EPF's recommendations for the upcoming negotiations in the European Parliament on the EU Biotech Act

Over the past few weeks, EPF has analysed the more than 2,000 amendments[1] tabled by Members of the European Parliament (MEPs) across political groups on the EU Biotech Act. As negotiations are expected to intensify in the coming weeks, it is crucial that the voice of the patient community is heard as compromise amendments are developed. **This is particularly important given the exceptionally fast pace of negotiations, which raises concerns that key issues may not receive the in-depth consideration they require, particularly in a broader political context where competitiveness is increasingly being prioritised over public health objectives. It also raises broader questions about whether such an accelerated process allows sufficient space for democratic scrutiny, meaningful stakeholder participation and informed debate on legislation with potentially significant implications for patients and public health**.

EPF's priorities for the coming weeks focus on five key areas[2]:

1. **Strengthening scrutiny and oversight of health biotechnology strategic projects;**
2. **Promoting transparency and accountability in access to public funding and support;**
3. **Deleting the proposed supplementary protection certificates (SPC) extension or, should it be retained, limiting its duration and subjecting it to strict and meaningful eligibility criteria;**
4. **Strengthening the involvement of patients and patient organisations throughout the implementation of the Act, ideally as permanent members of the Steering Group, and at least through mandatory consultation to ensure patient perspectives inform decisions in a meaningful and consistent way;**
5. **Promoting the quality of clinical trials, including patient safety and rights, while strengthening patients' meaningful participation in clinical research.**

We are encouraged to see that some MEPs have responded to several of our calls.

- In particular, EPF welcomes amendments seeking to strengthen the monitoring and assessment of strategic biotechnology projects, **by considering their contribution to public health, their benefits for patients and equitable access to the products developed through these projects** *(Amdt 493, Amdt 494, Amdt 1408, Amdt 1418),* **as well as strong transparency mechanisms and clear reporting requirements when financial support is provided under Union programme** (*Amdt 1726, Amdt 1727, Amdt 1728, Amdt 1999*).

- We also welcome proposals to strengthen **the participation of patients and patient organisations in developing measurable criteria for the designation and evaluation of the**

[1] https://www.europarl.europa.eu/committees/en/sant/documents/latest-documents
[2] https://www.eu-patient.eu/globalassets/28042026_general-position-on-the-eu-biotech-act-proposal.pdf

strategic projects (*Amdt 1461*), **as well as in the governance and support structures that would be created as part of the implementation of the Act.** This would be contributing to greater transparency and accountability in EU decision-making. We would in particular support permanent patient representation in the Health Biotechnology Support Network (*Amdt 1815*) and above all in the European Health Biotechnology Steering Group (*Amdt 1824, Amdt 1825, Amdt 1832*) as patients bring unique expertise that can help ensure decisions address the needs of the communities concerned. At a minimum, with regard to the European Health Biotechnology Steering Group, regular and structured consultation with patient organisations should be mandatory, creating genuine opportunities for dialogue and ensuring that patient perspectives are systematically considered in the Steering Group's work and decision-making (*Amdt 1861, Amdt 1862*). Such involvement must be meaningful and supported by adequate remuneration for the time spent preparing for and attending meetings (*Amdt 1824, Amdt 1825*).

- Similarly, several amendments have been tabled that could improve the provisions on clinical trials in ways that respond directly to priorities raised by the patient community for many years. These include proposals **to strengthen patient involvement in clinical trial design and governance** (*Amdt 2643, Amdt 2644, Amdt 2644*) **develop more harmonised approaches to informed consent** (*Amdt 2813*), **facilitate participation in clinical trials and cross-border access to clinical trials, which is particularly important for people living with rare diseases and other conditions with limited therapeutic options** (*Amdt 2427, Amdt 2878, Amdt 2880*)**, as well as provide greater clarity on patients' post-trial access to treatments** *(Amdt 969, Amdt 2812, Amdt 2816)*. These issues may appear less politically controversial and, as a result, are currently receiving less attention in both the negotiations and the broader public debate. However, they can make a concrete difference to the quality of clinical trials, the protection of patients' rights and the extent to which clinical research responds to patients' needs. **These elements should not be lost during compromise negotiations**.

However, EPF is concerned about some amendments, especially on the SPC extension.

- EPF remains strongly opposed to the proposed SPC extension, notably because of its impact **on timely patient access to medicines and the sustainability of healthcare systems, as well as the absence of a comprehensive impact assessment accompanying the proposal**. The subsequent Staff Working Document[3] did not provide clear evidence regarding the cost of the measures, including differences across member states, and the effectiveness of the SPC extension in driving meaningful innovation. While encouraging innovation in Europe that addresses patients' needs is an important public health objective, this should be pursued through measures with demonstrated effectiveness that deliver clear added value for patients, healthcare systems and public health, while supporting patients' timely and equitable access to medicines.

- **We are therefore very concerned by the proposed amendments that further prolong this extension** (*from 12 to 18 months (Amdt 2075) or to 24 months (Amdt 2076, Amdt 2144*) **or make it easier to obtain** *(by weakening the criteria that a medicine must fulfil to qualify for additional protection (Amdt 2091, Amdt 2115, Amdt 2132, Amdt 2150)).*

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52026SC0450

- In this context, **while EPF continues to support the deletion of the proposed SPC extension** *(Amdt 2051, Amdt 2053, Amdt 2054),* **should the European Parliament decide to retain it, we strongly call on MEPs to strengthen the conditions attached to it, ensuring that it remains limited in duration (to no more than 6 months –** *Amdt 2071***), targeted and subject to strict eligibility criteria that are cumulative** *(Amd 712).* These should include requirements that the medicine addresses patients' needs (*Amdt 2095*); setting a minimum number of member states in which that clinical trials are conducted, including in a minimum number of member states representing diverse geographical regions (*Amdt 2106 & Amdt 2108*); as well as concrete commitments to make the medicine available to patients (*Amdt 2131*). For that latest point, **we also call on the pharmaceutical industry and member states to make full use of the mechanism established under article 59 of the pharmaceutical legislation as an opportunity to improve transparency and create a favourable framework for successful negotiations that ultimately benefit patients.**

- **In this spirit, we also support amendments that aim to support the development and production of biosimilars in Europe,** which can contribute to expanded, timelier, and more equitable access to treatments while generating savings for healthcare systems that can be reinvested in meaningful improvements in patient care (*Amdt 2179, Amdt 2181*).

Regarding clinical trials, we recommend maintaining the timelines proposed by the Commission rather than introducing further reductions, as suggested by some MEPs.

- **EPF supported the shorter timelines** proposed by the Commission in its amendments to the Clinical Trials Regulation, provided that patient safety and rights remain at the centre of the system as well as that national competent authorities and ethics committees have sufficient capacity and resources to conduct robust assessments (*Amdt 2848, Amdt 2854*). However, **we believe these changes should first be implemented and their impact evaluated before considering any further reductions, as proposed by some MEPs**.

- As regards proposals for further centralisation of ethical assessment at EU level (Amdt 370), EPF **recommends first ensuring the effective implementation and evaluation of the changes already proposed by the European Commission,** including the strengthened role of the reporting member state. At the same time, we encourage **continued cooperation and exchange between ethics committees to support greater harmonisation and more efficient processes while maintaining the highest ethical standards for the benefit of all patients**.

As negotiations move towards compromise amendments, EPF calls on the rapporteur, shadow rapporteurs and political groups to safeguard proposals that contribute to improved **patient safety, patient access, patient involvement, and public-health accountability**. **Patients and patient organisations must also have a meaningful voice as these negotiations progress.** We call on the co-legislators to ensure sufficient consultation and involvement of patient organisations as compromises are developed, so that the final legislation adequately responds to patients' needs. **Getting legislation adopted quickly should not come at the expense of getting it right.**

As negotiations continue, EPF stands ready to work with the European Parliament and member states to ensure that the Biotech Act places patients at its core and promotes equitable access to meaningful innovation.