



European Biosimilar Medicines Sector: Delivering Impact Beyond Health - Economic, Scientific & Strategic Contribution

The European biosimilar medicines sector delivers high-impact contributions across health, economic growth, innovation, and strategic autonomy—forming a vital pillar of Europe's health biotech future. The Biotech Act needs to ensure the biosimilar industry's contribution to European patient health and economy can be sustained and expanded to meet European healthcare needs and global competitiveness goals.

EUROPE AS THE HISTORIC GLOBAL BIOSIMILAR HUB

+20 YEARS OF EUROPEAN BIOSIMILAR ECOSYSTEM



2006

First biosimilar approved in the EU



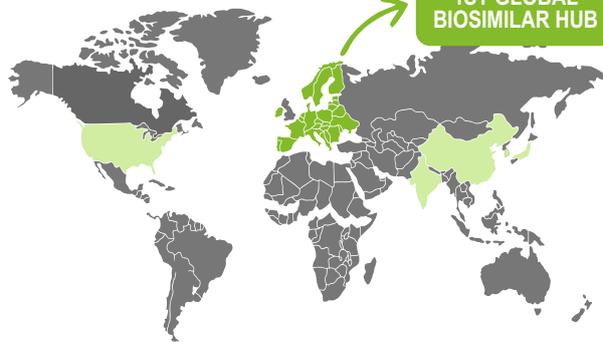
+160

Total approvals



Today

~100 companies form the European biosimilar ecosystem



1ST GLOBAL BIOSIMILAR HUB

Over the last two decades, Europe has developed into a leading global hub for biosimilar research, development, and manufacturing, alongside South Korea, India, China, and the United States.

- The 1st global biosimilar medicine was approved in 2006. To date, there are over 160 European biosimilar medicines approvals
- Biosimilar medicines approved are mostly **essential medicines**, used across a wide range of **major Non-Communicable Diseases** incl. Cancer, Diabetes, Rheumatology, Asthma, Ophthalmology, Neurology

ECONOMIC FOOTPRINT



European biosimilar medicines sector provides a significant contribution to European Gross Domestic Product (GDP)

- €25.6 billion of European GDP in 2024, representing some 6% of the total pharmaceutical industry contribution.
- 29% of the biosimilar Gross Value Added (GVA) is induced, highlighting deep economic spillovers.
- Biosimilar sales grew 15% annually (2020–2024) across five core therapeutic areas.



European biosimilar companies actively contribute to the European Biotech ecosystem and Value Chain

- ~100 companies active across the value chain: R&D, clinical trials, manufacturing, commercialization, as well as CDMOs and CROs operating in Europe.
- ~50% of annual European biosimilar sales originate from European-made products.
- 65% of biosimilar medicines produced in Europe are used by European patients
- Annual European investment in clinical trials for biosimilar candidate development is €0.7 billion, with 71% allocated to Comparative Efficacy Studies (CES)

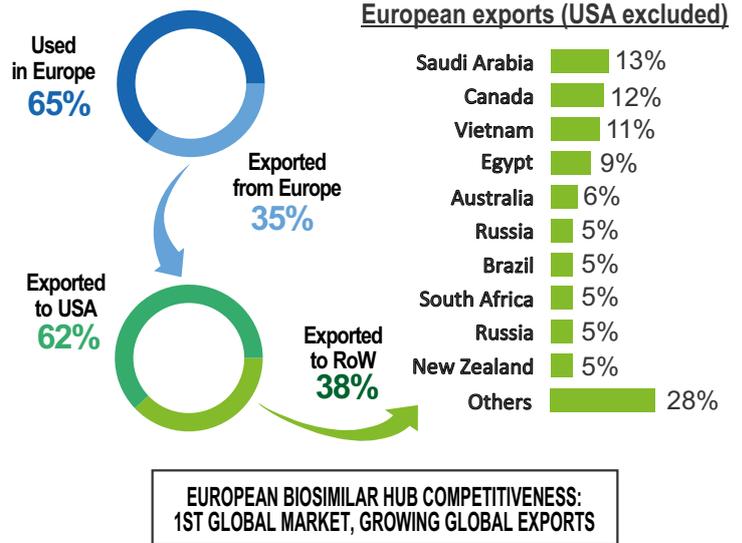


A provider for good career opportunities in Europe

- The biosimilar medicines sector supports ~81,000 jobs in Europe.
 - 16,000 direct jobs (20%)
 - 30% indirect (e.g., CDMOs, CROs)
 - 50% induced, demonstrating extensive value chain impact
- The biosimilar sector relies on a highly skilled workforce for R&D and Manufacturing jobs
 - 40% of direct employees (~7,000) are technically skilled
 - 70% hold university degrees.

A historic European hub fully integrated to the global biotech ecosystem

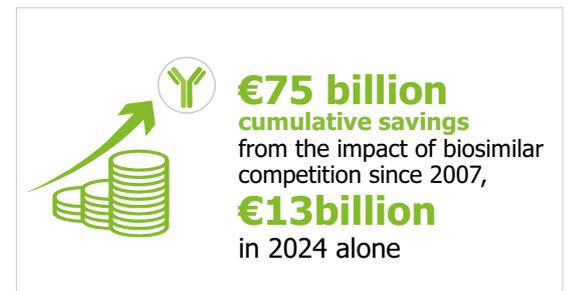
- One third (35%, volume) of biosimilar medicines manufactured in Europe are exported
- The United States represents the top export destination with 83% by value (2.4Bn€ in 2024) and 62% by volume of European biosimilar medicines exports.
- Diversification of exports to the Rest of the World (RoW; US excluded) is accelerating. In 2024, 17% by value (0.5Bn€) and 38% by volume of European-made biosimilar medicines were exported to Rest-of-World countries
- RoW export to 9 countries accounted for the majority of exports, with strong growth from MENA markets. Top 9 export markets Saudi Arabia, Canada, Vietnam, Egypt, Australia, New Zealand, South Africa, Brazil, Russia.



HEALTHCARE SUSTAINABILITY AND RESILIENCE

An essential driving force for the European health resilience strategy & Patient Access

- 160+ biosimilar medicines approved in the EU, across 15 therapeutic areas.
- Biosimilar medicines have generated 9.2 billion patient treatment days of cumulative real-world clinical experience.
- They are a cornerstone of healthcare sustainability, generating €75 billion in cumulative savings, including €13 billion in 2024 alone.
- Savings enable reinvestment into:
 - Wider patient access
 - New therapies
 - More resilient and fiscally sustainable health systems



A Key Driver of European Market Competition faced with Competitiveness challenges

Biosimilar medicines represent a smart investment with only 4% of the total pharmaceutical budgets (EU, list price) enabling further significant health, healthcare and economic value generation.

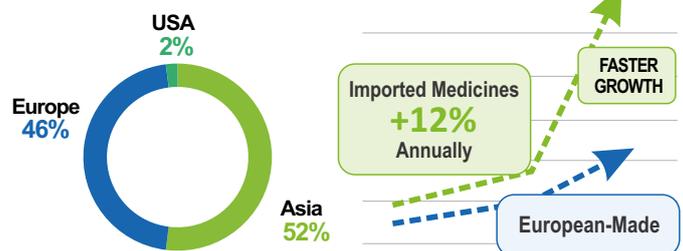
- **Fragmented Internal market:** European biosimilar dynamics in market, access and competition remain heterogeneous between and within countries, as a result of the different national biosimilar policy frameworks.
- **High-risk industry environment:** Segments of biologics may not benefit from biosimilar competition ('Biosimilar Void'): 121 biological medicines anticipated to lose protection by 2032 (~€55.9Bn opportunity between 2023–2032), 30% only have biosimilar medicines candidate in development

THE BIOSIMILAR VOID



FEWER THAN 30% OF BIOLOGICS LOSING EXCLUSIVITY HAVE A BIOSIMILAR CANDIDATE IN DEVELOPMENT

ORIGINS OF BIOSIMILAR MEDICINES USED IN EUROPE



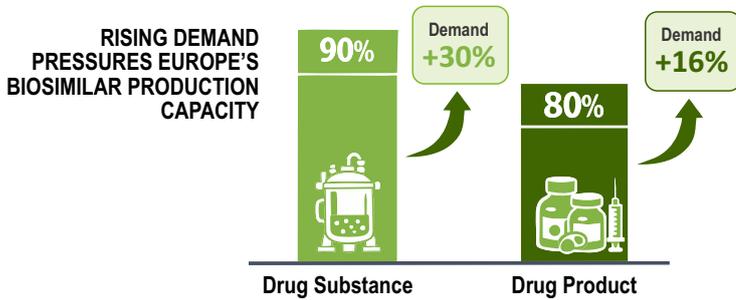
IMPORTED USE HAS INCREASED AT RATE OF 12% ANNUALLY SINCE 2020

Despite significant investment in the European biosimilar industrial footprint over the last two decades, such manufacturing facilities require additional investment in order to retain European competitiveness in the global biosimilar space

Emergence of fast growing global biosimilar hubs:

- 52% of biosimilar medicines originate from Asia
- 2% of biosimilar medicines originate from USA
- The use of imported biosimilar medicines increased at a rate of 12% annually since 2020, faster than the growth of European made biosimilar use.

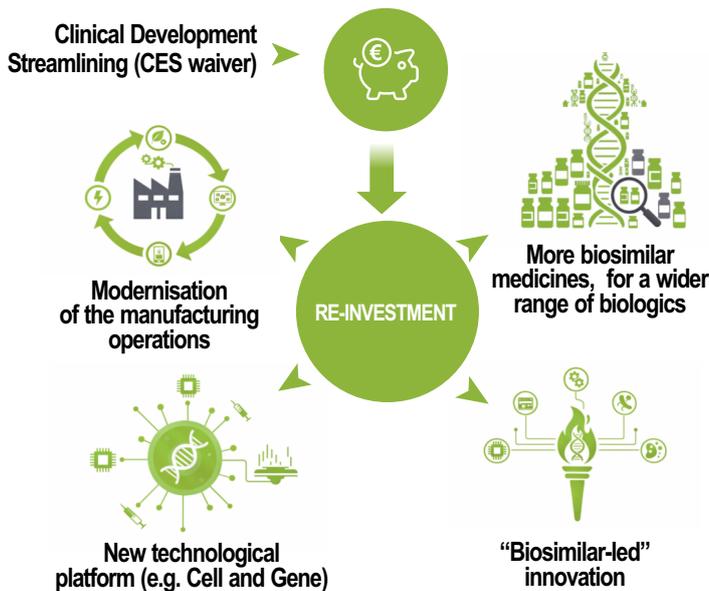
FUTURE BIOSIMILAR CONTRIBUTION TO THE STRATEGIC EUROPEAN SECTOR



- The Biosimilar industry has committed further European investment in R&D and manufacturing expansion (2025-2030):
- Both **drug substance** capacity and demand are **projected to grow, with projected demand rising by 30%**. By 2030, this will amount to 90% of the projected European capacity.

Drug product demand is expected to **grow at 16%** and reach ~80% of projected capacity by 2030 if investment remains unchanged

- **~9,000 technically skilled employees will be needed by 2030**, this means an additional 2000 trained biotech professionals needed.



- Under the current framework, the sector contribution to European clinical trials for biosimilar medicines candidates would amount to **€4.9 billion**.
- The Implementation of biosimilar clinical streamlining (Comparative Efficacy Waivers) would free **up an estimated €3billion over 5 years** (in clinical spending) which could instead be reallocated into other European R&D and Manufacturing investments:
 - Next-generation biosimilar medicines broader range of biologics, beyond blockbusters
 - "Biosimilar-led" innovation (e.g. dose regimen, route of administration, combination therapies)
 - New technological platforms: Anti-Drug Conjugate, Cell & Gene technologies
 - Modernisation of the industrial operations: manufacturing process & technologies, digitalization, automation, energy and resources management

ESSENTIAL CONSIDERATIONS FOR THE BIOTECH ACT

To continue deliver Impact Beyond Health: Economic, Scientific, Defense & Strategic autonomy, the following major challenges need to be tackled in the Biotech Act:

- **Legislative coherence** → Multiple ongoing reforms affecting directly and indirectly pharmaceutical supply and operations
- **Industrial policy** → Need for balanced measures to ensure full Biotech Value Chain competitiveness, including the strategic biosimilar sector
- **Access to Funding** → Ensure Strategic biosimilar projects status leads to effective, adequate and proportionate funding to ensure modernisation, digital and environmental transitions
- **Regulatory Frameworks** → Accelerate simplification of regulatory authorization processes and market reform
- **Intellectual Property and Trade** → prevent SPC extension, tackle inconsistencies in the application of intellectual property provisions, such as the Bolar exemption and adapt the SPC-manufacturing waiver in support of European biosimilar exports
- **Skills** → deploy a European-wide biotech skills strategy, tackle fragmented talent pools and barriers to professional mobility