Date: 2025-06-11

Lif's and SwedenBIO's position paper on the upcoming Biotech Act

Lif and SwedenBIO welcomes the opportunity to be a part of the creation of the Biotech Act and strongly support the intent to foster an innovation-conducive framework to improve the competitiveness of the EU biopharmaceutical sector. At the light of the geopolitical reality the EU now faces, ongoing and future regulation must ensure innovation and competitiveness without imposing additional regulatory burdens. Lif and SwedenBIO emphasize that the Biotech Act should not exacerbate the already complex regulatory environment within EU. A well-structured impact assessment is critical to fully address the biotechnology sector's needs while avoiding unnecessary hindrances to businesses, regardless of their size. It is vital that the Biotech Act supports both SMEs, start-ups and spin-offs and large corporations, recognizing their interdependence within the pharmaceutical sector and ensuring that its provisions enhance, rather than obstruct, growth and efficiency.

In light of the falling share of clinical trials conducted in the EU, the Biotech Act should focus on conducting a pragmatic implementation of the Clinical Trials Regulation, avoiding requirements beyond its scope. Changing this trend is an important step in increasing the competitiveness of the EU market.

The Biotech Act must align with existing legislation and ongoing initiatives, such as the General Pharmaceutical Legislation, Critical Medicines Act, AI in Science and Apply AI strategy, Urban Wastewater Treatment Directive, HTAR, and other relevant strategies and regulations. The EU must seize this opportunity to streamline legislation and foster a business and market environment that encourages innovation and competitiveness, allowing biotechnology companies to thrive. The market's success hinges on the actual use of biotechnology products, supported by efficient access systems and healthcare demand within the EU.

A well-functioning home market is imperative for a company to expand and succeed at the international level. By combining targeted incentives, infrastructure investment, regulatory modernization, establishing a centre of excellence for manufacturing innovation underpinned by resources, confidentiality and sandbox principles, and

Läkemedelsindustriföreningens Service AB/The Swedish Association of the Pharmaceutical Industry AB
Postadress/Postal address: Box 17608, SE 118 92 Stockholm | Besöksadress/Visiting address: Sveavägen 63
Tel: +46 8 462 37 00 | E mail: info@lif.se | www.lif.se | www.life-time.se | www.fass.se
Org.nr: 556170 1268 VAT No: SE556170126801

strategic support for innovation ecosystems, the EU can ensure that biotech companies not only thrive but lead globally from within Europe.
The Biotech Act might establish a center specifically designed for promoting the manufacturing of innovation. It should be supported by adequate resources and confidentiality and sandbox testing environments.

The Biotech Act also provides an important opportunity for strengthening the life science industries in EU via strengthening the IP framework. If EU established a best-in-class IP environment it would underpin and support critical R&D and encourage investment, resulting in new innovative therapies.

Reforming the next EU framework program to better align with industry requirements and societal objectives is essential. We urge policymakers to consider reforms to pension fund regulations that would unlock private investment by increasing liquidity for venture capital and SME financing.

Targeted strategic research and innovation initiatives to increase collaboration between academia, healthcare, and companies are necessary to enhance the ability to address the societal challenges faced by the biotech sector and, at the same time, connect scientists to the industry ecosystem.
To maximize health data's value for AI, interoperability between systems and AI-ready data formats are essential. It is essential that the proposed Biotech Act is designed in a manner that anticipates future developments and aligns seamlessly with existing AI- and Data-related regulations and strategies, such as the AI in Science Strategy, the Apply AI Strategy, and the EHDS.
In conclusion, the Biotech Act must strike a careful balance: ambitious in fostering innovation and competitiveness but cautious not to overburden companies with additional regulatory complexities. By aligning with existing frameworks and adopting a comprehensive, business-friendly approach, the Biotech Act can provide the foundation for a vibrant and competitive European biotechnology sector. If not aligned with existing or upcoming legislation, the Biotech Act runs the risk of becoming another example of regulatory burdens highlighted in the Draghi report.

Key priorities highlighted include

- **Scale: Bold and decisive action is imperative**
- **Future investments: Strengthening intellectual property protection**
- **Financing: Help innovations and companies grow in Europe**
- **Speed and Streamlining: Simplify regulatory and market pathways**

- **Skills: Unlocking the Potential of Europe's Workforce**
- **Artificial Intelligence: Use of data and AI in the Biotech sector**

Lif and SwedenBIO welcome the opportunity to contribute to the Biotech Act's development. While the key priorities highlight critical topics, additional factors must also be addressed during the impact assessment for a thorough evaluation. We look forward to continued collaboration with the European Commission to ensure the Act strengthens the EU's competitiveness, innovation, and public health, laying a strong foundation for the future.

Scale: Bold and decisive action is imperative

The European life sciences sector is currently facing formidable competition from global leaders such as the United States and China, both of which are making substantial investments to consolidate their dominance in biotechnology. Concurrently, the ongoing geopolitical dynamics have heightened the urgency of bolstering Europe’s production capacities to ensure resilience during periods of crisis. The European Union must not cede ground to the United States and China, whose ambitious biotechnology agendas have set a formidable precedent. The Biotech Act represents a pivotal opportunity for the EU to assert itself as a global leader in this strategic domain and secure its competitive edge in the rapidly evolving biotech landscape.
We strongly support the European Commission’s focus on creating an open, competitive, and at-scale business environment for biotechnology companies that makes full use of the market size of the EU and its innovative biotech clusters, such as Medicon Valley. A well-functioning home market is imperative for a company to expand and succeed at the international level. By combining targeted incentives, infrastructure investment, regulatory modernization, establishing a centre of excellence for manufacturing innovation underpinned by resources, confidentiality and sandbox principles, and strategic support for innovation ecosystems, the EU can ensure that biotech companies not only thrive but lead globally from within Europe.

The Commission is correct in that European companies are not competitive enough, but the Biotech Act should also acknowledge and act upon the need for and importance of attracting non-European companies to invest in the EU. For Europe to be an attractive market it is imperative that the Biotech Act acknowledges that market conditions for companies, European as well as non-European companies, in our member states are competitive in a global comparison.

The European Commission has appropriately highlighted the challenges encountered by SMEs, spin-offs, and start-ups in the biotechnology sector. However, it is imperative that the Commission also integrates the perspective of larger corporations into its considerations. Neglecting this perspective may inadvertently result in adverse impacts on these significant players, which could otherwise be mitigated through a more inclusive approach that acknowledges their importance and addresses the systemic challenges they face.

Future investments: Strengthening intellectual property protection

Intellectual property (IP) plays a pivotal role in the life science sector and is the key driver of medical innovation. A strong IP framework is necessary in order to attract investments, enable collaborations and to drive R&D into innovation. A strong IP framework in EU is also crucial in order to regain EU's competitiveness. However, several ongoing and past reviews have aimed to alter the EU IP framework in ways that risk undermining its foundational principles. Examples of this are recent proposals in EU legislative processes, such as shortening the regulatory data protection (RDP) period for pharmaceuticals, reducing market exclusivity for orphan medicines (OME), and expanding the Bolar exemption, have undermined investor confidence in the EU's IP framework. Additionally, the European Health Data Space (EHDS) initiative presents gaps in protecting trade secrets and intellectual property for biotechnology companies, especially concerning mandatory data sharing requirements. It is crucial to acknowledge that any changes to the IP framework, if implemented incorrectly or arbitrarily, will have significant consequences for European competitiveness. The Biotech Act must restore confidence in the EU's IP framework by ensuring strengthened protection for intellectual property.

A strengthened IP framework will bolster the EU innovation ecosystem and EU competitiveness. There are multiple viable avenues: reforming the SPC framework to fully compensate innovators for time lost due regulatory burdens and the pricing and reimbursement process; enhancing RDP protection for medicines for which patent protection is insufficient or unavailable; enacting a patent enforcement system with early resolution mechanisms to provide clarity for generic entry and treble damages for launches at risk. Predictable, stable, and enforceable IP underpins a competitive EU, and ultimately enhances patients' health with access to innovative medicines.

Financing: Help innovations and companies grow in Europe

We strongly advocate financial initiatives focused on improving access to capital, recognizing it as a cornerstone for fostering biotechnology innovation and sustaining competitiveness. Addressing Europe's capital availability challenge is critical. Much of

today's biotechnology innovation originating from EU research is maturing elsewhere, delivering commercial success and support to supply chains outside Europe. There is an urgent need to ensure that our innovation anchors and grows here, if EU future economic stability and resilience is to be achieved. To mitigate this, it is imperative to implement measures that enhance access to sufficient risk-tolerant capital and reduce regulatory divergence between Member States.

Reforming the next EU framework program to better align with industry requirements and societal objectives is essential. Such reforms should aim to establish more appealing conditions for industry participation in European research initiatives, partnerships, and clusters. These adjustments would help strengthen Europe's capacity in research and manufacturing, foster innovative collaborations and business models, and contribute to the production of high-quality, globally competitive research.

Moreover, the EU can both accelerate and fine-tune ongoing financial instruments and regulations to support the industry by applying the Savings and Investments Union to unleash capital into innovative projects, complete the Single Market by harmonising market and services regulations across the EU to remove non-tariff trade barriers and enable innovation at a European scale.

Speed and Streamlining: Simplify regulatory and market pathways

The current regulatory landscape for biotechnology is very complex. Many novel products from biotech do not reach the market in the EU at anywhere near the speed needed to serve economies or citizens. A simpler regulatory landscape would unlock the full power of the single market and industrial growth here rather than elsewhere.

To reduce time-to-market, the EU should establish streamlined approval procedures and promote best practices.
Fragmentation must be addressed through mechanisms that promote regulatory convergence and coordination across Member States. In this process, it is essential to ensure effective collaboration between the European Medicines Agency (EMA) and the Health Technology Assessment (HTA) processes, fostering a synchronized framework that minimizes delays, improves transparency, and enhances the efficiency of bringing innovative biotech products to market.

Create uptake incentives

Pathways and incentives for uptake of biotech solutions differ across every sector and Member State. The Biotech Act should ensure that citizens everywhere benefit from its advantages. The impact of fully integrated biotechnology and biomanufacturing unlocks investment, employment, healthcare, resilience and sustainability for all Member States.

- **Strengthen value chains from R&D to end-users**: Accelerated speed and scale of technology transfer and investment through the right incentives and pathways to match the urgency.
  This includes investment in shared infrastructures and scale-up facilities that can help transition research into industrial application faster and more effectively.
- **Simplify regulatory and market pathways**: This overcomes expensive and unpredictable barriers, accelerates time to market, especially for smaller innovators, and increases the uptake of biotech products and biomanufacturing processes.
  The EU should reduce administrative burden by eliminating redundant reporting requirements and reinforcing the “one in, one out” principle.
- **Ensure legislative coherence**: A predictable and harmonized regulatory framework is imperative. The erosion of the EU's industrial base, driven by incongruent regulatory measures, not only jeopardizes European competitiveness and economic growth but also heightens dependency on external actors for essential medical supplies and innovations.
  The Biotech Act should prioritize the establishment of legislation that is not only coherent and aligned across sectors but also adaptable to future advancements, ensuring the EU maintains its leadership in biotechnology and biomanufacturing on the global stage.
- **Assessment of legislation:** Conduct a comprehensive mapping and assessment of all legislations (global, EU, and national) applicable to biotechnologies to ensure consistency and avoid conflict. Review all relevant EU legislations and include a mandatory review clause in all legislations to future-proof it to science and innovation.
- **EU framework for clinical trials:** The Biotech Act should focus on conducting a pragmatic implementation of the Clinical Trials Regulation avoiding requirements beyond its scope; faster, harmonised, and coordinated processes for multi-country trials, including ethics reviews, with the use of reliance mechanisms; enabling parallel submissions of substantial modifications; resources and a dedicated platform for continued regulator/innovator dialogue beyond Clinical Trials Information System (CTIS), and a shift towards a product-based approach that optimises efficiency. Regulatory pathways should be aligned across

frameworks such as Medical Device Regulation/In Vitro Diagnostics Regulation/Genetically Modified Organisms legislation/etc to reduce duplication.

- **Center of Excellence:** The Biotech Act might establish a center specifically designed for promoting the manufacturing of innovation. It should be supported by adequate resources and confidentiality and sandbox testing environments. Future-proofing key regulations, like Annex 2 of the Medicines Directive (currently under negotiation) and the guideline on variation, would also be essential. The goal should be to implement regulatory changes with the least added regulatory complexity and also address the cumulative impact of chemical/environmental legislations on medicine manufacturing and simplifying permitting and auditing processes to tap into the potential of the EU in terms of scale and production.

Skills: Unlocking the Potential of Europe's Workforce

The EU currently faces a skills shortage within the life sciences industry. Effective AI utilization, mentioned below, could help mitigate these shortages but more needs to be done for this development to be mitigated.
A comprehensive EU approach is essential to aligning education systems more effectively with labour market demands, particularly within future-focused sectors such as life sciences and biotechnology. Concurrently, measures should be taken to improve labour mobility across the European Union and attract highly skilled professionals from non-EU countries through the expansion of the Talent Pool initiative.
The life sciences industry should be fully integrated into key EU initiatives such as the Pact for Skills, the Strategic Plan for STEM Education, and the Skills Portability Initiative. Additionally, the Erasmus+ programme should be extended to include researchers, thereby fostering cross-border mobility and facilitating the exchange of knowledge and expertise across Europe.

Targeted strategic research and innovation initiatives to increase collaboration between academia, healthcare, and companies are necessary to enhance the ability to address the societal challenges faced by the biotech sector and, at the same time, connect scientists to the industry ecosystem.

Artificial Intelligence: Use of data and AI in the Biotech sector

Both Lif and SwedenBIO align with the European Commission's assessment regarding the pivotal role of artificial intelligence (AI) in advancing biotechnology, while

simultaneously emphasizing the need for balanced safeguards to foster trust among stakeholders and patients. It is essential that the proposed Biotech Act is designed in a manner that anticipates future developments and aligns seamlessly with existing AI- and Data-related regulations and strategies, such as the AI in Science Strategy the Apply AI Strategy and the EHDS.

Establishing a well-calibrated framework that supports the secure and ethical application of AI within the biotechnology sector is crucial for enhancing the European Union’s competitiveness on the global stage. Furthermore, such a framework would play a vital role in attracting substantial international investments, reinforcing the Union’s position as a leader in innovation and biotechnology development. By ensuring coherence and adaptability in legislation, the EU can pave the way for a sustainable and prosperous biotech ecosystem that benefits both its citizens and its broader economic ambitions.

To maximize health data's value for AI, interoperability between systems and AI-ready data formats are essential. Integrating diverse data sources, such as omics and clinical information, can enhance diagnostics, treatments, and public health while strengthening EU companies' global standing. Future regulations should focus on secure, trustworthy methods for combining these data sources.