biosimilar medicines
better access. better health.

New Horizons for Biosimilar Medicines Policy: *Delivering better access, outcomes, and biotech manufacturing in the future*

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Europe has historically led the way in biosimilar adoption and policy development enabling biological medicine affordability and access for millions of European patients. A fit for the future biosimilar medicine policy should target broader, transformative opportunities for innovation in healthcare delivery, patient outcomes and technological progress.

Biosimilar medicines have proven their health value, generating nearly 7 billion patient treatment days of safe clinical use while contributing to the sustainability and resilience of healthcare systems with more than €56 billion in cumulated savings since 2006.

The four future opportunities for biosimilar medicine policies in Europe are:

1. **Availability, Affordability and Accessibility**: Future-proof the regulatory review process in-line with science and experience, drive competition at loss of exclusivity, and encourage multisource competition and supply in the market.
2. **Advancing Care and Outcomes for Patients**: Financial savings from the use of biosimilar medicines are a means to drive more efficient healthcare delivery for patients. Biosimilar policies should include re-investment and benefit sharing strategies aimed at improving overall patient care to further reduce the impact of non-communicable diseases on patients' lives. This will allow people to live productive lives and stimulate the economy.
3. **Innovation along Care Pathways**: take advantage of affordable biological treatment to reshape treatment and care pathways for patient benefit. Build on the pharmaceutical legislation and health strategy reform to explore untapped therapeutic potential through new combination therapies or repurposing in new indications.
4. **Stronger EU Global Leadership**: Europe is well-positioned to lead on the next generation of biosimilar medicines. The EU Biotech Act should spur investments in new technologies and innovation in product and process development by focusing on industrial know-how to ensure its competitive advantage on the global stage.

Speaking at Medicines for Europe's BIOS25 conference in Amsterdam, Sector Group Chair Isabell Remus said *"Biosimilar medicines have revolutionised the availability and cost-efficiency of biological therapies across Europe. Our industry now provides access to new, lifesaving and life-enhancing medicines to patients across the region, while also representing a cornerstone of Europe's biotech economy that drives next-generation technologies, digital solutions, and sustainable practices.*

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Yet there is more to do, particularly in using biosimilars to reshape European healthcare delivery. This will require removal of the default but unnecessary clinical efficacy studies, reform of EU procurement laws, and investment in the EU biosimilar ecosystem in preparation for the loss of exclusivity on the next generation of biological medicines – as well as support for biosimilar R&D and manufacturing in Europe. These steps, alongside the potential offered by the EU Biotech Act, will ensure the biosimilar sector continues to thrive in Europe for the benefit of patients and healthcare systems."

Resource hub

The Biosimilar medicines conference 2025 (BIOS25) takes place today in Amsterdam, bringing together leaders in the healthcare community, policy, industry, and academia to explore the next wave of opportunities for biosimilar medicines.More information on the BIOS25 event can be found at https://www.medicinesforeurope.com/events/bios25/

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.