
Das EU-Pharmapaket

Überblick zu patentrechtlich
Relevanten Vorschriften

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European
Commission

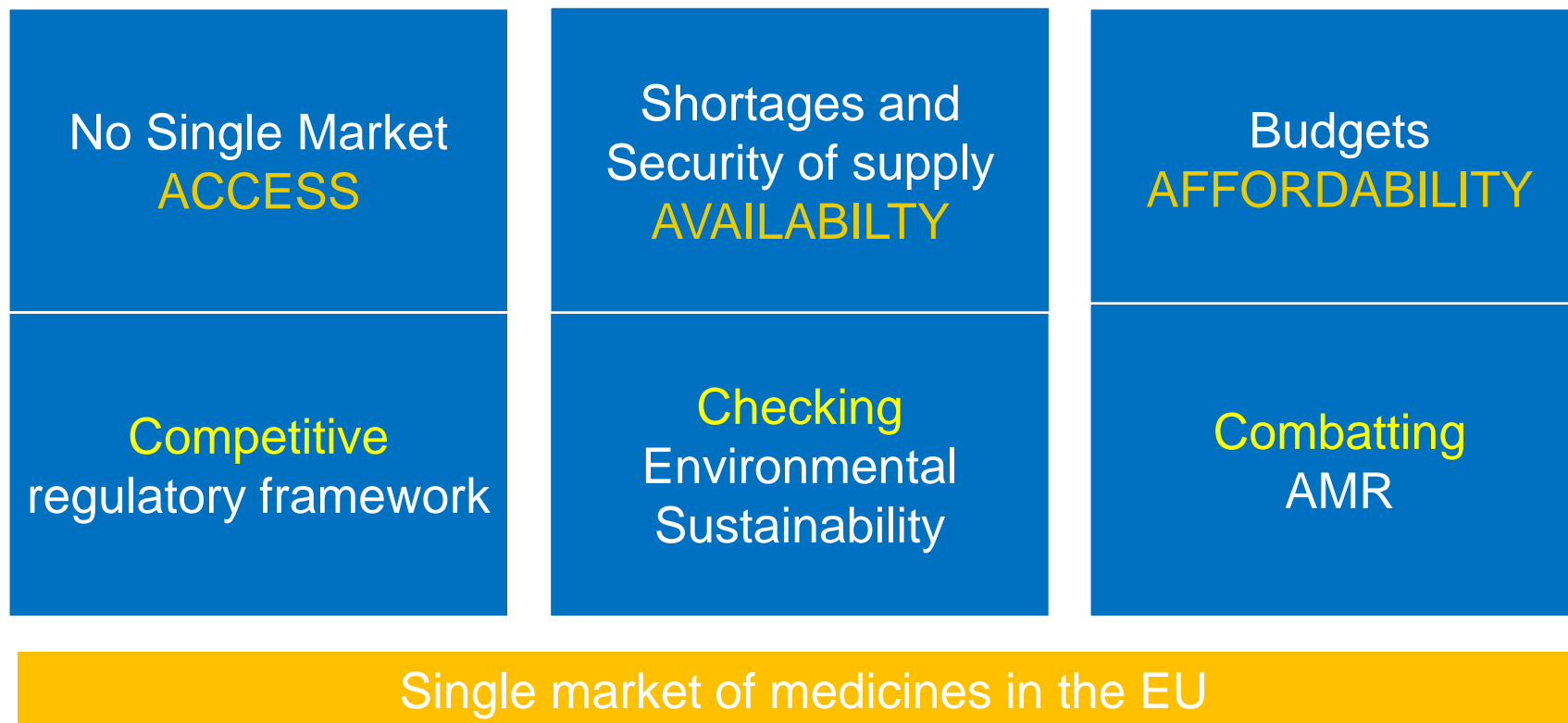
#HealthUnion

#EUPharmaStrategy

- Pharmaceutical strategy (2020)
- Ambitious long-term agenda in the field of pharmaceutical policy
- Objective: creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs
- Pharmaceutical reform, adopted Apr. 2023



Pharma reform: 6 Key political objectives

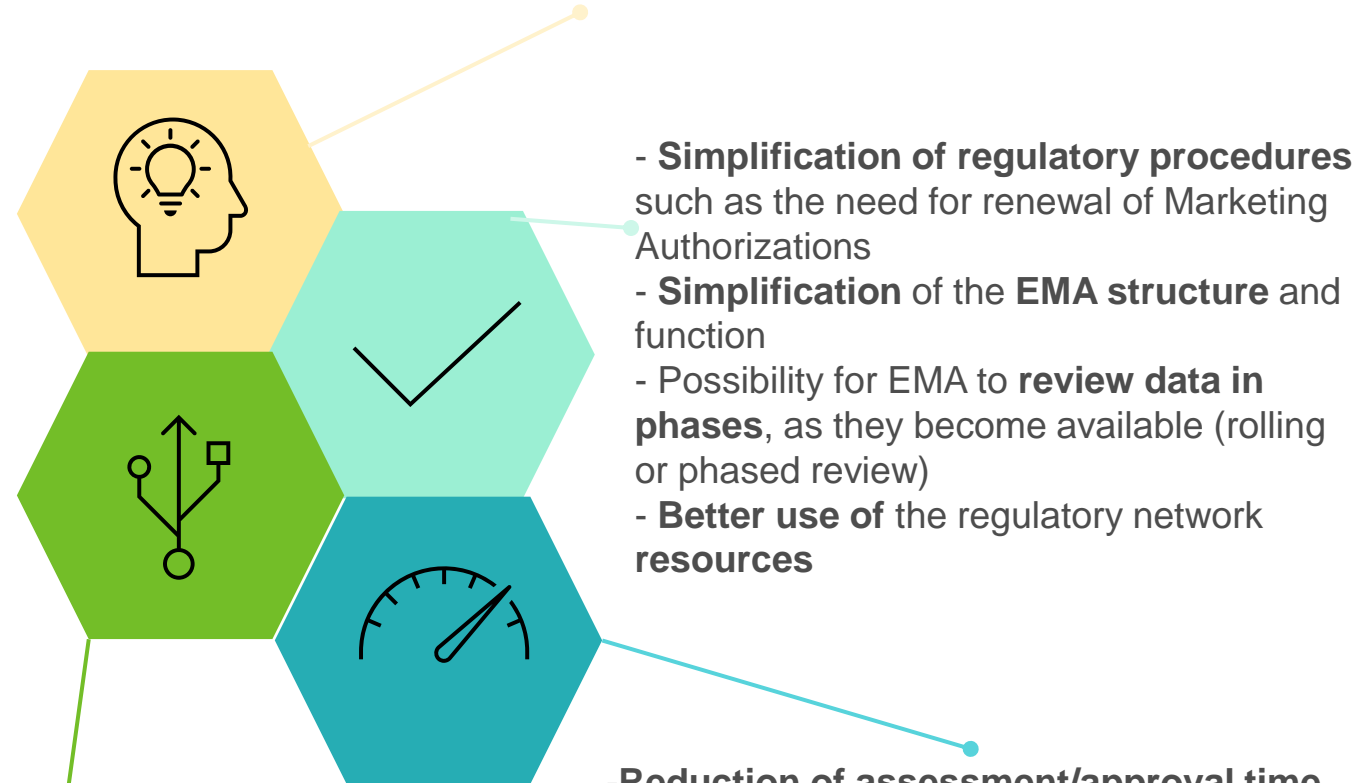


Regulatory excellence and simplification



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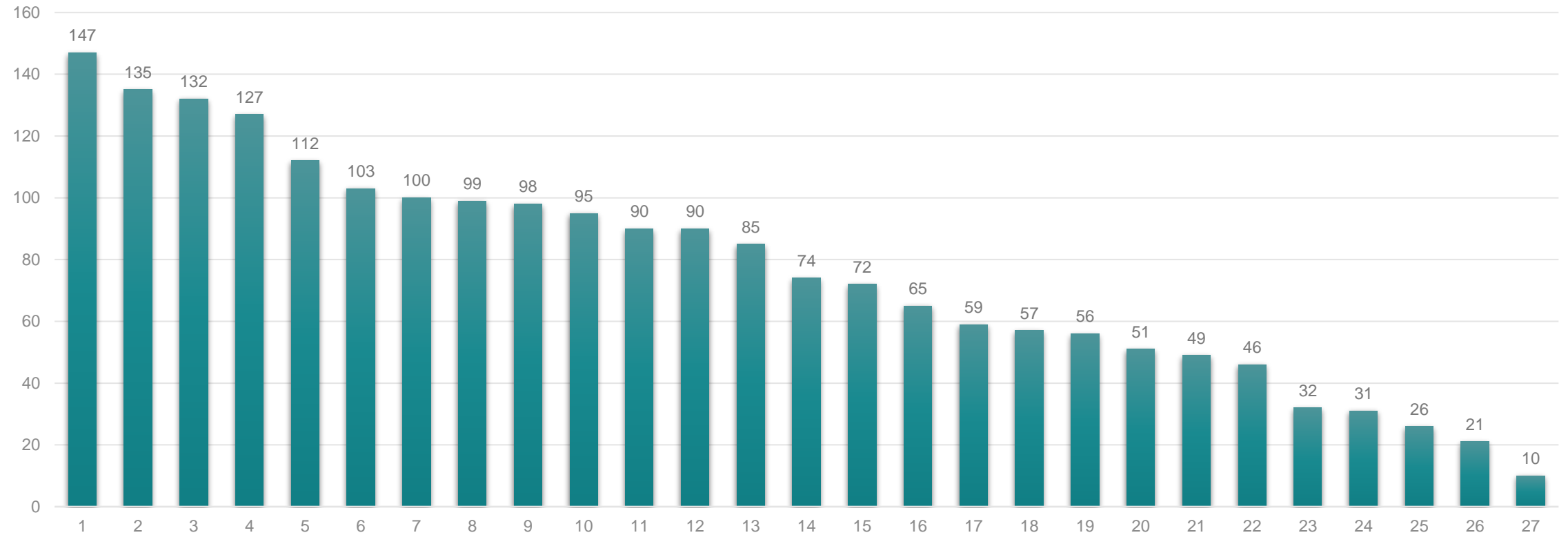
- Clarity of the **interplay** between Pharma and other frameworks
- Regulatory **sandboxes** to test new and innovative therapies
- **Adapted frameworks** with specific regulatory requirements tailored to the characteristics of certain novel medicines
- Strengthening the **early regulatory support** by EMA, particularly for promising medicines under development for unmet medical needs



- Use of **real-world evidence**, and of health data for regulatory purposes
- **Electronic submission** of applications
- **Electronic Product Information**

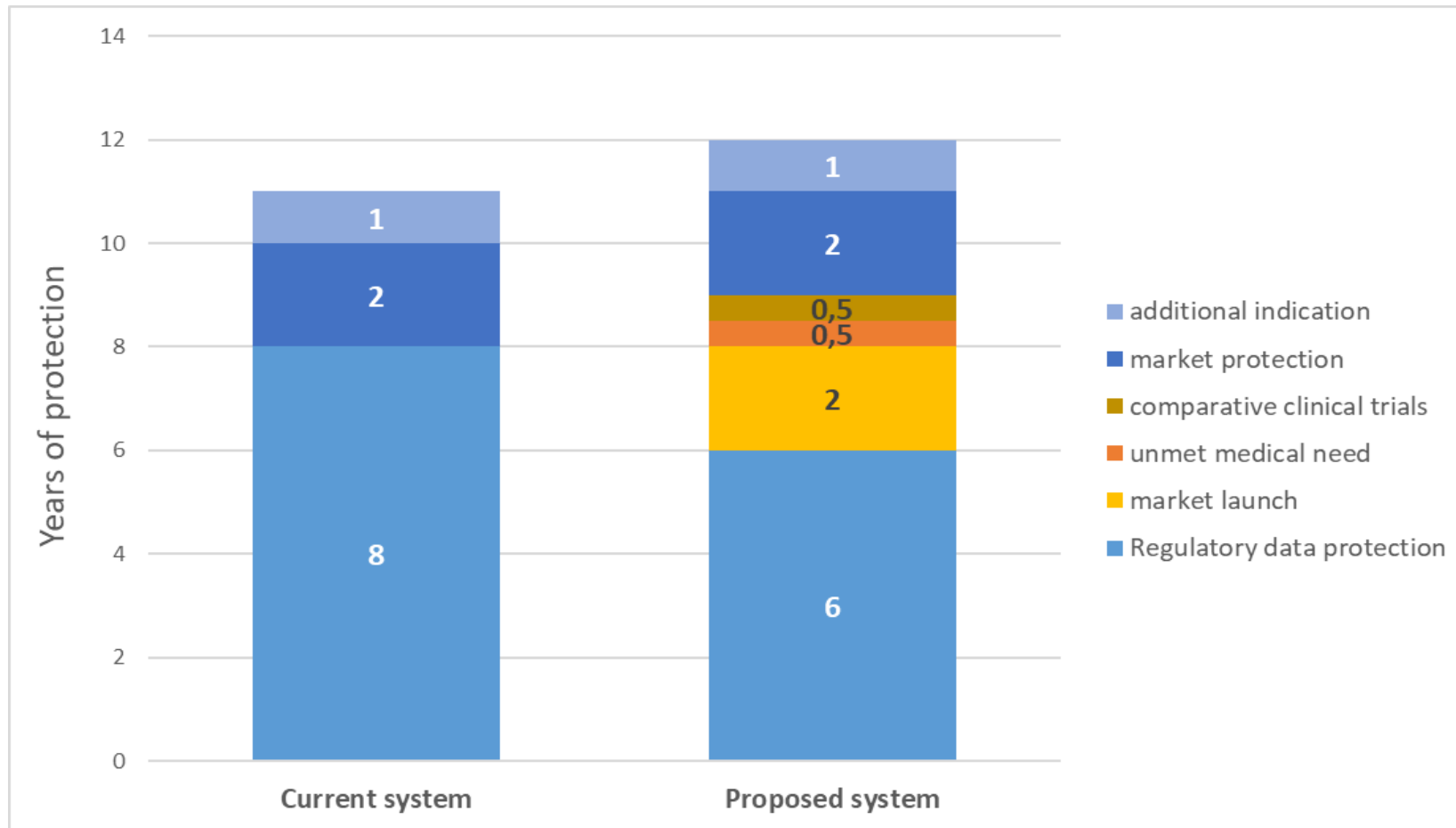
- **Reduction of assessment/approval time** from 277 days to 226 days (150 for accelerated)
- Reduction of **clock stops**
- Screening of **immature applications**

Access to medicines



Modulation for the majority of innovative medicines

Regulatory data and market protection today and as proposed



Current system, max 11 years protection

Proposed system, max 12 years protection

Links to IP legislation

- IP Rules and SPC → parallel system of protection (not influenced by the pharmaceutical revision)
- Bolar exception (DIR Art. 85)
- Compulsory licencing (DIR Art. 80(4))
- 6-month SPC extension for marketing authorisations including results in compliance with an agreed paediatric investigation plan (DIR Art. 86)

Combating Antimicrobial Resistance (AMR)

Current challenge:

AMR causes **35000 deaths per year** in the EU.
It amounts to +/-1.5 bn EUR per year in healthcare costs

By 2050, **10 million deaths globally each year**

Current market failure/ Lack of effective antimicrobials

Lack of market incentives
1,5 bln EUR cost of a new antibiotic

AMR toolbox

Measures on prudent use of antimicrobials – prescription, restricted quantities, education etc.

Regulatory incentives with transferable exclusivity vouchers under strict conditions

AMR voucher

- Additional year of data protection
- Strict conditions (only novel antimicrobials, full transparency of all funding, obligation of supply, max 10 vouchers in 15 years, review after 15 years, etc.)

Thank you



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