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Existing strength is valuable, but it is not a guarantee of future leadership

23.07.2026

Tags: Europe, EuropaBio, Biotech, Association, Investment

Europe's place in the global biotechnology race is entering a decisive phase. Scientific excellence and industrial depth remain powerful advantages, yet intensifying competition from the United States and China is exposing the need for faster execution, stronger capital markets, and a more coherent single market. Claire Skentelbery outlines why biotechnology should sit at the heart of Europe's competitiveness agenda, from healthcare innovation to advanced manufacturing and supply chain resilience, and why the next policy cycle could prove pivotal.

What is EuropaBio's role in Europe's biotechnology ecosystem, and what priorities are shaping its agenda today?

EuropaBio is the cross-sector association representing Europe's biotechnology industry, bringing together members that range from start-ups and SMEs to global multinationals. Through our corporate membership and the National Associations Council, a network of 25 national and regional biotech associations, we represent more than 5,000 biotechnology companies across Europe, around 4,600 of them SMEs. EuropaBio was founded around 30 years ago, at a time when Europe was beginning to develop legislation specifically related to biotechnology, particularly around genetically modified organisms. Since then, the sector has evolved dramatically, and biotechnology now plays an increasingly important role across healthcare, agriculture, food systems, industrial manufacturing, sustainability, and advanced materials.

Our first priority is to help create competitive markets for biotechnology products and processes in Europe. That means advocating for regulatory and legislative frameworks that support innovation at both EU and Member State level, while encouraging greater alignment across the single market. Much of our work is centred on ensuring that policy keeps pace with scientific progress and gives companies the certainty required to invest, grow, and bring new technologies to market.

A second priority is visibility. Biotechnology is often hidden behind the finished product, which means its economic and social value is not always fully recognised. In healthcare, people naturally think of cell and gene therapies, immuno-oncology, or mRNA platforms, but biotech is equally relevant in areas such as advanced manufacturing for active pharmaceutical ingredients, where industrial biotechnology is increasingly replacing traditional petrochemical processes. The same shift is taking place across many other industries, and part of our role is to make that contribution more visible.

Our third priority is to strengthen the wider ecosystem. We work closely with national associations on skills, investment, and regional development, helping create the conditions that allow strong science to translate into commercial success. We also partner with the WifOR Institute to measure biotechnology’s economic footprint in Europe, including its contribution to employment, productivity, exports, and wider growth. Alongside organisations such as EFPIA and EUCOPE, which each play important roles, EuropaBio’s distinct perspective is biotechnology as a frontier technology. That means focusing on how Europe enables the next wave of innovation, while ensuring that companies of all sizes, particularly the smaller firms often first to pioneer new platforms, can scale and succeed.

How should Europe view its position in the global biotechnology landscape, and where can it still create advantage?

It is easy to frame the current landscape as Europe being squeezed between a rapidly advancing China and a highly dominant United States, yet the reality is more balanced than that narrative suggests. Europe continues to benefit from a strong research base, excellent scientific talent, and deep technical expertise. Where it has historically been weaker is in translating those strengths into products, companies, and commercial scale at the pace seen elsewhere. That is partly a function of regulatory complexity, but it also reflects the challenge of operating across 27 Member States, particularly in healthcare, where many of the most important decisions remain national.

As a result, competitiveness is not simply a question for the European Commission. It also depends on the willingness of Member States to work in closer alignment. Full harmonisation of pricing and reimbursement is unlikely, but there is still substantial room to simplify procedures, share expertise, and reduce fragmentation across the system. A more coherent operating environment would make Europe materially more attractive for innovators deciding where to invest, run trials, and launch new medicines.

The United States has built clear structural advantages over many years through the scale of its domestic market, stronger rewards for innovation, and a mature investment ecosystem with greater risk appetite. China's rise should be seen through a similarly strategic lens. Long established as a manufacturing power, it has invested heavily in science and capability and is now emerging as a significant innovation centre in its own right. The increase in Chinese clinical trials, capital flows, and biotech transactions is therefore the product of sustained policy focus rather than a sudden shift.

Biotechnology, however, remains a global industry. Medicines are not developed for a single territory, and modern supply chains are too interconnected to be fully repatriated within national borders. Europe is unlikely to out-manufacture China or replicate the commercial scale of the United States, but it can remain a leading source of high-value innovation. The task now is to capture more of that value through stronger private investment, better scale-up pathways, broader patient access, and continued leadership in areas such as mRNA, advanced therapies, and globally relevant clinical research.

Why does the EU Biotech Act represent a generational opportunity for Europe, and how far does the current proposal go in meeting the region's needs?

The European Commission's Biotech Act is important because it reflects a wider shift in how biotechnology is now regarded across Europe. Over the past several years, biotech has moved beyond being seen as a specialist or sector-specific issue and is increasingly recognised as a strategic capability linked to competitiveness, economic resilience, healthcare, sustainability, and regional development. In that sense, the Act is not a stand-alone initiative, but the most visible expression of a broader political recognition that biotechnology matters to Europe's future.

That wider recognition can already be seen across the policy landscape. EuropaBio has identified more than 20 legislative and strategic files where biotechnology is already present, should be represented, or could make a material difference. These range from the revision of pharmaceutical

legislation to the Net-Zero Industry Act, the Strategic Technologies for Europe Platform, and proposals such as the EU Inc framework, which seeks to simplify how innovative companies operate across the EU's 27 Member States. Europe's biotech future will therefore depend not on one flagship file alone, but on whether the technology is properly integrated across multiple areas of policymaking.

The first Biotech Act proposal, published in December 2025, focuses mainly on health biotechnology, with some elements touching food and feed. Its strongest immediate contribution lies in clinical trials, regulatory simplification, and clearer pathways for complex technologies. Measures that accelerate multinational clinical trial authorisations could make a meaningful difference, particularly in a region where fragmentation has often slowed development. The proposal also includes a 12-month Supplementary Protection Certificate extension for eligible best-in-class biotechnology medicines and advanced therapy medicinal products, recognising the additional cost, complexity, and manufacturing burden often associated with bringing novel therapies to patients, especially in rare diseases and highly specialised indications.

Equally important is the acknowledgement that many modern technologies no longer fit neatly within traditional regulatory categories. Increasingly, innovation sits at the intersection of medicines, medical devices, and in vitro diagnostics, particularly in personalised healthcare. Dedicated pathways for combined studies, more harmonised templates, stronger coordination across Member States, and regulatory sandboxes all point to a more practical approach. At the same time, the real test will be implementation. The legislation will only succeed if those tools are clearly defined, consistently applied, and workable across national systems.

A second Biotech Act, expected to focus on industrial biotechnology and biomanufacturing, may prove just as consequential. While the first proposal touches manufacturing through strategic projects and investment mechanisms linked to the European Investment Bank, it does not yet address the full commercial and industrial challenge of scaling production in Europe. The EU retains significant strengths in skills, fermentation capacity, and scientific expertise, yet global competitors are moving with greater strategic intent. China has embedded biotechnology within long-term industrial planning, while the United States has also treated the sector as a strategic priority. If Europe wants to preserve leadership in healthcare while expanding in food, feed, materials, chemicals, fuels, and supply chain resilience, it will need to move faster. Existing strength is valuable, but it is not a guarantee of future leadership.

How can Europe strengthen its position in biomanufacturing, and where do you already see successful models emerging across the continent?

Europe is not going to compete by attempting to replicate the model of China, but that is not the choice before it. Its advantage lies in a different starting point. Biomanufacturing capability is already embedded across the continent, including in smaller Member States, whether in healthcare, food production, ingredients, or industrial applications. That makes the conversation with governments more immediate, because every country already has a domestic stake in the sector. Europe may not dominate bulk manufacturing volumes, but it can retain a meaningful global role in supply chains while continuing to move towards higher-value, innovation-led production. To do that, it must remain first-in-class in science, specialist capability, and advanced manufacturing rather than compete primarily on scale.

There are already clear examples of how that can work. During the COVID-19 pandemic, Belgium demonstrated the strategic importance of advanced production capacity through its central role in vaccine manufacturing. Lithuania has also become an increasingly visible life sciences centre, combining ambitious growth targets with a recognised scientific heritage linked to early CRISPR-Cas9 research. These examples show that size is not the sole determinant of success. Strategic intent, technical depth, and policy focus can be just as powerful.

Italy offers a broader industrial illustration. Alongside an established pharmaceutical manufacturing base, it has substantial strengths in food, materials, flavours, fragrances, and other sectors now being reshaped by biotechnology. In many of these areas, microorganisms are being engineered to create next-generation ingredients and more sustainable industrial inputs. That may sit outside the spotlight often given to advanced therapeutics, yet it remains genuine high-value innovation supported by specialist service providers, engineering talent, and applied scientific expertise. Europe’s opportunity is to connect these strengths more coherently and translate them into a stronger and more visible competitive advantage.

What gives you confidence in Europe’s biotech future, and what risks must policymakers still confront?

My main reason for optimism is that Europe increasingly recognises biotechnology as central to its future economic strength, supply chain resilience, and overall competitiveness. That awareness is materially stronger than it was only a few years ago, and the more proactive strategies pursued in other regions have helped reinforce the point that leadership in this sector will not happen by

default. There is now a clearer understanding that biotechnology requires a supportive framework if Europe is to convert its scientific excellence into sustained industrial and economic value.

My principal concern is complacency. There can be a tendency to assume that because Europe has historically been strong in science, it will naturally remain so, yet competitiveness does not work that way. Europe still needs to address fragmentation across the single market and recognise the important role Member States play in making the region easier to navigate for investors and innovators. From the outside, complexity remains a genuine barrier. If companies look at Europe and conclude that it is too difficult to enter or too cumbersome to scale within, investment will continue to gravitate towards regions that have made biotechnology growth faster, simpler, and more predictable.

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