Biosimilars 2025: A Turning Point for equitable access and EU competitiveness

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At the 9th *European Commission Multistakeholder Event on Biosimilar Medicines*, the Biosimilar Medicines Group urges coordinated EU and national action to fully unlock the value of biosimilar medicines for patients and healthcare systems.

Europe remains the global leader in biosimilar approvals (over 160) and real-world adoption, with **9.2 billion patient-treatment-days** cumulated, to date. In the past year alone, biosimilar medicines delivered **30% more patient-treatment-days EU-wide**, demonstrating their essential role in expanding access to critical biologic therapies.

The difference in EU Member states' biologic treatment rates remains significant. As an example, the ability to provide broader access to biologic medicines appears constrained in several Central and Eastern European (CEE) countries, with a significant gap remaining in comparison with Western Europe, despite the clear potential of biosimilar medicines to improve outcomes for chronic, immune-mediated and oncological diseases. The next phase of the EU-funded **AUGMENT** project is expected to help bridge the gap between policy design and effective implementation.

The upcoming **Biotech Act** presents another major opportunity to reinforce Europe's leadership in biosimilar development, manufacturing and long-term competitiveness and address the Biosimilar Void trends which see a biosimilar pipeline concentrated on a reduced number of biologic therapies. To seize it, the Biosimilar Medicines Group calls for:

- **Reformed EU medicines procurement rules** that enable fast, broad and sustainable biosimilar uptake at loss of exclusivity (LoE), built on multi-winner and pro-competition models;
- **An accelerated EMA roadmap** to streamline biosimilar development in Europe, drive evidence-based regulatory progress, and lead international biosimilar regulatory convergence to reduce divergence and complexity;
- **Robust horizon scanning and monitoring** to ensure measurable progress in closing biologic access gaps across EU Member States.

"The value of biosimilar medicines does not materialise automatically—it depends on coherent and sustained policy action," said *Julie Maréchal-Jamil, Senior Director, Pharmaceutical Policy*. **"Europe cannot afford a two-speed biologics landscape nor a worsening of the Biosimilar Void. The Biotech Act can strengthen EU competitiveness while ensuring all patients benefit from timely, high-quality biologic care."**

The Biosimilar Medicines Group is ready to work with the European Commission and all stakeholders to advance evidence-based, outcomes-driven policies that secure equitable access to biologic therapies for every patient in Europe.

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The Commission's annual stakeholder event continues to be a critical platform for aligning on strategies to close access gaps, strengthen competition and unlock the next wave of innovative and affordable biologic medicines for European patients.

Resource hub

More Information on:

- the European Commission's 9th biosimilar medicines event https://health.ec.europa.eu/events/biosimilar-medicines-multistakeholder-event-2025-12-04_en#:~:text=The%209th%20Biosimilar%20Multistakeholder%20Event,compared%20to%20their%20reference%20medicines.
- the AUGMENT project https://biosimilar medicines.goeg.at/en/about_project
- Assessing the Biosimilar Void (Europe) report https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void

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 15 years of positive patient treatment experience, biosimilar medicines today provide 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.