Case for the European Commission revision of the Pharma Package: **Ensuring patients across the EU have timely and equitable access to safe, effective, and affordable medicines**

Accessibility

- Despite medicines receiving a marketing authorisation for the EU-27 when receiving European Medicines Agency (EMA) approval, very few are launched across all Member States within the initial years after approval
- Often, this means that western EU countries have access to more innovative therapies while eastern EU countries wait longer to access the newest treatments
- While there is no single market for medicines, due to national healthcare systems, this situation goes against EU's value of fairness and equality between EU citizens

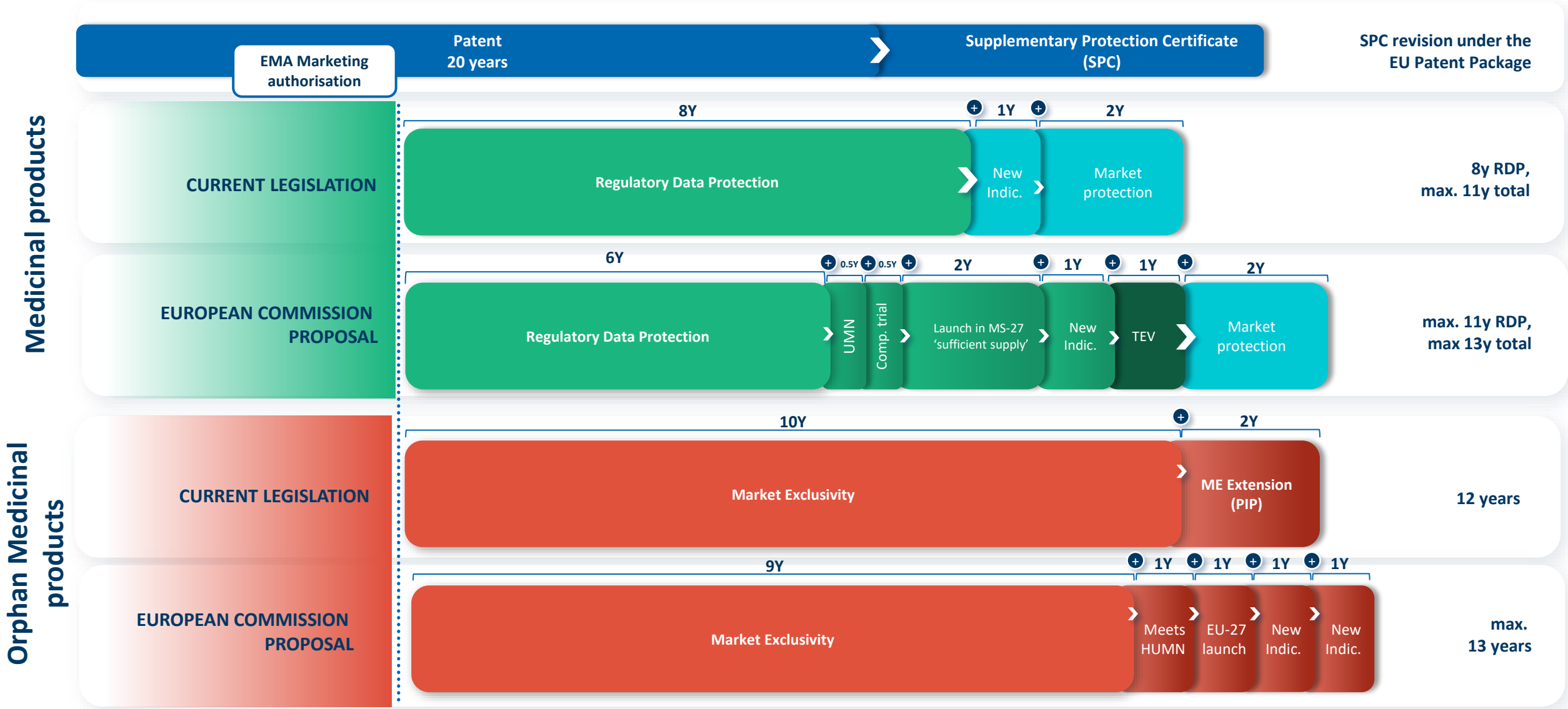
Affordability

- Publicly funded healthcare systems in Europe are under increasing budgetary constraints while new medicine prices are on the rise, with some reaching well over the million euro-per-patient
- 'Me-too' medicines and 'salami slicing' of medicines' indications to maximise intellectual property (IP) are fuelling frustrations of policy makers and national health authorities, who called for an overhaul of the framework
- Growing criticisms on the lack of transparency over medicines development cost, 'society paying twice' for the research and development (R&D) and the drug

Availability

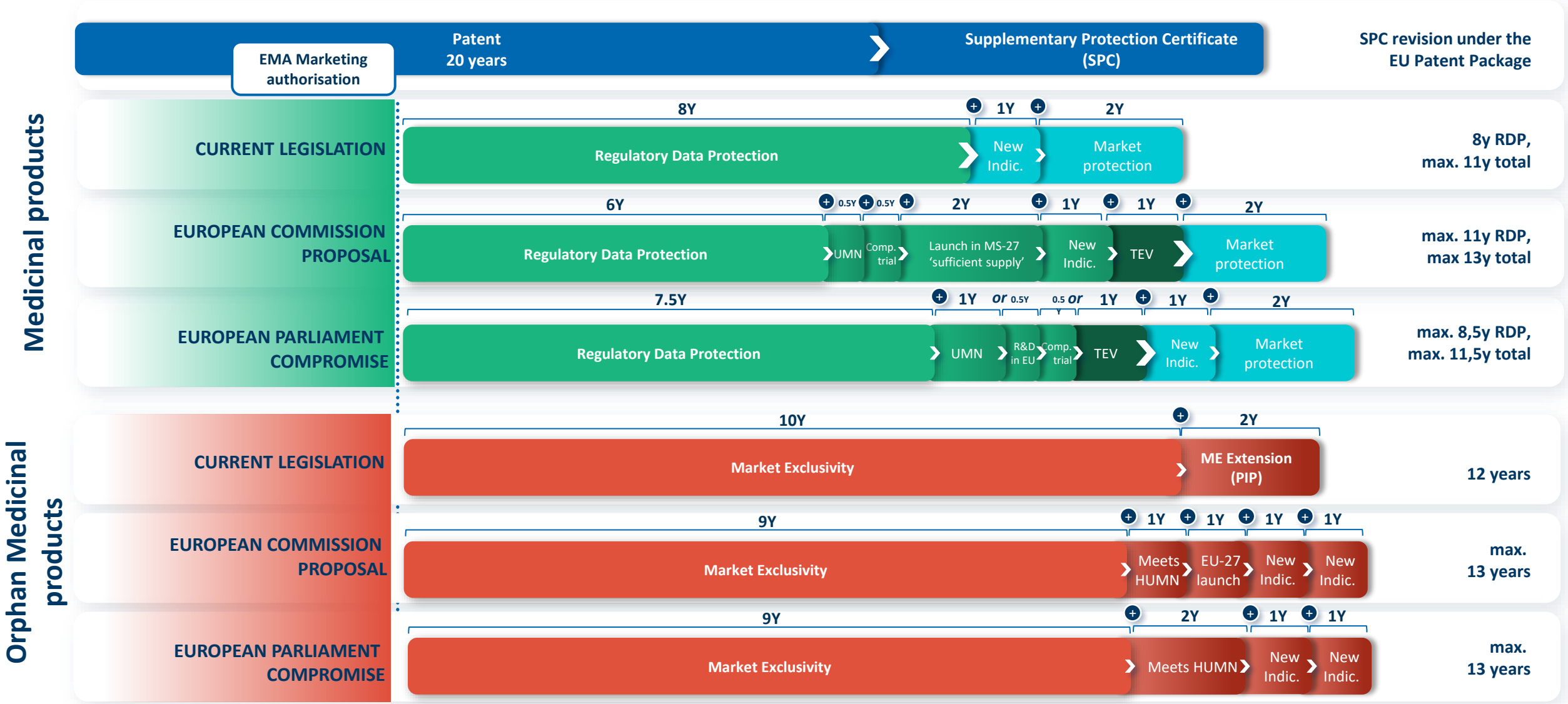
- Hundreds of generic medicines are currently not available equitably across European countries
- The lack of access to off-patent medicines is a growing concern and highlights the EU's dependence on the global pharmaceutical supply chains and API production in India and China
- Many of the older APIs for antibiotics and pain medication are no longer manufactured in Europe, making Europe vulnerable and reliant on imports, especially from Asia

Current legislation comparison to European Commission proposal on regulatory data protection (RDP) and market protection for (orphan) medicinal products



Comp. trial: Comparative trial; CT: Clinical Trial; D: days; Indic.: Indication; MA: Marketing Authorisation; Manf.: Manufacture MS: Member State; R&D: Research and Development; RDP: Regulatory Data Protection; TEV: Transferable Exclusivity Voucher; UMN: Unmet Medical Need; Y: Years

European Commission proposal, European Parliament compromise on regulatory data protection (RDP) and market protection for (orphan) medicinal products



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Which proposal best addresses the needs of patients and Member States' healthcare systems?

Thank you!

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Why was a compromise so difficult to reach in the European Parliament?

- A brief overview of the political group's priorities and asks, as expressed in their first negotiation position

Main coalition	***European People's Party*** *EPP; centre-right*	epp	*Proposed 9 years of RDP*	*Against an incentive to launch linked to RDP (to delete art. 82)*	
	Socialists & Democrats *S&D; centre-left*	S&D	*First negotiation position was 4 years RDP*	*Supporting an incentive to launch, linked to RDP (to keep art. 82)*	*Stronger provisions, obligation to report all public funding received*
	Renew Europe *RE; centre*	renew europe.	*Proposed 8 years RDP, would like to keep regulatory sandbox*		
	Greens/ European Free Alliance, *Greens/EFA*	THE GREENS/EFA in the European Parliament	*Could support 6 years of RDP*	*Would support an obligation to launch*	*Strict ERA provisions across entire medicine life cycle*
	European Conservatives & Reformists, *ECR; right*	ECR GROUP	*Could support 6 years of RDP*		
	Identity and Democracy, *ID, right*	ID	*Proposed 9 years of RDP*		
	The left; *left*	THE LEFT	*Could support 6 years of RDP*		

RDP: Regulatory Data Protection; ERA: Environmental risk assessment

How did the European Parliament land on a compromise?

-A short recap of some of the political group's victories in ENVI vote on 19 of March 2024

Regulatory Data Protection | **Availability of new medicines across EU-27** | **Transparency provisions** | **Sustainability**

Main coalition

	Regulatory Data Protection	Availability of new medicines across EU-27	Transparency provisions	Sustainability
European People's Party *EPP; centre-right*	*Asked for no less than 8Y, gave up 0.5Y*	*Got a new article on obligation to file for P&R, decoupled from RDP (deletion of article 82)*		
Socialists & Democrats *S&D; centre-left*	*Asked for no more than 7Y, accepted 7.5Y*		*Asked for stricter provisions on transparency of funding*	*Asked for stricter ERA provisions*
Renew Europe *RE; centre*	*Could support 8Y, 7.5 is reasonable. Kept the regulatory sandbox*			
Greens/ European Free Alliance, *Greens/EFA*				*Asked for strict ERA provisions across entire medicine life cycle, including manufacturing*
European Conservatives & Reformists, *ECR; right*				
Identity and Democracy, *ID, right*				
The left; *left*			*Asked for stricter provisions on transparency*	*Asked for stricter ERA provisions*

Y: Years; RDP: Regulatory Data Protection; ERA: Environmental risk assessment