EuropaBio position on the EU Life Sciences Strategy (16.04.2025)

EuropaBio, the European association for biotech industries, welcomes the future EU Life Sciences Strategy (EU LSS) and the opportunity to provide feedback. **Securing a world-class life sciences sector is strategically critical for future EU prosperity, leadership, and resilience**.

The **biotech industries are leading contributors to the EU economy and competitiveness**. Their gross added value doubled, and trade surplus increased sevenfold during 2008-2022, economic growth rate stands at 5,3%, productivity is 2.85 times higher than the EU average, and employment growth is six times higher than the overall EU economy.[1]

Against a background of geopolitical shifts and growing challenges to scientific knowledge, the **EU LSS must maximise EU global impact and position for its life sciences sector**. This strategic sector should be at the centre of this Commission's mandate, with an ambitious and cross-sectoral approach to basic and translational life sciences to deliver on EU strategic objectives. Uniquely, it can deliver the EU's next major generational scientific advance, combining the strengths of all Member States, with public and private actors, towards scientific progress that underpins a successful and resilient economy.

The EU LSS is an opportunity to **confirm EU as a global leader in the biotech revolution**, for the benefit of society and economy, together with an ambitious and transformative EU Biotech Act. It must ensure that EU impact from critical technologies, such as biotech and AI can match recognised global leadership from other regions and set goals for individual and institutional achievement from the bloc. It must create the **next generation of leading scientists in both basic and translational research**, with their own global reach and partnerships. It must lead synergies with other initiatives relevant for biotech such as the Start-up and Scaleup Strategy, the Bioeconomy Strategy, and the Clean Industrial Deal and inform EU and Member State actions to deliver their life science ambitions.

EuropaBio recommends that the EU Life Sciences Strategy should:

1. **Accelerate the development and deployment of innovative products** that can deliver competitive, healthy, resilient and sustainable economies and societies by creating favourable market and access conditions.
2. **Make the EU simpler and faster** by creating a streamlined and predictable legislative environment for innovators, from start-ups to large companies.
3. **Leverage the strengths of the EU-27** by fostering the harmonisation of Member States policies to fully realise the potential of the Single Market.

[1] Measuring the Economic Footprint of the Biotechnology Industry in the European Union - Europabio

Accelerating the Development and Deployment of Innovative Products

The **EU is a global leader in life sciences** with EU universities representing 18.1% of the global share of scientific publications and 22% of global R&D spending.[2] The EU has maintained its global leadership in both health and in industrial biotech where the EU holds more impactful publications and higher level of specialisation than other regions.[3]

But **where the EU has simply maintained its position**, relying on its historical strengths, **other regions have significantly ramped up investments and policies to support their life sciences sectors**. Today, the EU has been outpaced by both the USA and China across key metrics (R&D spending, scientific publications, company creation).[4]

The EU currently struggles in translating research into commercial products with a declining share of patent applications from 30% in 2000 to 17,3% in 2021. As a result, the **EU share of patents in key enabling technologies**, including life sciences, **is lower than the USA and China**. The EU ranks fourth in industrial biotech (behind the USA, China, and Japan) despite its strong scientific output.[5] Within healthcare, the share of clinical trials conducted in the EU has also significantly decreased in the past ten years, from 22% in 2013 to 12% in 2023.[6]

The EU's life sciences sector is also constrained by **weaker financial and capital markets**, slowing down or preventing the growth of innovative companies. Compared to the US, the European landscape for investment, both private and public, creates significant challenges for smaller companies in securing the necessary funding to grow in the EU.[7]

To reverse this trend, the EU needs to **urgently address the barriers to the translation of research and innovation into commercial products across value chains**. This requires actions towards R&D public spending, financial and capital markets as well as a fit-for-purpose regulatory market, and access pathways.

EuropaBio recommends to:

- Establish a **Biotech and Life Science Index** allowing biotech companies to raise capital, including in later stage where significant gaps exist, from EU investors in high liquidity markets.

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[2] European Commission, Science, Research and Innovation performance of the EU 2024 report (available here).
[3] Ibid. p. 184
[4] European Commission, Science, research and innovation performance of the EU (SRIP) 2024 report: EU facts and figures from the #SRIP report 2024 (available here).
[5] European Commission, Science, Research and Innovation performance of the EU 2024 report, pp. 82-83.
[6] IQVIA (2024), Assessing the Clinical Trial Ecosystem in Europe, available here.
[7] Charles River Associates (2024), Impact of the GPL on Europe's innovation ecosystem and biotechnology companies, pp. 24-25. Available here.

- Establish a **Biotech for Europe Initiative** to support the acceleration of R&D and development of biotech and biomanufacturing through direct financing (loans and grants) for development and/or scale up programme in the EU.
- Rapidly take forward the measures announced in the Commission Communication on a **Savings and Investment Union** to improve the competitiveness of EU financial and capital markets for innovation-driven industries.
- Accelerate the roll-out of the **Unified Patent System**, including creating a one-stop-shop for patent protection and enforcement across the EU, and encourage all Member States to rapidly ratify and implement the Agreement. This should be complemented through continued EU policy to **support competitive intellectual property protection** for biotech innovation, in the EU and globally.
- Support life sciences innovation by preserving "**Framework Programme 10**" funding levels and continue to support public-private partnerships such as **CBE-JU**, **IHI**, and **ERDERA**.
- Accelerate academic discovery into industry by **earmarking additional EU funding for universities with high tech transfers/spin-offs**, establishing metrics to measure impact of discovery of translational research and incentivise higher TRLs.
- **Remove barriers to financing for the bioeconomy** by taking a more inclusive view of feedstocks eligible for sustainable financing mechanisms therefore avoiding restrictions based on feedstock type

Making the EU Simpler and Faster

The EU must also **become simpler and faster for innovators**. Far too often, innovators of all sizes are experiencing incoherent regulatory requirements, significant administrative burden, and an unpredictable environment detrimental to long-term investments. The Life Sciences Strategy should put the EU on a path to simpler and faster setting up of R&D and manufacturing sites, faster time to market for innovative biotech products, simpler framework for multi-country clinical trials, and recognition of the **unique value of biotech innovation for people's health and EU sustainability objectives**.

A priority for the future EU Life Sciences Strategy should be to develop **coherent regulatory pathways**, so that Europe becomes a priority destination for homegrown and global innovation transfer to commercial products. This will give early access to EU citizens, unlock investment, and increase employment, therefore making Europe more resilient healthy, secure and sustainable.

EuropaBio believes the Commission's simplification agenda should be urgently applied to the life sciences sector but underlines the importance of regulatory frameworks in fostering trust in biotech innovation. Making the EU simpler will require **addressing incoherence and duplication across legislations and harmonising implementation of EU laws** across Member States. Rather than a one-time exercise, the EU should regularly evaluate the impact, incremental and cumulative, on new and existing policies on the competitiveness of the EU's life sciences sector and implement corrective measures when needed.

EuropaBio recommends to:

- **Accelerate the digital transformation**, including use of AI, in priority areas such as green processes, product approval processes and administrative requirements. This should include better use and availability of data, such as health, for research and innovation.
- Introduce "**Competitiveness**" and "**Fit for SME**" **criterion within the Better Regulation** guidelines and revise the "coherence" criteria to include impact across legislations beyond the immediate policy area, such as horizontal legislation (chemicals, environmental, sustainability etc).
- **Modernise biotech product approval pathways** to accelerate time to market and be innovation-proof for all biotech products, including from genetic modifications, as well as use of innovative tools such as regulatory sandboxes.
- **Review the Clinical Trials Regulation** to create an EU environment capable of supporting large-scale and multi-country CTs, including by improving the coordination between ethic committees and streamlining approval timelines for CTs to reduce burden on authorities and sponsors.
- **Modernise the EMA centralised procedure approval pathway** to introduce greater flexibility that can accommodate the growing number of biotech therapies in the pipeline, including fit-for-purpose requirements, quality controls, standards, and acceptance of real-world evidence.
- **Establish a level playing field with fossil-based products** by developing unbiased accounting mechanism for renewable products and considering inclusion of targets in product legislation.

Leveraging the Strengths of the EU-27

Most EU Member States have innovation-driven strategies, whether dedicated to life sciences (Sweden and Denmark), bioeconomy (Germany, Finland, Netherlands), or R&D strategies. Most EU countries host bioclusters with various degrees of maturity and specialisation. The future **EU Life Sciences Strategy should strengthen Member States policies and life sciences ecosystems** and foster harmonisation and coordination to fully leverage the Single Market.

The future Strategy should also draw from existing EU initiatives to deliver impact and benefits across economies and societies. In that respect, the Strategy should address the **entire life sciences value chains, from universities to start-ups to global companies**, but also from researchers to workers and end-users of biotech innovation. It should **foster cooperation and coordination between Member States** to tackle EU-wide challenges, such as climate change, rare diseases, preparedness, and industrial decarbonisation. The EU should also consider **strategic partnerships with like-minded countries**, as already identified in the March 2024 Communication on biotech and biomanufacturing.

EuropaBio recommends to:

- Create an **EU Biotech & Life Science Office, headed by a Chief Biotech Officer**, within the Commission Secretariat General responsible to improve coordination and collaboration across all Commission directorates to ensure coherence. Designate

national Biotech Offices to foster policy coherence and the creation and scale up of biotech innovators in our regions.

- **Scaleup genomic sequencing capacity** and connectedness of data in the EU to increase early diagnosis and screening to support better healthcare delivery. Improve the funding and coordination of national genetic testing programmes.
- Improve the **implementation of existing EU legislations** to address fragmentation across Member States and introduce faster mechanisms to update legislations as part of periodic assessments.
- **Improve the coordination and collaboration between EMA, EFSA, and ECHA**. Improve collaboration between European and third-country agencies with oversight on biotechnologies, including on standards, through mutual recognition agreements and memorandum of understanding.
- **Revise the Cross-border Healthcare Directive** to ensure its proper functioning and can support wider patient access to healthcare, including for highly innovative treatments such as ATMPs and rare disease therapies. Improve collaboration opportunities between ERNs and industry.
- **Accelerate cooperation with like-minded countries** and allies through Strategic Partnerships to remove trade barriers for biotech products and services, enable regulatory cooperation, diversify supply networks, and safeguard innovation.
- Establish, as part of Erasmus and European University Area, **pan-European programmes relevant for strategic technologies such as biotech**, including for manufacturing. Establish re-skilling and upskilling programmes for biotech and biomanufacturing to ensure sufficient workforce to support capacity scale-up.