EU Biotech Act

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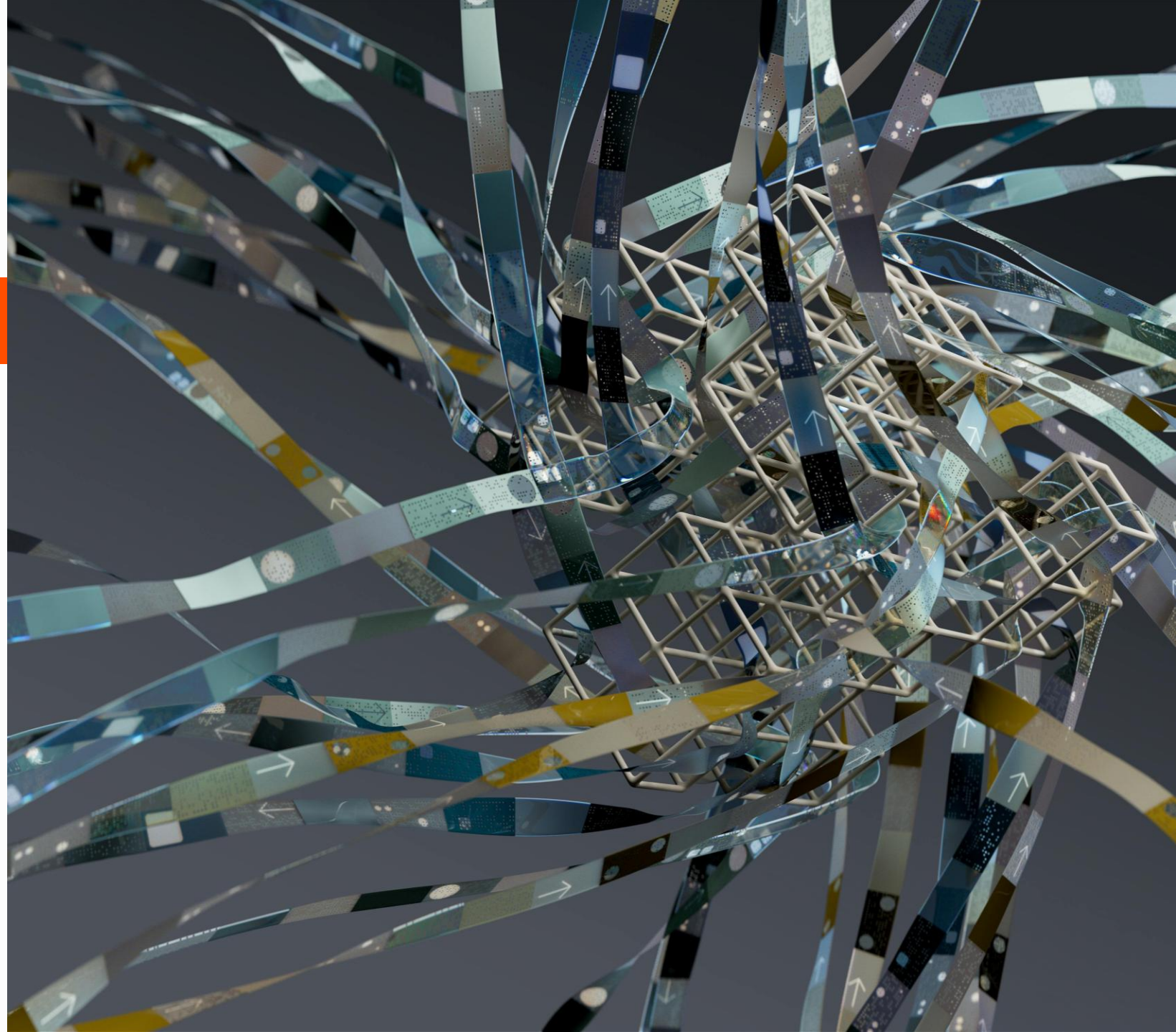
The context



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European life science sector – state of play

Draghi Report: *"The EU's position in other innovative sectors like pharma is declining due to the same challenges of low investment in R&I and regulatory fragmentation."*

EFPIA Barometer: *Europe struggles to translate scientific excellence into research investment, clinical trials and new medicines.*

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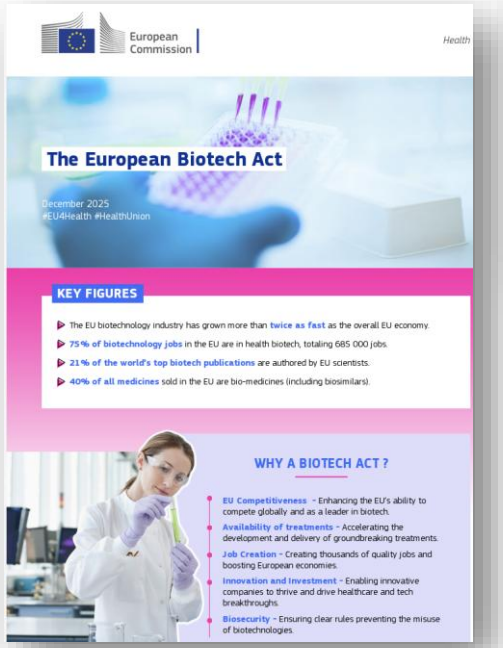
EU Biotech Act – part of a broader EU strategy

EFPIA's call for a Competitiveness Strategy for European Life Sciences (June 2024)

Result: EU Biotech Act proposal (December 2025)



"We want to win this competition. We have no choice but to win. We cannot afford to lose that."

Olivér Várhelyi, EU Commissioner for Health and Animal Welfare

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The details

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Five core pillars of the innovation friendly ecosystem addressed in the EU Biotech Act

Incentives

SPC Extension – Ensuring an effective and legally certain incentive

01

Improvements to Clinical Trials ecosystem

Reduction of fragmentation and strengthened coordination

02

Strategic projects - From concept to competitive delivery

A stronger innovation ecosystem aligned with pharma footprint

03

Access to funding

Extended duration of the pilot & ensure ambition and accessibility of funding instruments

04

AI Governance and access to data

Avoiding duplication and ensuring coherence

05

European eco-system that transforms ideas into innovation

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CTs: Current EU framework and challenges

The Clinical Trials Regulation (CTR) establishes the EU's current framework for clinical trials (2014). While it was officially adopted in 2014, **it became fully applicable on 31 January 2025.**

Objectives

Ensure the EU provides an attractive, safe, and transparent environment for large-scale clinical research.

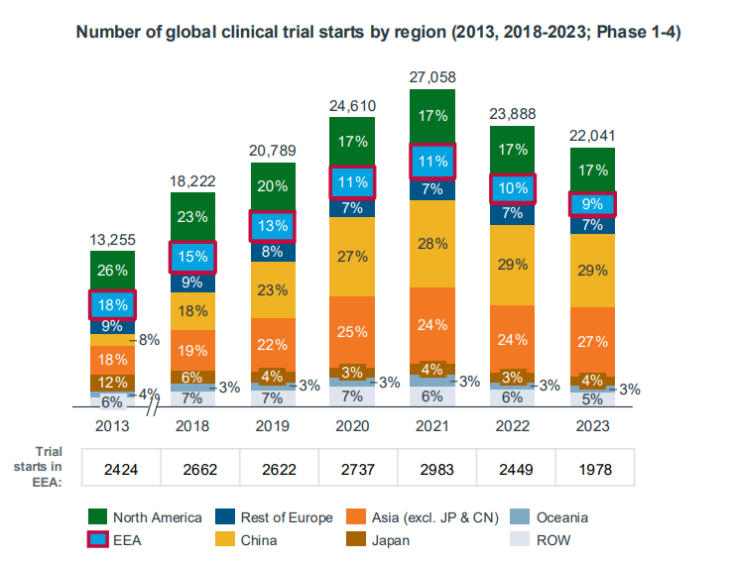
Harmonise assessment and supervision processes across the EU to facilitate multi-country trials.

Promote innovation and research in the EU.

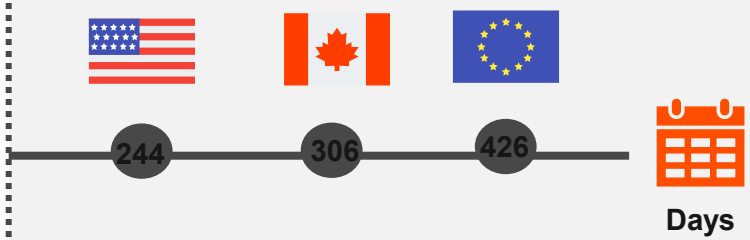
Existing challenges

1. Fragmentation and complexity*

2. Declining share of global commercial trials**



3. Slow new active substance approval timelines compared to other regions***



**Source:* European Commission data (2025)

***Source:* EFPIA, Assessing the CT ecosystem in Europe (2024)

**** Source: The Pharmaceutical Industry in Figures (2019)*

Act

What do EFPIA want to see?

faster, smarter, and more patient-centred clinical trials

Accelerate timelines for clinical trial start-up and assessment, to support a globally competitive ecosystem.

Ensure a single, streamlined process for multi-country trials, without additional national requirements.

Avoid duplications in review of separate clinical trials by introducing a reusable Core Dossier concept.

Improved life-cycle management by enabling parallel submission of substantial modifications and other simplifications.

Invest in future innovation through sustained funding for clinical research infrastructure, strengthening EU trial sites, expert talent and digital tools.

Make CTIS work for users by ensuring the Clinical Trials Information System is simple, reliable, flexible, and user-friendly.

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What is in the Biotech Act?

1. Stronger role of the Reporting Member State

The reporting Member State's role will be strengthened so that it can lead the scientific, ethical, and regulatory assessment harnessing mutual trust between Member States and reliance on the assessment of the reporting Member State.

2. Strict timelines, faster outputs

The Clinical Trial Application timeline would be reduced from 106 to 75 days, or to 47 days where no RFI is issued, while the assessment period for substantial modifications would be shortened from 96 to 47 days, or to 33 days without an RFI.

3. Mutual trust and reliance

The Reporting Member State, as the lead for scientific and ethical assessments for Part I (and for common elements in Part II), leverages reliance between Member States in the trial thus seeking to make decisions more consistent, reducing duplicative RFIs and allowing trials to start more quickly without lowering protection for patients.

4. Quicker and more efficient Substantial Modifications

Substantial modifications can be assessed more quickly through shorter timelines and a coordinated review led by the reporting Member State. These modifications may be submitted in parallel and examined at the same time where they concern independent elements, avoiding sequential approvals and reducing delays during the conduct of a trial.

5. Introduction of a Core Dossier facility

Sponsors can establish a reusable "Core Dossier" reflecting a single set of key documents (like the manufacturing information for the product or the investigators (brochure) that stay the same across all clinical trials for the same investigational product. Instead of

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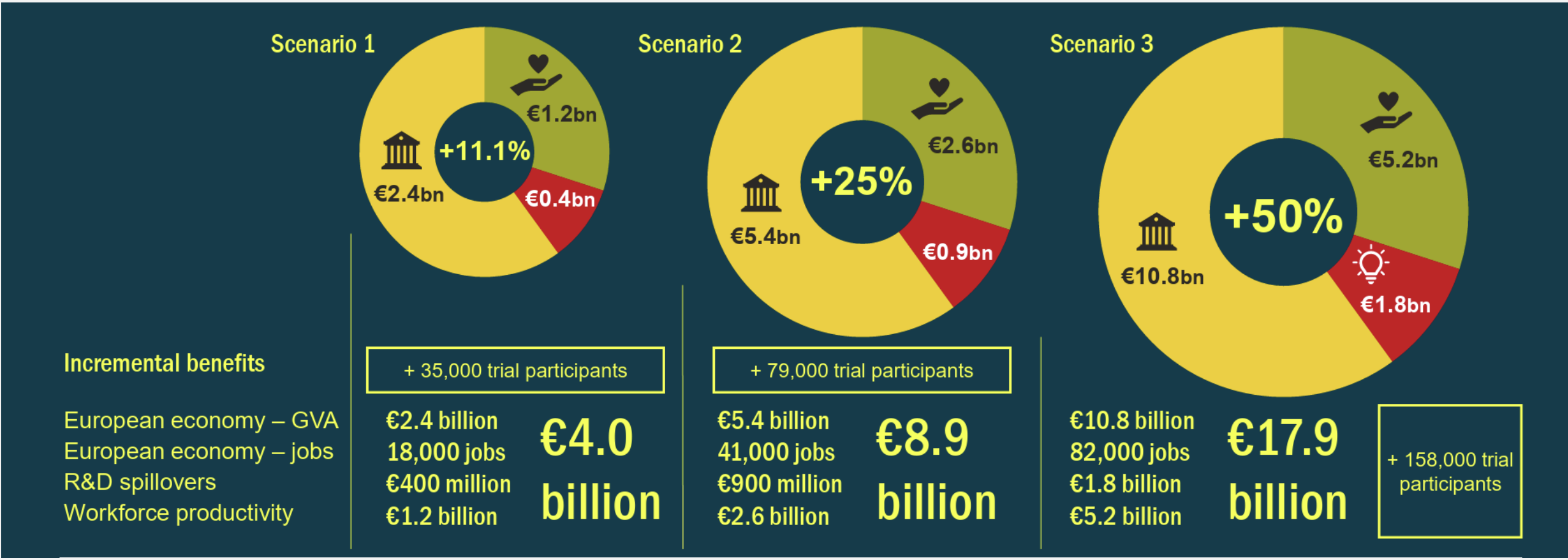
What could the EU Biotech Act deliver for European patients and economies?



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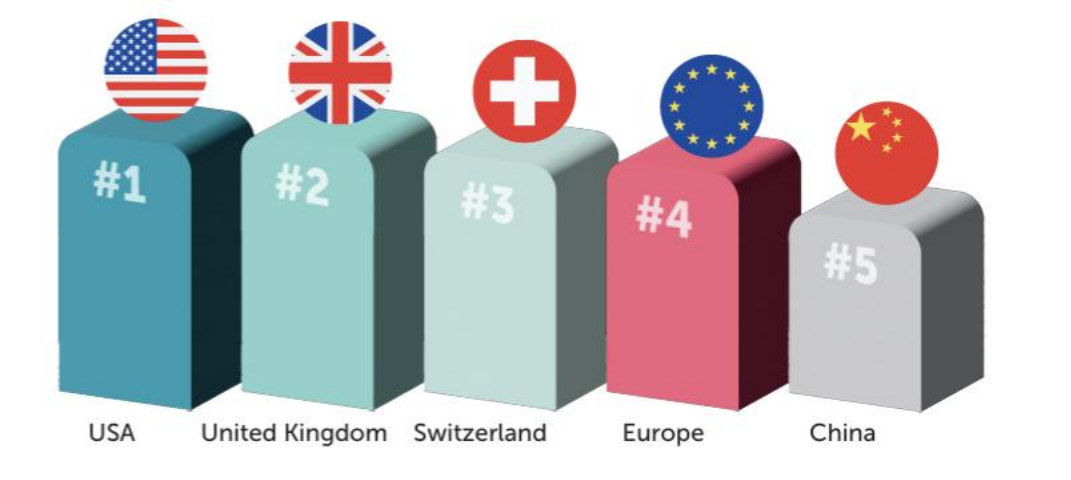
Source: Frontier Economics report

IP: Current EU framework and challenges

A robust IP system is critical to EU's competitiveness and economic growth



Source: EFPIA Barometer report

What is a SPC?

A **Supplementary Protection Certificate (SPC)** is an intellectual property right that **extends patent protection (PTEs) for medicinal product** in order to compensate for the effective **patent term lost due to the lengthy clinical testing and regulatory approval procedures** required before marketing authorization

Current Duration

SPCs take effect after patent expiry and **can last up to five years**, with total patent and SPC protection **capped at 15 years** from the date of marketing authorisation. A six-month **extension** is available for medicines that have completed an agreed **paediatric investigation plan**.

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What is in the Biotech Act?

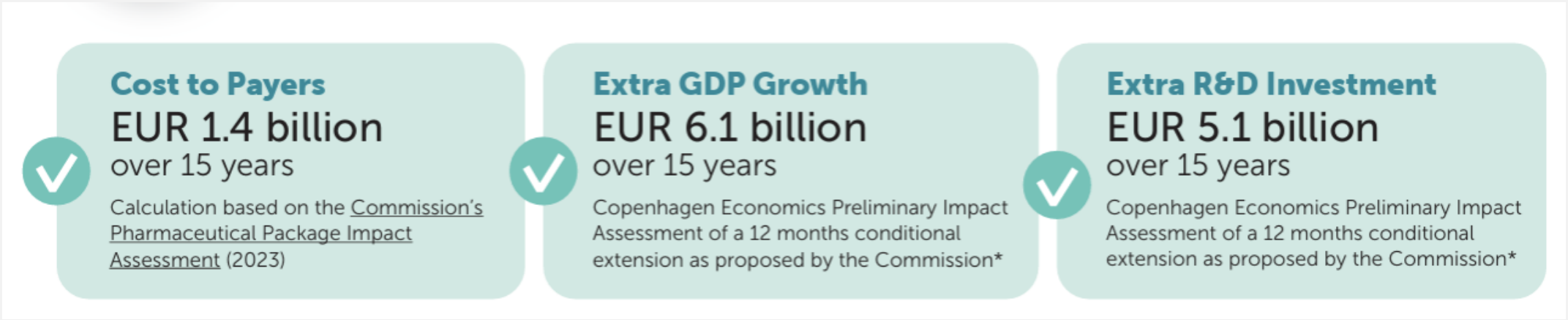
The EU Biotech Act proposal addresses SPCs with the objective of:

- Incentivising the development of innovative biotechnological products that deliver therapeutic benefits to patients.
- Supporting the clinical development, scale-up, and manufacturing of such products within the Union.

12-month extension of the SPC for products developed by means of biotechnological processes or to an advanced therapy medicinal product if 4 conditions are met:

- *new active substance distinctly different from any EU product*
- *mechanism of action distinctly different and level of safety and efficacy at least equivalent*
- *clinical trials in more than two Member States*
- *at least a manufacturing step in EU, excluding packaging, quality testing & certification*

What could Europe gain from extending SPC in the Biotech Act?



Source: Copenhagen Economics Report, April 2026

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Next steps

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Biotech Act I: Timeline and engagement opportunities

2025

Q2-Q4 2025
Open Call for Evidence and Public Consultation

16 December 2025
COM proposal for the Biotech I

2026

European Parliament negotiates and adopts position

Member States negotiate and adopt position

Q3 2026
COM proposal for the Biotech II

2027

Interinstitutional negotiations (Trilogues)

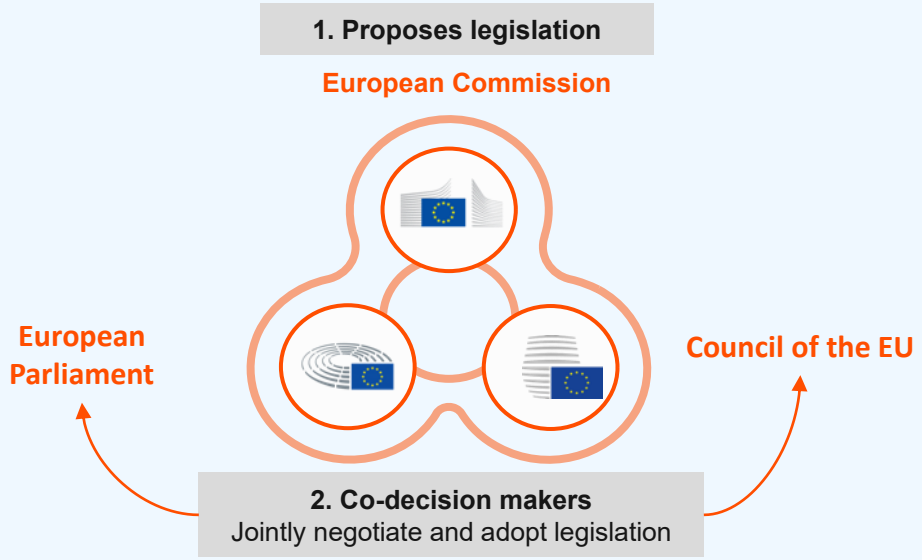
Formal adoption

2028

The new rules could apply in 2028 (tentative).

H2 2026 - 2027 Key window of opportunity to shape the Biotech Act I

Refresher: Roles of key EU institutions



Novartis proposals

The Biotech Act is a rare opportunity to strengthen Europe's life sciences competitiveness while improving patient access to advanced therapies. If implemented with ambition, and without dilution of its most meaningful levers, we believe it can become a cornerstone of a competitive, innovation-driven European biotech ecosystem.

To deliver on its ambitions, it must:

- ✓ *Ensure a minimum SPC extension of twelve months*
- ✓ *Apply a consistent, future-proof definition of biotechnology*
- ✓ *Protect ambitious clinical trial reforms and extend CTR to radiopharmaceutical trials*

Open discussion

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