EUROPEAN SOCIAL INSURANCE PLATFORM

ESIP Feedback to the

Call for Evidence for an Impact Assessment On the European Biotech Act

11-06-2025

The European Social Insurance Platform (ESIP), representing national social security and health insurance institutions across Europe, views positively the European Commission's initiatives to boost the EU life sciences sector, particularly the upcoming European Biotech Act. While supporting the broader goals of competitiveness and strategic autonomy, ESIP emphasises the necessity to root this initiative in public health priorities and the long-term sustainability of European healthcare systems.

A Coordinated and Sound Legal Framework for Pharmaceuticals

The upcoming European Biotech Act should be subject to a comprehensive impact assessment, focused not only on industrial competitiveness but also on the economic implications for healthcare systems. Efforts to enhance the competitiveness of the biotech sector must not undermine the financial viability of European health systems, nor result in unsustainable costs for patients and taxpayers.

In this context, the Biotech Act should be designed to complement rather than overhaul existing legislative frameworks governing clinical trials, marketing authorisation and health technology assessment (HTA). Its implementation must preserve coherence with existing legislative frameworks, ensuring that biotech innovations are introduced through pathways that uphold standards of safety, efficacy and effectiveness.

Innovation with Public Return

ESIP acknowledges efforts to improve biotech financing and to streamline regulatory pathways. Public investment in research and development (R&D) must lead to public benefit. Precisely, when public funding supports biotech development, it is crucial that society does not pay twice: once as funders, and again as consumers through high product prices. Priority-setting processes for publicly funded R&D should be demand-driven and inclusive of public health insurers, to reflect patient and societal needs.

Safeguarding Evaluation Standards

The Biotech Act seeks to facilitate the development and uptake of biotech innovations, including through mechanisms such as regulatory sandboxes. Importantly, any new or adapted regulatory pathway must not dilute evidentiary requirements. Accelerated approval processes are approached with caution, as they risk weakening the standards underpinning

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HTA and pricing and reimbursement (P&R) decisions. In particular, the use of expedited pathways for high-risk, cutting-edge therapies must not shift risks to the detriment of patients by compromising the robustness of pre-market data.

Enhancing Early Dialogues

A robust Biotech Act could incorporate early, multi-stakeholder dialogues - including with payers - before clinical trials begin. This would support evidence generation plans that align with HTA and P&R requirements and enable risk-sharing frameworks. Transparency on clinical uncertainties is essential to avoid undermining HTA and P&R decisions.

Avoiding Market Concentration in the Biotech Sector

Concerns might arise on the primary beneficiaries of a simplified, publicly supported biotech ecosystem. Incentives should primarily target the needs of SMEs, spin-offs, and start-ups, rather than large multinational corporations. The Biotech Act must ensure that benefits, especially those resulting from public funding or regulatory flexibilities, are equitably shared and do not incentivise market concentration or monopolistic practices by large pharmaceutical companies.

In conclusion, the Biotech Act presents a valuable opportunity to strengthen Europe's biotech sector. To succeed, it must deliver on both innovation and societal value. It is crucial that the biotech policy framework preserves evidence standards, promotes early dialogues and ensures return on public investment. ESIP stands ready to contribute to shaping an initiative that fosters health-driven biotech innovation while upholding the principles of access, affordability and sustainability.

Link to the ESIP feedback to the call for evidence for an impact assessment on the EU Biotech Act