biosimilar medicines

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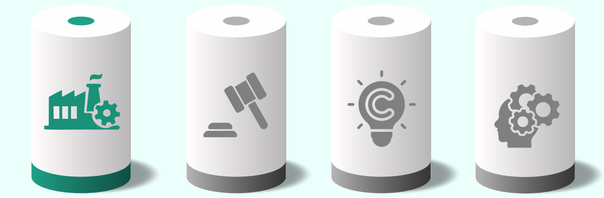
BIOTECH ACT 4 PILLARS



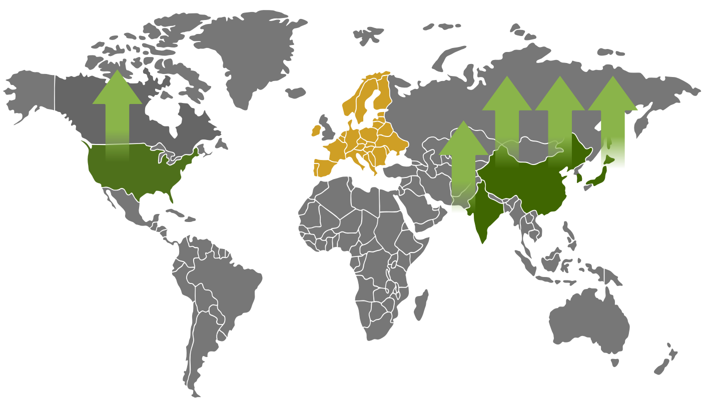
MANUFACTURING REGULATORY IP AND TRADE SKILLS

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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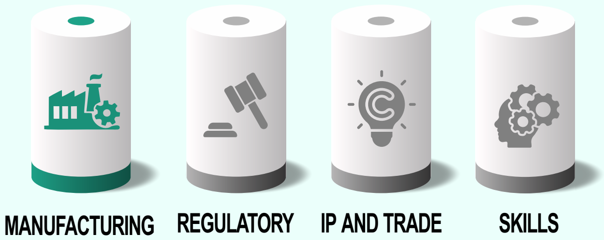

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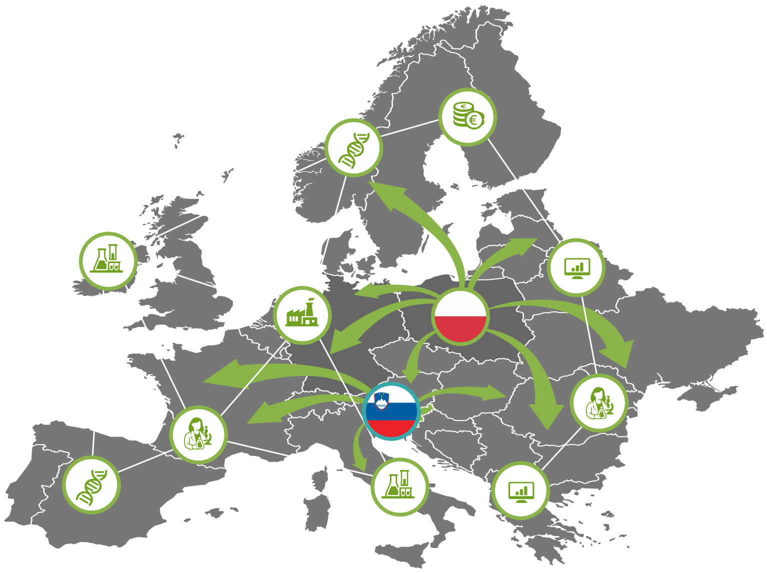

Replicating Success & Good Practices from European Biotech Clusters

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.

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BIOTECH ACT 4 PILLARS

SPC PROPOSAL

Biotech Act proposed 12-month Extension of the Supplementary Patent Protection (SPC)

The European Biotech Act proposal, published on 16 Dec 2025 aims to create an enabling environment for biotechnology products to reduce competitiveness gaps in biotech, despite EU scientific leadership, vis-à-vis other regions.

BACKGROUND

THE PROPOSED BIOTECH ACT I (HEALTH) PURSUES 3 MAIN OBJECTIVES:

Competitiveness & Internal Market

1) To improve the **functioning of the internal market** by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production.

Innovation & Market Access

2) To **create the conditions for the development and timely placing on the EU market**, of biotechnology innovations, products and services.

High Standards & Protection

3) While **safeguarding high standards for the protection of human health**, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

PROPOSED ARTICLE 27 OF THE BIOTECH ACT: 12 MONTH-SPC EXTENSION

APPLICANT MUST DEMONSTRATE ALL CONDITIONS ARE MET:

New Active Substance Distinctly Different from Authorized EU Meds

a) The medicinal product contains a new **active substance distinctly different from that of any authorised medicinal product** in the Union.

Different Mechanism of Action with Equivalent Safety and Efficacy

b) The medicinal product has a **mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent** to that of any authorised medicinal product in the Union for the same disease.

Clinical Trials in more than 2 Member States

c) The **clinical trials** evaluating the efficacy of the medicinal product and supporting its marketing authorisation were **conducted in more than two Member States.**

Manufacturing Step in EU Excluding Packaging, Testing and Certification

d) **At least a manufacturing step, excluding** packaging, quality testing and certification is performed in the Union.

EMA ASSESSMENT
Compliance assessed during Marketing Authorisation in statement.

→

COPY OF STATEMENT
included in the application for an SPC.

The EMA would assess compliance with the conditions as part of the marketing authorisation procedure and where compliance is confirmed, it shall issue a statement to that effect. A copy of the statement shall be included in the application for an SPC.

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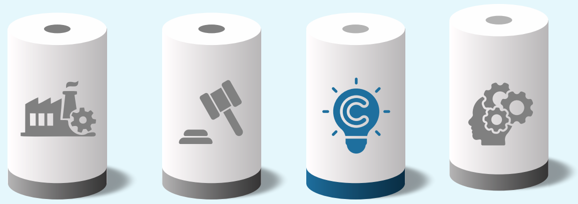
BIOTECH ACT 4 PILLARS



MANUFACTURING | REGULATORY | IP AND TRADE | SKILLS

WHY THE PROPOSAL IS UNACCEPTABLE FOR EUROPE

Medicines for Europe strongly opposes the proposal to extend the SPC protection that would **provide additional billions € profits to companies** that, despite multiple promises, have been investing in R&D outside Europe for decades now and **have publicly announced 99% of their future R&D investments in the US or China ($370B in US only)**.

CONTRADICTS EU POLICY OBJECTIVES

- **It contradicts broader EU objectives** on affordability, access, and competitiveness of the off-patent sector

NO EVIDENCE IT ATTRACTS R&D TO EUROPE

It is **inappropriate to propose an SPC extension** given that:

- The **SPC itself triggered delocalisation of biosimilar manufacturing out of the EU**: the 2020 Commission SPC evaluation shows that "*(t)he lawmakers had not anticipated in 1992 this negative impact of the SPC on the competitiveness of EU-based generics/biosimilars manufacturers*" .
- The 2020 Commission's & the Technopolis' evaluations of the SPC concluded that the SPC "*had a limited effect in tackling the objective of attracting R&D to the EU and preventing delocalisation, as other factors have a significant influence on the geographical location of innovation*", that "***the [SPC] regulation has not achieved its goal" & "the financial benefits fall mostly outside of the EU***".

Costs to the healthcare system for each year of delay in **biosimilar competition**

€7.7 BILLION

€ 4,4 BILLION | **€ 1,8 BILLION** | **€ 1,5 BILLION**

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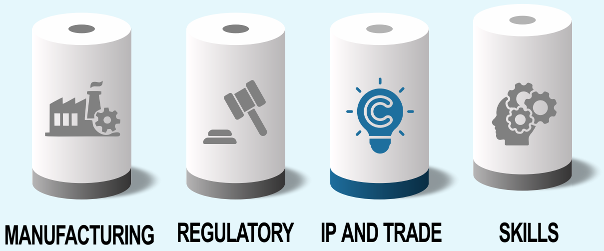
BIOTECH ACT 4 PILLARS



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WHY THE PROPOSAL IS UNACCEPTABLE FOR EUROPE

EUROPE ALREADY HAS THE LONGEST PROTECTION WORLDWIDE

- The **EU already has the longest SPC-like protection worldwide**. This would lead to up to 16.5 years of effective 'patent + SPC' protection in the EU vs. max. 14 years in the US.
- The Commission is proposing an even further **delayed competition as an industrial policy instrument**, instead of focusing on targeted investment measures.

STRUCTURAL AND LEGAL RISKS

- It creates **legal uncertainty** (with the involvement of a health authority in the granting process) **& administrative complexity** that will **trigger further SPC litigation.**

MASSIVE COST FOR HEALTHCARE SYSTEMS

- The estimated **cost to healthcare systems for each year** of delayed competition, **only considering 3 molecules** (Keytruda®, Darzalex®, Opdivo®): **€7.7 billion**, ie. more than half of EU annual savings from biosimilar competition (ie. €13 billion, in 2024).
- The **huge costs** of this proposal would be ultimately **financed by patients and healthcare systems.**

WEAKENS EU INDUSTRIAL COMPETITIVENESS

- It **discriminates against biosimilars R&D / production** as this reward applies only to patent/SPC holders.
- **It distorts competition** by favouring big, vertically integrated companies to **the detriment of SMEs.**

  Its scope seems to **go beyond only purely biological products** and the conditions **reward already existing practices** rather than stimulating genuine additional investments.

WHAT INCENTIVES SHOULD BE CONSIDERED INSTEAD

- Introduce a **correction of the SPC manufacturing waiver to effectively stimulate development & manufacturing of biosimilar medicines in Europe**. This should be done by
  1. **removing the artificial distinction between export & EU launch** (i.e., deleting the restrictive 6-month period that discourages biosimilar development in Europe as it does not reflect the realities of biotechnological production cycles), and
  2. **removing notification requirements** that are being misused for frivolous litigation to discourage biosimilars manufacturing in Europe. This is key since the SPC itself triggered delocalisation of biosimilar manufacturing out of the EU.
- Very importantly, **other regions of the world (eg. China) are going to introduce an SPC manufacturing waiver to stimulate strategic investments in biosimilar and generic R&D and production.** These regions are certainly going to learn from the European experience and will introduce such waiver without the obstacles to its exploitation that Europe has today in its SPC manufacturing waiver. **Therefore, these corrections have to be made now**.
- **Address evergreening practices** that delay biosimilar medicines market launches by evaluating their impact on the competitiveness of the biologic off-patent sector, competition, patient access, and healthcare budgets, drawing on documented examples — incl. those highlighted in the 2025 IGBA "Gaming the System" report — to inform future policy and enforcement mechanisms.

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BIOTECH ACT 4 PILLARS

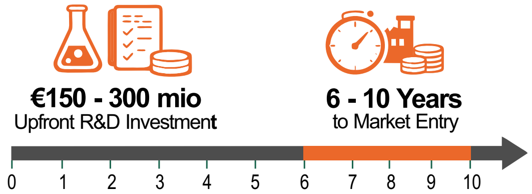
PILLAR 2: REGULATORY

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.

CHALLENGES

Resource Intensive R&D



CES Development Burden

Biosimilar Development Programme
Significant Development Cost

Pharmacokinetic Studies:
Pivotal for EU R&D attractiveness

The Biosimilar Void

Biosimilar candidates are **only available for 30%** of future biologic pipeline

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 million** 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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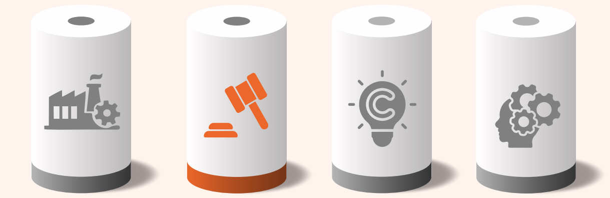

MANUFACTURING REGULATORY IP AND TRADE SKILLS

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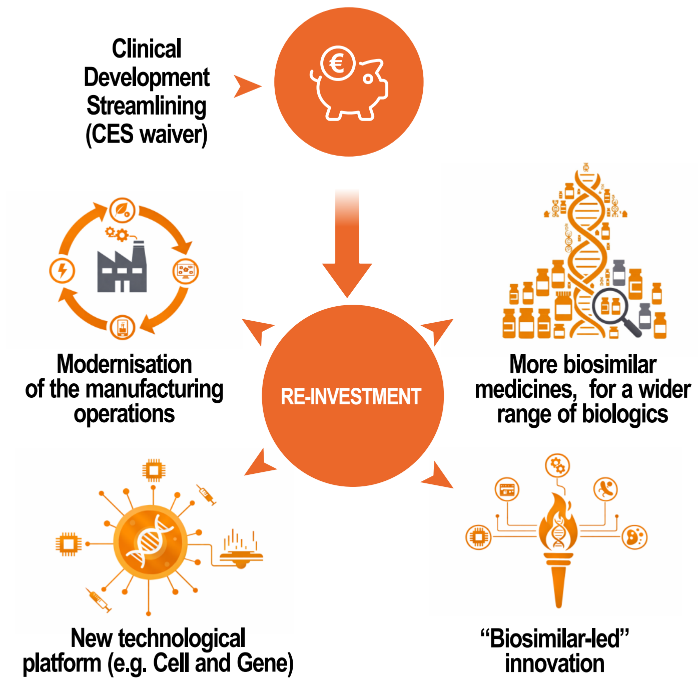

Regulatory Streamlining & Global Convergence for Biosimilar medicines

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.

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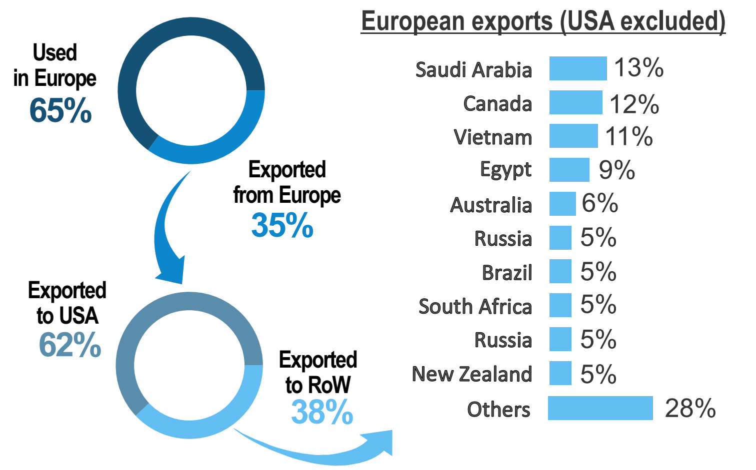
BIOTECH ACT 4 PILLARS

PILLAR 3: INTELLECTUAL PROPERTY (IP)

Optimising Intellectual Property (IP) Framework and Trade Partnerships

To preserve its competitiveness and strategic autonomy, Europe needs an unambiguous, harmonised freedom-to-operate framework and clear IP rules that support predictability, drive investment for companies with European-based operations into modernisation, innovation, and global trade.

CHALLENGES



EUROPEAN BIOSIMILAR HUB COMPETITIVENESS: 1ST GLOBAL MARKET, GROWING GLOBAL EXPORTS

Fragmented IP Framework Undermines Freedom to Operate

Inconsistent implementation of core intellectual property provisions, including the Bolar exemption, patent-linkage rules, and the SPC manufacturing waiver undermine the predictability of Europe's biosimilar market. Variable '**freedom to operate**' landscape leads to **delays EU biosimilar launches** and create structural disadvantages for biosimilar companies with European-based operations compared with competitors based in third countries.

Divergences in IP frameworks across Europe contribute to legal uncertainty, discouraging investment in European-based manufacturing operations and weakening the Biotech Value Chain ecosystem.

Legal Uncertainty Delays Market Entry

In some Member States, in spite of 20 years of biosimilar availability and commercialisation experience, biosimilar developers still face **uncertainty for essential pre-launch activities**—such as pricing and reimbursement submissions or participation in tenders. All administrative market steps may trigger litigation, lead to delays and reduce Europe's attractiveness as a launch market

Barriers to Competition Limit Patient Access

Such **inconsistencies negatively impact patient access**. For example, biosimilar competition has been blocked even after loss of exclusivity, e.g. in Romania where biosimilar trastuzumab and rituximab were prevented from participating in tenders for four years post-expiry—delays for which the patent holder has since been sanctioned by the national competition authority.

At the same time, **evergreening strategies** continue to interfere with competitive dynamics, contributing to the delayed uptake of cost-saving alternatives.

Europe's Export Strength Exposed to Growing Trade Risks

Europe already exports a large share of its biosimilar production: while 65% of all European manufactured volumes remain within Europe, Biosimilar medicines made in Europe are also exported internationally, primarily to the US (2/3 of total exports – volume, in 2024), and to the rest of the world (RoW) (1/3rd of total EU exports – volume – in 2024). Over the last 5-year, trends demonstrate an accelerated growth in RoW exports, both in volume and value. The European biosimilar manufacturing is faced with both opportunities and vulnerability, in a context of rising global protectionism.

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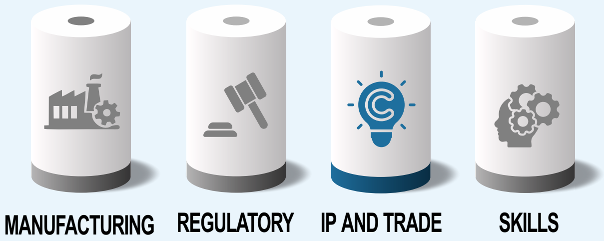

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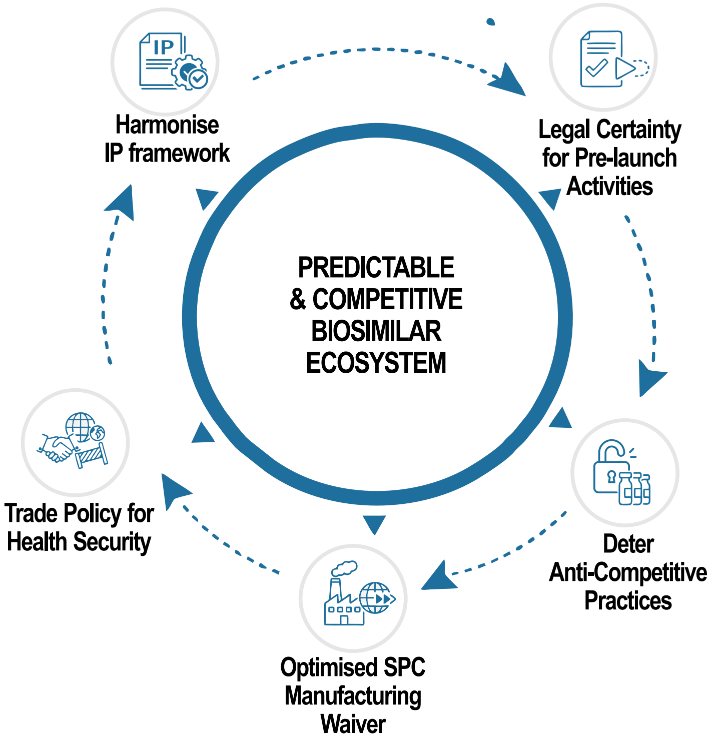

Harmonise EU Intellectual Property (IP) Provisions for Seamless Market Entry

Harmonise EU IP provisions, including the **Bolar exemption, SPC manufacturing waiver,** and ‘unlawful’ **patent-linkage prohibitions**, to ensure a predictable freedom to operate, ensure timely “Day 1” launch in Europe and competitive export conditions for European-made biosimilar medicines.

A harmonised IP framework delivers:

- Day 1 EU biosimilar launch
- Predictable investment conditions
- Stronger European manufacturing operations and exports

Legal Certainty for Pre-launch Activities

Reduce legal uncertainty around pre-launch activities by explicitly permitting pricing and reimbursement submissions, tender participation, and other administrative preparatory steps without the risk of triggering litigation, and by ensuring these rules are **uniformly applied** across all Member States.

Deter Anti-Competitive Practices

Reassess evergreening practices that delay biosimilar entry by evaluating their impact on competition, patient access, and healthcare budgets, drawing on documented examples—including those highlighted in the 2025 IGBA “Gaming the System” report—to inform future policy and enforcement mechanisms.

Optimised SPC Manufacturing Waiver

Review and optimise the SPC manufacturing waiver by removing the artificial distinction between export and EU launch, eliminating anti-competitive publication requirements, and revising the restrictive six-month period, which does not reflect the realities of biotechnological production cycles (lead times).

Trade Policy for Health Security

Strengthen Europe’s global competitiveness by embedding health security and biosimilar considerations into EU trade policy, advancing regulatory cooperation and mutual recognition agreements, and ensuring European producers can access international markets predictably and without unnecessary barriers.

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PILLAR 4: SKILLS

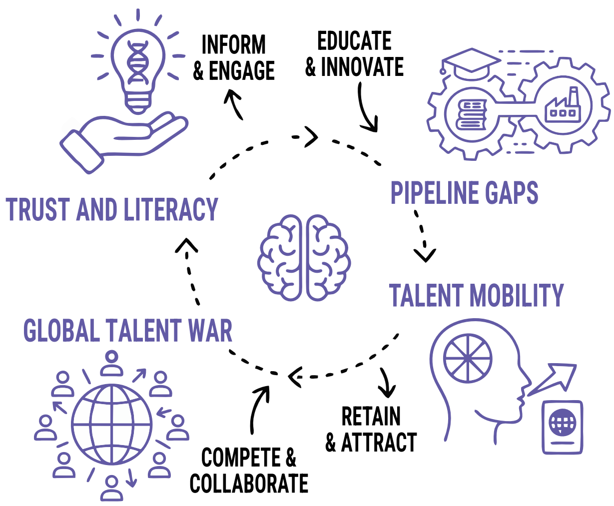
Developing Confidence in Biotech, Attractiveness, Talent and Skills

BIOTECH ACT 4 PILLARS

Europe needs to continue investing in scientific literacy around biotechnology as a key pillar of its Biotech Strategy. A coordinated, proactive strategy to develop, attract, and retain biotechnology talent will also support the European ambition for a competitive Biopharmaceutical industry, including the biosimilar medicines sector.

CHALLENGES

Science and Talent as foundation for a successful Biotech Strategy for Europe



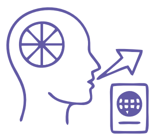
Continuous Efforts Needed to Build Public Trust in Biotech and Enhance Scientific Literacy

As with any significant medical or scientific advances, citizens will face new and overwhelming information. Europe must **renew its long-standing efforts to build trust, awareness, and scientific literacy around biotechnology** throughout medicines life-cycle, including when biosimilar medicines enter the market across more disease areas and/or next-generation biotechnology platforms (e.g. cell and gene)

Europe must foster trust and scientific literacy to ensure citizen and healthcare community confidence in next-generation biotechnology including follow-on biosimilar medicines.

Pipeline & Technological Gaps

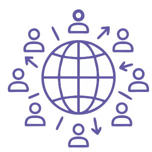
Europe's talent pipeline remains **uneven and fragmented. Biotech clusters** are geographically concentrated, with other regions providing limited opportunities. Academic curricula often lag behind industry's rapidly evolving needs, and there is still no European-level structure to effectively connect training providers with companies across the full talent lifecycle—**from initial education to vocational and continuous training**.



Talent mobility

Europe continues to face talent mobility pressures, variable STEM engagement across countries, and administrative barriers that hinder cross-border mobility and recognition of qualifications.

Without a coordinated, proactive European strategy to develop, attract, and retain biotechnology talent, Europe risks constraining the growth of its biosimilar and broader biotech industries at the very moment global competition is accelerating.



Global Talent War

Parallel to scientific progress, Europe's rapidly expanding biotechnology ecosystem is driving **intense competition for skilled talent**. With medicines becoming increasingly biologic in nature and digital and environmental transitions reshaping industrial processes, demand for technically skilled personnel is rising sharply, both at graduate and technician/operator levels. The competition for talent is happening within the pharmaceutical sector, on a global scale.

In addition, as European industries across sectors are all investing in digital and environmental transitions, this also contributes to a shortage in emerging skills and competencies.

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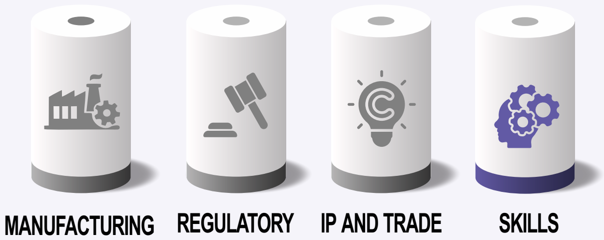

PILLAR 4: SKILLS

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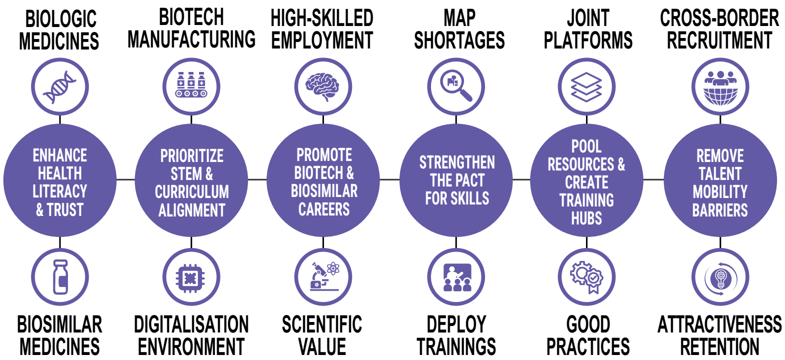


EUROPEAN BIOSIMILAR HUB: A COORDINATED AND PROACTIVE TALENT STRATEGY FOR GLOBAL COMPETITIVENESS

Enhance Health Literacy & Trust

In order to support the development of the strategic European Biotech sector, it is important to ensure unbiased, scientifically sound information and educational resources are made available. It should be understandable to all and prevent misleading information. Beyond general information about the biotech industry, biotechnologies and biotech products, continuous education on biosimilar medicines should be provided.

Build public trust in biotechnology and biosimilar medicines through communication on products, technology and professional opportunities.

Prioritize STEM & Curriculum Alignment

Reinforce **European and national investment in STEM education and academic capacity**, aligning curricula with evolving technological requirements in biotech, digitalisation, and sustainable manufacturing.

Promote Biotech & Biosimilar Careers

Develop the attractiveness of the European Biotech sector through appropriate and timely communication on the sector's high-skilled employment, scientific, economic and societal value, as well as on the professional growth potential.

Strengthen the Pact for Skills

Reinforce the mandate, scope, and funding of the **Pact for Skills** and the **Large-Scale Partnership for Health Industries** to map skills shortages and skill-demand evolution, foster partnerships among training providers and industry, such as those in clusters like Slovenia's Biotech Hills.

Pool Resources & Create Training Hubs

Pool resources across European biotechnology clusters by replicating successful training models—such as Ireland's NIBRT—through a network of European regional training hubs, establishing a shared platform for joint projects and infrastructure, and harmonising standards to facilitate cooperation and reduce fragmentation.

Remove Talent Mobility Barriers

Address talent mobility barriers across European countries and globally by identifying obstacles, benchmarking global biotech hubs' talent strategies, and enabling cross-border recruitment, knowledge exchange, and retention. Beyond academia, improve mutual recognition of vocationally trained professionals across Europe.

biosimilar medicines

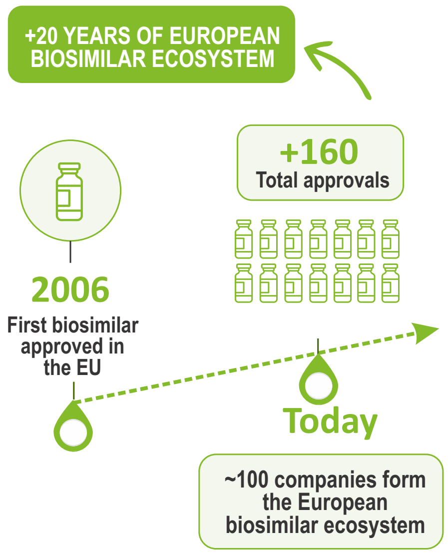
a medicines for europe sector group

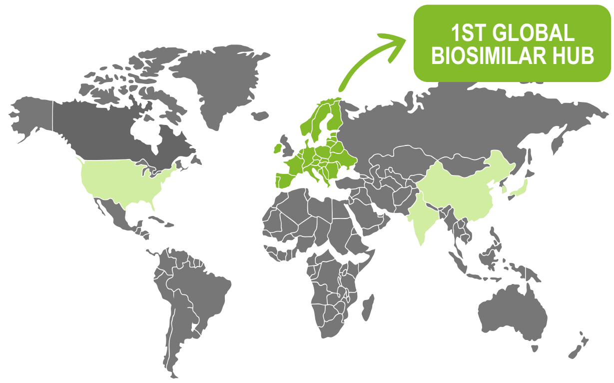
BIOTECH ACT'S FOOTPRINT

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





- 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

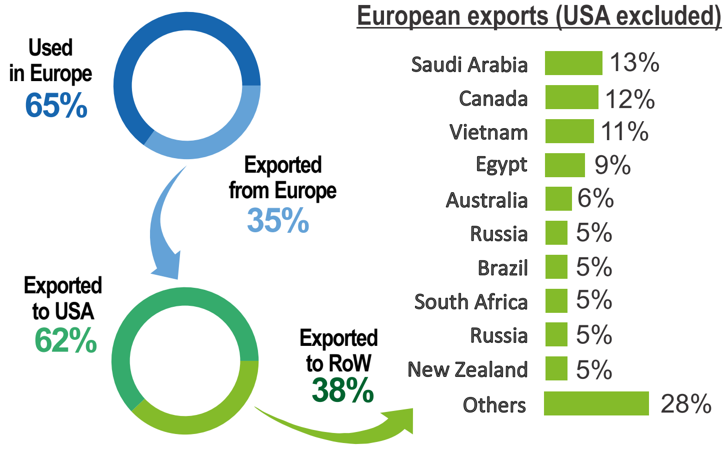
- **~100 companies** active across the value chain: R&D, clinical trials, manufacturing, commercialization, as well as CDMOs and CROs operating in Europe.
- **~50% of annual European biosimilar sales** originate from **European-made products**.
- **65% of biosimilar medicines produced in Europe** are 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 (0.5B€) 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.



EUROPEAN BIOSIMILAR HUB COMPETITIVENESS: 1ST GLOBAL MARKET, GROWING GLOBAL EXPORTS

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

€75 billion
cumulative savings
from the impact of biosimilar competition since 2007,
€13billion
in 2024 alone

A Key Driver of European Market Competition faced with Competitiveness challenges

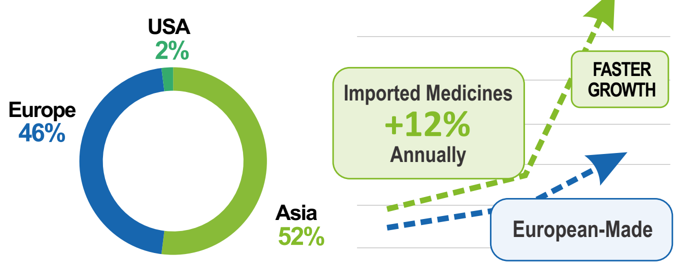
Biosimilar medicines represent a smart investment with only 4% of the total pharmaceutical budgets (EU, list price) enabling further significant health, healthcare and economic value generation.

- **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

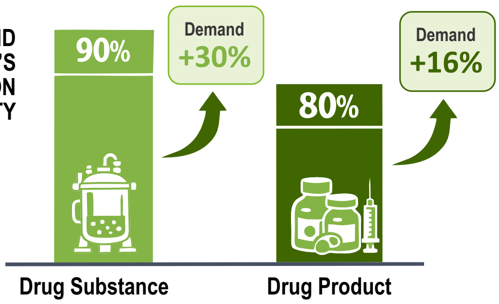
Despite significant investment in the European biosimilar industrial footprint over the last two decades, such manufacturing facilities require additional investment in order to retain European competitiveness in the global biosimilar space

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

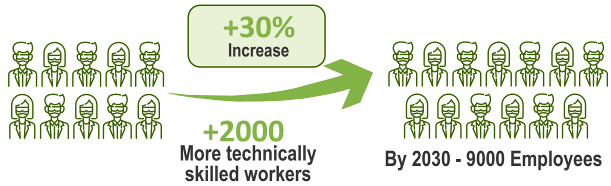
RISING DEMAND PRESSURES EUROPE'S BIOSIMILAR PRODUCTION CAPACITY

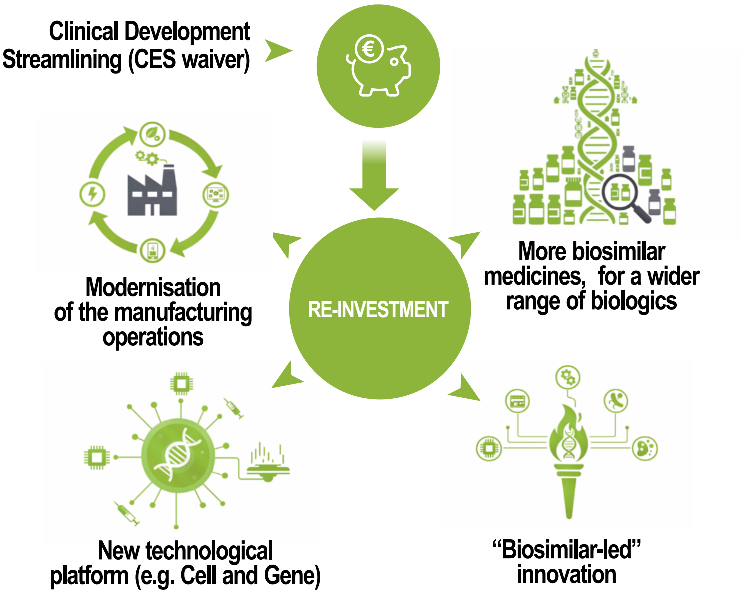


- The Biosimilar industry has committed further European investment in R&D and manufacturing expansion (2025-2030):
- Both **drug substance** capacity and demand are **projected to grow, with projected demand rising by 30%**. By 2030, this will amount to 90% of the projected European capacity.

  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 refomr**
- **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**