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NOTE

From:	Presidency
To:	Permanent Representatives Committee/Council
Subject:	European Biotech Act I Regulation: **-** *Policy debate*

Delegations will find in Annex a background note from the Presidency to steer the policy debate on the European Biotech Act I Regulation at the EPSCO Council (Health) on 16 June 2026.

The European Biotech Act I Regulation: how to boost health biotechnology in the EU?

On 16 December 2025, the Commission proposed the European Biotech Act, a legislative initiative composed by a Regulation and a Directive, designed to boost the competitiveness of the European health biotechnology and biomanufacturing sectors by enabling an environment that allows biotechnology products to move from the laboratory to the factory to the market – faster, at scale, and in the EU.

For the EU, health biotechnology not only presents a major economic opportunity but a strategic necessity: the ability to develop, produce, and deploy innovative biotechnologies is increasingly inseparable from Europe's health security, industrial sovereignty, and long-term competitiveness.

The numbers are telling. The EU biotechnology sector has grown more than twice as fast as the overall EU economy over the last decade. In 2022 alone, it accounted for EUR 38.1 billion of Union GDP and supported over 913 000 jobs – more than 75% of which are in health biotechnology. Each job in industrial biotechnology generates 3.4 additional jobs in the broader economy. In addition, the EU has a world-class scientific base, for example its publication record remains robust and is comparable with those of the US and China.

And yet, the EU is losing ground. Too many start-ups are choosing to scale up, go public, and create value outside the EU: the vast majority of European biotechnology companies that went public chose to list on non-EU stock exchanges. US biopharma start-ups received around nine times more late-stage funding than their EU counterparts between 2015 and mid-2025.

This is not a failure of scientific talent, but a structural problem with the scale-up of companies and commercialisation of products, fragmented governance, complex and slow regulatory pathways, insufficient access to scale-up capital, and underdeveloped biomanufacturing infrastructure are all cited as contributing factors. The result is that Europe invents, but others industrialise. Addressing this requires urgent and coordinated action

While rapid biotechnology advances bring many advantages, they can also lower the barriers to creating biological threats, requires stronger biological defences as well as a harmonised EU framework to control access to sensitive biotechnologies.

In particular, clinical trials are central to Europe's competitiveness and health systems. They generate an estimated EUR 35.7 billion in gross value added annually in the EEA and support over 165,000 jobs, while giving patients earlier access to innovative treatments. However, the EU's share of global clinical trials has fallen from 22% in 2013 to 12% in 2023, and multinational authorisations take about 116 days on average. The Biotech Act aims to deliver a faster, simpler and more predictable authorisation process while maintaining high standards of safety and data quality.

The accelerated procedures and mechanisms proposed in the Biotech Act are already being successfully piloted through the FAST-EU initiative on a voluntary basis. This pilot led by Member States with support from the European Commission and EMA has demonstrated the feasibility of the proposed approach, with initial authorisations granted in around 70 days, effectively serving as an early operational testbed for the future system. To date, 26 Member States participate in the initiative, with 15 clinical trials currently included and three already completed, underlining both the strong uptake and the practical viability of the accelerated model.

In parallel, the COMBINE pilot is testing the coordinated assessment of combined studies involving the investigation of a medicinal products and medical devices as proposed in the Biotech Act.

These initiatives demonstrate that a more coordinated and agile European system can deliver significantly faster and more predictable clinical trial processes while fully maintaining the highest standards of safety and data protection. Supported by digitalisation, AI and greater inclusivity, they provide concrete proof-of-concept for the reforms envisaged under the Biotech Act.

An ambitious Biotech Act is needed to scale and sustain these improvements, ensuring they translate into tangible benefits for patients across the Union.

The European Biotech Act as a comprehensive response

The Act is explicitly multisectoral in its design. It cuts across health, industrial policy, research, finance, digital, and security – reflecting the reality that no single intervention can shift Europe's competitive position in biotechnology on its own.

- Regulatory simplification and streamlining: targeted amendments to existing EU legislation – on clinical trials (CTR), advanced therapy medicinal products (ATMPs), substances of human origin (SoHO), veterinary medicinal products, and the general food law – to remove bottlenecks that slow down innovation and market access. This includes futureproofing: mechanisms to ensure the legislative framework keeps pace with rapid scientific and technological advances, enabling regulatory agility without compromising the high European standards for safety or data quality.

- (High impact) strategic projects: a framework to identify and accelerate health biotechnology projects – from development to manufacturing - of national and EU-level strategic importance, reducing time-to-market through coordinated administrative support and streamlined permitting, and potential funding opportunities.

- Access to capital: dedicated measures to mobilise public and private investment, including an EU health biotechnology investment pilot to address the persistent gap in late-stage financing.

- Incentivise development and manufacturing of breakthrough innovations in the EU; as well as strengthen the biosimilar industry.

- AI integration: provisions to facilitate the application of artificial intelligence across the biotechnology lifecycle, from product development to clinical research and biomanufacturing.

- Biosecurity: EU-level safeguards to prevent misuse of biotechnologies, harmonising currently divergent national rules and reinforcing European biodefence capabilities.

Align health and competitiveness objectives

The Act is an opportunity to align health and competitiveness objectives across Europe. Faster and more streamlined authorisation and conduct of multinational clinical trials for human medicines contributes to earlier patient access to innovative or optimised therapies. Stronger biomanufacturing capacity means greater resilience against supply disruptions. More competitive regulatory pathways mean the EU remains attractive for the research investments that ultimately translate into positive health outcomes.

Member States are invited to signal where national priorities align regarding the proposed response to the competitiveness gap with the US and China in this strategic sector, and to set the direction for the technical work ahead.

Questions for discussion

A. What priorities does your Member State have in relation to the European Biotech Act I Regulation proposal?

B. How can the European Biotech Act I Regulation be most effective in helping to improve competitiveness in the EU and access for patients and citizens to innovative products?