EPF's general position on the EU Biotech Act proposal

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The European Patients' Forum (EPF) welcomes the EU Biotech Act proposal published by the European Commission in December 2025. Biotechnology medicinal products can represent essential innovations for the treatment of many diseases and have the potential to significantly improve patient outcomes while addressing current unmet medical needs, in particular in the field of rare diseases and rare cancers. Advances in this area can serve as a foundation for wider therapeutic applications, with innovations initially developed for specific conditions later benefiting a broader range of patients. However, while we acknowledge that biotechnology and biomanufacturing have been identified as strategic areas for Europe's competitiveness and leadership in the development of innovative treatments and diagnostic tools, **it is essential to ensure that improving public health and addressing patients' needs remain at the core of the Act's objectives. In addition, true societal wellbeing can only be achieved when innovation is accompanied by equitable access, affordability, and patient-centred policies, with patient organisations actively involved as equal partners.**

It is important to remember **that medical products should not be treated like other commodities because they are life-critical goods that play a crucial role in patient outcomes**. This means ensuring meaningful patient involvement, transparency, and accountability.

We look forward to engaging with the European institutions to ensure that the Biotech Act places patients at its core and promotes equitable access to meaningful innovation.

Our 6 key priorities for the EU Biotech Act

1. **Enforcing greater scrutiny and oversight of health biotechnology strategic projects:** Those projects could positively contribute to strengthening Europe's health biotechnology ecosystem. This is the case through initiatives such as supporting centres of excellence for advanced therapies, SMEs, universities and research centres, as well as skill development and cross-border collaboration. However, greater scrutiny and oversight of health biotechnology strategic projects is necessary. In particular:
    - The current proposal **lacks clear provisions for meaningful patient involvement in their definition, governance, and evaluation**.
    - **Stronger scrutiny and accountability mechanisms are needed: the Act must introduce clear, transparent and measurable criteria for the designation and evaluation of strategic projects** to ensure that these initiatives effectively address real patient needs, by promoting the research and development of products that truly bring added value to patients' care and ultimately improve equitable access across Member States.
    - In addition, the broad scope of activities eligible as strategic projects may lead to a large number of initiatives seeking financial, technical, and administrative support, as well as accelerated authorisation procedures. **This raises concerns about the potential dilution of resources and the overall impacts of the framework**.

2. **Promoting transparency in access to funding tools**: EPF recognises that facilitating access to funding can play an important role in strengthening the EU's industrial biomanufacturing capacity. However:

- Improved access to funding must be accompanied by **strong transparency mechanisms, robust monitoring, and clear reporting requirements when financial support is provided under Union programmes, instruments and as foreseen by the European Investment Bank Group**.
- It is also essential to ensure that public investments **deliver clear added value for patients, including a direct link to improved access, affordability, and better health outcomes**. In this context, the access dimension should be integrated at a very early stage, before the development of medicines begins.
- Furthermore, there is a need to reflect on and promote **purpose-driven investment models to ensure that research and innovation address unmet and neglected medical needs,** while supporting equitable access for patients across Europe.

3. **Urgently assessing the impacts of SPC extensions:** EPF has serious concerns regarding the proposed 12-month extension of Supplementary Protection Certificates (SPCs), particularly in light of the recent political agreement on regulatory data and market protection length and conditions within the pharmaceutical package. Many advanced therapies are already out of reach for patients, especially in lower-income Member States. In this context, such an extension risks further delaying access to medicines and placing additional pressure on already constrained healthcare budgets across Europe.
    - **At present, in the absence of a comprehensive impact assessment, EPF has not seen sufficient evidence to demonstrate that this extension is proportionate, would effectively incentivise the development and availability of meaningful innovation, or ensure that the additional profits generated result in tangible benefits for patients and public health.**
    - Measures that entail such a financial burden should be based on robust, transparent, and evidence-based analysis, clearly demonstrating how they translate into better outcomes for patients.
    - **Furthermore, alternative approaches to incentivising innovation could have been considered.** These include a balanced mix of push and pull incentives, as well as milestone-based payments that reward progress throughout the development process. In addition, measures to support small and medium-sized enterprises, as well as public research institutions and universities, in playing a meaningful role across the full lifecycle of medicines development - not only in the early stages of research - should be explored.
    - In this context**, a staff working document alone does not provide the level of evidence and clarity required to justify this provision**.

4. **Expanding actions to support biosimilars**: Biosimilars play a crucial role in improving patient access to advanced biological therapies. By increasing competition and reducing costs, biosimilars allow healthcare systems to treat more patients. We welcome the Act's focus on the development of EMA guidelines and the steps taken by the Agency to provide tailored scientific advice to biosimilar developers. However:
    - The current provisions on biosimilars **could be further expanded to better support their development and uptake across the EU,** underpinned by high standards of quality, efficacy, and robust regulatory oversight, with due consideration for patient safety.

- In particular, input from EPF members also shows the need **to support patient organisations in delivering education and information campaigns to build trust and reduce hesitancy which can act as barriers to the uptake of these products. To fulfil this role effectively, patient organisations require adequate and sustainable public funding.**

5. **Involving patients and patient organisations in clinical trials: EPF supports the Biotech Act's objective to improve patient access to safe and high-quality clinical trials in Europe**. We also welcome the emphasis on improving representativeness of clinical research and hope that the outcomes of the READi project will support the implementation of practical approaches to better inclusion of underserved and underrepresented populations. To ensure that the Act adequately delivers for patients, we would like to stress that:
    - Shorter timelines must reflect more efficient and predictable approaches, including opportunities to streamline processes through parallel rather than sequential steps, avoid duplication – in particular through increased reliance on the reporting member state, and leverage digitalisation. **Patient safety must remain at the core of the framework. In this context, shorter timelines must be matched with adequate resourcing of both the reporting Member State and ethics committees to maintain high-quality evaluations**. Increased speed should indeed not come at the expense of robust evidence, transparency, and independent, patient centric ethical review. Exchanges of best practices among countries to combine efficient processes with thorough assessments should be further promoted.
    - **The inclusion of patients in ethics committees** remains an ask from the patient community.
    - **Further improvements** to the CTR should include:
        - **Stronger support for academic and other non-commercial actors,** including dedicated regulatory support and more accessible scientific advice at EU level, alongside improved coordination across Member States.
        - **Greater clarity on patients' right to post-trial access to treatments.**
        - **Enhanced cross-border clinical trials** to reduce inequalities in access across the EU, as many trials are currently concentrated in a limited number of countries and sites. When opening trial sites closer to patients' homes is not possible, facilitating cross-border access becomes essential.
        - **Harmonised patient information**, including guidance on informed consent, to ensure it is clear, written in lay language, and serves as a genuine decision aid rather than a legal formality.
        - **Mandatory inclusion of patient experience data** in clinical trials taking place in Europe and support to promote patient involvement in the design of clinical trials (see box below).

    - Of note, for medicines approved in Europe, **we would like to stress the importance of including data in marketing authorisation applications that are demonstrably relevant to the EU population and meet equivalent ethical and scientific standards**. Depending on future trends, additional requirements may be warranted to ensure that data submitted reflect EU patient populations and clinical practice.

A must be achieved

In an era of science distrust and misinformation, **improving the uptake of clinical trials in Europe also requires improving the infrastructure for recruitment, including embedding clinical trials within healthcare practice and leveraging digitalisation, as well as building patient trust, which depends on clear safeguards, high-quality data, and meaningful patient involvement throughout the research process**. This means involving patients from a very early stage of research, including in identifying unmet needs and what matters most to people living with a condition, shaping the right research questions, designing trials that are feasible, relevant, and less burdensome for patients, and supporting patient-centred trial management. **Across the research continuum, patient organisations play a key role in bridging patients and researchers to ensure the development of products that better address patients' needs. As a first step, we welcome EMA's Reflection Paper on Patient Experience Data, and we encourage the Agency to continue developing guidance in this area.**

6. **Addressing the lack of a comprehensive and high-quality impact assessment: We are concerned that this is the third time the European Commission has published wide-ranging health legislation without an impact assessment, limiting access to essential data and reducing transparency around the rationale underpinning key policy choices.**
    - An impact assessment would have been particularly important for measures such as the designation of strategic projects and the proposed extension of the SPC, where the expected benefits and added value remain unclear.
    - Impact assessments are also a key tool for patient organisations, which often operate with limited resources and capacity, enabling them to understand, assess, and meaningfully contribute to policy decisions based on clear evidence and defined criteria. In this context, a staff working document cannot replace a comprehensive impact assessment.
    - Finally, the urgency cited to justify this omission does not constitute a sufficient reason. It is preferable to adopt well-prepared and evidence-based legislation rather than measures that must be revisited due to insufficient analysis.

EPF remains committed to working with the EU institutions in the coming weeks to ensure that the EU Biotech Act places public health at its core and that its benefits are accessible to every patient across Europe. Advancing towards a true European Health Union for clinical trials and addressing persistent disparities in access to innovation are essential to this effort.

ABOUT EPF

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 82 members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu

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