The EU Pharmaceutical Reform

Pharmaceuticals Trade Mark Group
6 October 2023, Athens

Anthony Rodiadis, Policy Officer - DG SANTE

European Commission

#HealthUnion

57 years of EU pharmaceuticals regulation

SAFETY – EFFICACY - QUALITY

Thalidomide disaster exemplifies the need for EVIDENCE-BASED AUTHORISATION

1965
1st EC legislation: medicines need to be authorised before being placed on the market

1995
Centralised, EU-wide procedure for authorisation – creation of the EMA

2000
Legislation on medicines for rare diseases

2004
Last major revision – extending scope of centralised procedure, simplification

2006
Legislation on medicines for children

2007
Regulation on advanced therapy medicines

2010
New EU Pharmacovigilance rules: better prevention, detection and assessment of adverse reactions, direct patient reporting of adverse events

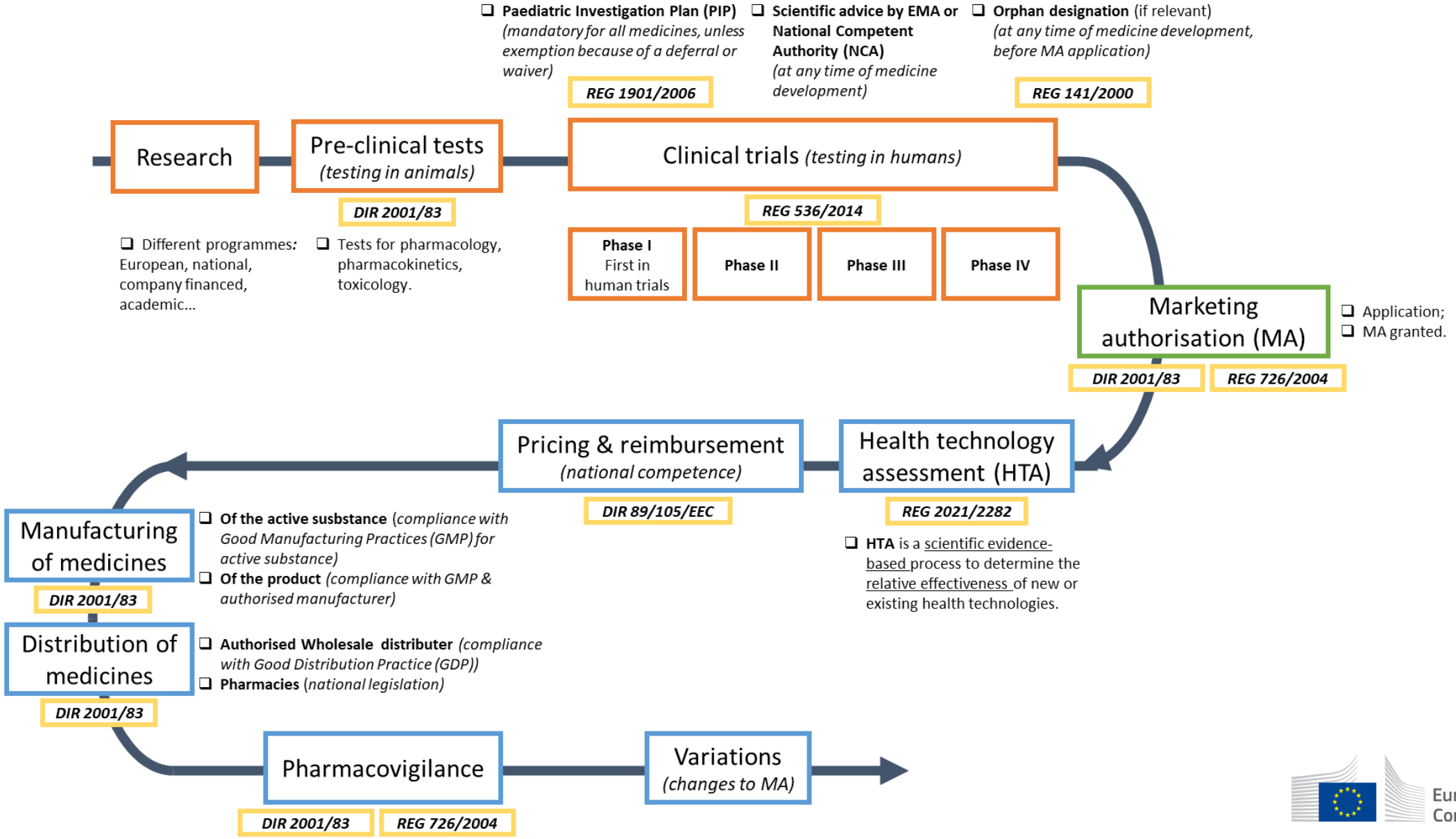
2011
Legislation against falsified medicines

2020
Pharmaceutical strategy for Europe: addresses long standing challenges, learnings from COVID-19

2022
Reform of general pharmaceutical acts packaged with revision of the O/P legislation

European Commission

Lifecycle of a medicinal product



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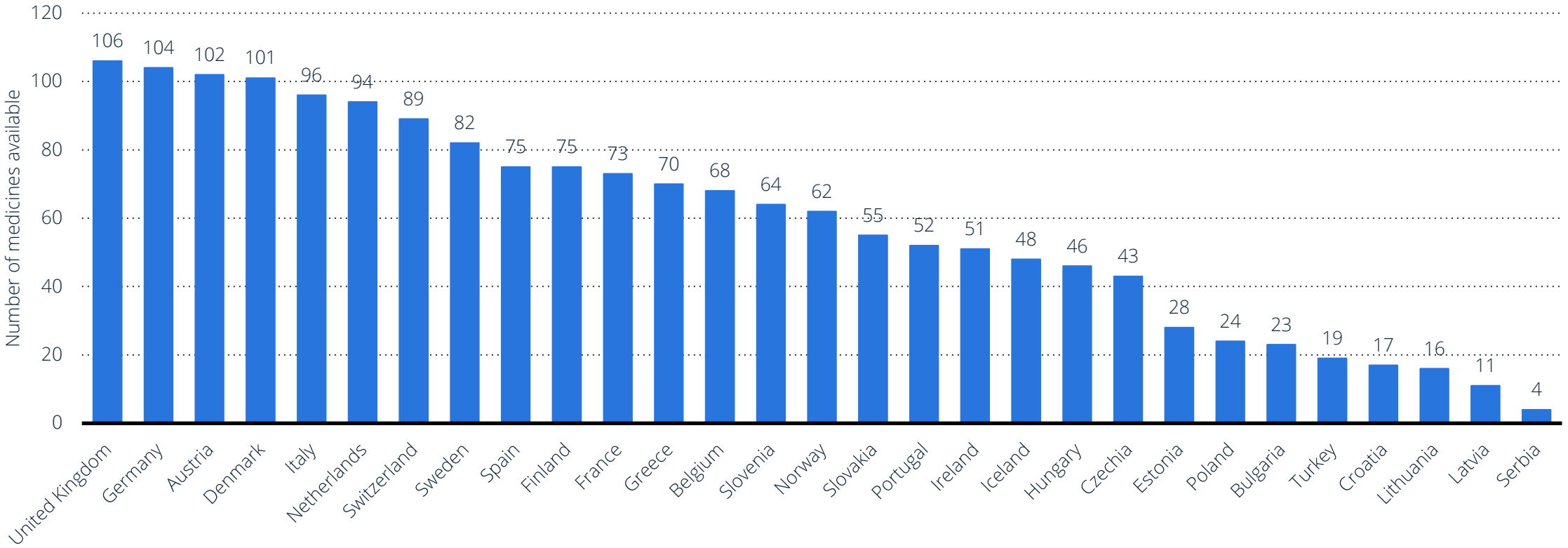
Access to medicines

Number of medicines approved by the EMA between 2015-17 available to patients in Europe as of 2018, by country



Note(s): Europe; 2017

Further information regarding this statistic can be found on page 8.

Source(s): IQVIA; ID 1011132

#EUPharmaStrategy

- Adopted in November 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

European Commission

A 4-part package

Chapeau communication

New Regulation

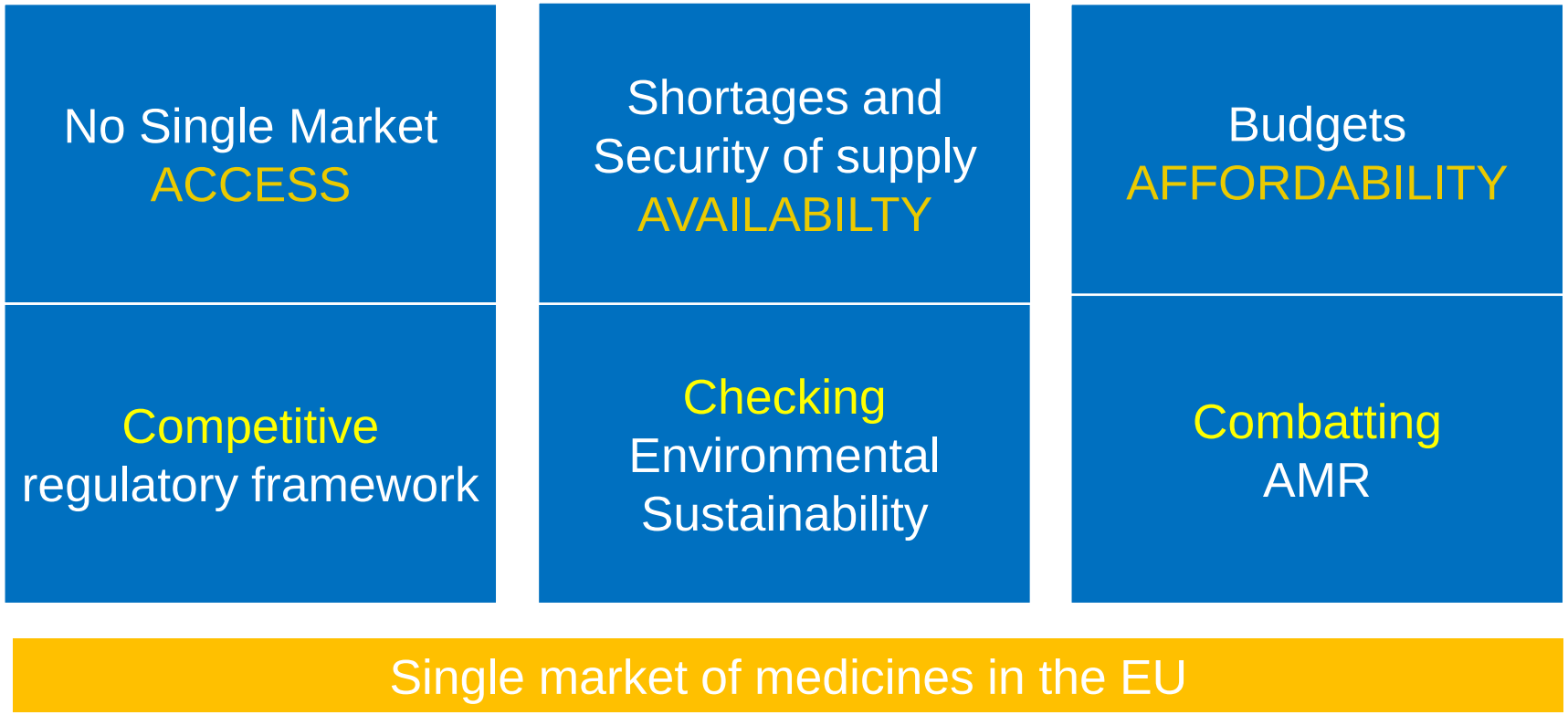
- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages and security of supply
- EMA governance

New Directive

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

Council Recommendation on AMR

6 Key political objectives



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:

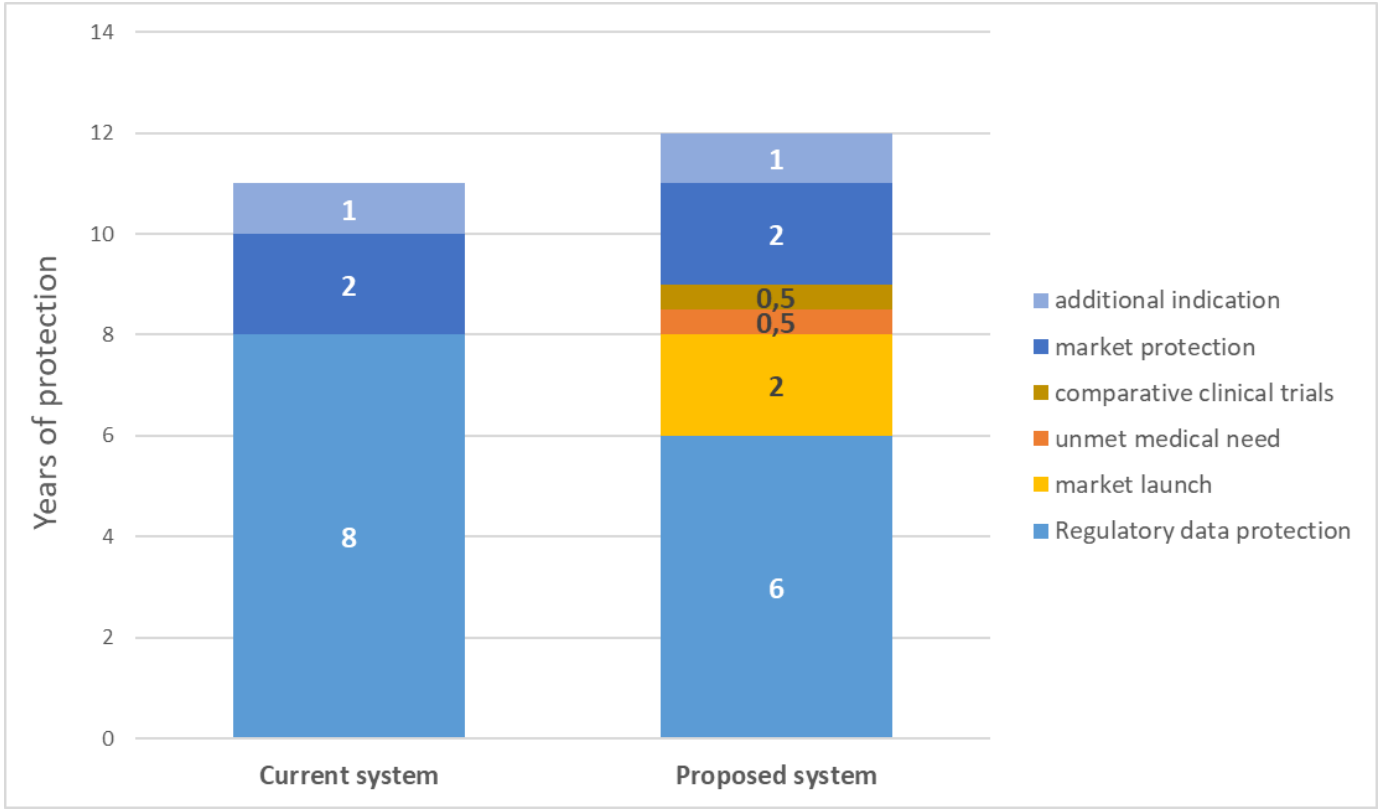
Targeted approach vs current “one-size-fits-all” unconditional data protection and market exclusivity (for orphans)

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

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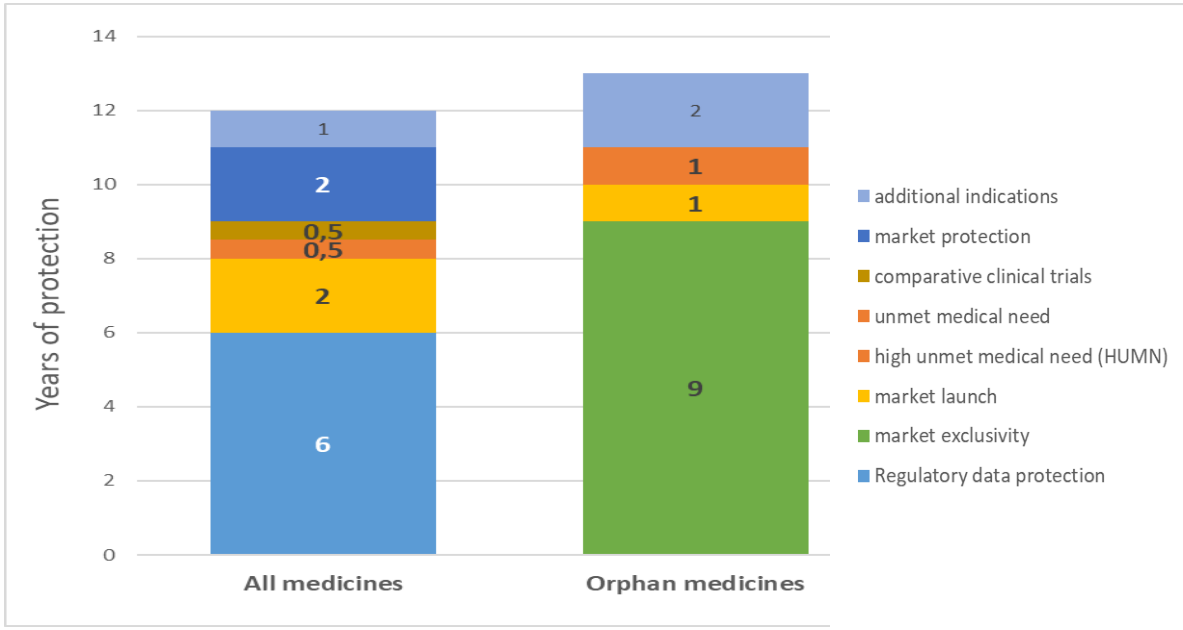
Access to medicines - proposed changes for medicines for rare diseases (orphan medicines)

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

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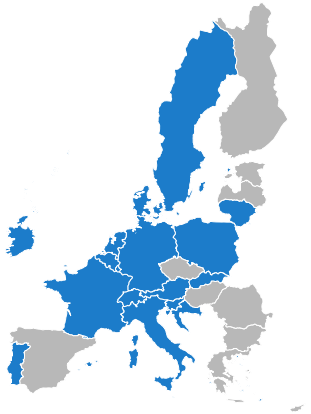
Market launch conditions

- Launch in all Member States where the marketing authorisation is valid (CP and DCP)



- **Actual placing** on the market and continuous supply for the needs of the patients in each MS (incl. presentations, quantities)
- **MS has 4+1 options**:
  - Positive/negative confirmation of actual supply;
  - Waiver;
  - Tacit;
  - [or] positive pricing and reimbursement decisions (based on Transparency Directive)

Availability – shortages and security of supply

Shortages: Multiple root causes

Quality and manufacturing issues

Commercial reasons, incl. market withdrawals, and unexpected increases in demand

EU dependency on non-EU countries for medicines for supply of certain pharmaceutical ingredients.

Current challenges

Growing concern for **all EU countries**

- **Critical shortages** of medicines; current examples thrombolytics, antibiotics
- Security of supply of **critical medicines**

Ad hoc processes for dealing with **critical shortages**

Proposed solutions

Improved **coordination, monitoring and management** of shortages, in particular critical shortages (MS and EMA); **Earlier** and **harmonised notification** of shortages and withdrawals (industry)

Shortage Prevention Plans

Union list of critical medicines

Stronger coordinating role for **EMA &** more powers for **MS** and **Commission**

Outside pharma package

- Other **Commission initiatives**, including the work of **HERA**
- **Joint Action** on shortages
- **IPCEI** in the area of health
- **National measures** e.g. State aid
- **EMA mandate extension** (Regulation (EU) 2022/123)

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 challenges:

Longer approval 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)

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.)

Environmental sustainability

Current challenges:

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 (less use of paper)

Other notable changes

- Medicines for rare diseases
  - Modulation of market exclusivity (*improve access*), High Unmet Medical Needs concept (*improve innovation*), possibility to adapt prevalence criteria, 7-year validity of orphan designation
- Medicines for children
  - Obligation to agree and conduct clinical studies (PIP) – rewards structure maintained;
  - Mandatory PIP on the base of the mechanism of action of a MP (same therapeutic area);
  - 6 months SPC extension following PIP completion also for orphan medicines.
- Possibility for electronic product information (ePI)
- Possibility for a delegated act to set a reduced list of mandatory labelling particulars for multi-country packages
- Duplicate marketing authorisations only available in cases of IP/SPC protection or co-marketing

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)

Thank you

European Commission