The EU Pharmaceutical Reform

Jornada de estudio presencial – Regulación económica de la industria farmacéutica. Situación actual y perspectivas de futuro en España.

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European Commission

#HealthUnion

#EUPharmaStrategy

- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- **Objective**:

  create a **future-proof**, globally **attractive regulatory framework** to support industry in **promoting R&D** of innovative therapies

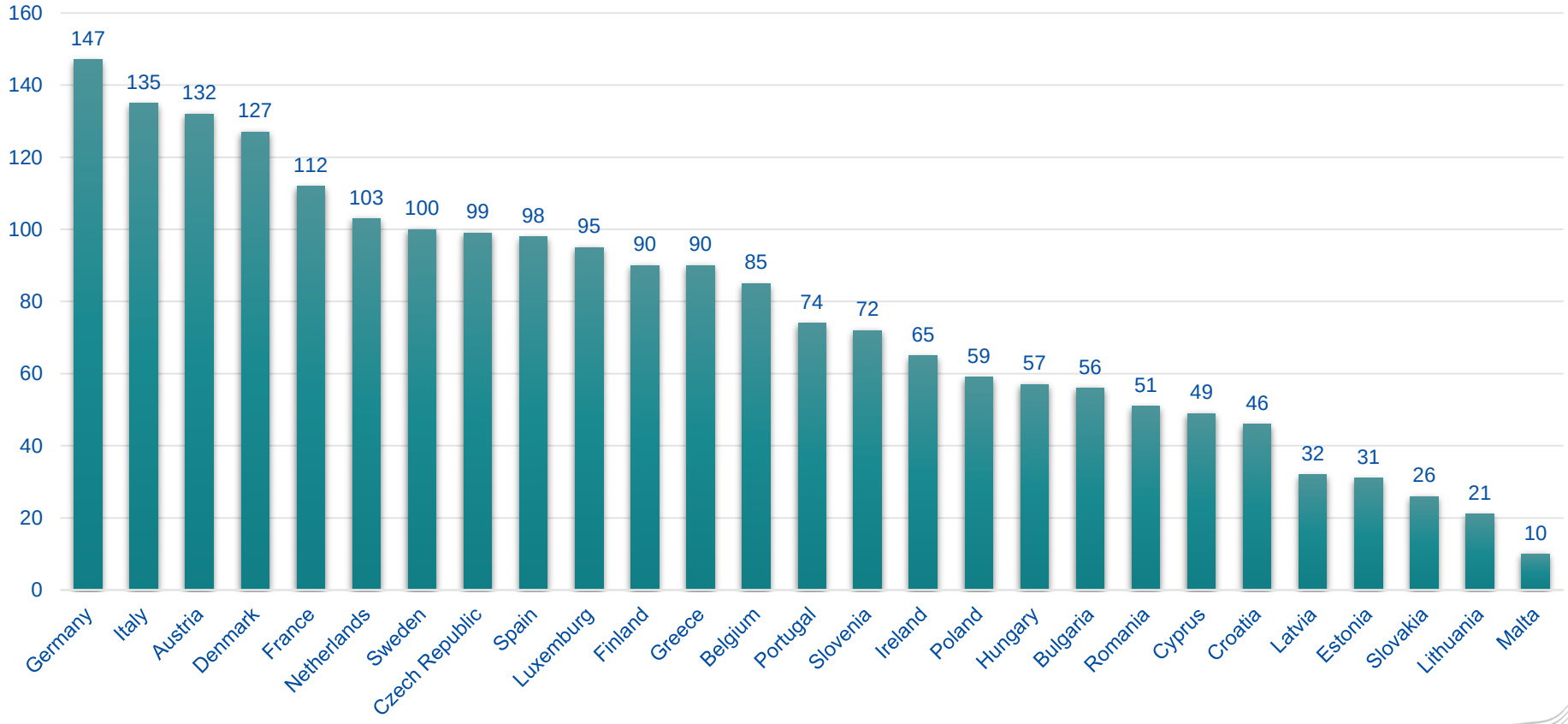
  that **reach patients** across the **EU** and fulfil their **therapeutic needs**

European Commission

Access

Access to medicines

Between 2018-2021, the Commission approved 168 medicines – the following were available to patients in the EU as of 2023, by country



European Commission

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

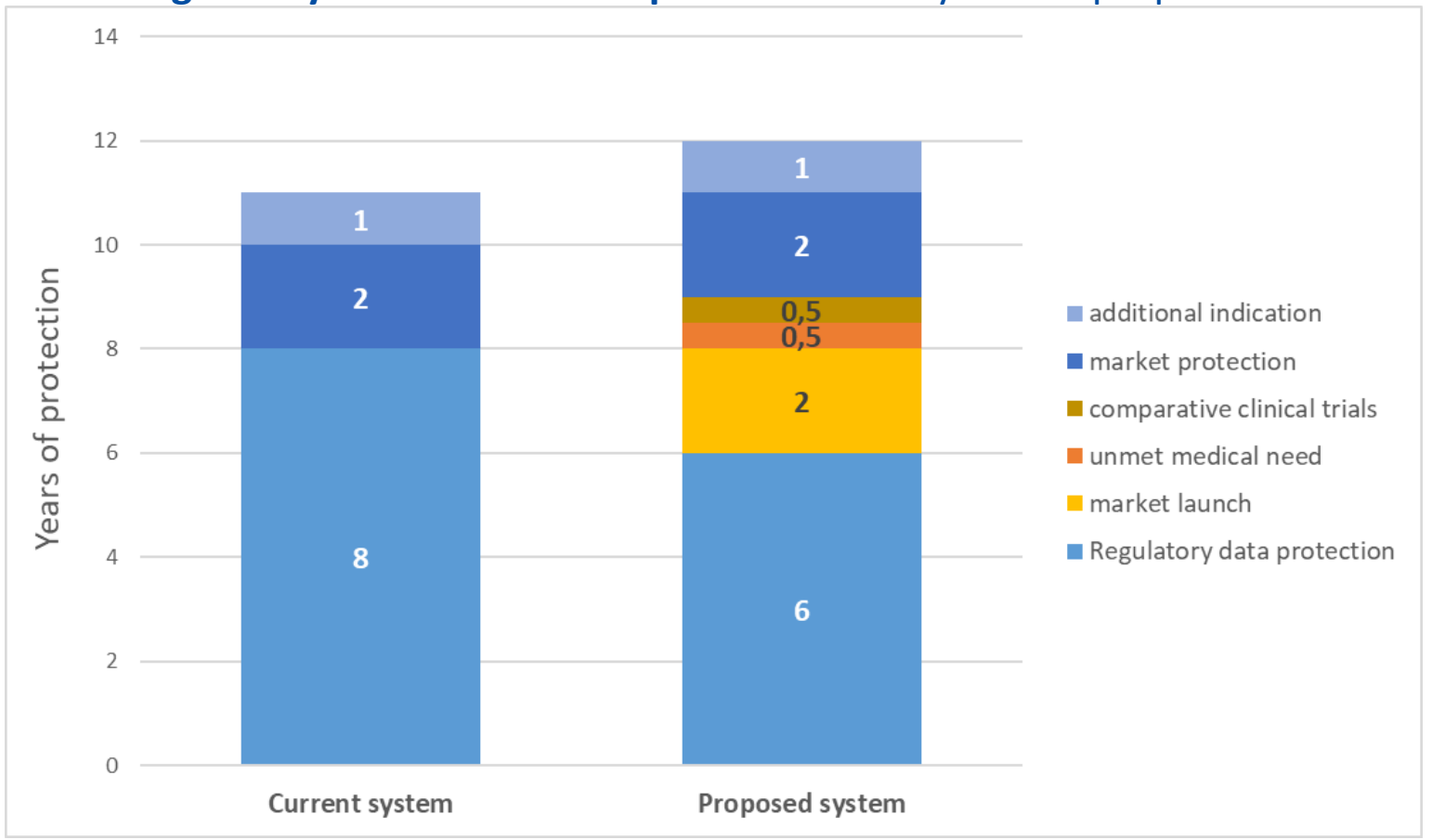
Earlier market entry of generic and biosimilar medicines

Faster authorisation

Pre-authorisation support

Modulation of incentives for innovative medicines

Regulatory data and market protection today and as proposed



Current system, max 11 y protection

Proposed system, max 12 y protection

European Commission

Competitive EU incentives

- 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
- Incentives apply 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	Application Approval Exclusivity (biologics)	4+8 years
Israel	Market Protection	6 or 6.5 years
China	New Chemical Entity	6 years
Japan	New Chemical Entity	8 years

Competitive regulatory framework, conducive to innovation

Innovation friendly, streamlined & agile regulatory framework

Current challenges

Longer approvals times than in other regions

Administrative burden and compliance costs for the industry

The clock stop mechanism

Proposed solutions

Faster authorisation:
a) 180 days standard procedure
b) 150 days accelerated procedure
Regulatory efficiency:
Improved EMA structure, simplified procedures, better use of data (EHDS) 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)

Availability

Availability

October 2023 Commission Communication on addressing medicine shortages in the EU

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**

Contributing to affordability and health system sustainability

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)

Environment & AMR

Environmental sustainability

Current challenges	Proposed solutions
Pharmaceuticals in environment can **harm environment and human health**	**Strengthening ERA requirements** in the context marketing authorisation of medicines
Submission of **incomplete Environmental Risk Assessment** (ERA) in marketing authorisation applications	**Extending ERA** to older medicines
Presence of **antimicrobials in the environment contributes to AMR**	Inclusion of **risk of AMR selection in the scope of ERA for antimicrobials**, also covering manufacturing

Combatting AMR

Current challenges

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

Proposed solutions

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.

Questions?

Factsheets with more info

[Factsheet - Incentives to steer innovation and achieve public health objectives - European Commission (europa.eu)]

[Factsheet - Steering innovation to address unmet medical needs - European Commission (europa.eu)]

[Factsheet - Access to medicines in all Member States - European Commission (europa.eu)]

[Factsheet - Addressing shortages of medicines and ensuring security of supply - European Commission (europa.eu)]