

# The Biosimilar Advantage: Powering patient access and industrial resilience

Amsterdam, 7 May 2026

Marking the 20th anniversary of the world's first biosimilar launch (somatropin) in Europe, global pharma and healthcare leaders are gathering today for the BIOS26 conference. The message is clear: **the EU Biotech Act should foster stronger European resilience to translate proven value into broader access and better outcomes for patients.**

As the industry looks toward the next decade, the conference highlights four imperatives:

- **Europe has led the world in biosimilar policy and now it must lead again in shaping the environment for the next-generation biosimilar medicines through the EU Biotech Act.** Twenty years after the first biosimilar somatropin was launched in Europe, biosimilar medicines have become a clear example of how smart pharmaceutical policy can expand access, improve affordability and support healthcare sustainability. With a new wave of **next-generation biosimilar medicines** on the horizon, Europe has a strategic opportunity to ensure that patients, healthcare systems and the biotech economy fully benefit from the next era of biological medicines.
- **Reshaping market policies and care delivery for improved patient outcomes.** Moving beyond purely financial metrics, the next phase of biosimilar policy must prioritize patient outcomes as the ultimate success indicator. By improving pricing and procurement practices and leveraging the efficiencies gained through biosimilar use, healthcare systems must implement structured triggers for the evolution of treatment paradigms, care pathways, including biosimilar-first policies, benefit-sharing schemes and reinvestment strategies, ensuring that freed-up budgets are redirected to enhance patient services and reduce the burden of chronic, non-communicable diseases.
- **Modernizing regulatory frameworks to unlock innovation:** To maintain global leadership, the EU must evolve our regulatory science implementation. A major milestone has been reached by [EMA](#) comparative clinical efficacy study requirements — yet more can be achieved in Europe and globally to design convergent, fit-for-purpose approaches. By streamlining processes, the availability of the next wave of biological medicines can be de-risked and accelerated, ensuring that the regulatory environment fosters, rather than hinders, the rapid deployment of biosimilar-led development and manufacturing innovation for life-enhancing therapies.

- **Driving Industrial Resilience and Global Leadership:** [Europe's biosimilar sector](#) is a cornerstone of the continent's biotech economy. The Biotech Act proposes a 12-month extension of the Supplementary Protection Certificates (SPC) for reference biologic drugs. This should be rejected as it will significantly and negatively impact pharmaceutical budgets. EU legislators have a unique opportunity to secure the biosimilar competitive advantage, encouraging robust investment in next-generation manufacturing technologies, via strategic projects and dedicated funding, but also through improved SPC-manufacturing waiver provisions, and ensuring a resilient, diversified supply chain for the future.

**Christine Berndt, Chair of the Biosimilar Medicines Sector Group at Medicines for Europe, stated:**

*"Twenty years ago, Europe changed the paradigm of biological medicine with approving the first biosimilar. Today, we are not just celebrating the transformative impact on patient access and outcomes; we are also committing to shaping the future. With the next wave of biosimilar medicines on the horizon, our mission is clear: we must continue to transform how we deliver care. By simplifying regulations, reforming procurement, enhancing market competition, and investing in the European biotech ecosystem, we will ensure that the 'Biosimilar Advantage' continues to deliver unparalleled access, economic resilience, and better health outcomes for every European patient."*

**Adrian van den Hoven, Director General of Medicines for Europe, commented:** *"The Biotech Act is Europe's opportunity to retain its Biosimilar hub in a competitive global market. Europe pioneered biosimilar medicines and still represents the largest market with 47% of global sales. To remain competitive the Act must deliver on targeted funds for biosimilar production and sustainable market reforms. Intellectual property (SPC) should not be extended beyond the current total 15.5 years as Europe has already the longest IP framework in the world. An SPC will cost healthcare systems billions of euros every year that healthcare systems cannot afford."*

## Resource hub

- [Factsheet series on the Biotech Act](#)
- [Key BIOS Facts and Figures - 2025](#)
- [Biosimilars in the EU: Approval Overview and Therapeutic Areas](#)

The Biosimilar Medicines Conference 2026 (BIOS26) 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 BIOS26 event can be found at <https://www.medicinesforeurope.com/events/bios26/>.

## The Biosimilar medicines group

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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.