biosimilar medicines

a medicines for europe sector group

BIOTECH ACT 4 PILLARS

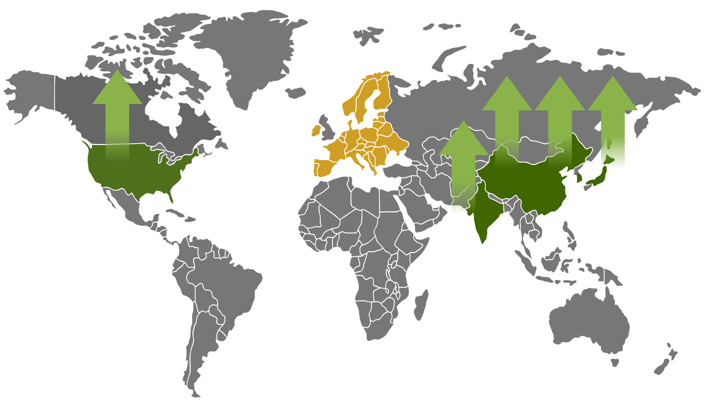
MANUFACTURING REGULATORY IP AND TRADE SKILLS

PILLAR 1: MANUFACTURING

Investing in Biotech R&D and Manufacturing Platforms

The European biotech ecosystem would be stronger, more competitive, and biopharma supply more resilient with a sustainable, innovation-ready biosimialr manufacturing and R&D footprint.

CHALLENGES



Global competitive Imbalance:
Major global biotech hubs already benefit from strategic investments

South Korea India China Japan United States

Europe faces increasing global competition in biotech, including biosimilar manufacturing biosimilar

Despite **pioneering** and continuous **private investment** in the biosimilar medicines industry over the last two decades, Europe is falling behind global biotech hubs such as South Korea, India, China, the United States or Japan.

The absence of a comprehensive unified European biotech strategy together with an ambitious funding has impacted Europe's industrial attractivity across the value chain.

Uneven global playing field

Beyond labour costs differences, **substantial support** e.g. public funding, fiscal incentives, and long-term industrial strategies has been observed in other global hubs. This affects Europe overall attractiveness and companies investment choices (new or existing biomanufacturing operations).

Unbalanced investment across Europe's Value Chain

Current limitations in European support for investments in local biosimilar manufacturing operations (drug substance/product) restrain Europe's ability to **enhance supply chain security and mitigate product and technology vulnerabilities** (i.e dependence on single source or ex-Europe sourcing).

Rapid biologic demand growth requires a multisource capacit

With biologic medicines accounting for 40% of overall pharmaceutical sales, demand for biosimilar medicines will grow sharply, driven by major losses of exclusivity, increasing adoption of advanced biotechnologies, and rising patient needs. Today's biosimilar manufacturing operations are preparing to meet projected demand growth (drug substance +30%, drug product +16% by 2030) through investments. Reponding to supply fluctuation will depend on **Europe's commitment to building further resilience in the ecosystem.**

Fragmented clusters and skills across Europe

Europe's biotech clusters and skills base remain unevenly distributed, further hampered by a lack of **coordinated strategies for capability development, infrastructure planning, and funding**.

Slow regulatory evolution adds unpredictability to investment decisions

Upcoming changes in European and global biosimilar clinical evidence requirements have the potential to free significant R&D resources (~€3B), but reallocation into European R&D investment will largely depend on the availability of supportive funding instruments, biosimilar-friendly industrial strategies and streamlined regulatory frameworks.

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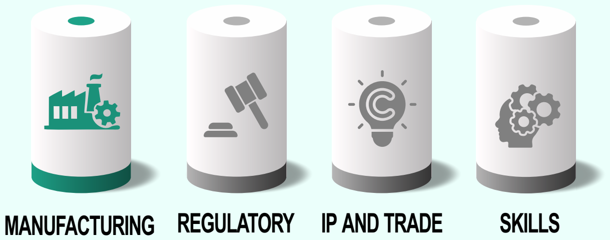

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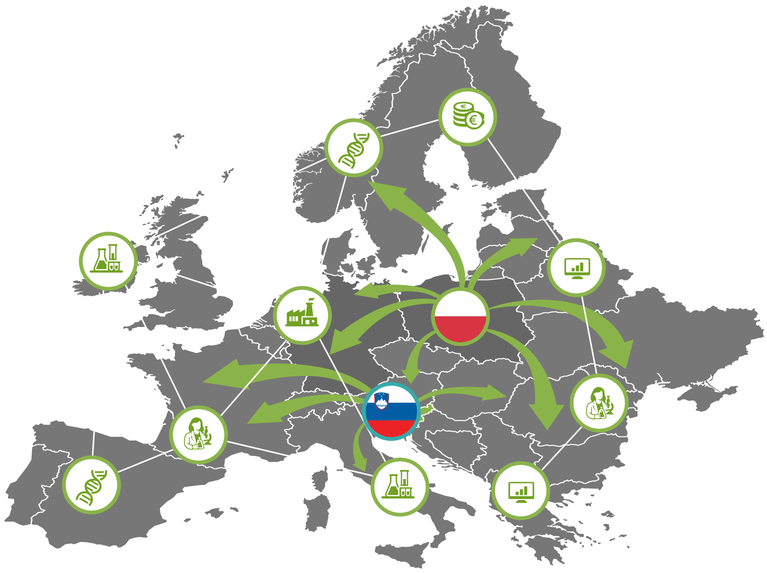
KEY RECOMMENDATIONS



Replicating Success & Good Practices from European Biotech Clusters

Poland's national biotechnology strategy

Slovenia's Biotech Hills

Support the creation, coordination and upgrading of "Biotech Centers of Excellence"

Map existing national and regional cluster strategies and organizations.

Integrated approach: Combine skills development, advanced infrastructure, and targeted investment incentives.

Replicate successful models like Slovenia's Biotech Hills and Poland's national biotechnology strategy across the EU.

A robust network of interconnected Centres of Excellence is crucial for a strong Europe's biotech Value Chain, competitiveness, innovation and resilience.

From Mapping to Scaling up

Map → Replicate → Integrate & Innovate → Invest & Scale Up

Boost EU Biotech Manufacturing Investment

Increase **EU biotech (incl. biosimilar) manufacturing funding and investments** through dedicated EU support for **scaling and modernising facilities**, including green and digital upgrades, next-generation biotechnologies (antibody drug conjugates, advanced therapies), and second-wave innovation such as improved bioprocesses. Enable AI adoption across R&D and manufacturing through fit-for-purpose regulatory frameworks.

Simplify & Open Access to Funding

Improve **transparency and accessibility of funding instruments** - simplify and clarify national/EU funding schemes, including eligibility rules, and update the definition of "innovation" to allow financial support for upgrading existing facilities. Update state-aid rules to ensure biosimilar developers and CDMOs can access IPCEI and other major financing mechanisms.

Align Long-Term EU Biotech Policies

Ensure **coherent, long-term policy alignment to support resilience, industrial competitiveness, innovation, and the green/digital transitions**.

Secure European Clinical Trial Capacity

Secure **sustained access to European clinical trial capacity**, and **regulatory simplification for clinical trial applications**, to ensure continued availability of high-quality clinical research infrastructure as biosimilar evidence requirements evolve.