

Response to the European Commission Call for evidence on the EU Biotech Act

At Invest Europe – the association representing Europe’s private equity, venture capital (PE/VC) and infrastructure sectors, including fund managers and investors in biotech and life sciences – our members are committed to unlocking the potential of competitive sectors, including biotech. Yet, persistent structural barriers are limiting progress and competitiveness.

Despite Europe’s foundation in world-class biotech research and IP generation, it continues to lag in translating innovation into commercial products. This innovation gap – between lab and market – threatens Europe’s competitiveness, autonomy, and ability to attract global private capital. If left unaddressed, this will lead to job losses, reduced capacity, and growing dependency on third countries for strategic products. The European Biotech Act is an opportunity to close this commercialization gap by addressing systemic barriers.

To help bridge this innovation gap, action is needed in the following areas:

- **Accelerating time to market:** IP rights are critical not only to protect innovation but to signal value to potential investors. However, many innovations stall due to regulatory complexity. Delays in trials, approvals, and commercialization affect PE/VC-backed biotech firms. With the commercial window limited by patent life, reducing time to market for high-impact innovations and strengthening mechanisms for early, structured engagement with regulators is essential. Equally important is ensuring Europe is not seen as commercially unattractive due to untimely or low reimbursement, as companies may deprioritize it in favor of other markets – potentially limiting access to breakthrough innovations and weakening Europe's position in global biotech.
- **Bridging the investment gap:** European R&D spending has lagged behind both the US and China in recent years, contributing to a lower rate of innovation output and diminished global competitiveness. Compounding this, rising global protectionism – particularly US policy shifts – has altered the landscape for biotech investment, prompting a shift in innovation hubs. Europe must protect its strategic position in biotech value chains and retain biomanufacturing capacity. Targeted investment incentives and instruments – such as R&D tax incentives and mechanisms operated by the EIF and EIB – are needed to attract long-term capital and businesses. Public investments must act as catalysts that de-risk innovation and crowd in private capital by addressing market failures, particularly in early-stage biotech.
- **Unlocking data, AI and quantum computing:** access to data and emerging technologies like AI and quantum computing has the potential to reduce development timelines, cut costs, de-risk R&D and enhance investors’ confidence. Yet, Europe’s biotech firms face fragmented access to data, computing power and testing environments. Some datasets – especially when combined with AI and quantum computing – could unlock significant breakthroughs and transform current processes. We support the fast implementation of high-quality, interoperable European data environments that enable responsible innovation, such as the European Health Data Space. In parallel, biotech-specific regulatory sandboxes should be established – secure and flexible environments where start-ups can test new models, including AI-led discovery and platform trials, without full regulatory burden upfront while supporting safe acceleration.
- **Strengthening the entrepreneurial workforce:** a strong entrepreneurial talent base helps scale biotech companies, but most new biotech start-ups are now created in the US, while

company formation in key European regions is declining. Alongside a talent shortfall, this trend threatens innovation, capacity, and delivery. Entrepreneurship must be supported by a strong equity framework, including improved equity compensation schemes to attract and retain talent, and EU-wide mobility tools like a unified start-up visa.

For further questions, please reach out to publicaffairs@investeurope.eu