biosimilar medicines

a medicines for europe sector group

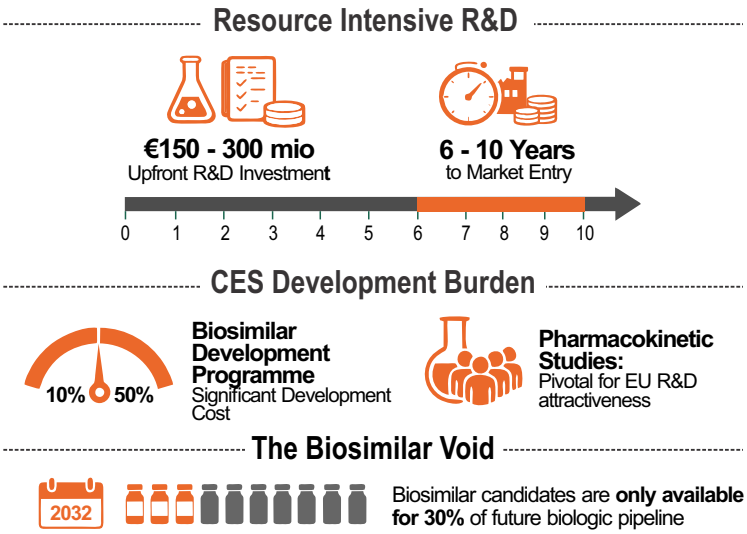
PILLAR 2: REGULATORY

Reforming Regulations, Market Entry and Competition for Biosimilar medicines

State-of-the-art, predictable regulatory requirements, processes and market conditions are critical to de-risk investment in biosimilar R&D and manufacturing. Procurement aspects of this reform should be included in a dedicated guidance for procurement of pharmaceuticals connected to the proposal for the revision of the Public procurement directive.

BIOTECH ACT 4 PILLARS

CHALLENGES



High barriers to biosimilar development and market entry

Biosimilar development is complex, resource-intensive and high-risk, requiring advanced scientific and manufacturing capabilities, long timelines and significant upfront investment. Outdated regulatory requirements, complex national pre-launch activities and unsustainable market conditions further increase costs and uncertainty, discouraging biosimilar development ('Biosimilar Void') and limiting competition.

Unfit requirements and processes affect biosimilar investment decisions, and ultimately the future ability for Europe to have a resilient biotech ecosystem.

High-cost, high-risk biosimilar development

Biosimilar development is, as any biotechnology endeavour, **resource-intensive** and requires advanced scientific and engineering capabilities. It typically demands **€150–300 millio**n in upfront R&D investment and 6–10 years before market entry, reflecting the involved complexity of biotechnology processes, biologic manufacturing and stringent regulatory requirements.

Outdated regulatory requirements (CES burden)

Europe has played **a global pioneering role in biosimilar regulation** since 2004, but the framework now requires **a new phase of evolution**. There is a growing **international scientific consensus** that comparative efficacy studies (CES) should no longer be required by default due to their limited scientific added value in the regulatory decision-making process (so-called **streamlined biosimilar development**). CES represent the largest development costs within biosimilar development, ranging between 10 and 50% of total development costs. Pharmacokinetic studies, in healthy volunteers and patients will remain a pivotal element of European biosimilar R&D competitiveness.

The "biosimilar void" for newer and non-blockbuster therapies

For several newer therapies CES are increasingly infeasible, creating barriers to development and contributing to the **"biosimilar void"** where many biologics lose exclusivity without attracting biosimilar competition, leading to perpetual monopolies and high cost burden. It affects all biologics, non-blockbusters more severely.

Unsustainable market conditions for existing biosimilar medicines

For existing biosimilar medicines, aggressive pricing, price-only tenders, and single-winner procurement reduce market predictability for manufacturers, weaken supply resilience, and dampen incentives to invest. As a result, **fewer than 30% of biologics losing exclusivity by 2032 have a biosimilar in development**. This development Void signals vulnerability of supply, patient access, healthcare budgets and the long term sustainability of Europe's biosimilar ecosystem.

Risk of losing Europe's clinical and scientific leadership

In spite of Europe being the leading region for **biosimilar clinical trials**, with 83 trials conducted between 2020–2025 and roughly €700 million invested annually. Without predictable regulation, sustained access to high-quality clinical trial capacity (for Pharmacokinetic studies), supportive market structures and investment-enabling policies, Europe loses momentum, scientific leadership and future industrial competitiveness in biosimilar medicines at a time when global demand for biologics is rising.

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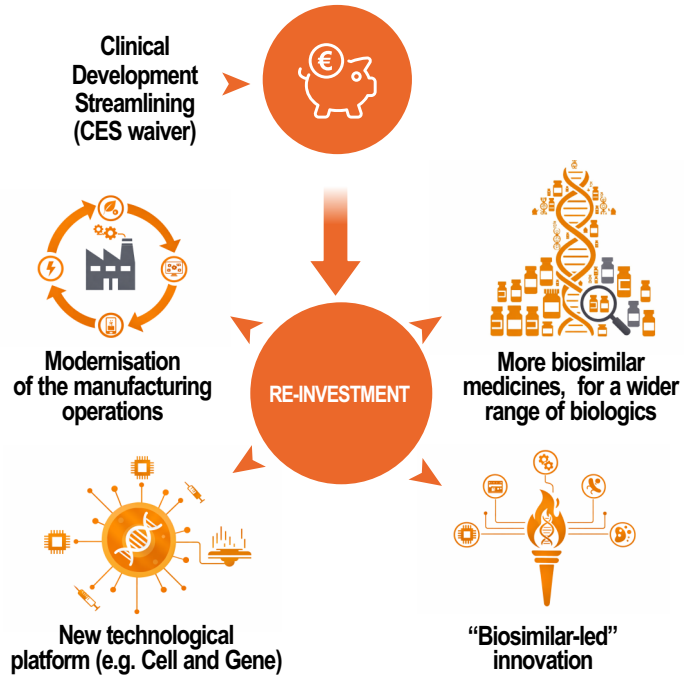
KEY RECOMMENDATIONS



Regulatory Streamlining & Global Convergence for Biosimilar medicines

Adopt and accelerate regulatory streamlining implementation, including CES waivers, and **lead global convergence efforts** through EMA within eg ICH, IPRP and WHO, while establishing **early guidance for next generation biosimilar medicines** (e.g. cell and gene therapies). CES waivers offer a major opportunity to overcome an important driver of the Biosimilar Void. An estimated **R&D spend of €3 billion** (over five years) **would be freed-up for re-investment.**

Clinical Development streamlining (CES waiver) would actively participate to European competitiveness through reinvestment opportunity into modernisation of operations, development of a wider range of biosimilar candidates, deployment of new technological platforms and biosimilar-led innovation.

Coherent European & National Biosimilar Strategies for Uptake and Access

Develop robust European and national biosimilar strategies to reduce disparities in availability across Member States, fully deploy authorised biosimilar medicines, and support uptake through updated prescribing rules, first-line biosimilar use, appropriate incentives, and targeted healthcare community education.

Sustainable Pricing & Reimbursement to Support Biotech Manufacturing

Align pricing and reimbursement policies with sustainable manufacturing conditions by:

- reflecting real biotech production costs, inflation and multilayer regulatory obligations
- ensuring predictable operational margins that enable reinvestment in upgrading facilities (eg digitalisation, environment) and developing new technological capabilities.

Fit-for-Purpose Pharmaceutical Procurement Frameworks

Reform procurement frameworks by implementing in a dedicated guidance on pharmaceuticals procurement, MEAT criteria beyond price, establishing multi-winner tender designs, and improving predictability through clear volume expectations and adequate lead times to maintain healthy, long-term multi-supplier competition. Capacity building in national procurement agencies (eg, AUGMENT project) should be prioritised.

Flexible and Risk-Based Stockholding Requirements

Address rigid national stockpiling practices that increase waste and add burden on manufacturers' operations. Reassess requirements to achieve fit-for-purpose, flexible, risk-based stockholding models, and ensuring remuneration where additional inventory obligations are imposed.