Europavertretung der österreichischen Sozialversicherungen

Proposal for a Regulation on the Biotech Act

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Position Paper of the Austrian Social Insurance

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The Austrian Social Insurance welcomes the European Commission's initiative aimed at strengthening the competitiveness of the biotechnology sector in the Union as well as the overall strategic autonomy, especially in view of the current geopolitical situation. We fully support strengthening the "Made in Europe" principle to boost the attractiveness of Europe through targeted incentives to attract and retain investment in the sector. Nevertheless, we emphasise that measures to foster innovation should take the public and societal good, i.e. ensuring patients' access and affordability, closely into account. Moreover, the successful implementation of the Biotech Act will depend on a strong common commitment from the Member States and close cooperation among all relevant stakeholders. Coordinated action at Union as well as national level will be crucial to ensure coherent implementation and to translate the objectives of the Act into tangible results for patients' needs, innovation and European competitiveness.

To this end, we would like to recall the guiding principles for the recent revision of the pharmaceutical framework: (1) Improving availability and access to affordable medicines; (2) Increasing the attractiveness of the European Union as a location for pharmaceutical industry; (3) Promoting and rewarding real innovation (4) Ensuring effective competition to guarantee affordable medicines within a fair and efficient internal market. These should also be the guiding principles in the forthcoming negotiations between the co-legislators regarding the biotechnology sector.

On a general note, we criticise however the up until now missing assessment of the impact of the proposed measures on healthcare budgets and publicly financed healthcare systems which are supposed to be extensive. We strongly call for a thorough, evidence-based impact assessment regarding the proportionality, adequacy, sustainability and especially efficacy of the proposal in relation to its initial aim. This should not be limited to the economic competitiveness of the sector but should also take every potential implication for national healthcare systems and their financial sustainability closely into account.

- **Impact of excessive intellectual property protection**

First and foremost, we strongly oppose the introduction of an extension by twelve months of exclusive rights and thus a further strengthening of intellectual property rights in the form of supplementary protection certificates (SPC) **(Article 27)**. We have serious concerns regarding

a potential extension of exclusivity rights and a further strengthening of intellectual property rights in the pharmaceutical sector. In order to maintain patients' access to affordable therapies, the development and market launch of biosimilars and thus price competition should not be hampered. According to Boldrin and Levin, there is no empirical evidence that overly extensive patent rights or the protection of intellectual property promote innovation and productivity.[1] The figures presented by Medicines for Europe show that the proposed twelve month SPC extension would impose major additional costs on healthcare systems, with delayed competition estimated to cost EUR 7.7 billion per year for just three molecules alone.[2] In light of the growing pressure on public healthcare budgets, this extension would undermine affordability and timely patient access.

It should also be noted in this respect that the current EU legal framework for the protection of intellectual property (IP) rights is currently already equipped with a strong IP protection system according to the 2020 roadmap for the IP Action Plan.[3] Furthermore, it needs to be stressed that the initial goal of the SPC Regulation (EC) No 469/2009[4] was exactly the same as the goal of the proposal for a Biotech Act, namely to strengthen the European pharmaceutical industry and to keep innovation in Europe. Different evaluations in 2018 came however to the conclusion that the effect of the Regulation was unclear since the time between the reward and the R&D decisions by companies was too big[5]. And even more important is the fact that manufacturers continuously moved away from Europe Hence, we have to ask ourselves if we really want to introduce once again an incentive which has already proven to have only limited effects on the initial goal?

The Max Planck study even states that the patents applied for at the early stages of drug development are not by the companies bringing the medicinal product to the market; 35 % of the molecules of originators are bought later.[6] This is also supported more recently by Kennedy et al. in 2023, concluding that large pharmaceutical companies are the sole originator of only 14% of cancer drugs approved by the FDA from 2010 to 2020. 46 % of the new products originated in small biotech companies and 14 % in academic labs.[7] And while the EU remains a global leader in academic biotechnology research, this excellence is still insufficiently translated into clinical application and economic value within Europe. As stressed in the explanatory memorandum of the proposed Biotech Act, a key bottleneck lies in the lack of available financing for start-ups and scale-ups, particularly in the capital-intensive later stages of development. Given the evidence, prolonging exclusivity rights is in our view hardly the right instrument to boost Europe’s biotechnology ecosystem. The main structural weaknesses identified in the Biotech Act are financing gaps, especially for scale-ups and late-stage development, as well as regulatory fragmentation and complexity, not insufficient patent protection. Extending SPC protection may instead delay competition and increase pressure on healthcare budgets, without convincingly addressing the factors that currently drive biotech companies and investment away from Europe.

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[1] https://pubs.aeaweb.org/doi/pdf/10.1257/jep.27.1.3

[2] Pillar 1-2-3-4-FOOTPRINT-SPC-Biotech-Act-facsheets-16-03-2026.cdr

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12510-Intellectual-Property-Action-Plan; https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12510-Intellectual-Property-Action-Plan/F543428

[4] https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32009R0469&from=DE

[5] Technopolis Group, Effects of supplementary protection mechanisms for pharmaceutical products, 15.06.2018, https://technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/

[6] Study on the legal aspects of Supplementary Protection Certificates in the EU, 27.05.2018, https://ec.europa.eu/docsroom/documents/29524

[7] Kennedy et al., Small biotechs versus large pharma: Who drives first-in-class innovation in oncology?, Drug Discovery Today, Volume 28, Issue 2, 2023, https://www.sciencedirect.com/science/article/pii/S1359644622004494

- **Strengthening R&D and manufacturing capacities in the EU**

Concerning the extended and facilitated support for strategic projects in the biotech sector **(Articles 3, 4, 25, 26, 29)**, we generally welcome measures promoting and increasing investment in such projects as well as simplifying regulatory processes. However, we must note that the proposal lacks sufficient legal provisions to ensure that the benefits granted to such projects are efficiently linked to clear and enforceable obligations. Ensuring public return on public investment must be key in the future Biotech Act. Therefore, we call for strict requirements to be firmly enshrined in the legislation when introducing such measures to boost the sector as well as binding transparency requirements for subsidies, direct or indirect financial support and increased investment with public money. Given the significant public support and regulatory facilitation envisaged for such projects, it is essential that these privileges are matched by corresponding commitments from manufacturers. In this respect, it should also be noted that the current legislative text does not appear to provide for clear consequences or enforcement mechanisms in cases where obligations are not fulfilled, including those related to the security of supply within the Union and the public return on public investment.

Even more important in this respect would be in our opinion the introduction of a governance framework to efficiently interlink and to closely coordinate respective initiatives on Member State level to avoid a fragmented and thus inefficient EU landscape. Uncoordinated national actions as to subsidies, regulatory processes etc. would once again jeopardise a strong European strategy and vision for the future the biotech sector as well as hamper the strategic autonomy overall.

Regarding biosimilars, it needs to be emphasised that those are one of Europe's most important success stories in the biotechnology sector and should be recognised as a strategic priority in the EU Biotech Act. As the first region to approve a biosimilar in 2006, Europe has played a pioneering role in this field and should aim to preserve its global leadership. Biosimilars generate significant value for healthcare systems: while accounting for a relatively limited share of pharmaceutical expenditure, they create substantial savings and can significantly improve patient access to treatment. Considering the major losses of exclusivity in the coming years, it is essential to prevent a growing biosimilar void and to establish market conditions that support sustainable competition as well as market entry of biosimilars from day one on after loss of exclusivity.

Against this background, the Austrian Social Insurance expressly welcomes the objectives of Chapter V, i.e. measures to enhance the competitiveness in biosimilars **(Articles 28-30)**. However, the provisions currently proposed do not appear sufficient to effectively promote biosimilars and their manufacturing sites within the European Union. In addition, the definitions and scope of application in this key chapter remain notably broad and vague. It remains particularly unclear what exactly constitutes an "innovative biomanufacturing capacity" and what level of contribution to research and related activities is required in order to qualify for access to the support measures **(Article 29)**.

- **Ensuring transparency, regulatory integrity and stakeholder involvement in regulatory sandboxes**

The mentioned regulatory sandboxes being currently discussed under the pharmaceutical legislation are initially welcomed but raise significant reservations due to their unpredictability and potential to undermine the independence and quality of European regulatory procedures.

To better interlink regulatory processes and ensure timely market access for innovative products, we strongly recommend incorporating early, multi-stakeholder dialogues - especially with the payer and HTA community – prior to clinical trial design. This would efficiently support evidence generation plans that align with HTA and P&R requirements and enable efficient risk-sharing frameworks. Transparency on clinical uncertainties is essential to avoid undermining HTA and P&R decisions.

Equally important in this context is also a close involvement of HTA and payer organisations in the framework of the regulatory sandboxes **(Articles 39 and 40)** intended to establish a structured framework for testing innovative technologies and processes in a real-world setting. However, this tool must be in our view treated with great caution due to its potential, unknown impact on the soundness of regulatory processes in the future. We generally acknowledge the need for such a regulatory alternative pathway for certain kind of products. However, we would like to stress that these sandboxes have never been tested before in the context of healthcare provision and treatment, meaning that their consequences cannot yet be foreseen. And even in areas where such sandboxes have already been used since several years, e.g. Fintech, "there is no consensus in the literature over the ultimate benefit of establishing a regulatory sandbox"[8]. Furthermore, Guio Español/Koenig argue that regulatory sandboxes should primarily serve as a possibility to increase policymakers' understanding of respective technologies developed and tested within a sandbox, rather than solely a protected environment to support research and development as well as an alternative authorisation pathway.[9]

- **Balancing limited public budgets and sustainable biotech financing**

Eventually, we generally urge the co-legislators for further clarifications as to the unclear financing questions as to the measures foreseen. Greater transparency is needed concerning the sources of funding, the allocation of financial support to strategic projects, and the conditions attached to such funding. It should be clearly specified how Union and national resources are to be mobilised, what criteria govern their distribution, and how accountability for the use of public funds will be ensured. In this context, it is essential to avoid overlaps with existing funding instruments and to ensure coherence with established EU programmes.

In this context, it must be clearly stated that public budgets are already under significant pressure and cannot absorb additional large-scale financing needs of the biotechnology sector. Public healthcare systems across the Union are facing increasing expenditure due to demographic change, rising demand for care, and the introduction of high-cost innovative

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[8] Gumbo et al, Regulatory sandbox as a frontier for innovation and sustainability: a systematic review, 29.05.2025, https://www.tandfonline.com/doi/full/10.1080/23311975.2025.2510555.

[9] See Guio Español and Koenig, Regulatory sandboxes for AI in the majority world: A learning-centric approach to legal adaptation, 10.12.2025, https://www.cambridge.org/core/journals/cambridge-forum-on-ai-law-and-governance/article/regulatory-sandboxes-for-ai-in-the-majority-world-a-learningcentric-approach-to-legal-adaptation/2352427E99FCEA2B34F4B8DB1DC18095.

therapies. Against this background, it is neither realistic nor sustainable to expect that the necessary investment for the growth of the biotech sector can be provided from public sources.

Therefore, mobilising private capital is not merely an option, but a necessity[10]. The Biotech Act acknowledges this challenge by aiming to improve access to finance and to leverage private investment. However, further efforts are required to create a truly attractive investment environment within the Union. In particular, public-private partnerships (PPPs) could be simplified and strengthened significantly, administrative burdens reduced, and regulatory frameworks made more predictable in order to effectively crowd in private investment.

Only by ensuring a stronger role for private financing can the Union succeed in translating its scientific excellence into tangible benefits for patients and sustainable economic growth, without placing additional strain on already limited public resources. Further clarifications are also needed regarding the overall wording of the text. In some parts of the proposed text, the definitions and scope of application are notably broad and vague **(e.g. Article 3)**, which covers health biotechnology strategic projects – these appear to require further clarification or interpretation. In some cases **(e.g. Article 4)**, implementing acts by the Commission are envisaged to provide further clarification; this raises the question of why greater clarity cannot instead be established within the Biotech Act itself.

- **Clarifying data access, data protection and public return regarding the Data Quality Accelerator**

Eventually we call for a significant revision of the provisions for the Biotechnology data quality accelerator **(Article 33)** concerning access to and use of data within the scope of the proposed text. It remains insufficiently specified which entities will be granted access to such data, under which conditions, and to what extent data held by public institutions, including social insurance data, may be involved, given the high sensitivity of such data. Especially, the relation with the European Health Data Space (EHDS) and the General Data Protection Regulation (GDPR) requires further specification. The interaction between these frameworks should be clearly defined in order to avoid legal uncertainty, ensure full compliance with data protection standards, and guarantee that data access and use remain aligned with key principles such as purpose limitation, data minimisation and secure processing. In addition, greater transparency is required regarding the distribution of economic benefits derived from the use of such data, especially where publicly held data contributes to commercially valuable outcomes. In this context, it is essential to ensure an appropriate public return on publicly held data.

[10] The scale-up finance gap in the EU: Causes, consequences, and policy solutions - PMC