biosimilar medicines
better access. better health.

Press Release

The EU Biosimilar industry, which is central to competitiveness, needs Ambitious, Coherent, & Competition-Driven Biotech Policies

16 December, Brussels, Belgium

Summary

- The prioritization of the health biotech agenda and recognition of the important economic role of the biosimilar industry in the European ecosystem should set the tone for a strong EU Biotech Act.
- The focus on competitiveness needs recalibration: intellectual property extensions have not delivered on R&D in Europe, while pro-biosimilar policies have encouraged R&D, scientific leadership and manufacturing investment across Europe.
- The key deliverables for a competitive industry are: industrial incentives, fit-for purpose Bolar exemptions, adapting the Supplementary Protection Certificate (SPC) manufacturing waiver to biosimilar timelines, predictable and pro-competitive markets to serve growing patient needs and regulatory simplification and harmonisation.

The Biosimilar medicines group, a Medicines for Europe sector group, welcomes the prioritisation of Biotech Act I focused on Health, as a constructive step toward strengthening Europe's biotech capacity. The Act's recognition of the economic and industrial importance of the biosimilar medicines industry, in addition to its significant contribution to patient access and to healthcare, confirms their essential role in Europe's strategic autonomy, supply resilience, competitiveness and sustainable access to biological therapies.

However, the industry urges policymakers to recalibrate the competitiveness measures, shifting focus away from additional intellectual property extensions which have always promised but never delivered on R&D in Europe. **A simulation shows that for just 3 cancer blockbuster drugs (Keytruda® / Darzalex® / Opdivo®) each year of delayed competition would cost healthcare systems 7.7 billion EUR** (table below). The EU should learn from other global biotech hubs instead, by supporting industrial incentives, streamlined access to funding, clear Bolar exemptions, a biosimilar fit-for-purpose SPC manufacturing waiver, predictable market demand, and a framework that rewards competition. This also aligns with the core recommendations of the Draghi Report. A life-cycle approach is also needed for regulatory simplification efforts. Beyond the accelerated implementation of streamlined biosimilar development pathways, guaranteeing access to EU clinical trial capacity for biosimilar clinical programmes is essential. This will strengthen Europe's capability to maintain and expand biosimilar R&D and deliver affordable, high-quality biologic therapies to patients.

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"Our industry, together with the EU, pioneered the Biosimilar Medicines industry in the early 2000s. We need to build on this leadership to as Europe charts its biotech future. **Adequate funding** and **policy coherence is essential for this R&D intensive sector**," Julie Maréchal-Jamil, Sr Director Pharmaceutical Policy said. "All legislative initiatives affecting biotechnology—across **health, supply resilience, crisis preparedness, defence, strategic autonomy, and competitiveness**—should be aligned to deliver a stable and predictable ecosystem attractive for investments. Contradictory or siloed policymaking risks undermining Europe's ability to build a relevant, robust, innovative, and competitive biotech sector."

The biosimilar industry will engage strongly in the legislative process to secure an innovation-friendly, and access-driven biotech ecosystem for Europe.

Table on IP extension

Product (Trade Name)	Molecule	Therapeutic area	Cost of 1-year delay of competition, in EUR (list price)
Keytruda	Pembrolizumab	Oncology	4.376.083.459
Darzalex	Daratumumab	Oncology-Haematology	1.834.575.461
Opdivo	Nivolumab	Oncology	1.490.777.065
			TOT 7.7 billion EUR

The Biosimilar Medicines Group

The Biosimilar Medicines Group is a sector group of **Medicines for Europe** representing the leading companies developing, manufacturing and/or marketing biosimilar medicines across Europe. With more than 10 years of positive patient treatment experience and 20 products successfully launched, biosimilar medicines provide today a huge opportunity to deliver significantly improved access to modern therapies for millions of European patients in both chronic and acute care. Our members bring competition to the biological medicines market, thereby increasing access to highly innovative treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.