EUROPEAN SOCIAL INSURANCE PLATFORM

ESIP comments on the upcoming EU Biotech Act

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The European Social Insurance Platform (ESIP) welcomes the European Commission's initiative to strengthen the competitiveness of the EU biotechnology sector and enhance Europe's strategic autonomy. ESIP and its member organisations, including pricing and reimbursement (P&R) authorities, public healthcare payers and several health technology assessment (HTA) bodies, support efforts to build a strong and sustainable biotechnology ecosystem in Europe, grounded in public value, transparency and affordable access to effective health technologies.

ESIP supports initiatives to enhance Europe's biotech sector through targeted incentives that attract and retain investment within the Union. However, any measures to stimulate innovation must remain firmly anchored in the public and societal interest, ensuring that biotechnological progress translates into accessible, affordable and effective treatment options for patients. Public support and financing, whether through the upcoming Critical Medicines Act, Important Projects of Common European Interest (IPCEI) or other targeted incentives, must be guided by the principle of public return on public investment. Conditionalities such as binding transparency and accountability requirements for receiving public subsidies, financial support and other forms of public investment are crucial to ensure that public resources deliver tangible societal value.

ESIP emphasises that reinforcing Europe's competitive advantage in biotechnology manufacturing requires a predictable, transparent and science-based EU regulatory framework. Predictability is fundamental to competitiveness, providing stability and clarity for manufacturers, investors and decision-makers alike, thereby fostering sustainable investment and informed decisions across the product lifecycle. A tailored regulatory framework for biotechnologies should uphold the EU's high standards for safety, efficacy and effectiveness, while preserving fair competition. This balance is essential to encourage innovation on the one hand, and on the other ensure the timely market entry of biosimilar alternatives, which play a crucial role in safeguarding affordability and access.

With a view to the potential simplification of regulatory frameworks to accelerate the market entry of innovative biotechnologies, ESIP cautions that faster authorisation does not automatically equate to better care or improved patient access. For complex biotechnological products, accelerated pathways based on immature evidence may shift the evidentiary burden from pre- to post-marketing phases, posing risks to patients and health systems. ESIP therefore urges prudence in the use of accelerated mechanisms and expresses reservations about regulatory sandboxes, which, if not clearly defined and transparently governed, may undermine the predictability and quality of EU regulatory processes.

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On the other hand, the implementation of the EU HTA Regulation provides an important opportunity to improve predictability, coherence and alignment of evidence requirements across Europe. Early, structured multi-stakeholder dialogues among regulators, HTA bodies, payers, health technology developers (HTDs) and patients, ideally prior to clinical trial design, could also foster mutual understanding, align evidence expectations and reduce duplication. For HTDs, early dialogues can foster a more coherent environment for research and development. For HTA bodies & P&R authorities, transparency around clinical uncertainties is essential to safeguard the integrity of assessments and to consider effective, evidence-based risk-sharing frameworks.

Finally, ESIP recommends leading a comprehensive, evidence-based impact assessment for the forthcoming Biotech Act, evaluating the proportionality and suitability of all proposed measures. This assessment should extend beyond economic competitiveness to include implications for national healthcare systems, patient access and financial sustainability. Close alignment with the ongoing reform of the EU general pharmaceutical legislation and the Critical Medicines Act will be essential to create a coherent, predictable and future-proof framework for pharmaceuticals and biotechnologies in Europe.

Clarification on willingness to pay: The HTA and payer community remains cautious about paying a premium for biotechnology products. Willingness to pay depends on the demonstrated value of a technology (demonstrated clinical effectiveness and added therapeutic benefit) rather than its novelty. Public payers are willing to reward innovation only when robust evidence confirms significant benefits for patients as well as clinical superiority compared to existing products.

About the European Social Insurance Platform (ESIP)

The European Social Insurance Platform (ESIP) represents 47 national statutory social insurance organisations in 19 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

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