AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Blueprint for progress: shaping the future of life sciences in the EU

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €4 trillion in 2023, directly supports more than 4.6 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Executive summary

At a critical juncture for the sector, the EU's upcoming Strategy for European Life Sciences must enhance innovation, bolster competitiveness and ensure sustainability while streamlining regulatory burden. The European Commission should develop this strategy in close collaboration with relevant stakeholders to gain a deeper understanding of the sector's challenges. This collaboration would ensure that the strategy is based on initiatives that can make a difference for the sector and for the EU.

Introduction

This position paper delves into key elements anticipated in the EU's Strategy for European Life Sciences. The first section examines the critical factors for the strategy's success. The second section analyses which legislative files should be advanced and introduced to strengthen the necessary framework. Finally, the third section highlights the resources required to ensure the strategy achieves its objectives. Following the public consultation, the European Commission should continue to build its strategy with a holistic approach that accounts for all impacted stakeholders.

An end-to-end Strategy for European Life Sciences

To ensure Europe's continued leadership on the global stage and the growth of its life sciences sector, the EU needs an end-to-end strategy that champions the contributions of all stakeholders. This holistic approach should cover the entire industry value chain and every stage, including investment in research and development (R&D), a future-proofed regulatory framework, manufacturing and uptake of the final product. A variety of factors are critical for its success.

Buy-in from all 27 EU Member States

Each Member State brings unique capabilities to the table. A unified EU strategy should harness these diverse resources, fostering collaboration and sharing best practices across borders to drive innovation and competitiveness. Positioning life sciences as an attractive, high-value sector for investment would ensure Member States give it the necessary resources to thrive, ultimately benefiting patients and contributing to Europe's economic growth.

Inclusion of companies of all sizes and origins

Companies, irrespective of their size or headquarter location, play a critical role in the European life sciences ecosystem. They drive innovation by providing the necessary resources for large-scale R&D and keep the sector balanced and dynamic. Recognising and supporting their contributions in the strategy is vital.

R&D investment

The European life sciences sector stands at the cusp of a transformative era, driven by advancements in precision medicines and digital technologies. However, the EU is falling behind, particularly in the areas of early to pre-clinical research and clinical trials. The strategy should focus on unlocking the potential of health data and the use of artificial intelligence to drive innovation and improve patient

outcomes. Many European academic institutions, health systems and healthcare professionals measure up to the highest global standards. The strategy should encourage collaboration within and between healthcare systems, academia and industry, especially for translating research into practical applications that benefit patients and society.

European Life Sciences Council

The creation of a European Life Sciences Council is imperative to ensure efforts to support the sector are well informed and consistent. This Council would focus on the framework for the life sciences industry by coordinating regulatory action, streamlining regulations and fostering innovation across Member States and at the European level. It should bring together public and private stakeholders that represent the whole life sciences ecosystem, including members from the industry, universities, clinicians, patient groups, the European Commission, Member States and the European Parliament.

Key indicators of success

The Strategy for European Life Sciences should define key performance indicators and targets, such as the number of viable life sciences companies created per million inhabitants across the EU and the number of clinical trials conducted per million inhabitants. Such concrete metrics provide a clear framework for measuring the sector's growth and its ability to provide patients with quick access to innovative, effective healthcare solutions.

Competitiveness checks

The strategy should include regular competitiveness checks and retrospective assessments of how administrative and reporting processes impact the life sciences sector. These assessments should promote alignment between EU competitiveness objectives and national-level actions. Additionally, the strategy should incorporate international benchmarks to compare the EU to other global regions in terms of R&D investment and manufacturing trends to ensure that Europe remains attractive on the global stage. Furthermore, the strategy should aim to reduce unnecessary red tape by a certain amount (eg at least 50%) by 2029.

Strong IP protection

Intellectual property rights play an important role in promoting innovation and protecting investment. A reliable intellectual property (IP) framework is the best way to harness creativity and enable innovative enterprises to grow. The European Commission must look for mechanisms to strengthen the current European IP regime, as it is an integral part of Europe’s strengthened business predictability and overall competitiveness.

Skilled labour force

Attracting and training a skilled labour force is essential for Europe’s growth and development, especially in highly technical industries such as life sciences. Continued investments in education and training programmes are crucial for all Member States. One of the strategy’s key performance indicators should focus on the number of science, technology, engineering and mathematics graduates across the EU. Additionally, attracting and retaining a highly skilled international workforce should also be an integral part of the strategy.

International regulatory convergence

The EU must improve its position relative to other global regulators. Strengthening international regulatory convergence among leading global regions can help streamline requirements for companies. By bridging evidentiary and regulatory requirements between different regions and improving its life sciences ecosystem, Europe can facilitate more cross-border collaboration and innovation and become a more attractive destination for investments in life sciences.

Global partnerships and industry-specific agreements

The EU should consistently strive to collaborate with other global regions such as the US and Asia-Pacific. This would help establish robust supply chains by facilitating the cross-border movement of goods and data, eliminating trade barriers, harmonising regulations, diversifying networks and promoting innovation through skills and technology. Geographic diversity is crucial for the resilience and strength of global supply chains.

Fair competition for all businesses

Mechanisms like R&D offsets intended to reward investment are often static, may not encourage additional investment and can result in localisation and unfair advantages. If the strategy provides unfair benefits to companies with significant R&D or manufacturing activities in the EU, it might potentially harm competitiveness, especially if other countries and regions adopt similar strategies.

Cohesive legislative framework to support EU competitiveness

A coherent legislative framework that incorporates ongoing revisions of key files and new proposals is essential for enhancing the competitive edge of the EU life sciences sector. A framework grounded in evidence-based policymaking would ensure regulatory clarity, foster innovation and create a stable environment for investment and growth. To create an evidence-based and coherent framework, the European Commission must allow for adequate time to consult with the stakeholders who would be most impacted by the proposed changes. Several legislative files should be advanced and introduced to strengthen the framework.

The Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR)

The MDR and IVDR's heavy regulatory burden, lengthy approval processes, increased uncertainty and higher clinical evidence requirements have hindered patient access to medical devices and reduced the EU's competitiveness in developing new products. The revision of these files must tackle these issues by enhancing predictability, leveraging international regulatory convergence opportunities, improving cost-efficiency and utilising IVDs in clinical trials of medicines. Addressing these challenges is crucial for the Strategy for European Life Sciences' regulatory framework to best serve patients, healthcare professionals, industry and Europe's healthcare systems.

The General Pharmaceutical Legislation (GPL)

The revision of the General Pharmaceutical Legislation presents a key opportunity to strengthen the pharmaceutical sector in the EU. However, due to the GPL's proposed cuts of regulatory data protection, the EU risks losing its appeal compared to other global regions. Co-legislators must modernise the regulatory framework to ensure the legislation is fit for purpose in the contemporary landscape.

The Critical Medicines Act

The sense of urgency and determination with which the new European Commission is approaching key issues such as supply and medicines shortages is highly commendable. However, it should not rush to introduce a legislative proposal without adhering to the EU's Better Regulation principles and the simplification agenda. The Critical Medicines Alliance is actively engaged with European institutions and continues to prioritise its commitment to those principles and understanding the regulatory hurdles of globally diverse supply chains in the life sciences sector. More information about how to ensure resilient supply chains is available in the American Chamber of Commerce to the EU's position paper.

The Biotech Act

Building on the European Commission communication on *Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*, it is critical to adopt measures that boost biotechnology and biomanufacturing across the EU. These provisions include streamlining regulatory pathways, establishing regulatory sandboxes and strengthening biotech-related skills. International collaboration and harmonised standards are also key to facilitating trade and cooperation.

The EU is losing competitiveness in clinical trials, especially pre-clinical and Phase I clinical trials. There are significant discrepancies between Member States in Eastern versus Western Europe with regards to quantity and quality of clinical trials, persisting in various disease areas. Across the EU it is especially difficult to facilitate multi-country clinical trials because of differences in requirements from the national ethics committees. Establishing a 28th regime is essential to streamline clinical trial procedures, eliminate nationally imposed barriers and foster innovative products, such as cell and gene therapies and combination products, which are part medical device or in-vitro diagnostic and part medicinal product. European science is stronger when it is inclusive and representative of the diverse European population. For this reason, multinational clinical trials hold great value.

Robust financing for the EU life sciences ecosystem

A successful Strategy for European Life Sciences hinges on securing adequate funding to support its various initiatives. The financial envelopes within the next Multiannual Financial Framework must prioritise financial resources for the life sciences sector, as stated in President Ursula von der Leyen's Political Guidelines. The following components must be addressed in the strategy:

- **A fully-fledged Savings and Investment Union (SIU)**. Through the new SIU, deepening capital markets integration is essential for providing companies with better access to funding for their innovative projects. A fully integrated and efficient capital market would facilitate the flow of private capital into the life sciences sector, enabling companies to secure the necessary

investments to scale their operations and bring new products to market. This would not only boost innovation but enhance the EU's economic resilience and competitiveness.

- **Foreign direct investments.** By 2030, a shared goal for Europe must be to achieve inward investment levels higher than those of 2024. To support this, European framework conditions must be conducive to investment in R&D.
- **Ringfenced healthcare budgets in regional and structural funds**. To properly address disparities in healthcare access and equity across Europe, the EU's regional and structural funds must allocate for dedicated healthcare budgets. These funds should be used to improve healthcare infrastructure, enhance medical services in underserved areas and ensure all EU citizens have access to high-quality healthcare. By targeting investments in regions with the greatest need, the EU can promote social cohesion and reduce health inequalities.

By addressing these key areas, the EU can support its life sciences strategy with robust and sustainable funding. This would enable the sector to thrive, drive innovation and deliver tangible benefits to European citizens.

Conclusion

The EU's Strategy for European Life Sciences must be holistic in order to create a more competitive life sciences sector. The European Commission's strategy should outline ways to: foster collaboration with all stakeholders; purposefully review whether existing regulatory regimes are fit for purpose; and attract additional public and private financing. In turn, the strategy can provide an inclusive and concrete action plan that prioritises innovation to ensure the EU's continued leadership in setting industry standards while bolstering the sector's competitive edge through international regulatory convergence.