Pharmaceutical package

DG SANTE

A 4-part package

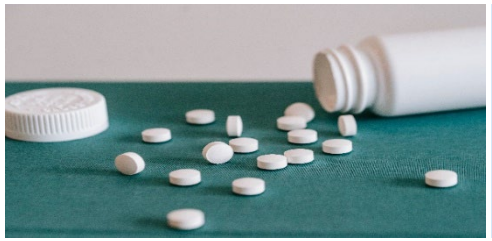
Chapeau communication

New Regulation

- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages
- EMA governance

New Directive

- Placing on the market of all medicines
- Authorisation and labelling requirements
- Strong incentives for access



Council Recommendation on AMR

The political objectives of the reform

Access
Single market

Availability
Shortages

Affordability
Budgets

Innovation & Competitiveness

Regulatory simplification& Innovation

Environment

Combat AMR

Access to medicines

Current challenges:

Access is not timely and differs across Member States:

90% variance between Northern and Western European countries and Southern and Eastern European countries

Average waiting time across the EU is from 4 months to 29 months

Proposed solutions:

Incentives for innovation and access:

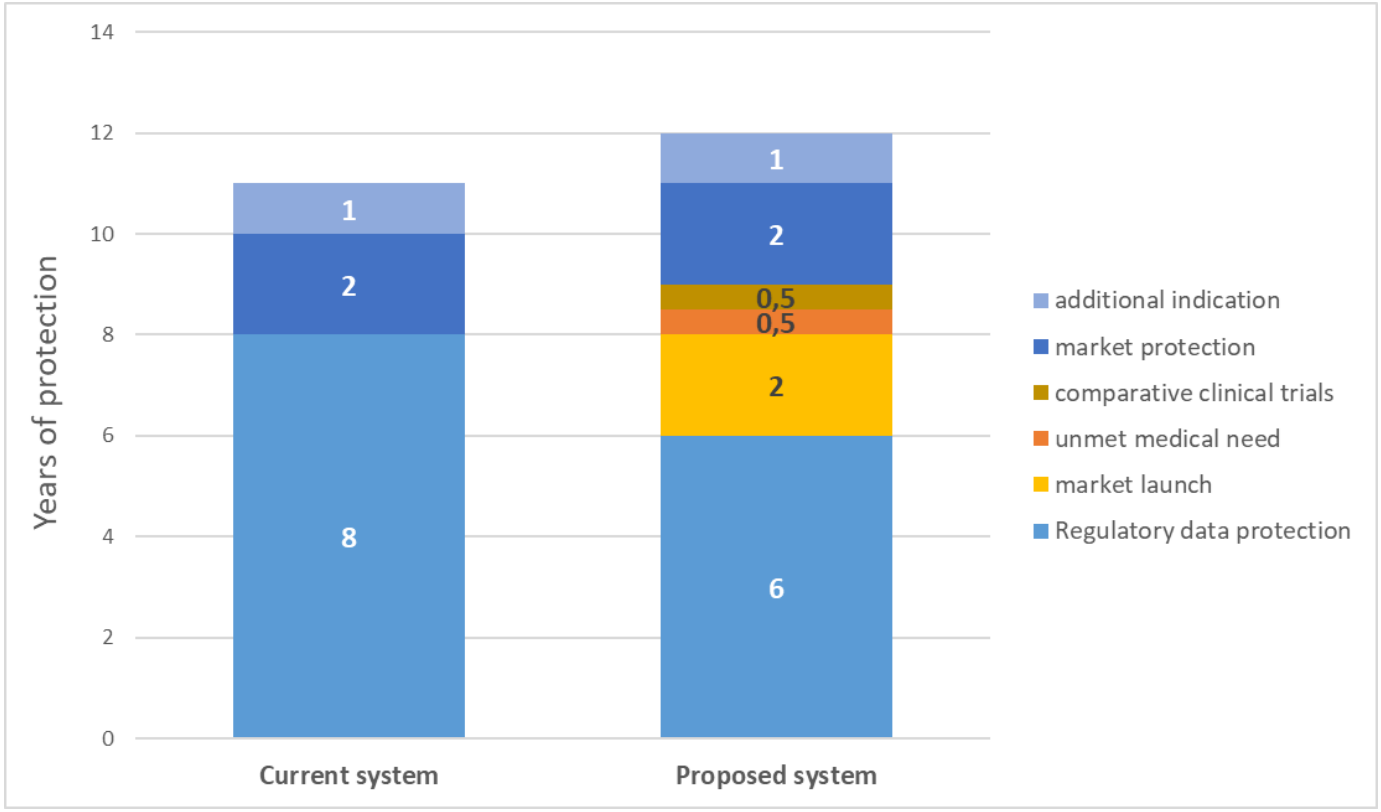
Targeted approach vs current “one-size-fits-all” unconditional data protection and market exclusivity (for orphans)

Earlier market entry of generic and biosimilar medicines

- Faster authorisation
- Pre-authorisation support

Modulation for the majority of innovative medicines

Regulatory data and market protection today and as proposed



Current system, max 11 years protection

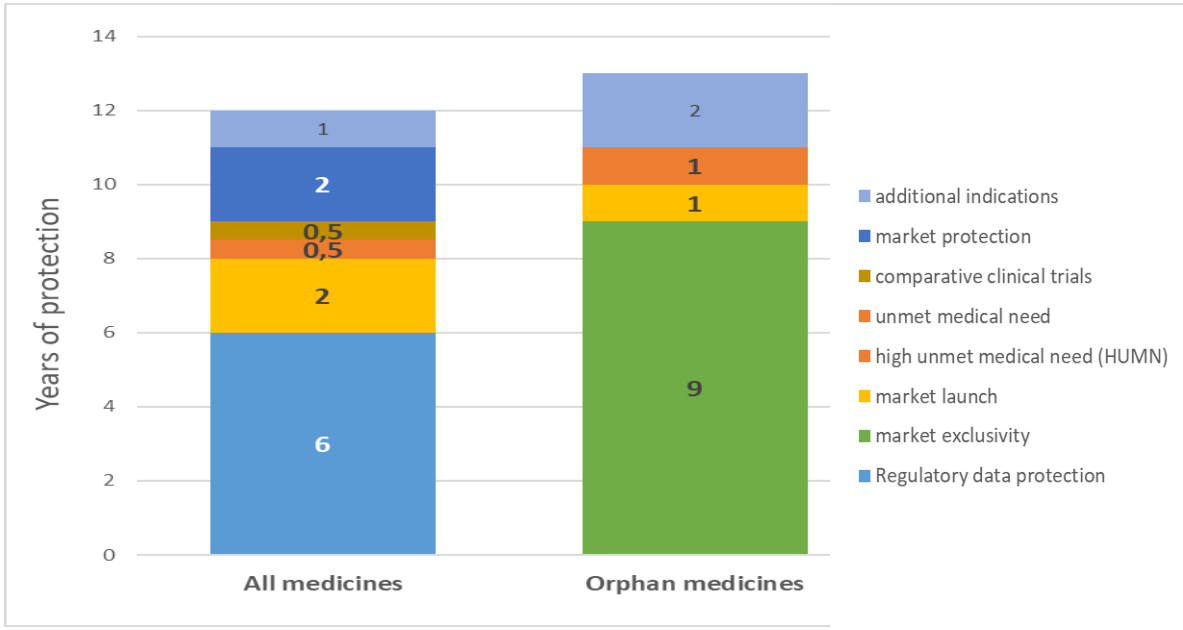
Proposed system, max 12 years protection

European Commission

Access to medicines - proposed changes for medicines for rare diseases (orphan medicines)

Modulation of data protection

Modulation of market exclusivity



List of changes

- Default market exclusivity is 9 years (from 10 today)
- Products addressing HUMN get +1 year market exclusivity = 10 years
- Launching in all MS adds +1 year market exclusivity

max 12 years protection

max 13 years protection for orphan medicines

European Commission

Modulation of incentives and EU competitiveness

- IP rights outside scope of pharmaceutical legislation will not be affected
- Ability to have the same regulatory protection as today
- EU system of regulatory incentives is already one of most generous (table)
- The incentives apply equally to all products, regardless of where they are developed – in the EU or elsewhere

Country	Protection	Duration
Canada	New Chemical Entity+ Market Protection	6+2 years
EU	New Chemical Entity+ Market Protection	8+2+1 years
Switzerland	New Chemical Entity	10 years
USA	New Chemical Entity (small molecule)	5 years
USA	Biosimilar Application Approval Exclusivity (biologic)	4+8 years
Israel	Market Protection	6 or 6.5 years
China	New Chemical Entity	6 years
Japan	New Chemical Entity	8 years

Unmet medical needs

All rare diseases-orphan medicines automatically considered UMN

Indication criterion: Therapeutic indication must relate to a *life threatening [*OR] *severely debilitating* condition

Comparison to authorised medicines:

- *No medicine is authorised* in the EU

[OR]

- A medicine *is authorised* in the EU but disease is associated with remaining *high morbidity / mortality*

Effect criterion: Use of the medicine results in *meaningful reduction in disease morbidity / mortality* for the relevant patient population

EMA to set *scientific guidelines* for the application of the article + consultation process of downstream actors and stakeholders (HTA/P&R bodies (possibility to include patients, industry, others).

European Commission

Addressing the needs of rare disease patients

All orphan medicines

No insuffient return on investment criterion
Incidence – if prevalence not possible
No review of market exclusivity after 6 years

New orphan condition for the same active substance = **prolonged market exclusivity**

Global marketing authorisation concept

High unmet medical need

To boost developments where there are no treatment options and to reward game changers

Not for well established use products

EMA to adopt scientific guidelines

Market exclusivity from 10 to 13 years for HUMN orphans

Addressing the needs of children

Paediatric investigation plans

Step-wise PIPs to allow innovation

Adaptation of the PIP requirements for step-wise PIPs, paediatric only and PUMAs

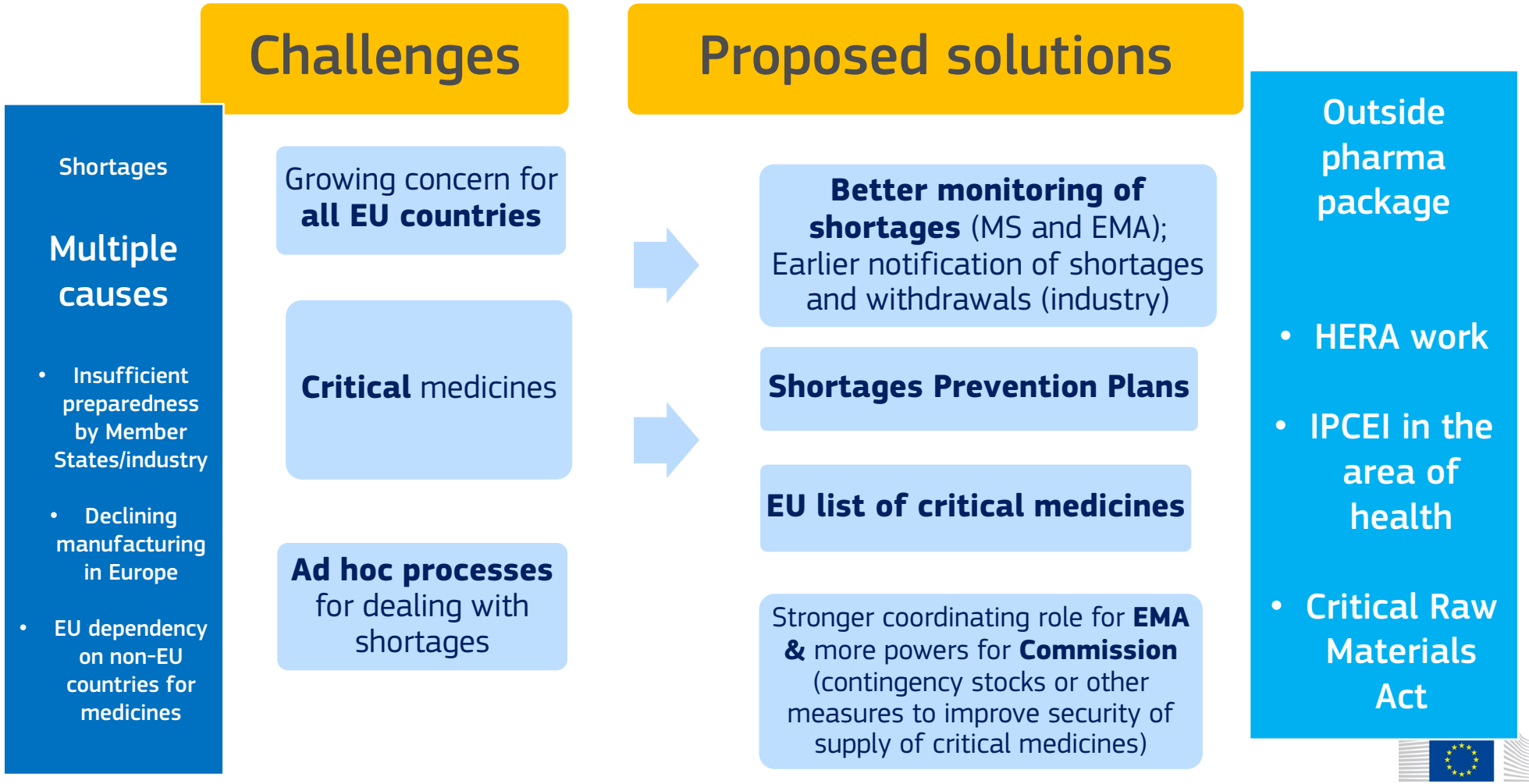
Mandatory PIPs medicines for children, also based **on mechanism of action**

Increased transparency on PIP conducted for discontinued medicines

Temporary waiver from PIP obligation during public health emergencies

Foster **multi-stakeholders discussions** about prioritisation of paediatric R&D

Availability - preventing shortages



Affordability

Current challenges:

- Pricing, reimbursement and procurement of medicines is a **national** competence
- High prices endanger national health systems' sustainability **& restrict patient access**
- Lack of **transparency of public funding** is a growing issue
- Lack **of streamlined coordination** among national authorities

Proposed solutions:

- **Earlier market entry of generics/biosimilars** to increase competition and reduce prices
- Increased **transparency on public contribution** to R&D
- Comparative **Clinical Trials** to support national decisions on pricing
- Further support for **information exchange** between Member States (cooperation on pricing, reimbursement and payment policies)

Streamlined and agile regulatory framework catering for innovation

Current challenge:

Longer approvals times than in other regions (US 244 days)

Administrative burden and compliance costs for the industry

The clock stop mechanism

Proposed solutions:

Faster autorisation:
a) 180 days standard procedure
b) 150 days accelerated procedure
Regulatory efficiency:
Improved EMA structure, simplified procedures, better use of data and digitisation, regulatory sandboxes

Pre-authorisation support to promising medicines to accelerate development and attract investments

Lower regulatory burden (especially important for SMEs and not-for-profits)

Environmental sustainability

Current challenge:

Pharmaceuticals in environment can **harm environment and human health**

Presence of antimicrobials in the environment exacerbates AMR

Weak enforcement of current rules

Proposed solutions:

Better enforcement of the current rules on **Environmental Risk Assessment** (part of the application)

Extending ERA to **medicines already on the market before 2005**

Stricter environmental rules for AMR, also covering manufacturing

Electronic leaflet and **electronic submission** of applications

European Commission

Combatting 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

0,5 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

Financial incentives with **procurement mechanisms** (HERA)

5 Targets, incl on the total **EU consumption of antibiotics for humans** (ECDC) → reduction by 20% by 2030

(Council Recommendation)

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

Slide 2: source iStock.com

European Commission