

EuropaBio's Public Consultation Response to the European Commission's 28th Regime proposal

Biotechnology is one of the most critical technologies to Europe's autonomy, prosperity and ability to compete globally.¹ Biotech contributes over €75 billion of added value to the EU economy each year and provides some of the continent's highest-value jobs. These numbers nearly doubled in the last decade.²

Despite the sector's growth, established infrastructure, talent and experience, Europe is not improving its global competitiveness. While company creation and startup activity kept pace with other leading global regions, **many biotech companies feel forced to relocate to less regulatory restrictive and more liquid capital markets.** Such as the United States of America or in Asia. There, they can scale operations and secure investments more easily. Some biotech founders, pragmatically, reported not even expecting to reach profitability within Europe.

Against this backdrop, and with a sense of urgency, EuropaBio strongly supports the development of a long-overdue 28th Regime Regulation within the framework of the European Startup and Scaleup Strategy.³

To contribute to this consultation, **we focused our feedback collection and analysis on startups and early-stage SMEs with innovative projects.**

We spoke with over a dozen European biotech founders and investors, senior experts from leading think tanks such as Bruegel, and our members - including 26 national and regional associations representing over 4,500 biotech startups and SMEs active across all biotech sectors. **We have summarised their contributions on why and how biotech startups and SMEs operate in Europe, their challenges and recommendations.** We have structured our feedback aligned with the European Commission's consultation framework.

- 1) Creating in Europe: Europe vs abroad, challenges incorporating and an EU label
- 2) Structure and core elements of the 28th Regime companies. Simple, flexible and fast procedures and rules
- 3) Attracting investment to 28th regime companies, stock options for employees and taxation
- 4) European biotech companies' main assets to compete: capacity to attract talent and IPR

¹ Identified in the [STEP Regulation \(EU\) 2024/795](#) and [M. Draghi's report on EU competitiveness](#)

² €75.1 billion total gross value added in 2022, and €38.11b. in direct GDP contribution, WifOR Institute (2025) [Measuring the Economic Footprint of the Biotechnology Industry in Europe](#)

³ EuropaBio's contribution to the [European Commission Call for Evidence for the EU Startup and Scaleup Strategy](#).

Creating in Europe: Europe vs abroad, challenges incorporating and an EU label	
Choosing where to start a company	<ul style="list-style-type: none"> Proximity to biotech clusters: access to universities, incubators, other companies, and founder networking (knowledge-sharing, mentoring, advising). VC-dense cities such as Berlin and Munich. Cultural and personal consideration - wish to remain a "European company".
Why companies move across the EU and abroad	<ul style="list-style-type: none"> Affordable manufacturing. Accessible infrastructure (e.g., roads, airports). Access to high liquidity markets. Higher company valuations. Market expansion. Avoid trade implications and political uncertainty.
Main challenges in the incorporation process	<ul style="list-style-type: none"> Too many steps. Lengthy and cumbersome procedures. Navigating different types of legal entities (<i>e.g.</i>, SA, GmbH). Outdated requirement to appear in-person before a notary, with significant cost variations across Member States (MS). "Cannibalisation of public funds" - companies have reported national and regional grants' obligations to withdraw operations from other MS. Company cross-border mobility: compliance requirement for a "clean cut" in accounting at year-end, rather than at any given moment. Opening bank accounts can be a very bureaucratic and slow process (e.g., the obligation to submit shareholders' documentation on their other investments, the type of customers, service providers, and the countries they expect to receive transactions from).
Thoughts on EU label	<ul style="list-style-type: none"> Overwhelmingly positive: being European is perceived abroad as high quality and standards. Companies will only consider reincorporating if there are clear incentives and benefits (e.g., on talent attraction or lower tax costs). Main concern: if by opting into the 28th Regime that could lead to losing access to national and regional grants.

Recommendations

- Provide affordable legal advice on the procedures for setting up a 28th Regime company, on investing in companies across all MS, and on how to navigate different national company laws.
- Ensure full implementation of the "once-only" principle.
- Enable fully digital, free (*or at minimal cost*) registration procedures, without the need for in-person notaries. Accessible both in the national languages and English.
- Guarantee clear and fast timelines for registration procedures (no longer than 48h).
- Create incentives for companies choosing to incorporate under an EU brand (e.g., on talent attraction and tax exemptions).

Structure and core elements of the 28 th Regime companies Simple, flexible and fast procedures and rules	
What type of company should a 28th Regime company be & Who can set it up	<ul style="list-style-type: none"> • Entrepreneurs should be able to register 28th Reg. companies as private limited liability companies (LLC) and public liability companies.⁴ • Startups and SMEs with innovative projects.
How a 28th Regime Company Can Be Set Up	<ul style="list-style-type: none"> • Creation from "scratch" or conversion (domestic and cross-border). • Companies should be allowed to have their registered office and central administration in different MS. • Careful consideration for companies to not lose their 28th Regime status once they scale into larger companies.
Minimum capital requirement	<ul style="list-style-type: none"> • The lower the requirement, the less restrictive it is for entrepreneurs. • For venture capital in the biotech sector, minimum capital requirement is not a deciding factor for investment decisions.⁵

⁴ Europe does not have a developed Unified Stock Market. Until then, companies that wish to be traded in Europe must do so at the national level. The EU should not limit its support for companies raising private investment in national capital markets.

⁵ First considerations for startups are on IP and Board members' experience.

<p>Barriers setting private LLC fully online & overall use of digital tools</p>	<ul style="list-style-type: none"> • Most entrepreneurs are unaware that LLCs can already be set up fully online. • Many are also unaware of the European Business Wallet. • Registration still requires notaries or in-person legal intermediaries. • The process remains burdensome, time-consuming, and lacks the “once-only” principle.
<p>Instrument of Constitution & the Articles of Association</p>	<ul style="list-style-type: none"> • Companies do not perceive navigating the instruments of constitution and the articles of association as major challenges. There are already high-quality, standardised, available documents. • However, they are not harmonised across the EU. • Articles will likely need to change as new investors join, and companies mature. • There should be a flexible, modular approach that allows for both the use of a standardised template for faster registrations (investors' priority) and other more flexible options for companies that choose so.
<p>Recommendations</p> <ul style="list-style-type: none"> • Focus the 28th Regime’s initial design on startups and SMEs with innovative projects. • Ensure that if 28th Regime companies are limited to startups and SMEs they do not lose their EU brand status as they scale into larger companies. • Upgrade digital tools to enable simple, fast, and flexible procedures for changes in company seat, conversion, legal form, and shareholders. • Set no minimum capital requirement for registration. • Create fast procedures for STEP technologies companies. Ensure these procedures are closely coordinated with national authorities responsible for the certification and support of startups and SMEs, including national Ministries of Research, Development Agencies, and academic institutions. • Set a modular framework, allowing multiple registration possibilities. i.e., possibility to register a company faster using standardised documents and other options with more flexibility. Even if it takes longer to register (but still within a clearly defined and visible timeline for users. No longer than 48h). • Allow flexibility to amend the Instrument of Constitution and Articles of Association later, as companies scale and adapt. 	

Attracting investment to 28th regime companies, stock options for employees and taxation	
Main barriers to attracting private funding	<ul style="list-style-type: none"> MS have different legal and tax rules for cross-border investment. Some companies reported a % threshold limit on how much can be invested in a foreign company without changing their tax bracket. Markets are over-regulated and lack liquidity. To improve overall liquidity, companies suggested utilising pensions, sovereign, and endowment funds, along with obligations for such funds to diversify their portfolios. Similar to the US model.
Employee stock options, taxation, best practices and concerns	<ul style="list-style-type: none"> There are no harmonised practices across the EU. The main instrument is virtual stock options (VSOPs). Companies and employees strongly oppose taxation before exit events and options being taxed as income rather than capital gains. Concerns that using VSOPs may negatively impact subsequent funding rounds and company valuations. Best practices and events to explore: Germany's VSOP Ruling ⁶ and the "Non-Optional" initiative founded by Index Ventures.⁷
Share transfer restrictions, pre-emptive rights, and lock-in periods	<ul style="list-style-type: none"> Options should be tradable. As in the USA, companies should have the ability to offer "real" shares more easily. Employees should be able to exercise them immediately. Most share agreements have "drag along and tag along rights" that would impact share-transfer dynamics. There should be no trading restrictions (except to prevent unfair competition linked to material non-public information). If restrictions are necessary, pre-emptive rights are the only practical option. Stewardship and asset lock provisions were not flagged as relevant for biotech startups and SMEs.

⁶ Germany's new VSOP ruling (Bundesarbeitsgericht, 10 AZR 67/24) prohibits companies from revoking vested virtual stock options when employees leave.

⁷ 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 ESOP policies across Europe to help startups attract and retain top talent. They present recommendations for policymakers and investors.

<p>Access to regulated capital markets for scale-up</p>	<ul style="list-style-type: none"> • Not a concern for most startups, which are not yet scaling. Very significant for SMEs. • In Europe, scaling up via capital markets is nearly impossible. There is no unified stock market, and companies are undervalued due to low liquidity and overly stringent regulation. • For those biotech companies interested in listing, the USA remains their preferred option.
<p>Taxation</p>	<ul style="list-style-type: none"> • Most biotech startups and SMEs are not yet profitable. Taxation is therefore not a priority. • Most companies expect that revenue will only be generated in other jurisdictions. • Companies often depend on costly third parties (consultancies) to navigate cross-border tax laws. • EU label companies should have tax incentives. • Tax incentives periods, as in the case of exemptions, should only be applicable from when companies start to become profitable and not from when they are registered.
<p>Recommendations</p> <ul style="list-style-type: none"> • Ensure no market distortions or unfair competition via subsidies or grants' obligations to withdraw operations from other Member States. • Develop harmonised documentation for employee stock options. Explore best practices, such as those in the "Non-Optional" initiative. • Apply "no taxation without realization." Tax employee stock options as capital gains, not income. • Do not restrict employees from trading stock options. If restrictions are required, apply only pre-emptive rights. • Explore and assess alternative stock option instruments for employees under this Regime. • Continue efforts toward a Single European Stock Market, ideally a NASDAQ-equivalent for biotech, and the Savings and Investments Union. • Provide better guidance for SMEs on how to navigate different national tax systems. • Provide tax incentives for companies that chose to be incorporated into the 28th Regime. Incentive periods should be set from the moment a company becomes profitable. Not at the time of registration. 	

European biotech companies' main assets to compete: capacity to attract talent and IP	
Navigating and managing Intellectual Property	<ul style="list-style-type: none"> • IPR are one of the main considerations for investors. • Startups and SMEs need stronger support not only for patent registration but also for IP management and litigation. • Many universities often hold unrealistic expectations regarding the value of their IP, time to market and potential returns. • There is a need for a standardised EU-wide document for IP licensing and spin-off terms. • Companies are increasingly cautious about IP infringements when manufacturing abroad, particularly in Asia. • Global IPC patents are prohibitively expensive and difficult to enforce.
Hiring across MS and abroad - the need for faster recognition of talent	<ul style="list-style-type: none"> • For investors, Board members' profile is one of the most important investment considerations when looking at startups and SMEs. • Hiring non-EU professionals is a cumbersome process with experiences uniformly slow across MS.⁸ • Cross-border remote workers are often hired as contractors, with companies relying on third-party providers to manage healthcare, social contributions, and other compliance obligations as they do not have the expertise or the resources.
Recommendations <ul style="list-style-type: none"> • Develop standardised EU frameworks for IP licensing and spin-off terms. Use, as best practice, the recently published ETH Zurich's spin-off policy framework.⁹ • Harmonise Visa application procedures for highly specialised, in-demand talent from outside the EU. Use national best-case models for talent attraction and for entrepreneurs (e.g. Lithuania and Estonia Startup Visa). • Introduce Visa fast-track procedures in partnership with trusted universities and institutions (e.g., for biotech talent from Ukraine and Bosnia and Herzegovina). • Support 28th Regime companies in navigating healthcare and social obligations to facilitate cross-border remote work within the EU. 	

⁸ Reported cases include waiting over six months for a visa approval (including family applications) with delays linked to the recognition of marriage licenses. Professional held a PhD and had over 20 years of experience in the field.

⁹ [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 founders as one of the most recent best models.