
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

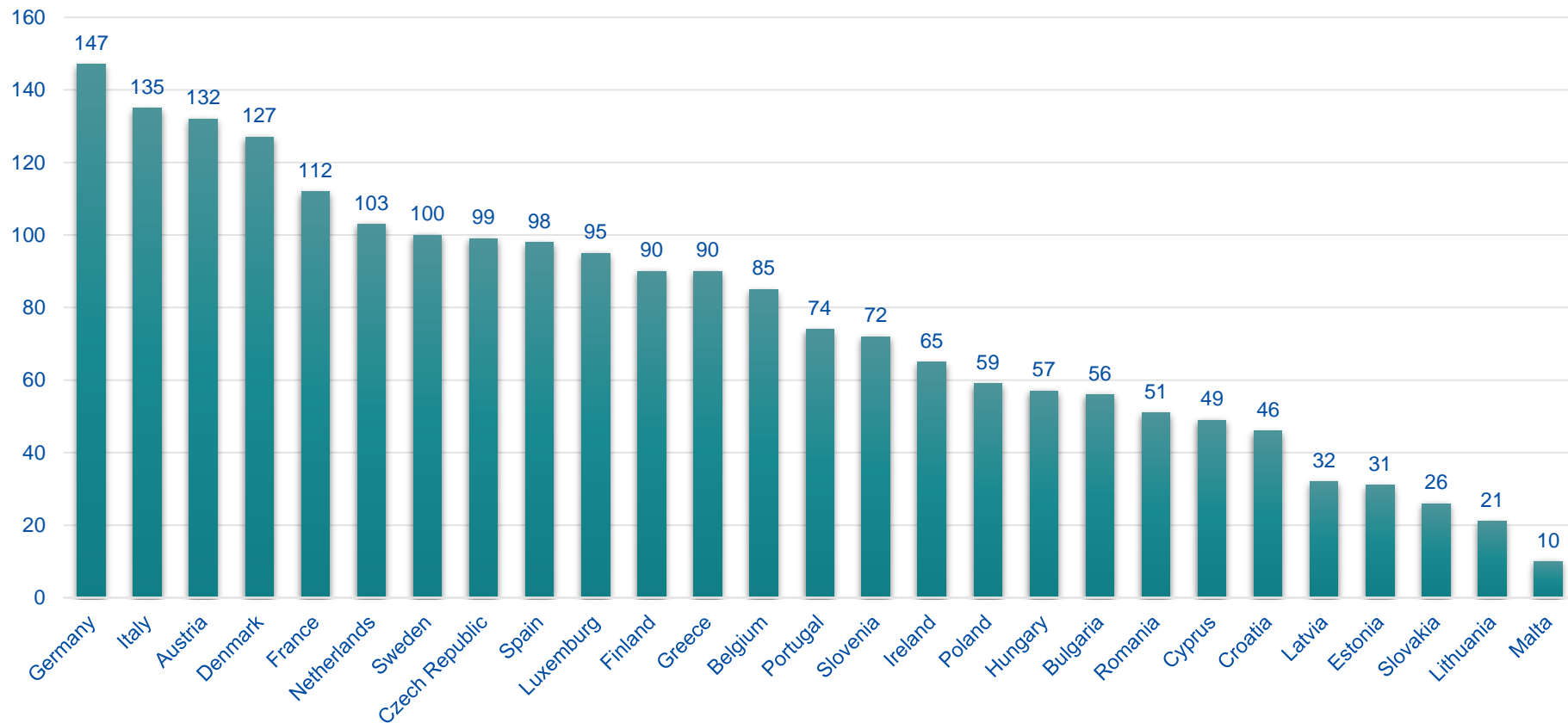
- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- **Objective:**
create a **future-proof**, globally **attractive regulatory framework** to support industry in **promoting R&D** of innovative therapies that **reach patients** across the **EU** and fulfil their **therapeutic needs**



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



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

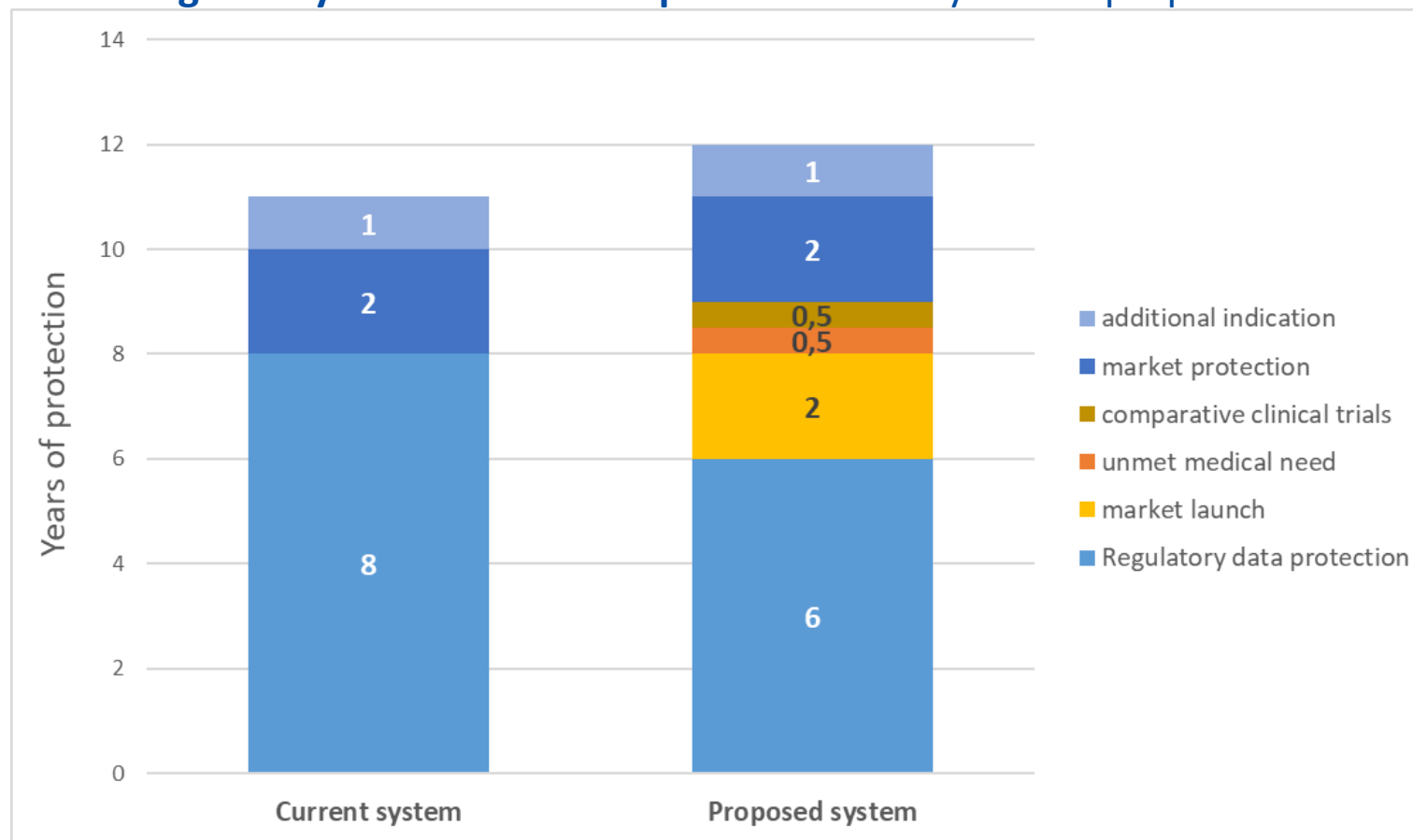
Incentives for innovation and access:
Targeted approach vs current “one-size-fits-all” unconditional data protection and market exclusivity

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

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

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

Submission of **incomplete Environmental Risk Assessment (ERA)** in marketing authorisation applications

Presence of **antimicrobials in the environment contributes to AMR**



Proposed solutions

Strengthening ERA requirements in the context marketing authorisation of medicines

Extending ERA to older medicines

Inclusion of **risk of AMR selection in the scope of ERA for antimicrobials**, also covering manufacturing

Combating 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 \(europa.eu\)](#)



EU Pharmaceutical Reform:
Incentives to steer innovation and achieve public health objectives

February 2024

Modulation of regulatory data protection for all medicines

- Today: A one-size-fits-all system that gives all innovative medicines 8 years of data protection and 2 years of market protection.
- With the reform: A more **targeted approach aimed at achieving public health objectives** i.e. 6 years of standard data protection and 2 years of market protection + conditional extensions.
- No changes to intellectual property rights (patents and supplementary protection certificates).

Data protection: during this period, data from pre-clinical tests and clinical trials of an innovative medicine are protected and a generic or biosimilar version of this medicine cannot refer to those data in its own application for a marketing authorisation.

Market protection: during this period, applications for generic and biosimilar marketing authorisation can already be filed and assessed by the relevant authorities and marketing authorisations granted. However, generic or biosimilar products cannot be placed on the market until the expiry of this period. They can be made available to patients after the expiry of data and market protections.

Intellectual property rights: property rights are granted for an invention for a specified period. They also protect from competition and apply in parallel to the data and market protections. They are not affected by the reform of the EU pharmaceutical regulation.




EU Pharmaceutical reform:
Steering innovation to address unmet medical needs

February 2024

WHY THE REFORM?

Many serious diseases still lack appropriate treatment. Current investments in developing medicines do not always prioritise the greatest unmet medical needs. This is particularly true for diseases that face scientific challenges (e.g. limited understanding of the disease) or limited commercial interest (e.g. rare diseases). As a result, there are serious diseases, such as certain cancers or neurodegenerative diseases, where satisfactory treatments are still lacking. In addition, there are over 6000 known rare diseases, with 95% currently having no treatment option.



WHAT DOES THE REFORM ADDRESS?

Our proposal aims to steer pharmaceutical investment into medicines for unmet medical needs. The proposal defines **specific criteria for unmet medical needs (UMN)** to ensure that the products concerned bring an added therapeutic value to patients that suffer from serious diseases that are not yet sufficiently addressed by existing treatments.

The EMA will develop detailed guidelines for the application of these criteria with input from health technology assessment (HTA) bodies, pricing & reimbursement (P&R) authorities, patient organisations and other relevant groups and will establish a forum for regular exchanges of information and pooling of knowledge on general scientific and technical issues.



EU Pharmaceutical Reform:
Access to medicines in all Member States

February 2024

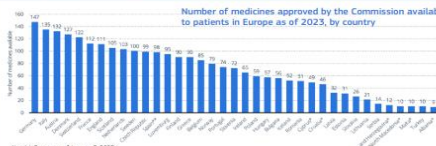
Context:

When a company receives an EU-wide Marketing Authorisation for a medicine, it can market the medicine in all EU Member States. Currently, companies are not obliged to market a medicine in all EU Member States and may decide not to market it in certain countries. After authorisation, and before a new medicine is made available to patients in a particular EU country, most medicines are subject to a Health Technology Assessment and national decisions about pricing and reimbursement or their inclusion in the national health assessments insurance scheme.

Challenges:

Medicines are currently made available to patients at different times in different Member States. In some cases, they are never marketed in some Member States, resulting in unequal patient access. Between 2016 and 2019, out of 152 centrally authorised medicines, up to 88% were accessible to patients in bigger Member States. Patients in small or low GDP Member States had access to fewer than 32% and had to wait significantly longer to access medicines.

Since 2016, the Council and the European Parliament have repeatedly called for action to improve patient access to medicines and to ensure health system sustainability.



Number of medicines approved by the Commission available to patients in Europe as of 2023, by country.

Source: EMA, as of January 5, 2023
Source: IQVIA, IQVIA ID 1011132



EU Pharmaceutical Reform:
Addressing shortages of medicines and ensure security of supply

February 2024

Problem:

Medicines shortages can have serious consequences for Europe's national health systems and for the health of patients in the EU, including their right to access appropriate medical treatment. Shortages can be triggered by many factors, including highly complex and specialised supply chains, the lack of geographical diversification when sourcing certain key ingredients and medicines and perceived regulatory complexity.

Why the reform?

The EU's pharmaceutical reform aims to mitigate and address shortages of medicines and enhance security of supply so that medicines are available for citizens across the EU at all times.

There is a clear need for greater EU-wide coordination, increased legal empowerment of authorities and appropriate measures to safeguard the supply and availability of medicines for EU citizens, not only during public crises but at all times. Continued coordinated action is also needed to address potential challenges in the supply of critical medicines and to make Europe's medicine supply chains more resilient in the long run.



European Commission