

Strengthening Europe's Health Biomanufacturing Value Chains with the Biotech Act I

The European Fine Chemicals Group (EFCG), a sector group of Cefic representing the European manufacturers of fine chemicals including Active Pharmaceutical Ingredients (APIs), drug substances, excipients and intermediates, supports a strong Biotech Act I that strengthens the competitiveness of European biotech and biomanufacturing sectors, which are essential for EU health security and strategic autonomy.

The members of EFCG call for a policy approach that reflects the complexity of the health biotechnology value chain and anchors key manufacturing steps in Europe. This approach should address all strategic elements of the health biomanufacturing value chain, ensure access to key biomanufacturing inputs, deliver consistency across legislation, and provide fit-for-purpose financing and funding for scale-up and modernisation—ultimately strengthening competitiveness and EU health security.

Acknowledging the complexity of the health biotechnology value chain

While the Biotech Act I advances several key biotech objectives - particularly by supporting the role of CDMOs¹ and providing flexibility for their access to specific funding, it does not fully reflect the complexity of biomanufacturing value chains.

Pharmaceutical biomanufacturing is not limited to a single production step; it comprises a series of interconnected stages that vary depending on the production route. Reducing dependencies and vulnerabilities therefore requires addressing potential gaps across the value chain.

Beyond supporting innovative projects and molecules, the Biotech Act I should ensure that biotech and biomanufacturing processes are also used to modernise the production of existing critical molecules, and that critical « manufacturing steps »² are identified and addressed.

Anchoring key manufacturing steps in Europe

The location where biomanufacturing steps are performed directly affects supply resilience, scalability, work force capabilities, and innovation. To ensure resilient EU supply chains for advanced therapies, manufacturing should be established in Europe from the outset.

To ensure the enforceability and effectiveness of the Biotech Act I provisions, at least the two key manufacturing steps of the drug substance should be anchored within the EU:

¹ See EFCG position paper on the role of Contract Development and Manufacturing Organization (CDMOs) in biopharma: [2025-Dec-Role-of-CDMOs-in-biopharma.pdf](#)

² Draft Regulation COM (2025) 1022, art 27



- **Upstream Biomanufacturing:** the bioproduction phase where cells or microorganisms are designed and cultivated to produce a desired biological product.
- **Downstream Biomanufacturing:** the bioproduction phase where the biological products are harvested and purified.

The European Medicines Agency recognises³ that, in biotechnology, any change to manufacturing process—including a change of site—carries inherent risk and may require new non-clinical or even clinical studies. As a result, the origin of manufacturing is far more critical for biological medicinal products than for traditional pharmaceuticals. Once a biological medicinal product is approved, relocating production comes with significant regulatory and quality challenges and a long lead time - often multiple years - whilst maintaining supply continuity during the transition.

Addressing all strategic elements of the health biomanufacturing value chain

Because a core objective of the Biotech Act I is to support a strong biomanufacturing industrial base in Europe, it should also recognise the need to secure the production of key ingredients in Europe and reflect this in the eligibility criteria for targeted project funding.

Alongside drug substances, pharmaceutical excipients are a strategic asset of the pharmaceutical sector and an integral component of health biotechnologies, driving the sustainability and innovation of EU medicines. Representing up to 95% of a finished medicinal product by volume, excipients enable drug substance delivery and play a crucial role in improving access to therapies, supporting patient friendly formulations, and ensuring stability, bioavailability, and controlled or targeted release.

The Biotech Act I should therefore explicitly acknowledge the role of both drug substances and pharmaceutical excipients and ensure their inclusion across relevant provisions - particularly the eligibility criteria for targeted funding instruments and incentive mechanisms, as well as conditions linked to supplementary protection certificate (SPC) extensions.

Ensuring access to key biomanufacturing inputs

Biopharma depends on key biomanufacturing inputs—critical raw materials, reagents, media, and precursors—as well as on agricultural feedstocks such as sugars used in fermentation and cell-culture processes.

Supporting access to all types of sustainable biobased feedstocks at competitive price is crucial to enable a thriving European biotech sector. According to the “cascading use” principle, resource efficiency can be achieved by prioritising biomass use “according to its highest economic and environmental added value”⁴.

³ [Guideline on Comparability after a change in the Manufacturing Process- Non-Clinical and Clinical Issues](#)

⁴ Directive (EU) 2023/2413 of the EP and the Council of 18 October 2023 (RED III)



Continuous strain innovation and improvement⁵ are essential to increase yields, ensure quality, support scalability and reduce environmental footprint.

In light of the EU's recognition of the strategic importance of health biotechnology and its relatively limited biomass needs, fair access to biomass for health biomanufacturing should be prioritised.

Consistency across legislation

To build and maintain a robust biotech and biomanufacturing sector in Europe, the European Union should pursue a coherent and streamlined approach across existing and forthcoming legislation. This includes ensuring consistency of provisions across the EU Critical Medicines Act, the revised EU Pharmaceutical legislation, the Industrial Accelerator Act, the Public Procurement package revision and Biotech Act II.

Regulatory fragmentation across different legislative instruments creates uncertainty for investors and industry. While the Commission's proposal aims at shortening clinical trial timelines, the EU should also ensure consistent authorisation processes at both European and national levels, supported by a streamlined legislative framework for the health sector that prioritises regulatory efficiency and simplification.

This should translate into shorter and more predictable administrative procedures, enabling faster scale-up and deployment and ultimately reducing time to market.

Financing and funding

Europe faces higher feedstock, energy, permitting, and construction costs than other regions, undermining its competitiveness and highlighting the need for faster, clearer, and more effective funding mechanisms. Today, fragmented and complex EU and national funding instruments make it hard for companies to identify and blend the right financing, creating inefficiencies and slowing innovation and scale-up. The EU Biotech Act I aims to streamline funding through instruments such as the EIF, EIB, InvestEU, and the new EU Health Biotechnology Investment Pilot, but it lacks the legal clarity needed for effective implementation. Dedicated mechanisms to scale and modernise facilities—including green and digital upgrades—are essential for current and next generation medical biotechnologies. The Act should clarify the division of roles between national and EU schemes, allow more flexible state-aid programmes, and ensure biosimilar developers and CDMOs have effective access to IPCEI⁶s, strategic projects investments

⁵ Strain innovation refers to the range of tools used to develop and enhance biological strains. These include genomic, analytical, computational, and automation-based technologies for discovering, engineering, screening, characterising, and scaling improved strains.

⁶ Important Projects of Common European Interest



and other major EU, regional and national funding instruments. Providing concrete and enhanced support to biosimilars would represent a strategic recognition of the sector's importance in strengthening the EU's strategic autonomy.

Moreover, the definition of "innovation" should also be broadened to include upgraded technologies, new formulations, and process optimisation. A dedicated budget should be channelled towards industrial investments, including capacity expansion, job creation, supply diversification, as well as the modernisation and technological innovation of manufacturing facilities in Europe.

Europe will not attract the private capital needed to lead in health biotechnology unless it backs innovation with production. The European Commission should treat enabling infrastructure and Europe's CDMO ecosystem as strategic industrial assets: they deliver proven, high-volume biologics manufacturing, create high-skill jobs, and provide the fastest, most reliable route to scale next-generation biotechnologies in Europe. Yet EU support still focuses on early-stage R&D, while investment in manufacturing capacity is lagging behind rising global demand for bio-manufactured medicines. mRNA platforms prove why biomanufacturing means health security: they are no longer exceptional pandemic tools, but strategic, modular technologies for oncology, rare diseases, and personalised vaccines - capabilities Europe must be able to produce at speed, at scale, and under EU control. The Biotech Act must therefore bring advanced biomanufacturing—explicitly including mRNA—within its investment scope, and mobilise funding instruments accordingly. This is essential to strengthen Europe's innovation base, build resilience, and secure strategic autonomy in medicines.

Europe's biotech ambition will be won or lost on industrial capability. EU resilience and competitiveness require an end-to-end Biotech Act - one that anchors upstream and downstream manufacturing in Europe, secures critical inputs from feedstocks to excipients and drug substances, delivers consistency and faster procedures across the EU rulebook, and mobilises fit-for-purpose financing to modernise and scale capacity. Without these steps, Europe will remain exposed to shocks and dependent on others; with them, the EU can deliver medicines, jobs, and strategic autonomy.

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