Council of the European Union
General Secretariat

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Interinstitutional files:
2025/0406 (COD)

Brussels, 08 June 2026

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LIMITE

SAN	**COMPET**
PHARM	**RECH**
AGRI	**PI**
AGRILEG	**FOOD**
ENV	**FEED**
CODEC	**VETER**
BIOTECH	**DENLEG**

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés)
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission

Delegations will find attached the presentation given by the Commission on the European Biotech Act staff working document at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 8 June 2026.

European Biotech Act

Staff working document

DG SANTE

08 June 2026



European Commission

#HealthUnion

Purpose and structure of the SWD

The SWD presents the expected impacts of the measures set out in the proposed Regulation and the proposed Directive (collectively referred to as the 'Biotech Act') based on supporting studies, stakeholder input and available evidence.

Structure:

- Background on the sector
- Problem definition
- Objectives & intervention logic
- Description of measures (presented in 17 packages of interventions)
- Analysis of impacts per package of interventions
- Analysis of cumulative impacts
- Monitoring and evaluation

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Political and policy context in the SWD

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Biotech is an area of strategic importance: a critical technology, key for competitiveness, resilience and modernisation of the EU economy. The SWD presents the BTA interaction with existing frameworks and its alignment with the broader EU innovation and competitiveness agenda.

Existing legislative framework

The SWD refers in particular to:

- Clinical Trials Regulation
- ATMP Regulation
- SoHO Regulation
- Veterinary Medicinal Products Regulation
- Legislation on human organs transplantation
- Food and feed legislation
- GMO deliberate release Directive

Institutional and policy background

- The Competitiveness Compass
- The Life Science Strategy
- The Communication on Biotechnology and Biomanufacturing,
- The EU Economic Security Strategy,
- The reports by Enrico Letta, Mario Draghi and Sauli Niinistö,
- Council conclusions on competitiveness and biotechnology,
- European Parliament resolutions on biotechnology and biomanufacturing.
- AI and data strategies

The problem in numbers

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Not unique to Biotech...

The EU competitiveness gap vs the US and China is a cross-sector challenge shared by tech, industry and beyond.

But Biotech is different

Long development timelines, capital intensity, and high failure rates make biotech uniquely hard to fund and scale — even within tech sectors.

€40bn
annual EU investment gap
(EIB estimate)

9x
more late-stage VC in US vs EU biopharma
€219bn US vs €25bn EU (2015-2025)

18% → 9%
Decline in the EEA share of global trials

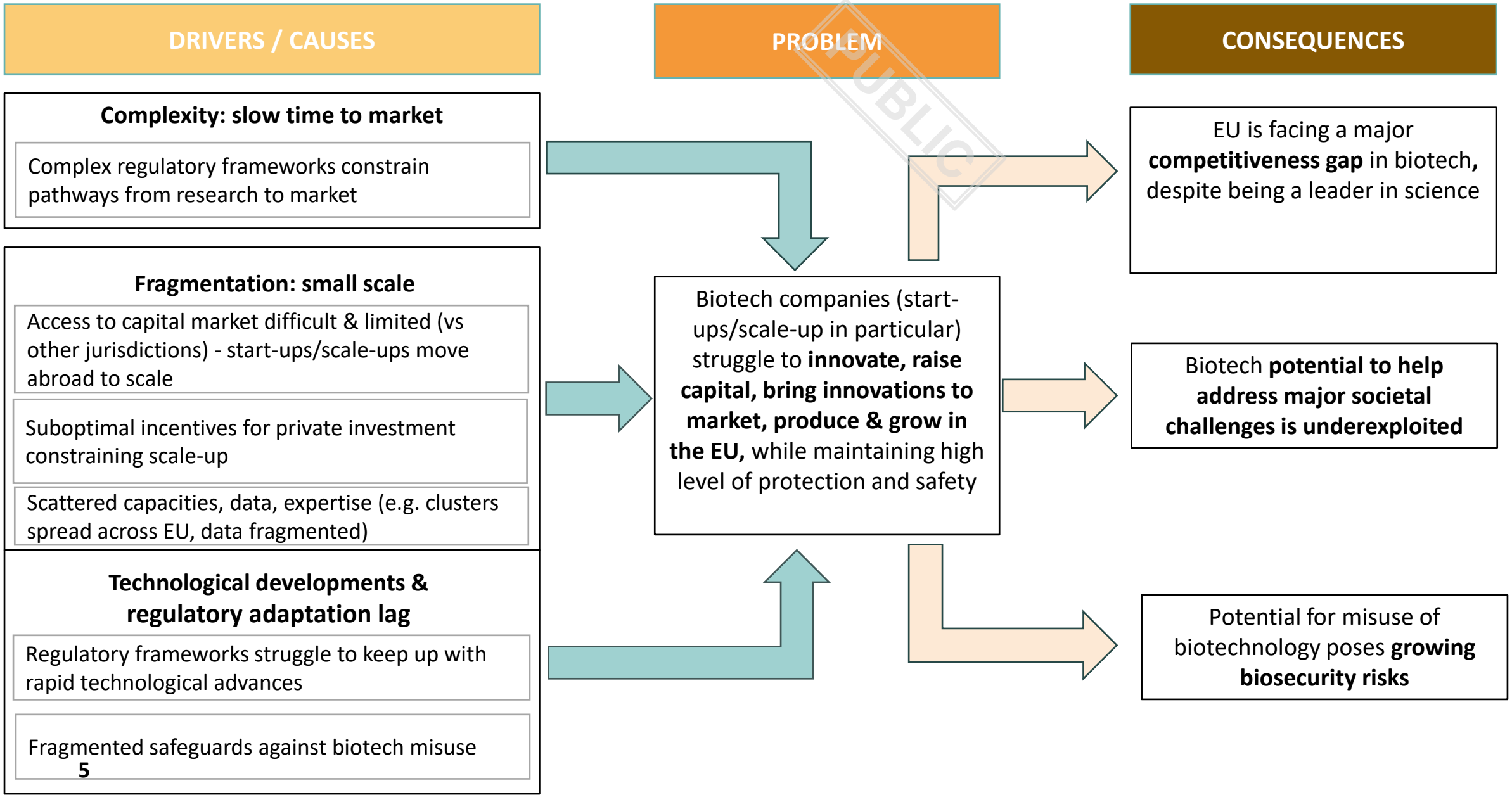
106 days
Authorisation timeline for multinational CT

≤10%
of EU health biotech start-ups raise >€10M

→ Massive healthcare & economic impact. High risk. Long timelines. But it can still be turned around — if we act now.

Biotech act aims to turn this around…

Problem tree



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Intervention logic

DRIVERS / CAUSES

Complexity: slow time to market

- Complex regulatory frameworks constrain pathways from research to market

Fragmentation: small scale

- Access to capital market difficult & limited (vs other jurisdictions)
- Suboptimal incentives for private investment constraining scale-up
- Scattered capacities, data, expertise (e.g. clusters spread across EU, data fragmented)

Technological developments & regulatory adaptation lag

- Regulatory frameworks struggle to keep up with rapid technological advances
- Fragmented safeguards against biotech misuse

GENERAL OBJECTIVES

Improve **internal market functioning** through a framework to strengthen health biotech sector **competitiveness**

Create conditions for **development & timely placing on the market** of biotech innovations, products, services

Maintain high standards for the protection of human & animal **health**, patients and consumers, the environment, **food and feed safety**, **biosecurity** and other **societal objectives**.

SPECIFIC OBJECTIVES

Reinforce EU R&D development and production capabilities

Support investments & access to finance

Improve manufacturing capacity & expertise in biosimilars

Facilitate AI application in EU biotech

Ensure innovation-friendly legislative framework for health biotech

Prevent biotech misuse &strengthen biodefence capabilities

Ensure legislative frameworks (clinical trials, VMP, food & feed safety) enable policy measures' effectiveness

AREAS OF INTERVENTION

Regulatory streamlining and future proofing (health, food, non-food GMM)

Access to finance

AI & Data

Health Biotech Strategic projects & Clusters

Biosimilar & Innovative biotech

Biosecurity & Biodefence

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Methodology

Evidence base and stakeholder consultation

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Stakeholder consultation activities:

- Call for Evidence: 222 valid responses and 149 attachments
- Public Consultation: 464 responses and 119 attachments
- targeted interviews, workshops, surveys and expert consultations

Main analytical support for the SWD:

- 'Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU' -> assessing significant impacts of Biotech Act measures

Other supporting studies and evidence sources

- **'Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU'**
- **'Landscape analysis study of the biotechnology sector in the Union with a view to foster its competitiveness and innovation'**
- Evidence and data provided by European Medicines Agency

Example of additional supporting evidence:

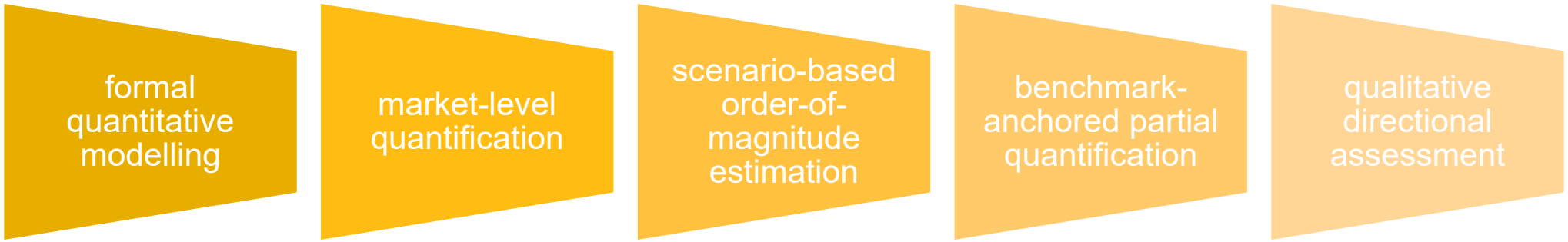
- 'Study supporting the Performance Evaluation of the European Food Safety Authority 2017–2024'
- JRC case study and pipeline analysis on GMMs
- 'Fast-track landscape analyses to assess the regulatory clinical trial eco-system in the EU/EEA and in other relevant regions'

Analytical framework and methodology

- **Overarching analytical framework –** aligned with Better Regulation rules: structured analytical sequence (baseline development, impact assessment and cumulative impact analysis)
- Common analytical framework applied across the 17 policy intervention assessments -> **common impact dimensions** (as relevant for each intervention)**:**



- **Impact estimation approaches** were calibrated to the nature of each intervention and available evidence, ranging from:



- **Time horizon:** near-term 2025–2030, medium-term 2030–2038 -> Adapted where necessary depending on intervention logic and sectoral dynamic

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Areas of intervention and selected impacts

Areas of intervention as analysed in the SWD

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Interventions for regulatory simplification:

1. Regulatory facilitation for novel health biotechnology products
2. Targeted regulatory reform of the General Food Law Regulation
3. Targeted regulatory reform of the Advanced Therapy Medicinal Products (ATMPs) framework
4. Targeted regulatory reform of clinical trials
5. Targeted regulatory reform of Veterinary Medicinal Products framework (VMPs)
6. Targeted regulatory reform of the substances of human origin (SoHO) framework
7. Targeted regulatory reform of the Directive on the deliberate release into the environment of GMOs
8. Targeted regulatory reform of the Directive on human organs intended for transplantation

Interventions on industrial enablers:

9. Strategic projects framework
10. High-impact projects framework
11. Health biotechnology ecosystem support framework
12. Biosimilars competitiveness framework
13. SPC extension for biotechnology medicines
14. Facilitating access to funding
15. Use of Artificial Intelligence and Data
16. Prevention of biotechnology misuse
17. Biodefence

Regulatory simplification – measures and selected impacts

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Intervention 1: Regulatory tools for novel health biotech products

- Regulatory status repository
- Health Biotech Support Network
- Foresight Panel
- Regulatory sandboxes

➢ Make the EU regulatory system more predictable, efficient, and innovation-friendly without compromising safety requirements.

➢ Benefit-to-cost ratios ranging from 3/1- 10/1 over three to five years.

Intervention 2: General Food Law Reform

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- EFSA's Pre-submission advice broadened and simplified
- Reduction of procedural consequences regarding noncompliance with the notification of studies
- EFSA to chair Scientific Panels/Committee (with no voting rights)
- Broader EFSA's mandate on nutrition

➢ Reduced dossier costs resulting from delays and faster market access for food chain products, supporting innovation and ensuring coherence

Intervention 3: Advanced Therapeutic Medicinal Products

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1. Risk-proportionate ERA exemption

ERA exemption for ATMP gene therapies with no/negligible GMO risk

Sponsors exempt from Environmental Risk Assessment for clearly low-risk GMO-ATMPs during clinical trials. ERA still required at marketing authorisation — safety fully maintained.

2. Future-proofed ATMP definitions

Delegated power to amend tissue-engineered product definitions

Resolves classification gaps: acellular therapies, in vivo tissue generation, and bio-synthetic hybrids fall outside the current definition, which assumes ex vivo manufacture.

Baseline

- Currently, EU presents 22.1% of global gene therapy market share (At risk vs North America & APAC without reform)

Impacts

- **Reduce administrative burden in the authorisation procedure**
  => Expected to remove approximately 0.15–0.3 FTE years of effort per CTA.
- **Enable ATMP gene therapy sponsors to benefit from the reform across more than 20 Member States, particularly SMEs and academic developers.**
  =>Support more than 580 ATMP developers in the EU and facilitate further expansion of the developer ecosystem in the region.

Intervention 4: Targeted regulatory reform of clinical trials

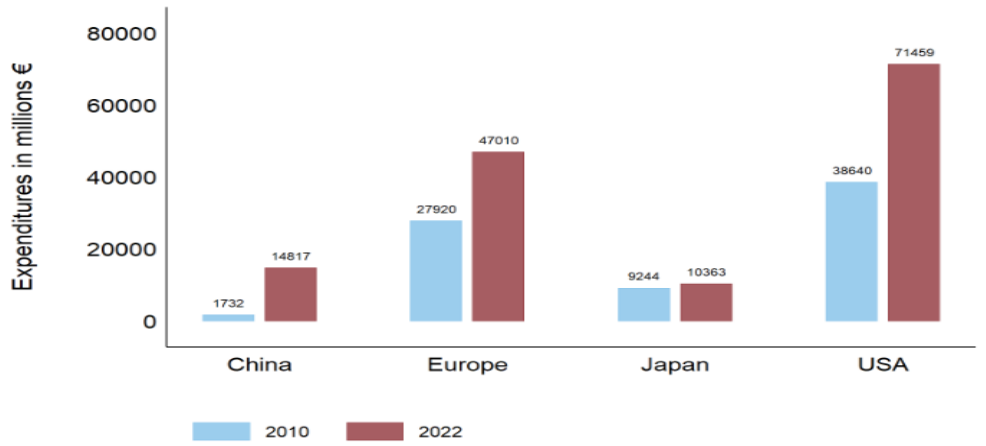
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Baseline

Clinical Trial Activity

- **Globally the number of clinical trials has been substantially increasing over the last decade.**
- **Shift in geographical distribution of clinical trials.**
  - **EEA's share of global clinical trials declined from 18% in 2013 to 9% in 2023**
  - China's share increased from less than 10% to nearly 30%

Pharmaceutical R&D expenditures*



Key Take-aways

- **PAST TREND:** The EU did not capture a proportional share of the growth in clinical trials.
  - ➢ Leading to a **widening competitiveness gap** relative to other regions with potential implications for **economic performance and patients in the EU.**
- **FUTURE:** Risk of this gap widening further unless the regulatory framework is strengthened to increase the attractiveness of conducting clinical trials.

- approximately 60% of the expenditures can be on average allocated to clinical trials (Source: EFPIA report 2024)

Intervention 4: Targeted regulatory reform of clinical trials

Accelerated authorisation timelines	• Faster assessment timelines for initial applications and substantial modifications • Removal of extra 50-day assessment phase for ATMP trials
More predictable and efficient authorisation procedures	• Greater reliance on the reporting Member State • More predictable timelines (7-day system) • Introduction of a product core dossier containing documents common elements to all trials with the same medicinal product • Increased inclusivity through increased participation rights for vulnerable population
Context-specific authorisation procedures	• Single assessment procedure for combined studies • Fast-track authorisation procedure in the context of Public Health Emergencies • Strengthened risk-proportionate approach
Innovation and Harmonised Data Governance	• Integration of AI and digital tools • Decentralised trial elements, including direct shipment to patients and e-informed consent • Regulatory sandboxes • Single legal basis for processing of personal data
Governance and Enforcement	• Increased trust and reliance between Member States • Supervision by Member States

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Intervention 4: Targeted regulatory reform of clinical trials

Impacts

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~ 10% to 30% more clinical trials in the EU

Economic Impacts

Competitiveness: Boost competitiveness based on survey results from industry, academics and Member States

Commercial Trials

Economic gains: EUR 3.6bn to EUR 10.7bn per year

- **GVA:** EUR 2.2bn to 6.5 boost GVA
- **R&D spill-over:** EUR 0.4bn to EUR 1.1bn
- **Work productivity:** EUR 1bn to EUR 3.1bn

Employment: 16,500 to 49,500 additional jobs per year

Simplified cost-benefit analyses (based on different methodologies and assumptions)

(1) Annual cost-savings of EUR 1.24bn for a subset of policy measures included the proposal

(2) Annual direct cost savings for sponsors of EUR 1.5bn to 3.1bn and indirect savings of the same amounts for sponsors (considering the total set of measures included in the proposal)

Public Health Impacts

Increased inclusivity

- through strengthened rights for vulnerable population
- Introduction of decentralised elements

Additional participants enrolled per year

- **in commercial trials:** 7,847 to 23,540
- **in non-commercial trials:** 10,381 to 31,145

➢ **Increased access to new treatments by 5 to 10 years**

Intervention 6 – SoHO Framework

- **Binding time limits for regulatory status consultations via implementing acts**
- **New regulatory sandbox for SoHO innovations**: flexible pathway for 5–10% of SoHO activities currently without a clear regulatory route
- **Reduced uncertainty** and early dialogue speed up process (-40%), common/joint sandboxes build harmonized approach, tailored to open/public innovation
- SoHO framework responsive and adaptive to scientific and technological advances — supporting the safe introduction of 9-40 new therapies/year for 350-4000 patients.

Intervention 5 – Veterinary Medicines

- **GMO-VMP exemption**: 1–3 month CT application saving; €5–14.5m cumulative admin savings
- **Variations reform**: €22.5m PV staff savings; 45–55% fewer submission events
- **SPC extension for zoonotic biotech VMPs** → EU manufacturing incentive
- €2.5m/year vs. fee savings for applicants + €150–300k one-off EMA IT cost (variations reform)

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Intervention 7: GMM deliberate release

- **Tailored risk assessment and authorization procedure** for GMMs aligning with latest scientific evidence
- **Accelerated authorization path** for GMMs meeting certain conditions
- **Contribution to various fast-growing bio-based sectors**, e.g. biofertilisers with projected global market by 2030 of €2.5 – 4.5bn and projected CAGR of 10-13%
- Reducing regulatory costs and uncertainty, clarifying a route to market for GMMs, render more projects investable, thereby supporting innovation

Intervention 8: Organs

- **Increase organs available for patients on transplant waiting lists -** 1,435 additional transplants/year by 2035 (around +5%)
- **Coherence** when organ processing requires use of medicinal products or other therapies under other EU frameworks
- Common EU-wide approach, essential to allow **cross-border exchange** and optimal matching/use of limited nr of organs
- MS share and leverage assessments and authorisations - **administrative simplification** that speeds up EU-wide uptake of new transplant technologies
- Facilitate Organ processing innovation by achieving legal clarity, streamlining and coherence

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Industrial enablers - measures and selected impacts

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	Impacts
Intervention 9: Strategic Projects	**Single contact points · 10-month permitting · Public interest status** → 60–70 projects (medium uptake scenario) -> €15–28bn mobilised investment
Intervention 10: EU High-Impact Projects	**8-month permitting · Priority funding access · Biotech accelerators** → 12–15 projects (medium uptake scenario) -> €4–12bn mobilised investment
Intervention 11: Ecosystem Enablers	**EU Health Biotech Support Network · Cluster mapping · Steering Group coordination** -> complement and enhance the impacts of other industrial enablers

🎯 **Combined impact: Up to €40bn in mobilised investment by 2038**

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Intervention 12: biosimilars competitiveness framework

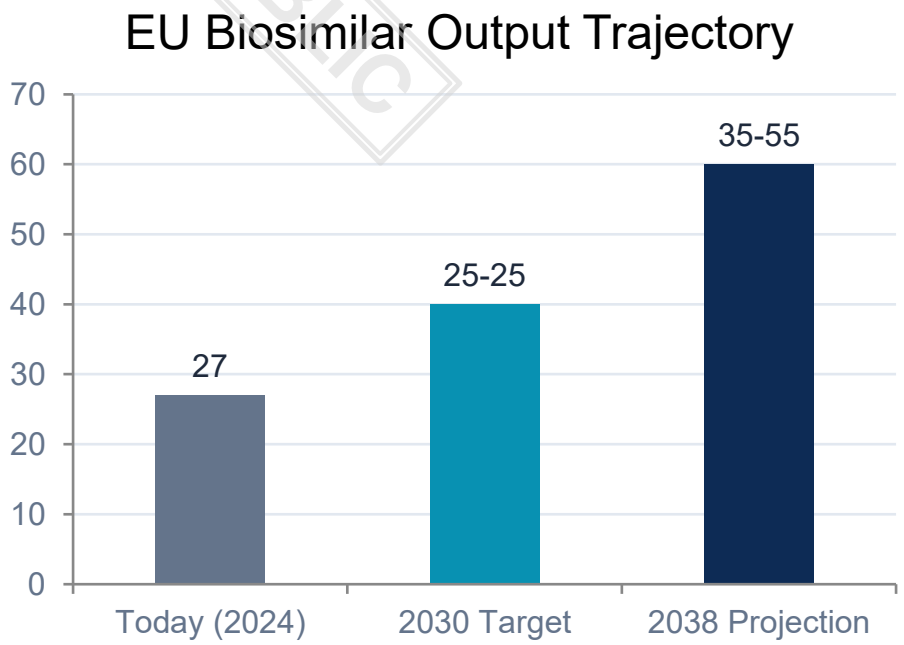
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Baseline

- EU leads in approvals: 151 vs. 72 in the US
- But manufacturing is migrating to Asia
- 79% of biologics losing exclusivity by 2032 have NO biosimilars in development

Impacts

✓ EMA guidelines: tailored risk-proportionate CES requirement*
✓ Strategic projects: €0.9–7.6bn for EU manufacturing by 2038
✓ 12–18 months faster to market



***€1.5–2.8bn/ 5 years**

from biosimilar market expansion

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Intervention 13: SPC extension for biotechnology medicines (human medicinal products)

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Reminder: eligibility conditions

12-month extension

Added on top of the existing SPC (max 5 ½ *-year patent extension) for biotech medicines and ATMPs.

First-in-class Breakthrough

New active substance + mechanism of action must be distinctly different from any already-authorised product for the same disease.

EU clinical trials

Late-stage trials must be conducted in more than two Member States.

EU manufacturing

At least one manufacturing step (excluding packaging and QC) must be performed in the Union.

Financial impact per +1 year of protection

	Per medicine	Annual (3 products)
Originator gross profit	EUR 230m	EUR 690m
Biosimilar gross profit	− EUR 80m	− EUR 240m
Cost to public payer	EUR 70m	EUR 210m
Economic impact of deferred patient coverage	EUR 135m	EUR 405m
Payer + patient combined	EUR 205m	EUR 615m

Scope:

- ~2–3 products/year currently
- up to 5/year if more sponsors comply with EU trial + manufacturing conditions.

- Based on 12 SPC-reliant biologics (2016–2024), avg revenue EUR 740m/product prior to expiry.
- List prices; net prices would be lower.

*6 months if a PIP is completed

Intervention 15: Use of AI & Data

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High impact projects: trusted AI-enabled biotechnology testing environments & biotechnology data quality accelerators

Illustrative uptake scenarios	Impacts		
	Low uptake	Medium uptake	High uptake
Recognised projects	2–3 testing environments and accelerators	5–8	10–15
Companies and data users served per year	20–45 companies; 100–450 data users	100–200 companies; 1,000–3,200 data users	250–600 companies; 4,000–12,000 data users
Infrastructure investment	EUR 85–205m	EUR 650m–1.3bn	EUR 2.4–7.2bn

Combined with EMA guidance on the use of advanced technologies, impact would be:

Innovation and research
- reduced regulatory uncertainty
- improved validation capacity
- improved usability and interoperability of datasets
- support for translation of research into scalable innovation

Competitiveness and investment attractiveness
- reduced firm-level validation constraints
- improved access to shared infrastructure
- lower data fragmentation and “data friction”
- stronger enabling conditions for AI-enabled biotechnology development in the EU

- **Public health and safety**
- improved validation of AI-enabled biomedical tools
- support for more reliable and consistent deployment of AI-enabled products

Intervention 14: facilitating access to funding

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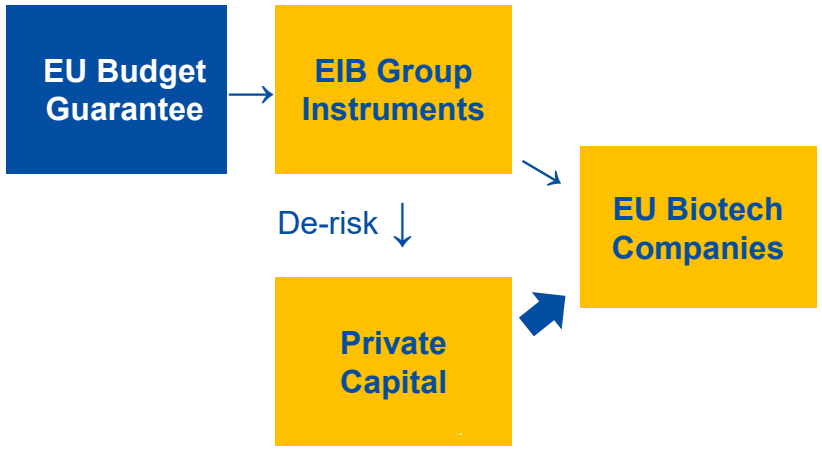
EU Health Biotechnology Investment Pilot

Partnership: EIB Group and European Commission

Goal: Tackle €40 billion EU – US annual investment gap

Combines instruments along investment life-cycle:
- Start-ups → EIF-backed equity investments
- Scale-ups → EIB venture loans
- Corporates → EIB corporate loans

Investment Flow



Impacts Scenario analysis over 7 years

	EU budget guarantee needed	Total investment mobilised
Continuation	€ 2.2 bn	~€70 bn
Closing 25% of investment gap	€ 4.5 bn	~ €140 bn
Closing 50% of investment gap	€ 6.7 bn	~€210 bn

Intervention 16: Prevention of biotechnology misuse

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Threat

- Biotech progress also increases biorisk
  - DNA synthesis costs fell 100x over 20 years
  - Makes dangerous pathogen material more accessible
- Annual risk estimate:
  - 1% deliberate attack
  - 1.5% accidental release

Intervention

- Providers verify customer identity and legitimate need
- Only for highest-risk products: DNA of dangerous pathogens
  - (= critical bottleneck for attacks/accidents)
- **Harmonises common industry practice**
  - Replacing fragmented national rules
  - In line with US & UK frameworks

Impacts

Cost

- Targets narrow segment: custom DNA is ~0.1% of EU biotech market
- Practical for firms
  - ~0.5-1 FTE → €10.5 million annually across ca. 70 firms
  - Costs falling as tools automate

Estimated annual cost (incl. indirect): **~€176m**

Benefit

- ~98% of EU orders screened; +10% non-EU orders screened
- Reduces misuse risk ~35% and accident risk ~86%
- Shields biotech sector from backlash or a research pause after a serious incident

Estimated annual benefit: **~€2.9bn**

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Intervention 17: Biodefence

Threat

- Deteriorating security environment: Wars in Ukraine and Iran raise risk of release
- Biotech + AI broaden access to the means of misuse
  - Modelling: annual risk of an attack-driven epidemic could rise ~6x
  - Engineered pathogen could exceed COVID-19 in scale

Intervention

Biodefence capability projects: broad range of bioresilience projects qualify as high-impact strategic projects

- Particular consideration for funding in EDF & Horizon Europe

EU Biothreat Radar: high-impact strategic projects for early detection of biological threats

Impacts

- **Cost**: two scenarios for environmental + traveller genomic surveillance (incl. sequencing, processing & analysis)
  - Scenario 1: **~€46.5m/year**
  - Scenario 2: **~€110m/year**
  - ECDC estimates **€25m coordination & €20m lab costs** over 7 years
- **Benefit**: earlier detection results in fewer deaths, lower illness costs, shorter lockdowns

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Cumulative impacts

The Biotech Act as a systemic competitiveness reform for Europe’s biotechnology ecosystem.

Regulatory simplification and administrative burden

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Shorten time-to-market/patient and reduction of burden is key competitiveness driver

Clinical Trials Reform

EUR 1.5–3.1 bn/year direct cost savings for sponsors.

Biosimilars

50 - 75% reduction in Biosimilar CES trials; 12–24 months faster development, equaling EUR 0,7 - 2.8 bn/5-year savings
Or EUR 222–467m annual savings across the sector.

CT Digitisation savings

EUR 112–225m savings over 15 years; standardised digital-by-default handling.

SME Focus

Reduction in fixed-cost compliance burdens & improved access to infrastructure and data resources for innovation/scale-up

EUR 5.2–5.5 bn

combined annual regulatory cost savings for sponsors across CT and biosimilar reforms

EUR 3.6–10.7 bn

Economic gains from commercial CT increase' (10-30%)

16,500–49,500

additional jobs from trial growth

Competitiveness and investment attractiveness

The EU faces a EUR 40 billion annual investment gap vs the US. The Biotech Act proposes targeted instruments to close it.

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Strategic projects	Financing Instruments	Biosimilars & SPC
▸ Strategic projects: EUR 15–28 bn mobilised by 2038	▸ EU Health Biotech Investment Pilot targeting EUR 40 bn gap	▸ EU biosimilar market: ~EUR 17 bn (world's largest)
▸ High-impact flagship tier: EUR 4–12 bn additional	▸ BioTechEU: aims to mobi-lise EUR 10 bn in 2026–2027	▸ Biosimilar reform: 12–24 months faster market entry
▸ Combined: EUR 19–40 bn total investment	▸ Medium scenario: EUR 41.6 bn mobilized over 7y	▸ SPC extension: ~EUR 230m additional gain/product/year
▸ Delay cost avoidance: EUR 265m–1.16 bn	▸ Reduces annual investment gap ~EUR 10 bn/year	▸ EU market share maintained at 45–55%

Innovation and research

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Europe leads in biotech publications but struggles to translate science into clinical and commercial products. Three channels address this.

Channel 1: Regulatory Sandboxes

Regulatory readiness of frameworks, resolving regulatory uncertainty for very innovations products which challenge existing requirements

Channel 2: Financing & Infrastructure

Investment Pilot targets EUR 40 bn gap. High-impact projects support 4–40 additional trial applications/year and 60–600 firms annually. BioTechEU mobilises EUR 10 bn in 2026–2027.

Channel 3: AI & Data Framework

1,100–3,400 companies served/year (medium uptake). EUR 650m–1.3 bn in infrastructure investment. 14-month average reduction in development timelines.

KEY METRICS

14 months
avg timeline reduction

18%
trial timeline reduction with AI

EUR 1.3 bn
max AI/data infrastructure

3,400+
companies served / year

Public health and safety

Competitiveness gains translate directly into concrete health outcomes for EU patients and healthcare systems.

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Patient Access — Biosimilars	Organ Transplantation	Supply Resilience & Biosecurity
EUR 22–35 bn/year healthcare savings by 2035–38	**~1,435** additional transplants/year by 2035	**18–60** EU biomanufacturing deployments by 2038
EUR 300–450 bn cumulative savings	**EUR 158 m** cumulative dialysis cost avoidance	**35% / 86%** reduction in biological misuse / accident risk…
79% of 100 biologics losing exclusivity by 2032 have no biosimilar in development	**EUR 443–695 m** total monetised benefit 2028–2035	**EUR 5.5 bn/yr** … resulting in expected annual benefits by 2036

EU Regulatory Sandboxes as regulatory tools in BTA and other recently revised legislation

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EU Regulatory Sandboxes as regulatory tools in BTA and other legislation

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Main Objective
Regulatory sandboxes facilitate innovation by allowing highly innovative products, technologies, services, or regulatory approaches to be tested and developed under adjusted regulatory requirements, where further development under ordinary rules would be impossible or severely hindered.

EU Regulatory Sandboxes as regulatory tools in BTA and other legislation

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Objectives and characteristics

Support Innovation
Offer products, whose development is hindered as they challenge regulatory frameworks, regulatory options

Exceptional & targeted
Reserved for very innovative products that cannot be accommodated by standard rules — not an alternative

Tailored approach
Not a fast-track, not a direct path to market — a time-limited, dialogue-driven pathway for regulatory-challenging

Regulatory learning
Signal to innovation; builds regulatory readiness and capacity.

Controlled and time limited
Products are tested in a supervised environment under a sandbox plan agreed with competent authorities.

Evidence-generating
Evidence generated can feed the authorization process (or adapted framework), and regulatory learning

Safety preserving
Strict conditions safeguard public health, animal health, and food safety throughout the sandbox period.

Cross sector
BTA: dialogue between sandboxes and subsidiary sandbox for novel health biotech products

EU Regulatory Sandboxes as regulatory tools in BTA and other legislation

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Sandbox & Legal Basis	Authority	Output	
Clinical Trials (CTR) Art. 27d — BTA Art. 58	European Commission	Validation of new clinical trial approaches	BTA New
Subst. of Human Origin (SoHO) Art. 39a — BTA Art. 61	Member States	Support for evidence generation	BTA New
Veterinary Medicines (Animal Health) Art. 136a — BTA Art. 59	European Commission	Market placement through a Commission decision	BTA New
Food chain inputs incl. GMOs Art. 49a, 49b, 49c GFL — BTA Art. 56	Member States	Testing products/ data & regulatory requirements	BTA New
Medicinal Products Arts. 113–115 pharma legislation	European Commission	Guidance on evidence generation	Pharma
Medical Devices (MDR/IVDR) Arts. 59b/c, 54b/c	Member States or European Commission	Real-world use & validation of regulatory approaches	MDR
Subsidiary Sandbox Art. 40 BTA	European Commission	Recommendation on most appropriate regulatory pathway	BTA New

EU Regulatory Sandboxes as regulatory tools in BTA and other recently revised legislation

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Purpose

Accommodates very innovative (novel) health biotech products that do not fit any existing area-specific sandbox framework.

Novel products only



Benefit

- Offers the developer a regulatory option where none exists today — removing a critical barrier to development.
- Allows the regulator to gain deeper understanding of highly novel products.

Fallback regulatory pathway - Deeper regulatory insight



Outcome

Facilitates access of very innovative products into the regulatory system by eventually referring them to the most appropriate framework.

Pathway to right framework

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Thank you



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