essential as well as the supply of medical devices and in vitro diagnostics to diagnose and treat patients. These strengths present the EU with a unique opportunity to consolidate and strengthen its global position. However, realizing this potential requires decisive and targeted measures to enhance competitiveness and resilience. The EU thus needs to ensure a more efficient, sustainable and resilient health-care infrastructure throughout the future multi-annual financial framework.

The European life sciences sector faces fierce competition from the United States and China, both of which are making substantial investments to strengthen their positions. The Draghi report highlights that Europe has lost 25% of its global Research & Development investment share over the past two decades, while its share of clinical trials has declined from 25.6% to 19.3%. Simultaneously, escalating geopolitical tensions underscore the need to reinforce Europe's production capacity to ensure greater resilience in times of crisis. These developments emphasize the urgency of a renewed European strategy—one that not only addresses these challenges but also enhances the EU's attractiveness as a destination for Research & Development investment, manufacturing, and clinical trials.

The EU's New Life Sciences Strategy

The announcement of a new European life sciences strategy is a highly welcomed initiative. A coordinated strategy is essential to create the right conditions for restoring EU's leadership in the sector. Since 2019, Sweden has successfully implemented a national life sciences strategy, with several initiatives that could be scaled up to benefit the entire EU. The new EU strategy should incorporate the following key elements to enhance the sector's global competitiveness:

- **Effective governance through a dedicated Life Sciences Office**
- **Facilitating access to groundbreaking innovations**
- **Strengthening conditions for research and innovation**

- **Improving framework conditions for production in the EU**
- **Promoting free and fair trade**

By integrating these elements, the EU can reinforce its position as a global leader in life sciences while driving innovation, economic growth, and resilience across the sector.

Effective governance through a dedicated Life Sciences Office

Policy coordination through a new Life Sciences Office: The EU's life sciences sector faces significant bureaucratic challenges due to a fragmented regulatory environment, where responsibilities are divided among multiple Directorates-General within the Commission and various national authorities. To establish an effective and coordinated strategy, clear allocation of responsibilities and close collaboration between relevant stakeholders are essential. Sweden has had a Life Sciences Office for several years to coordinate efforts across different ministries - the European Commission should follow this example.

Recommendation:

- Establish an EU Life Sciences Office within the European Commission, with a clear mandate to coordinate and harmonize all policy areas affecting the sector.

- The EU Life Science Office should be supported by an EU Life Sciences Forum, bringing together representatives from EU institutions, regulatory agencies, academia, patient organizations, and industry.

Reducing administrative burdens: In the past mandate, several new regulations and directives have come into force, impacting the EU's life sciences sector. The increasing level of detail in regulatory frameworks, combined with more extensive and demanding reporting requirements, has resulted in a heavy administrative burden for companies. This, in turn, hampers their ability to innovate and ultimately affects patients' access to innovative, value creating, treatments within the EU. This challenge is particularly pressing for the life sciences sector, which competes globally with companies in countries where regulations are more balanced.

Recommendation:

- The European Commission should maintain regulatory simplification as a top political priority. The first omnibus packages presented in February were a positive step, but further initiatives are needed to reduce the regulatory burden. To strengthen the Better Regulation agenda, the Commission should:
  - Reinforce the "one in, one out" principle to prevent excessive regulatory expansion. Eliminate redundant reporting requirements and regulatory overlaps to reduce administrative burdens.

- Ensure that all proposals are accompanied by impact assessments to ensure that policies foster innovation rather than hinder it. It is regrettable that the Medical Devices Regulation (MDR), In Vitro Diagnostics Regulation (IVDR) and Critical Medicines Act (CMA) were introduced without such an assessment.
- Institutionalize regular consultations with industry to ensure legislation remains effective, relevant, and aligned with the needs of the life sciences sector. The focus in new regulation should be on increasing access to, and the implementation of, innovation within the sector.
- A sector-specific Omnibus including a structural reform of the sectors' regulatory system.

Facilitating access to groundbreaking innovations

Improving conditions for the introduction of innovative treatments and preventive measures: To remain competitive, EU must accelerate the adoption of breakthrough technologies such as personalized medicine, advanced therapies, and AI-driven health solutions. Future-proof legislation, adaptable data infrastructure, and stronger cross-border collaboration - leveraging successful national models - are essential to fostering innovation. One step is an effective implementation of the EU Health Technology Assessment Regulation (HTAR), which may streamline clinical evaluations and accelerate patient access to cost-effective treatments. However, its success depends on sufficient resources and strong coordination with national authorities. Establishing an EU Life Sciences Forum, as suggested in the section above, could further enhance patient access by fostering sector-wide collaboration, while strong EU leadership is essential for addressing shared challenges.

Recommendations:

- The EU life sciences strategy must accelerate the introduction of breakthrough innovations by ensuring that existing and future regulations are fit for purpose and support innovation. Priorities include future-proofing and streamlining the implementation of MDR, IVDR, and HTAR, while modernizing the EU's regulatory framework and data infrastructure to eliminate barriers and facilitate the adoption of new technologies.
- The strategy should emphasize the importance of EU-wide coordination in tackling strategic and high-priority challenges. Specific areas where joint EU action is essential include meeting the needs of patients with rare diseases and strengthening efforts to combat antimicrobial resistance (AMR).

Strengthening conditions for research and innovation

Scientific breakthroughs must translate into market-ready treatments to attract research and innovation investments. Stronger intellectual property protection, better access to skilled

professionals, improved financing, and a clearer path from research to market are key to developing new medicines and technologies and strengthening the EU's life sciences sector.

Facilitating multinational clinical trials: Despite the adoption of the Clinical Trials Regulation (CTR), MDR and IVDR, conducting multinational clinical trials in Europe remains complex and time-consuming, particularly for advanced healthcare solutions such as precision medicine. Regulatory fragmentation and a lack of coordination between Member States discourage companies from choosing the EU as a trial location, ultimately weakening Europe's competitiveness in research and development.

Recommendation:

- The strategy should promote effective coordination mechanisms between national ethics committees and regulatory authorities. It should also establish a binding EU body responsible for approving multinational clinical trials, significantly simplifying and accelerating trial startups across Europe.

From Discovery to Application: The Case for Shared Innovation Platforms: To strengthen Europe's innovation capacity, the EU must invest in shared research infrastructures and scale-up environments—such as analytical platforms, laboratories, and pilot facilities—that support the transition from discovery to industrial application. Access to excellent academic research and world-class research facilities is essential for attracting corporate investments and is thus a key catalyst for increased European competitiveness and growth.

These resource-intensive infrastructures require joint funding and should be designed to promote collaboration between academia and industry. Testing, validation, and scale-up in such settings are essential to turning research into market-ready solutions.

Stronger incentives are also needed for collaborative research across the entire value chain. Long-term partnerships will be key to secure Europe's leadership in health and life sciences.

Recommendation***:***

- The strategy should prioritize investment in shared research and scale-up infrastructures that enable collaboration between academia and industry. This includes targeted calls to modernize existing facilities and ensure they remain technically up to date and relevant. Dedicated funding should also incentivize joint use of these facilities, ensuring that research with high industrial relevance can advance efficiently toward application.

Maximizing the potential of the European Health Data Space (EHDS): To enhance patient care and foster innovation, the use of health data for research and development must be expanded while ensuring robust personal data protection. The EHDS will serve as a crucial resource for the EU life sciences industry, streamlining access to and sharing of health data. This will optimize the use of healthcare data in research, enhance AI-driven healthcare applications, improve the framework for clinical trials, and strengthen the evidence base for regulatory and policy decisions.

Recommendation:

- Ensure the swift and effective implementation of the EHDS regulation by enabling easy access to pseudo-anonymised patient data and strengthening national health data bodies. Focus resources on EU-wide standards to facilitate cross-border healthcare and enhance patients' rights to structured, interoperable health data, in line with the EU's principle of free movement.

Strengthening intellectual property protection: Intellectual property (IP) is crucial to the life sciences sector, safeguarding companies' investments in research and development and providing the necessary incentives to drive groundbreaking medical advancements. However, recent proposals to shorten the regulatory data protection (RDP) period for pharmaceuticals, reduce market exclusivity for orphan medicines (OME) and expand the Bolar exemption have weakened investor confidence in the EU's IP framework. Another example is the EHDS, where there is incomplete and insufficient protection for companies' trade secrets and IP in relation to companies' requirements to release and share data. If the EU is to strengthen its global competitiveness, maintaining a robust IP framework is imperative.

Recommendation:

- The strategy must restore confidence in the EU's IP framework by ensuring long-term protection for intellectual property, including maintaining adequate data protection and market exclusivity periods as well as upholding trade secrets.

- The EU must address its challenges in translating academic research into market-ready innovations by establishing a legal framework that supports the commercialization of intellectual property. This could be achieved through a fair and transparent royalty distribution model between institutions and researchers, creating stronger incentives for research outcomes to reach the market.

- To support the use of the EU's unitary patent system and strengthen intellectual property protection, training programs for IP specialists should be enhanced and financially supported, improving expertise and understanding in the field.

Enhancing the EU's innovation capacity and updating the EU framework programme for research & innovation: Horizon Europe is too fragmented, with funding spread across too many areas, making access to financing difficult and prioritisation unnecessarily complex. The next EU framework program must be reformed to better align with industry needs and maximize its potential to address societal challenges. At the same time, it must create more attractive conditions for industry engagement in European research programs, partnerships, and clusters. These improvements would strengthen Europe's capacity in both research and manufacturing, foster new collaborations and business models, and contribute to high-quality, globally competitive research.

Recommendation:

- Simplify public-private partnerships within the next framework program and reallocate resources to support disruptive innovation and breakthrough research. The decision-making process should be streamlined and led by experienced innovation leaders, while reducing administrative burdens to facilitate participation.

- The framework programs should be leveraged to strengthen strategic European clusters in medical devices, In Vitro Diagnostics (IVD), biotechnology and pharmaceuticals and support incubators that help startups grow and succeed.

- Prioritize the creation of a European Research Area to improve coordination of public Research & Development funding among Member States. Increased funding for the next framework program and a European Action Plan for Research & Innovation should support this effort.

- Establish an EU-wide platform to centralize and disseminate information on all available funding opportunities within the life sciences area, making it easier for companies and researchers to navigate the support system.

Promoting access to skilled professionals: As global competition for talent intensifies, the EU must prioritize skills development and lifelong learning, particularly in life sciences. An European Investment Bank study identifies talent shortages as a key barrier to long-term investment, a challenge exacerbated by Europe's aging population, which reduces the workforce and increases demand for specialized expertise.

Recommendation:

- A comprehensive strategy is needed to better align relevant education systems with labour market demands, with a specific focus on future-oriented sectors such as life sciences and biotechnology. Simultaneously, labour mobility within the EU should be improved, and the EU must actively attract skilled professionals from third countries by expanding the Talent Pool initiative.

- The life sciences sector should be fully integrated into key EU skills initiatives, such as Pact for Skills, the Strategic Plan for STEM Education, and the Skills Portability Initiative.

To enhance cross-border collaboration, the Erasmus+ program should be expanded to include researchers, fostering mobility and knowledge exchange across Europe.

Improving framework conditions for production in the EU

The Swedish life sciences sector supports the EU's goal of climate neutrality by 2050 and recognizes the sector's role as a driver of this transition. As a high-tech sector, it has already made significant progress in developing climate-smart production methods. However, to ensure success, the transition must safeguard competitiveness and prevent European industry from being disadvantaged compared to international competitors. Stronger coordination between climate, environmental, and competitiveness policies is essential to avoid regulatory overlaps and inefficiencies.

Proportionate regulation: The life science industry produces life-saving products and treatments, some of which contain essential substances and components that require careful management to prevent environmental harm.
Rather than relying on general exemptions from EU regulations, new legislative initiatives—such as the revised Urban Wastewater Treatment Directive (UWWTD), IVDR, MDR, AI Act, the EU pharmaceutical legislation revision, and the upcoming Chemicals Industry Package including modernizing REACH and rules on PFAS —should be guided by a systematic, science-based assessment of regulatory consequences.

A predictable and consistent regulatory framework that evaluates both societal value and environmental impact is essential. This includes weighing the benefits of maintaining industry presence in the EU, access to critical medical products and key enabling technologies against potential environmental risks, and applying strict controls and risk management measures where necessary. A diminished industry presence, driven by misaligned assessments of regulatory consequences, undermines European competitiveness, economic growth and resilience, while increasing dependence on non-EU countries for essential medical products.

<u>Recommendation:</u>

- The EU strategy should promote proportionate regulation of substances and components used in the life sciences sector. The critical role of the life science sector should be acknowledged in the strategy and considered in legislative processes. This would ensure that access to critical medical products is preserved while environmental and public health are protected. This approach strengthens both sustainability and industrial resilience in a global context.

- Ensure that new regulation create an optimal balance where patient safety, security, sustainability and innovation are all important factors with the aim to create good conditions for innovators to work and evolve within EU, and for companies to grow.

Revise the Public Procurement Directives to promote innovative and sustainable products: To accelerate the development of clean production methods, a strong market demand for sustainable pharmaceuticals and medical devices is essential. One of the most effective ways to create this market is by introducing minimum environmental sustainability requirements in the EU's procurement directives, as public procurement accounts for approximately 14% of the EU's GD.

Approximately 70-80 percent of the medical devices reaches the health care through public procurement. This makes the procurement regulation crucial for creating an innovation-friendly and well-functioning market. The procurement regulation should enable SMEs to participate in procurements. It is essential that requirements should, as far as possible, be formulated based on needs and what the procuring organisation wants to achieve, rather than technical specification.

We have taken note of the public procurement provisions in the CMA. We acknowledge these efforts but will need to analyse them in detail to assess their implications and effectiveness.

Promoting the use of AI: New health technology solutions and digital services have significant potential to improve healthcare efficiency through preventive measures, habilitation, rehabilitation, and contributions to public health. Medical device systems are already used in the health care to predict risks for individual patients, examine x-ray scans in search of cancer and to assist medical professionals in their decision-making processes.

AI can play a key role in transforming the EU life sciences sector by enhancing research processes, clinical trials, and production of new products, leading to more efficient and innovative practices across the industry. Additionally, effective AI utilization could help mitigate the skills shortage facing the EU's life sciences industry. To achieve this, clear and timely guidance is needed on how AI should be integrated into all phases of medicine development as well as development of medical devices and IVDs. This guidance should be gradually implemented by 2027, led by EMA and national medicines agencies as part of their AI work program. It must also leverage opportunities created by the upcoming EHDS Regulation and AI Act. For pharmaceuticals the guidance should cover the analysis of clinical raw data submitted to EMA, pharmacovigilance data, and enable broader use of health data for research, strengthening the EU's research and development capacity.

<u>Recommendation:</u>

- The EU life sciences strategy should develop AI guidelines for medicine development, development of medical devices and IVDs, support the analysis of clinical data and secondary use of health data, and ensure data integrity and security through targeted programs for digital infrastructure.

Promoting free and fair trade

The life sciences sector relies on open trade and interconnected global value chains to secure essential inputs and access international markets. However, rising geopolitical tensions, protectionism, and new tariffs are disrupting global trade flows. To safeguard supply chains and competitiveness, the EU must diversify its trade partnerships and reduce unilateral dependencies on third countries. Free and fair trade should be promoted, and tariffs on health products, such as therapeutics or active pharmaceutical ingredients, must be avoided.

It is equally important that also medical devices, IVDs and components thereof are exempt from tariffs and other trade restrictions. The European medical device and IVD industry relies on global supply chains and is therefore highly vulnerable to these types of actions.

The EU should take a proactive role in reforms and trade negotiate and partnership agreements to counter growing trade barriers. The inclusion of strategic partnerships in the CMA is a welcome step in this direction. Additionally, new tools are needed to attract foreign direct investment (FDI) in life sciences, including stronger coordination between national trade and investment agencies. A strategic and diversified trade approach is essential to maintaining Europe's leadership in life sciences amid shifting global policies

Recommendation:

- The EU should continue to support free trade in order to ensure global supply chains required by the life sciences industry.
- The strategy should support the sector-specific strategic partnerships, such as announced in the CMA.
- The strategy should also support foreign direct investment and enhance collaboration between national trade and investment agencies, with the goal of strengthening the EU's competitiveness and resilience in the life sciences sector.