

Press release

ESIP warns against IP extensions in the EU Biotech Act

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The European Social Insurance Platform (ESIP), representing statutory social and health insurance institutions across Europe, expresses concern about the intellectual property (IP) provisions included in the European Commission's proposal for the EU Biotech Act.

While supporting the EU's ambition to strengthen Europe's biotechnology ecosystem, ESIP warns that EU patent and supplementary protection certificate (SPC) frameworks already provide among the most generous protection globally. Any additional extension would create unpredictable and substantial costs for social security systems.

ESIP cautions against any SPC extension beyond current levels, as this could further delay competition after already lengthy exclusivity periods, worsening affordability at a time of unprecedented pressure on public payers.

ESIP also recalls that the Commission's SPC evaluation found limited impact on attracting or retaining R&D in the EU, an assessment echoed by the Draghi report, which instead underscores the importance of competition to stimulate productivity, investment and innovation.

With a reported risk of a biosimilar void and fewer biosimilar candidates in the pipeline, EU policies should prioritise competition and remove artificial barriers to timely market entry.

ESIP urges to ensure that the Biotech Act:

- avoids any new IP exclusivity extensions that postpone competition and shift costs to public payers and insured people;
- strengthens legal certainty for day-1 competition after IP expiry through harmonised EU rules across different pharmaceutical legislative frameworks;
- supports a robust, harmonised Bolar framework so that competitors can complete necessary regulatory and administrative steps to enable day-1 competition.

'Europe's competitiveness must not be built on longer monopolies financed by public health systems. The Biotech Act must instead safeguard affordability through biosimilar competition starting on day one after existing IP expires. Extending exclusivities would delay competition, undermine sustainability and ultimately restrict patient access.' Yannis Natsis, ESIP Director



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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