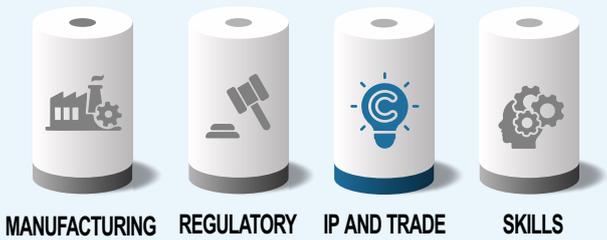


Optimising Intellectual Property (IP) Framework and Trade Partnerships

To preserve its competitiveness and strategic autonomy, Europe needs an unambiguous, harmonised freedom-to-operate framework and clear IP rules that support predictability, drive investment for companies with European-based operations into modernisation, innovation, and global trade.

BIOTECH ACT 4 PILLARS



CHALLENGES

Fragmented IP Framework Undermines Freedom to Operate

Inconsistent implementation of core intellectual property provisions, including the Bolar exemption, patent-linkage rules, and the SPC manufacturing waiver undermine the predictability of Europe's biosimilar market. Variable 'freedom to operate' landscape leads to **delays EU biosimilar launches** and create structural disadvantages for biosimilar companies with European-based operations compared with competitors based in third countries.

Divergences in IP frameworks across Europe contribute to legal uncertainty, discouraging investment in European-based manufacturing operations and weakening the Biotech Value Chain ecosystem.



EUROPEAN BIOSIMILAR HUB COMPETITIVENESS: 1ST GLOBAL MARKET, GROWING GLOBAL EXPORTS



Legal Uncertainty Delays Market Entry

In some Member States, in spite of 20 years of biosimilar availability and commercialisation experience, biosimilar developers still face **uncertainty for essential pre-launch activities**—such as pricing and reimbursement submissions or participation in tenders. All administrative market steps may trigger litigation, lead to delays and reduce Europe's attractiveness as a launch market



Barriers to Competition Limit Patient Access

Such **inconsistencies negatively impact patient access**. For example, biosimilar competition has been blocked even after loss of exclusivity, e.g. in Romania where biosimilar trastuzumab and rituximab were prevented from participating in tenders for four years post-expiry—delays for which the patent holder has since been sanctioned by the national competition authority.

At the same time, **evergreening strategies** continue to interfere with competitive dynamics, contributing to the delayed uptake of cost-saving alternatives.



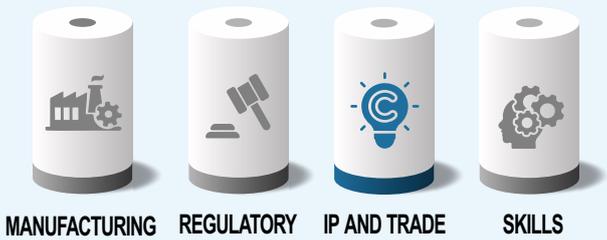
Europe's Export Strength Exposed to Growing Trade Risks

Europe already exports a large share of its biosimilar production: while 65% of all European manufactured volumes remain within Europe, Biosimilar medicines made in Europe are also exported internationally, primarily to the US (2/3 of total exports – volume, in 2024), and to the rest of the world (RoW) (1/3rd of total EU exports – volume – in 2024). Over the last 5-year, trends demonstrate an accelerated growth in RoW exports, both in volume and value. The European biosimilar manufacturing is faced with both opportunities and vulnerability, in a context of rising global protectionism.

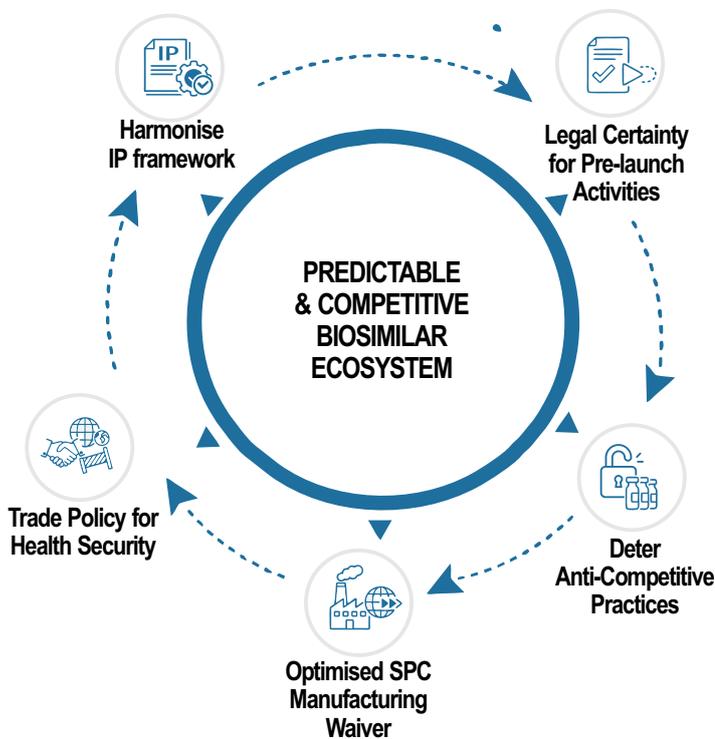
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KEY RECOMMENDATIONS



Harmonise EU Intellectual Property (IP) Provisions for Seamless Market Entry

Harmonise EU IP provisions, including the Bolar exemption, SPC manufacturing waiver, and 'unlawful' patent-linkage prohibitions, to ensure a predictable freedom to operate, ensure timely "Day 1" launch in Europe and competitive export conditions for European-made biosimilar medicines.

A harmonised IP framework delivers:

-  Day 1 EU biosimilar launch
-  Predictable investment conditions
-  Stronger European manufacturing operations and exports



Legal Certainty for Pre-launch Activities

Reduce legal uncertainty around pre-launch activities by explicitly permitting pricing and reimbursement submissions, tender participation, and other administrative preparatory steps without the risk of triggering litigation, and by ensuring these rules are **uniformly applied** across all Member States.



Deter Anti-Competitive Practices

Reassess evergreening practices that delay biosimilar entry by evaluating their impact on competition, patient access, and healthcare budgets, drawing on documented examples—including those highlighted in the 2025 IGBA "Gaming the System" report—to inform future policy and enforcement mechanisms.



Optimised SPC Manufacturing Waiver

Review and optimise the SPC manufacturing waiver by removing the artificial distinction between export and EU launch, eliminating anti-competitive publication requirements, and revising the restrictive six-month period, which does not reflect the realities of biotechnological production cycles (lead times).



Trade Policy for Health Security

Strengthen Europe's global competitiveness by embedding health security and biosimilar considerations into EU trade policy, advancing regulatory cooperation and mutual recognition agreements, and ensuring European producers can access international markets predictably and without unnecessary barriers.