The EU Pharmaceutical Reform

DGRA-Jahreskongress May 2023

European Commission

#HealthUnion

The EU pharmaceutical sector

Revenue of worldwide pharmaceutical market is EUR 1 trn+ per year, tripled in last 20 years

Approx. 20% of all EU **R&D** spending
EU is the second biggest R&D investor after US

The EU pharmaceutical sector

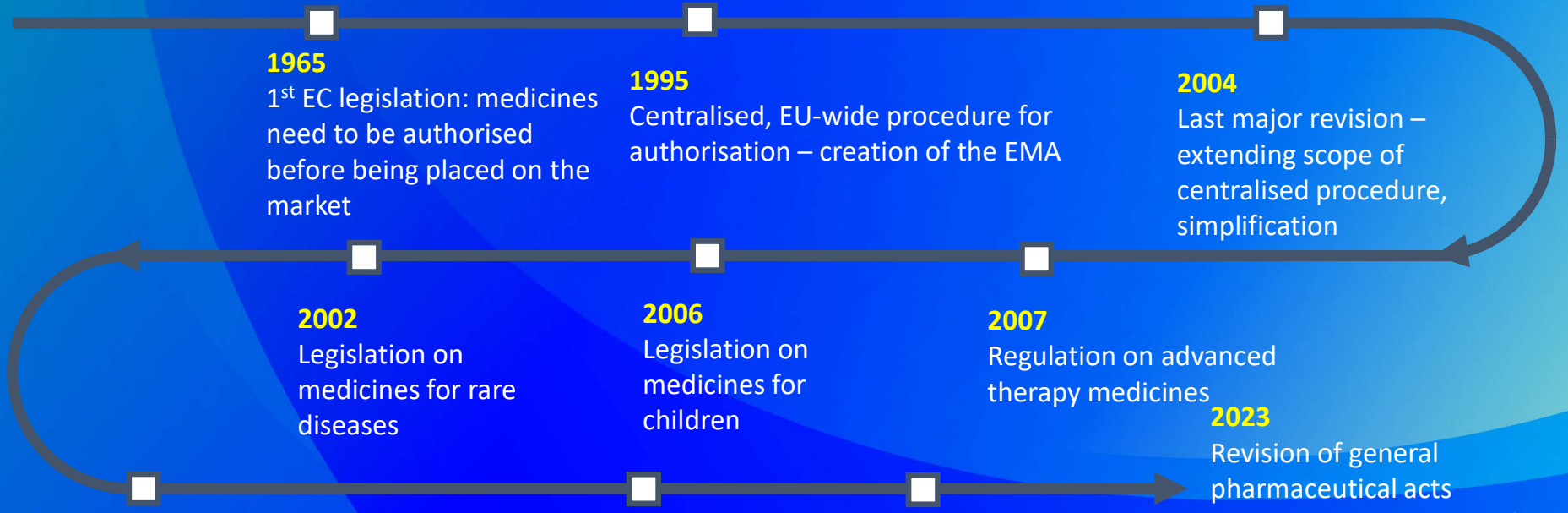
1,5-2% of EU GDP is **spent** on pharmaceuticals

89 new medicines authorised in 2021 at EU level

The biggest single contributor to **EU's trade surplus** – EUR 235 bn in exports

+ EUR 136 bn trade balance (tripled in last 10 years)

A quick look back



#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

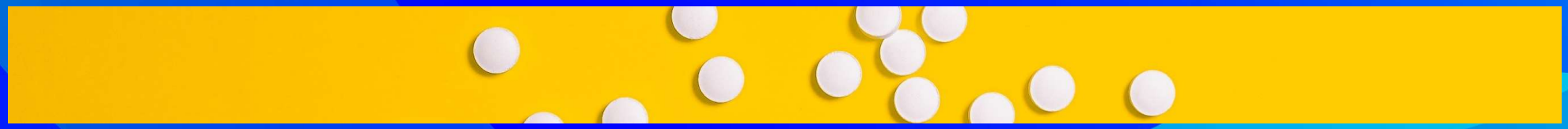
EU Pharmaceutical Reform

Builds on the Pharmaceutical Strategy for Europe (2020)

Supports EU citizens and industry

Addresses long-standing challenges and public emergencies

Marks a European Health Union milestone



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

6 Key political objectives

"TRIPLE A"

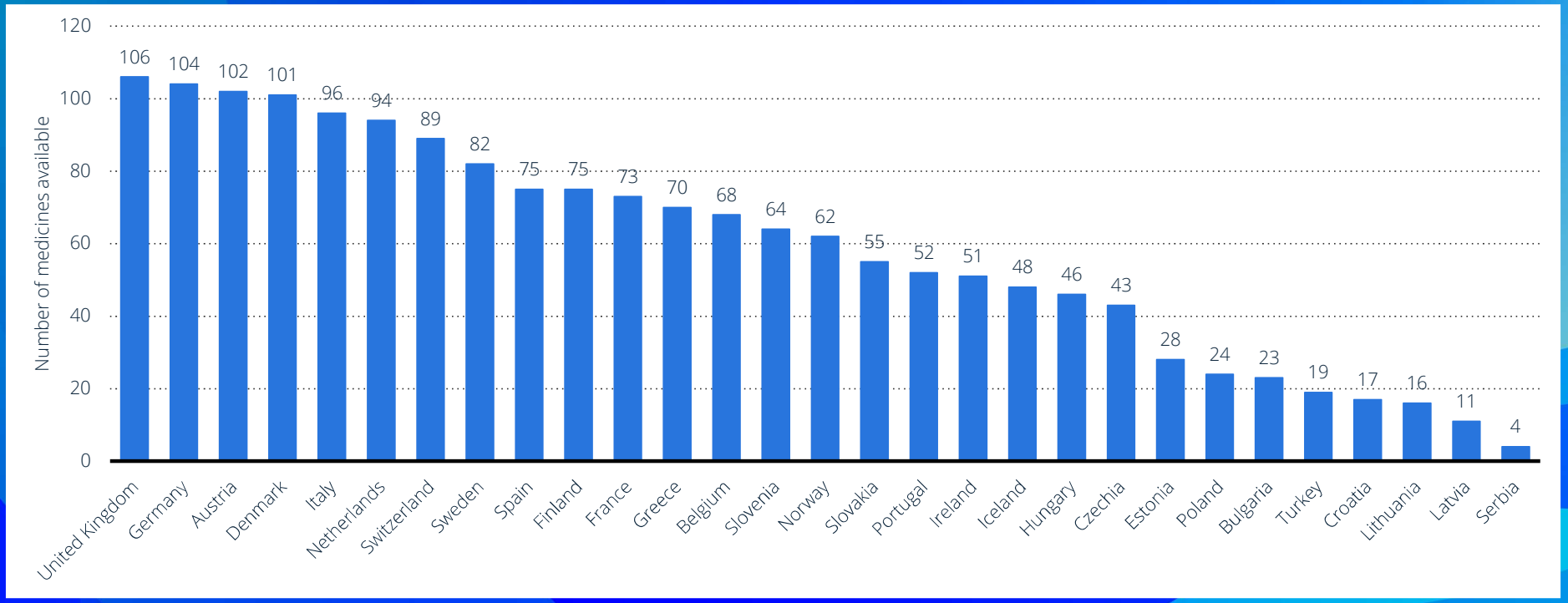
No Single Market ACCESS	Shortages AVAILABILTY	Budgets AFFORDABILITY
Competitive regulatory framework	Environmental Sustainability	Combat AMR

Single market of medicines in the EU

Access to medicines

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

Availability of new medicines in Europe in 2018, by country



Note(s): Europe; 2017

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

Source(s): IQVIA; ID 1011132

statista

1. 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:

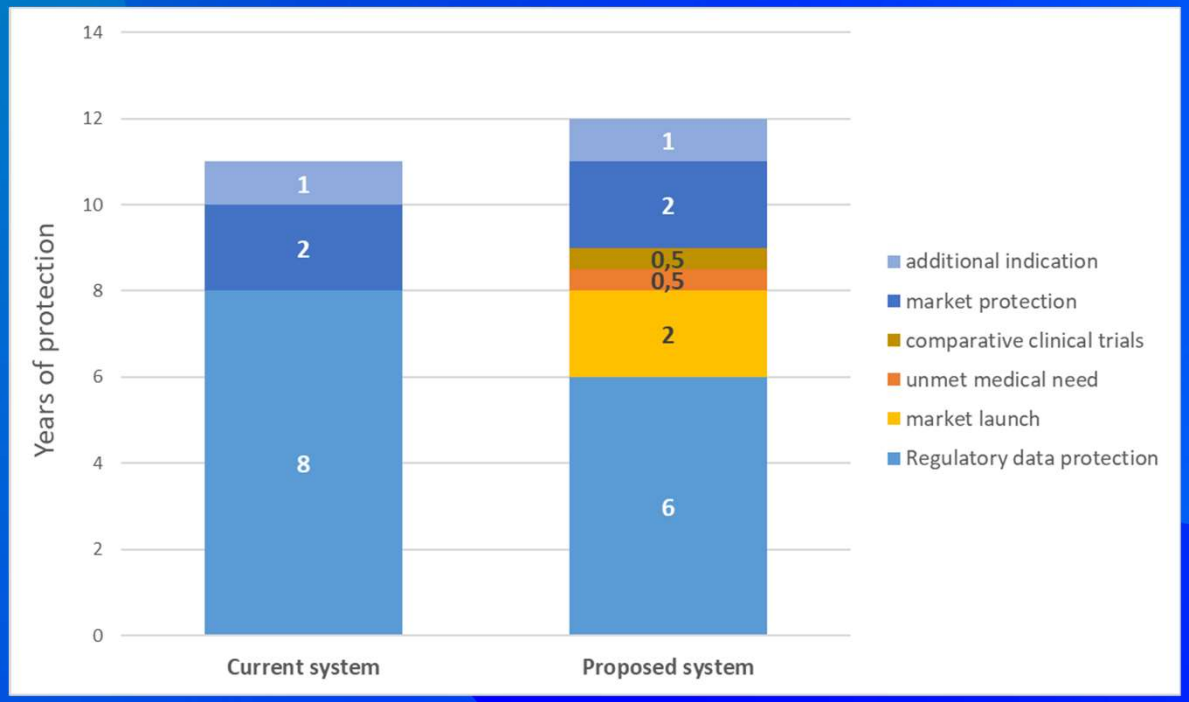
Incentives for innovation and access: Targeted approach vs current "one-size-fits-all" with 8 years of unconditional data protection

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

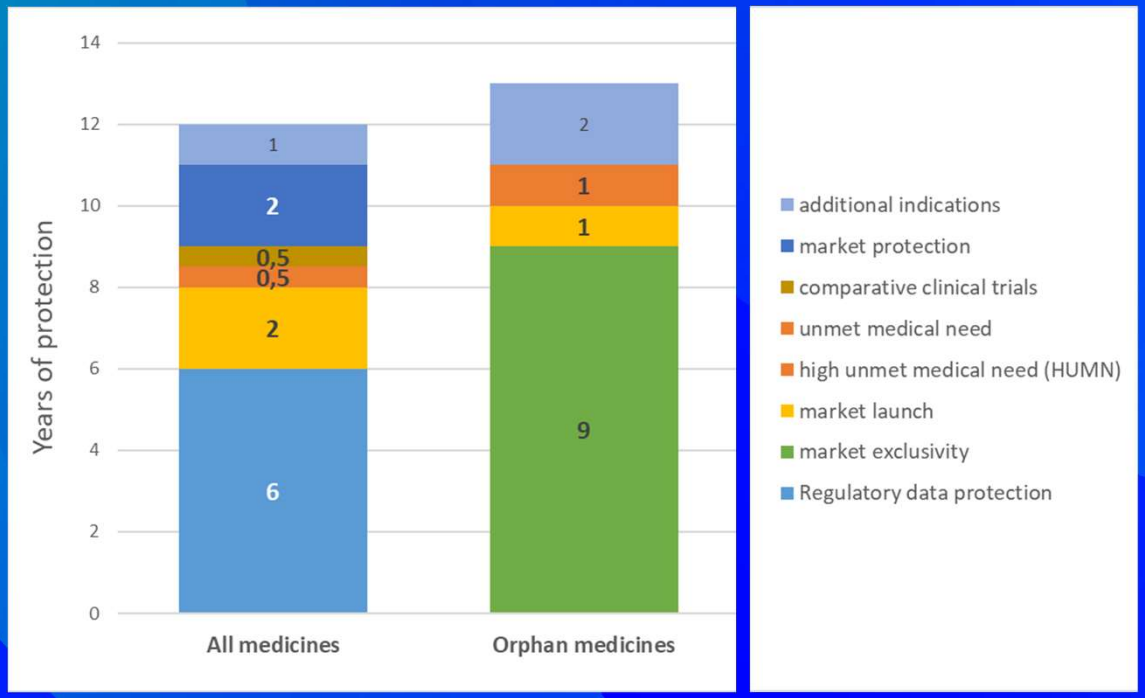


Current system, max 11 years protection

Proposed system, max 12 years protection

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

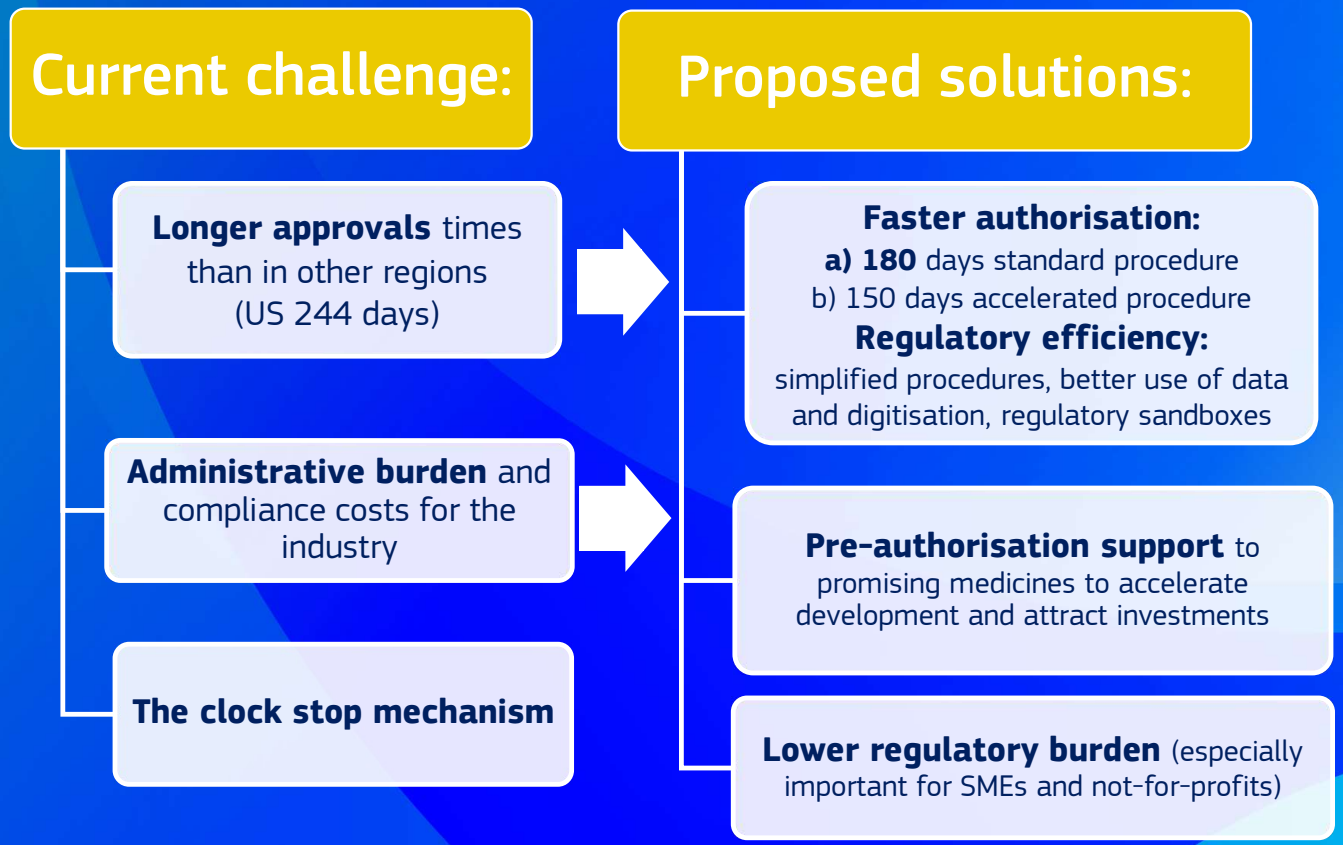
max 12 years protection **max 13 years protection for orphan medicines**

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

2. A streamlined regulatory framework



3. Availability - preventing shortages

Shortages

Multiple causes

- Insufficient preparedness by Member States/industry
- Declining manufacturing in Europe
- EU dependency on non-EU countries for medicines

Challenges

- Growing concern for **all EU countries**
- Most affected medicines: **antibiotics, painkillers** (also in paediatric formulations)
- **Ad hoc processes** for dealing with shortages

Proposed solutions

- **Better monitoring of shortages** (MS and EMA); Earlier notification of shortages and withdrawals (industry)
- **Shortages Prevention Plans**
- **EU list of critical medicines**
- Stronger coordinating role for **EMA &** more powers for **Commission** (contingency stocks or other measures to improve security of supply of critical medicines)

Outside pharma package

- HERA work
- IPCEI in the area of health
- Critical Raw Materials Act

4. 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)

5. 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

6. 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 for your attention

#HealthUnion #EUPharmaStrategy #AMR

European Commission