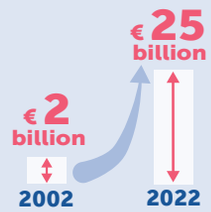
REGULATORY DATA PROTECTION

Closing the R&D investment gap between Europe and other regions of the world

Regulatory Data Protection is a type of **intellectual property protection** that is crucial to **incentivise innovators** to develop new medicines and new indications. It:

1) **Protects innovative companies' significant investment** in generating extensive preclinical and clinical data to demonstrate the quality, efficacy and safety of a medicine.
2) **Creates predictability and stability** for investors and companies, especially for complex therapeutics that take longer to develop.
3) **Is a critical investment consideration** for 100% of medicines and the last form of protection for 30% of medicines.

R&D investment gap between the US and the EU



What does that mean for Europe?

- ↘ Fewer opportunities to participate in clinical trials
- ↘ Longer delays to access innovative medicines
- ↘ Fewer jobs & slower growth
- ↘ Loss of know-how

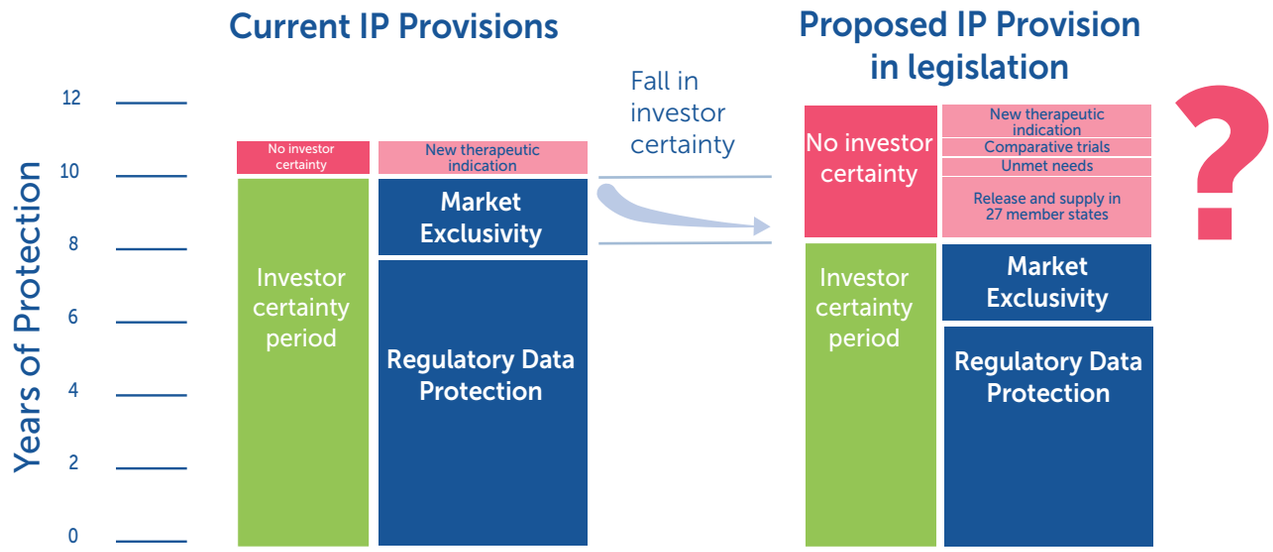
Why is the US more attractive for R&D?

	The US	Europe
1	A system prevents generics from launching before patent expiration and protects from IP infringements.	Non-existent
2	Immediate in all 50 states	Differs between 27 member states
3	Market-based	Regulated and subject to cost containment
4	12 years (4+8)	11 years (8+2+1)
5	5 years (6-7 effective market protection)	11 years (8+2+1)

Today, Europe's only advantage over the US is longer RDP for small molecules. Reducing RDP will make Europe even less competitive in the global race to attract life science investments, deliver new treatments to patients first and generate jobs and growth.

EU PHARMA LEGISLATION

12 years of conditional RDP: an impossible target for medicines' developers



Criteria to extend RDP in the Commission proposal are unclear and dependent on decisions outside of the control of medicine developers:

27 different processes

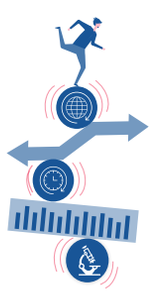
While IP rights depend solely on the innovative company, getting medicines to patients does not. Making the **recovery of 2 years of RDP dependent on release and supply decisions** which are in the hands of governments, payers, and providers, will undermine R&D in Europe while failing to address access to medicines for patients.

Introducing a narrow definition of unmet medical need risks excluding the development of important therapies for patients, as companies would have to adapt their research focus to fit the criteria.

Comparative trials are standard practice in some therapy areas, but in many clinical circumstances it is not possible to conduct such trials (e.g. small patient populations, therapy areas without a standard of care).

- Medicines meeting an unmet medical need for which there is no existing treatment will not be able to receive 1/2 year of RDP for completing comparative clinical trials.

This proposal would create an unpredictable system and force companies to plan investments based on a de facto 6 years of RDP.
This would impact decisions about which research projects to invest in, and where to invest.
This isn't in the best interest for patients: a shorter RDP baseline will only slow down R&D of new medicines in Europe.



In line with the March 2023 European Council Conclusions, Europe needs to strengthen, rather than cut, the region's RDP baseline as well as creating separate incentives to drive innovation and meet health care challenges.