European Commission

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.

- Conditional extensions of data protection:
  - **+ 6 months** if a medicine addresses **'unmet medical needs'**:
  - **+ 6 months if the applicant has** carried out **comparative clinical trials:**
  - **+ 2 years** if a medicine is available **in all Member States where the marketing authorisation is valid** within 2 years after authorisation (3 years for SMEs and not-for-profit entities);
  - **+ 1 year for any additional therapeutic indications:**

The current maximum of regulatory protection (data and market protection together) is 11 years. In the future, it will be 12 years.

Modulation of regulatory data protection for orphan medicines

- Today: A one-size-fits-all system of unconditional market exclusivity of 10 years.
- With the reform: A more targeted approach aimed at achieving public health objectives i.e. a standard market exclusivity of 9 years (5 years for medicines authorised on the basis of scientific literature) + conditional extensions.

> **Orphan market exclusivity:** during this period, any similar medicines for the same orphan indication cannot be placed on the market.

- Conditional extensions of data protection:
  - **+1 year** if a medicine is available within 2 years after authorisation (3 years for SMEs and not-forprofit entities) **in all Member States** where the marketing authorisation is valid;
  - **+1 year** if they address a **high unmet medical need within rare deseases** (all orphan medicines are considered unmet medical need);
  - **+1 year for any additional therapeutic indications** for an already authorised orphan medicine (up to 2 years).
  - **The current maximum of regulatory protection is 10 years. In the future, it will be 13 years.**

Impact on patients and health systems

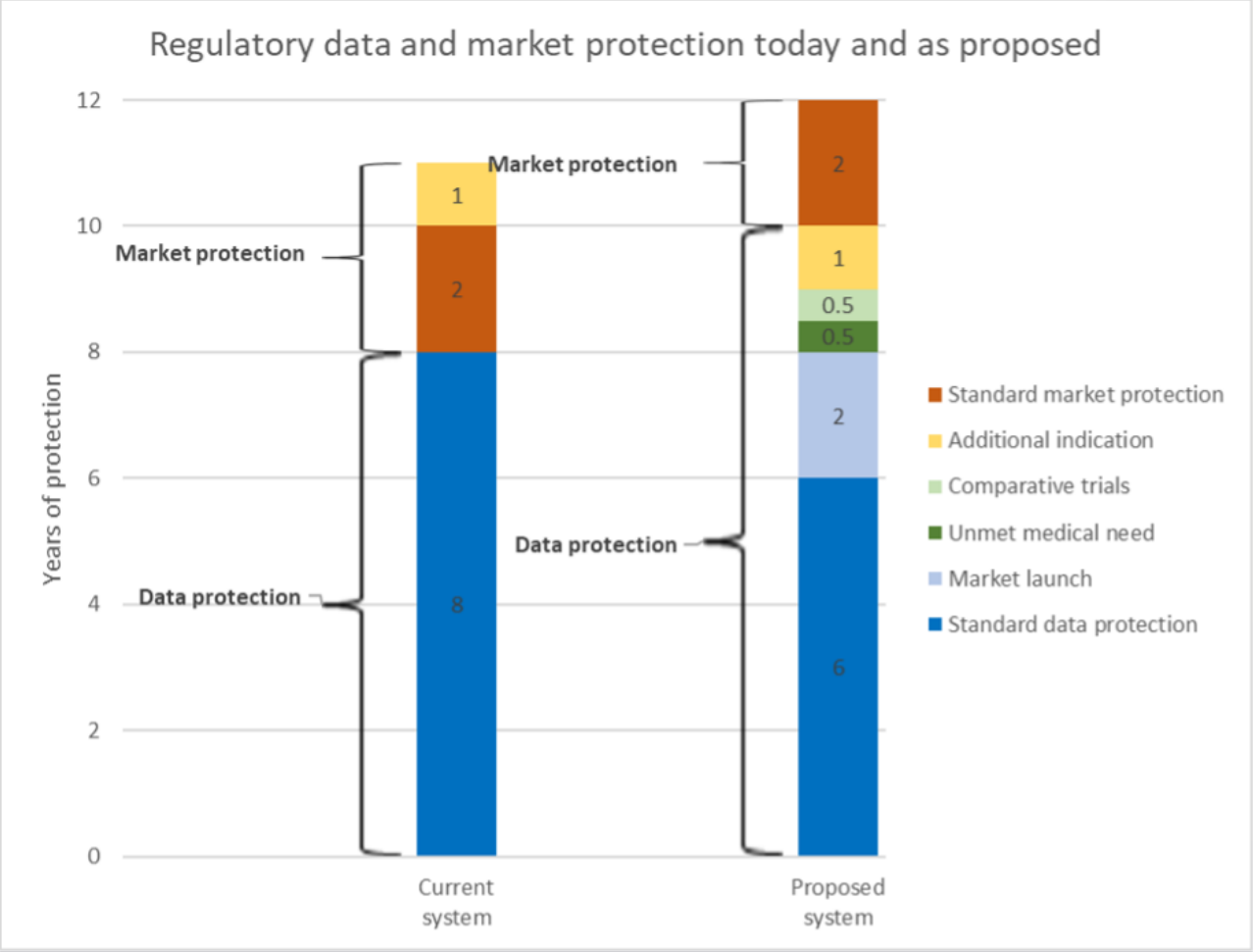
- The combination of intellectual property rights and regulatory data protection will ensure that the EU continues to have **one of the most generous systems of incentives in the world**.
- The reform will bring a 15% increase in access to innovative medicines, benefiting an **additional 67 million patients** in the EU.
- The reform's simplification measures will lead to **EUR 300 million annual savings** - EUR 100 million for the industry and EUR 200 million for Europe's health systems – due to simpler rules, shorter market authorisation procedures and more future proofing and digitalisation.
- Topping up the Commission proposal with an additional year of regulatory data protection would come with a price tag of EUR 1.23 billion for health systems due to the delayed entry of generics. The cost of any additional year would be significantly higher. For orphan medicines, the cost for an additional year of market exclusivity for health systems would be €0.41 billion. This would put Member States' health budgets under further strain. In addition, patients who could, for the first time, have access to treatment through generic or biosimilar entry, would have to wait longer.

Impact on competitiveness

There is no direct link between regulatory incentives and where the innovation takes place. Pharmaceutical R&D decisions are primarily driven by other factors than the protection periods provided in a given region. Such factors include tax policies, skills, investment in research universities etc.

Moreover, the reform introduced many measures aimed at enhancing innovation and therefore competitiveness of EU pharmaceutical industry.

Modulation of incentives for all innovative medicinal products



Modulation of incentives for orphan medicines as opposed to other medicines