EuropaBio's Public Consultation Response to the European Innovation Act proposal

Europe is at a critical point in defining its innovation agenda. Despite having world-class science and a strong research base, too many promising ideas are failing to reach the market.

Innovative companies, particularly in biotechnology, face structural barriers in accessing capital, talent, and cross-border opportunities. With global competition accelerating, Europe must ensure that public investment and regulatory frameworks translate into commercial success and industrial leadership.

The Startup and Scaleup Strategy, the 28th Regime and this Act are an important opportunity to adapt policies and instruments to the realities of small biotech companies, strengthen Europe's capacity to commercialise critical technologies, and secure its long-term competitiveness and strategic autonomy.

Access to an easier more coordinated framework

Most critical technology companies, including those in the biotech sector, do not fit traditional growth models. **In biotech**, **value is created through long R&D pipelines, regulatory milestones, and intellectual property, rather than early revenue** or personnel growth.

Therefore, the Commission's proposal to define "startup," "scaleup," or "innovative company" could be counterproductive if set rigidly. Narrow criteria risk excluding early-stage businesses from support schemes and public funding, directly undermining their ability to scale.[1]

Instead, EU policy design should focus on integrating tools for disruptive technologies. For example, mandatory **innovation stress-tests into the Better Regulation toolkit**.[2] Each legislative proposal should explicitly assess its impact on the ability to develop and bring innovative products to market. Where risks are identified, proportionate **mitigation** should be triggered. This could include the use of regulatory sandboxes delivered by Member States.[3]

At national level, fragmentation of innovation policies continues to create duplication, funding gaps, and barriers to cross-border scaling. Biotech SMEs feel this the most since they often

[1] We urge the Commission to not design a rigid definition that could jeopardise biotech companies' ability to access EU, national or regional funding. If efforts are made to harmonise national definitions, the Commission should consider conventional metrics, such as those explored by the OECD, together with sector-specific qualifiers for the biotech industry.

[2] Building on the Innovation Principle within the *Better Regulation framework* and ensuring innovation impacts are assessed in early stages.

[3] EuropaBio has prepared a Biotech Sandbox Toolbox (BST) with considerations on how to design regulatory sandboxes for biotech. Indicative examples under the BST are also explored. This document was shared with the Commission and will be available at EuropaBio's website.

rely on multiple national and regional grants and incentives that cannot be combined. They face inconsistent eligibility rules, reporting standards, and timelines.[4]

As a result, **promising projects frequently stall between jurisdictions, further deteriorating Europe's competitiveness** compared to more integrated ecosystems, such as those in the USA or China.

One way forward, as explored by the Commission, is to establish a formal **EU Innovation Forum** with a clear mandate. This body could serve as a permanent coordination hub, with non-binding competences, **aligning national and EU programmes**, pooling strategic investments, and setting **joint priorities**, such as clinical trial infrastructure and biomanufacturing capacity.[5]

Funding critical technologies: closing the gap and the use of IPR-backed financing

Biotech innovation is exceptionally capital-intensive, with products often taking decades to reach the market. Costs accumulate at every stage of product development, and **commercialisation requires far more than early-stage R&D investment.**

Europe suffers from a persistent late-stage financing gap, where scaleups typically raise far less capital than their US counterparts. Closing this gap is crucial in a sector where long timelines and regulatory requirements demand large and patient capital.[6]

Public funding plays a key role in stimulating private investment. The EU can strengthen its toolbox by bridging and scaling funds (as it has been doing with, and building from, the Competitiveness Fund), deploying pull mechanisms such as **public procurement**, and introducing **tax incentives for STEP companies**.

These measures are necessary, but not sufficient. Without **a Single Unified Stock Market** and delivering the **Investment and Pensions Union**[7], European biotech will remain constrained by illiquid markets.[8]

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[4] Within the scope of the Biotech Act, EuropaBio recommends conducting a comprehensive mapping and assessment of all legislation (global, EU, and national) applicable to biotechnologies. Review all relevant EU legislation and include a mandatory review clause in all legislation to future-proof it to science and innovation. Please refer to *EuropaBio Position on the EU Biotech Act: Prosperity, resilience and leadership for the European Union.*

[5] With an additional focus on cross-sectoral integration platforms converging critical technologies, such as biotech and AI. Cross-sectoral hubs will encourage faster innovation pipelines and product development. An example of this is the work done in Bulgaria through AI Cluster Bulgaria and the Bulgarian Health and Life Sciences Cluster.

[6] The International Federation of Pharmaceutical Manufacturers & Associations reports that developing a new medicine typically takes 10 to 15 years and costs an average of $2.6 billion USD, considering the cost of failures.

[7] The industry strongly supports the creation of a single unified stock market, a "EU-NASDAQ equivalent for Biotech." This is an ask strongly reinforced at national level. (e.g., from Belgium and Spain)

[8] According to M. Dragui's report, in 2021-2022 US biotech companies received USD 62.5 billion in venture finance, compared with the USD 11.2 billion by European companies. This challenge is particularly acute for SMEs, which play a crucial and ever-growing role in the pharmaceutical ecosystem.

In practice, at the moment, **the main asset biotech startups can use to raise financing is their intellectual property.**

Despite this, IPR-back financing is often not feasible since European banks and institutional **investors remain too conservative**. They lack experience in valuing biotech IP and impose costly third-party valuations that are out of reach for most SMEs.

Practical EU action to **reduce the cost and uncertainty of IPR-backed financing** may include issuing clear guidance and providing funded training for banks, startups, and investors on IP valuation, and offering a simple and accessible EU valuation tool for biotech SMEs.

Institutionally, the Commission could also explore a dedicated de-risking facility operated via the EIF/EIB, as well as enable the use of secondary markets to improve liquidity.

Access to talent: attraction and retention

Choose Europe is a much needed and timely initiative for the biotech sector. However, on its own, it will not be sufficient to attract and retain top talent.

What is missing is a long-term, stable framework that extends beyond the volatility of national or global political cycles. The proposed 28th Regime and Innovation Area Act can be a valuable next step toward it.

Evidence gathered by EuropaBio through interviews with biotech founders and investors confirms the European Commission's analysis. Employee stock options (ESOPs) are among the most effective tools for recruiting and retaining talent in early-stage companies looking to scale.[9] Nevertheless, the European market remains too fragmented to fully leverage this tool. Variations in taxation rules, administrative procedures, and valuation standards result in costs and uncertainty for both companies and employees.[10]

To address this, biotech entrepreneurs consistently highlight two priorities. First, the **creation of harmonised documentation and standards for ESOPs**, drawing on initiatives such as the *Non-Optional*.[11]

Second, the principle of **"no taxation without realisation**." Stock options should be taxed only when gains are realised, and always as capital gains rather than employment income.

[9] For the 28th Regime, we also explored ESOP transfer mechanisms. Founders have recommended that there should be no transfer restrictions. Except to prevent unfair competition linked to material non-public information. If any restrictions were necessary, the only practical option would be pre-emptive rights.

[10] Eberhartinger, E., Figari, F., Fleischanderl, H., Petutschnig, M., Pistone, P., & Zagler, M. (2025). *Tax barriers and cross-border workers: Tackling the fragmentation of the EU tax framework*. European Parliament

[11] The *Not Optional initiative* is a pan-European campaign launched by Index Ventures and backed by over 700 CEOs, founders, and investors. Its goal is to reform employee stock option policies across Europe to help startups attract and retain top global talent. They present recommendations for policymakers and investors.

Without this, European ESOPs will remain globally uncompetitive. As it will Europe's ability to attract and retain talent.

Creating green, sustainable economic growth and strategic autonomy through better procurement policy design for industrial biotech products

The public sector can act as an early adopter. It can establish a buyer group, which will trigger the industry to scale. We have seen this in renewable-energy rollouts, notably solar, where coordinated public demand has led to rapid scaling and cost reductions, resulting in economic growth, increased autonomy, and the creation of millions of jobs.[12] Public procurement, therefore, has proven to be a valuable industrial policy lever for creating resilient supply chains and fostering large domestic markets.

The Commission already recognises procurement as a core demand-side tool to translate public needs into market-ready solutions. Still, **public procurement remains underused**. Particularly urgent **for scaling strategic technologies**.[13]

The continent requires a long-term vision and well-designed EU and national action plans or roadmaps. In such, **R&I programmes should explicitly incentivise and fund innovation procurement for priority sectors, such as biotech**. They should **contemplate dedicated funding** in Horizon Europe and Mission calls. Capacity building should be embedded in those programmes with funded training[14] for public buyers and assistance schemes for SMEs. Payment modalities must also be adapted to SME realities (anticipated, milestone or accelerated settlement) to ensure their participation.[15]

An EU action plan, involving all Member States, could help anchor funding, templates, evaluation criteria and capacity building into both EU R&I cycles and national strategies. A non-binding **EU list of award criteria, which includes,** for example, **sustainability and contribution to EU tech sovereignty**, could help harmonise practices across Member States.

Encouraging commercialisation of publicly funded research and innovation

Publicly funded R&I already delivers strong economic returns. The Horizon Europe interim evaluation estimates that every euro invested could generate up to €11 in GDP over 25 years.[16]

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[12] Shan Hu, Ziwei Zhao, Lang Wu, Zhuang Zhang, 2025 *Does public procurement promote renewable energy innovation? Firm-level evidence from China*, Journal of Cleaner Production.

[13] European Commission, 2025. *Bringing down legal barriers for innovation procurement.*

[14] Building on already existing programmes, as the *latest* *Innovation Procurement Training Programme for Public Buyers.*" *f*rom the European Commission.

[15] *Commission Notice, Guidance on Innovation Procurement*, 2021. Further steps needed to support biotech SMEs.

[16] The industry strongly welcomes FP10's latest funding increase proposal. We draw attention that in the current geopolitical moment, Europe needs more than ever to continue to collaborate with its non-EU European partners, including the United Kingdom and Switzerland and other like-minded countries.

In the latest public consultation, nearly half of the respondents reported that their projects would not have gone ahead without this funding. [17]

However, **conversion of public investment into commercial products remains weak**.[18] The European Patent Office's work shows that only a little more than a third of university/RTO inventions are being exploited[19], and that biotechnology is one of the largest fields of academic patenting (closely following and second only to pharmaceuticals).[20] Therefore, **improving valorisation in biotech must be a strategic priority**.

Part of the problem is rooted in institutional culture and practice. Many universities and research organisations remain structurally oriented towards publication and academic metrics rather than to rapid, market-facing transfer. Technology transfer offices are unevenly resourced, and negotiations over IP and licenses are often slow.

In this regard, and also within the scope of the Biotech Act, EuropaBio recommends **earmarking additional EU funding for universities that excel in academic research and have a proven track record in technology transfer and spin-offs;** introducing metrics to assess the maturity and impact of translational research and creating targeted incentives to achieve a higher technology readiness level.

Additionally, spinoff founders also report mismatched expectation with universities and RTOs over IP value, time-to-market, and returns. A practical next step recommended by entrepreneurs for the 28th Regime was the **development of EU-standardised frameworks for IP licensing and spin-off terms.** (As best practices, it was mentioned the recently published ETH Zürich revised spin-off framework[21].)

Lastly, startups and SMEs cite high costs and burdens for IP management and worry about IP infringement in overseas manufacturing. They have requested enforcement support of their IPR and increased access to expert IP management (for example, through a pooled of EU legal assistance and litigation support facility).

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[17] EC (2025) *Horizon Europe: Research and Innovation at the heart of competitiveness* (COM(2025)189)

[18] Given biotechnology's cross-sectoral nature and different definitions, it is challenging to compare global funding levels. However, despite the size of Horizon Europe, we can safely affirm that, to date, the USA has invested far more in R&I into biotech than Europe. This is reflected in the total global number of biotech patents. The USA leads in development (39% of total global patents in 2020), followed by the EU (18% share), and China advancing quickly (10% share). In this scenario, public R&I investment in biotech and its commercialisation must be a priority. For a comprehensive issue overview, please refer to Joint Research Centre (2024) *Exploring the global landscape of biotech innovation: Preliminary insights from patent analysis.*

[19] European Patent Office (2020). *Valorisation of scientific results – Patent commercialisation scoreboard: European universities and public research organisations*.

[20] European Patent Office (2024). *The role of European universities in patenting and innovation.*

[21] *ETH Zurich's revised spin-off framework (July 2025)* streamlines company creation with clear, founder-friendly processes, a fast-track licensing path, a 2% equity cap for ETH, distinct labels for spin-offs and start-ups, and integrated support. It was flagged by several founders as one of the most recent and best structured models.