

POSITION PAPER

of Pharma Deutschland e.V.

Input and Key Considerations for the forthcoming “European Biotech Act”

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Introduction

Pharma Deutschland represents the interests of the pharmaceutical and biopharmaceutical industry both nationally and internationally, engaging with policymakers, authorities, and all relevant stakeholders in the healthcare sector. With around 400 member companies, including both international corporations and small and medium-sized enterprises (SMEs), Pharma Deutschland is the largest national association in the pharmaceutical and medical device sector in Europe.

A modern legislative framework is urgently needed to improve translational capacity, reduce regulatory fragmentation, and facilitate market and global access for biotech products. Pharma Deutschland therefore welcomes the European Commission’s decision to divide the forthcoming European Biotech Act into two separate parts. This approach provides much-needed clarity and allows for a more effective policy design that reflects the diverse nature of biotechnology across sectors. Pharma Deutschland strongly supports this two-step approach, as it ensures that Part I will address areas of direct relevance to the pharmaceutical and healthcare biotechnology sector. We view this as a key opportunity to establish a robust, forward-looking regulatory framework that strengthens Europe’s capacity for medical innovation & biopharmaceutical production.

Health-related biotechnology encompasses a broad spectrum of products, technologies, and industrial applications. While Part I of the Biotech Act will likely focus on advanced and high-technology areas such as vaccines, CAR-T cell therapies, and personalised medicine as major drivers of global competitiveness, it is equally important to maintain a strong biotechnological foundation — particularly in areas such as immunology and oncology. Within this broad landscape, biosimilars play a vital role as established therapeutic options for chronic and life-threatening diseases, contributing significantly to patient access, healthcare system sustainability, and Europe’s industrial value creation. Their continued support within the Biotech Act is therefore essential to preserve technological leadership and supply resilience within the EU.

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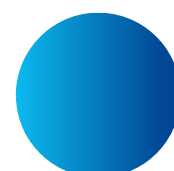
By focusing on the full continuum of health-related biotechnology, including advanced therapy medicinal products (ATMPs), molecular diagnostics, novel therapeutic modalities and biosimilars, the Act can provide clear, predictable, and efficient rules tailored to patient needs and the realities of biotech innovation. Such a health-focused Biotech Act will foster a more competitive, resilient, and innovation-driven Europe within the global life sciences landscape.

Pharma Deutschland would therefore like to share the perspective of biopharmaceutical companies and highlight the following key aspects: To further enhance regulatory efficiency, the Biotech Act should ensure coherence and alignment across the various legislative and non-legislative frameworks that affect companies. Overlapping and complex requirements in clinical trials, health data governance, and environmental regulation can slow innovation. The Act should therefore identify areas where requirements can be simplified, harmonised, or removed rather than adding new layers of regulation. Sector-specific needs of the pharmaceutical industry, including market access and authorisation processes, must be explicitly considered to avoid administrative duplication and regulatory fragmentation.

1. Enabling Innovation and Reducing Barriers

Biotech innovation is to be enabled by an adaptable and flexible regulatory framework. The Biotech Act should therefore ensure, for example:

- Investing in the development of animal-free models to accelerate innovation in pharmaceutical R&D and ensure easier implementation of alternative (non-animal) testing methods (e.g. cell-based assays) by simplifying the validation and acceptance process compared to legacy pharmacopoeial methods. This would encourage replacement of in vivo tests with ethical, scalable alternatives.
- The Biotech Act should also aim to create a future-proof regulatory framework with clearer, more predictable, and streamlined pathways for accelerated approvals. Any new or emerging regulatory requirements must include a dedicated impact assessment for the healthcare sector, identifying solutions that prioritise patient needs, support innovation, and align with the EU's sustainability objectives.
- Ensuring appropriate resourcing for the European Medicines Agency (EMA) and the European network of regulatory authorities; increasing the use of expedited regulatory pathways; and enhancing regulatory recognition with non-EU authorities.
- In addition, the Biotech Act should strengthen market sustainability for biologics and biosimilars by addressing pricing and reimbursement frameworks that reflect the specific nature of biotechnology development and production. Biopharmaceutical R&D involves high



upfront investment, long development cycles, and substantial risk. Therefore, reimbursement systems must strike a balance between cost-efficiency, market access, and supply security.

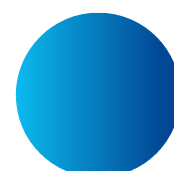
- A regulatory or reimbursement ‘genericisation’ of the biosimilar market must be avoided. The Act should encourage Member States to implement dynamic pricing mechanisms to offset inflation-driven cost increases and to prohibit tender models that rely solely on lowest-price selection. This would align with the objectives of the Critical Medicines Act, which calls on Member States to establish programmes supporting sustainability and resilience for critical medicines within six months of its entry into force. A comparable provision in the Biotech Act would help prevent economically driven supply risks and ensure a stable European biosimilar ecosystem.

2. Clinical Trials – Improving Efficiency and Coordination

To strengthen Europe’s attractiveness as a location for clinical research, the Biotech Act must address systemic inefficiencies in clinical trial authorisation and management. Over the past five years, approximately 60,000 EU patients have missed participation in clinical trials due to administrative bottlenecks and fragmented approval systems.

Pharma Deutschland therefore recommends:

- Reducing national requirements for clinical trial applications to ensure faster approvals and lower administrative burden when submitting amendments to ongoing trials (substantial modifications).
- Harmonising the approval process for multinational clinical trials by fostering mutual trust in the assessment of the reporting Member State and improving coordination among ethics committees throughout the EU.
- Strengthening the role of reporting Member States to streamline the authorisation of clinical trials across multiple EU countries, including parallel submissions for substantial modifications.
- Harmonising the regulatory requirements for clinical trials, medical devices, and in vitro diagnostics for combination product investigations and reducing approval timelines.
- Furthermore, as regulatory frameworks evolve, it is crucial to ensure that efforts to streamline clinical development are implemented consistently and scientifically across Member States. Particularly for biosimilars, the emerging concept of tailored or streamlined clinical development, reducing the need for confirmatory Phase III trials, should be applied



responsibly to avoid misuse or premature generalisation. The Biotech Act should reaffirm that regulatory efficiency must go hand in hand with scientific integrity and competitiveness, ensuring continued patient safety while enabling fair market entry for high-quality biosimilar medicines.

3. Standardisation and Regulatory Clarity

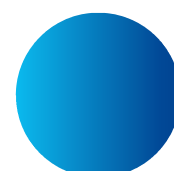
One of the core pillars of the upcoming Biotech Act should be the standardisation of regulatory requirements to reduce uncertainty for developers and manufacturers of medicinal products across the EU. This does not refer to legislative acts alone but also to guidelines and common standards such as the European Pharmacopoeia (Ph. Eur). Considering continued developments in biotechnology, the Ph. Eur. should include a broader set of biological and biotechnological substances, reflecting the diversity of modern biotech-based medicinal products.

Regulatory gaps in Good Manufacturing Practice (GMP), for example, in areas such as postbiotics, probiotics, or cleaning validation, should be closed through targeted EU-level guidance. Furthermore, the Biotech Act should suggest scientifically sound criteria that can help to assess the comparability of substances.

4. Improved and Accelerated Market Access

To make Europe globally competitive, the Biotech Act must address market entry and export barriers for medicinal products:

- Regulatory requirements should be designed to reflect recent scientific developments and enable innovation. Existing biosimilar guidance by therapeutic class should be further developed, including models for PD comparability and the application of physico-chemical characterisation tools. This would ensure transparency, lower development costs, and enhanced reproducibility.
- To reinforce the EU's leadership role, existing rules and guidelines should be reassessed considering scientific progress. Earlier restrictions based on historical knowledge gaps can now be reconsidered or lifted, enabling broader use of efficient, evidence-based methodologies.
- Strengthening the European Biosimilar Ecosystem: To ensure long-term supply security and industrial resilience in Europe, public procurement practices of biosimilars must move beyond a purely price-driven logic. Tender procedures that focus exclusively on the lowest price risk undermining the economic viability of biosimilar manufacturers across the EU. This not only threatens competition and innovation but also increases the likelihood of shortages.



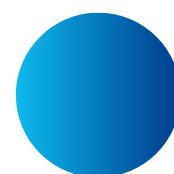
Biosimilars must be recognised not only as cost-saving tools but also as innovative products developed through highly complex biotechnological processes. Supporting this segment requires policies that acknowledge its distinct characteristics and contribute to maintaining high manufacturing standards within Europe.

- In addition, the EU should leverage digital and AI technologies to advance research and clinical development while ensuring secure data sharing and access. If implemented effectively, the European Health Data Space (EHDS) and the AI Act could provide the private sector with access to critical datasets that unlock transformative innovation, provided intellectual property and trade secrets are safeguarded. Interoperability and alignment across Member States will be essential to scale innovation. The Applied AI Strategy and AI Factories should prioritise key fields such as oncology and immunology to promote effective AI use in biotechnology.
- EMA and national authorities must be sustainably resourced with top expertise, supported by cloud-based infrastructure to optimise workflows. Furthermore, Real-World Evidence (RWE) should play a larger role in scientific evaluation. The expansion of EMA's DARWIN-EU federated data network would enable broader use of real-world data in decision-making.

5. Improving Framework Conditions for Biotech Innovation

We further recommend the following measures to strengthen biotech innovation:

- Enhance intellectual property protection and optimise regulatory data protection schemes to offset long-term risks for biotech SMEs.
- Biotechnological production processes for this group of medicinal products are highly complex and should be supported accordingly. Therefore, establish a well-resourced competence centre for pharmaceutical manufacturing applying sandbox principles to support innovation in industrial-scale production.
- The Biotech Act should also ensure adequate financing and scaling mechanisms for biotechnology in Europe. A robust, predictable, and enforceable intellectual property framework, combined with timely access to venture capital, is critical to maintaining Europe's innovation competitiveness. Instruments such as IPCEIs, EIB financing, public procurement mechanisms, and tax incentives could help bridge the gap between laboratory research and GMP-scale production investment.
- Consider the cumulative impact of chemical and environmental legislation to avoid unintended barriers to biopharmaceutical production within the EU.



- To improve operational efficiency, the EU should explore faster and leaner processes for authorisations and audits related to research and manufacturing, for example, import licences for biotech platforms, SoHOs, or environmental permits. Simplified and coordinated procedures would avoid unnecessary workload, accelerate innovation cycles, and prevent negative impacts on patient access.

Conclusion

The European Biotech Act represents a unique opportunity to establish a future-ready legislative framework that supports scalable innovation, reduces administrative burden, and fosters both public and private investment in biotechnology.

While some of the measures outlined above may ultimately be implemented through secondary legislation, it is essential that the Act itself anchors the core principles of predictability, flexibility, and competitiveness.

Furthermore, the Biotech Act should strengthen workforce development and resilience across Europe's biotechnology ecosystem. Continuous upskilling in digital, regulatory, and bioprocess competencies will be crucial to maintain Europe's leadership in biopharmaceutical innovation. In parallel, resilience measures should address supply chain security, biosecurity, dual-use governance, and crisis preparedness, thereby safeguarding Europe's health sovereignty and strategic autonomy.

Pharma Deutschland stands ready to support the European Commission in shaping an ambitious yet pragmatic regulatory vision for biotechnology in the healthcare and pharmaceutical sectors.

