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EU Pharmaceutical Legislation Reform

Intense Debate Over Proposed Changes to Regulatory Data Protection and Market Exclusivity

TRENDING TOPICS

European Proposal

In 2020, the European Commission (EC) proposed a New Pharmaceutical Strategy for Europe focused on patients, aiming to ensure the quality and safety of medicines while **boosting the sector's global competitiveness**. During its April 2024 plenary session, the European Parliament adopted its position at first reading on two Commission proposals to revise the EU's pharmaceutical legislation. The file will be followed up by the new Parliament after the 6 - 9 June 2024 European elections.

Among several initiatives, one of the most important is the change of regulatory data protection for all medicines, including Orphan medicines which is part of the incentives to steer innovation and achieve public health objectives.

To better understand this initiative and its impact on medicine access, it's essential to revisit three key concepts: **'Intellectual property rights', 'Data protection' and 'Market protection'**.

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.

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.

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Intellectual property rights shall remain unaffected by the reform of the EU pharmaceutical regulation. However, Data and Market Protection will be impacted. The reform proposes to reduce the duration of data protection currently in force. Nevertheless, certain conditional extensions will be implemented. If the Marketing Authorization Holder (MAH) complies with these conditions, they will have the opportunity to extend regulatory protection by one or two years, depending on the type of medicine. These changes are concisely summarized in the table below.

Table 1 – EU Adjustment of the incentives for all innovative and orphan medicines

	Current	Proposed	Summary
All Innovative Medicines	Data protection: 8 years Market protection: 2 years	Standard data protection: 6 years plus Conditional extensions: + 6 months for 'unmet medical needs' medicine + 6 months for comparative clinical trial + 2 years medicine available in all MS (1) + 1-year additional therapeutic indication Market protection: 2 years	Data and Market protection together: Current: 11 years Proposed: 12 years
Orphan Medicines	Unconditional market exclusivity: 10 years	Standard market exclusivity: 9 years (2) plus Conditional extensions: + 1 year for 'unmet medical needs' medicine within rare diseases (3) + 1 year medicine available in all MS(1) + 1-year additional therapeutic indication (4)	Maximum of regulatory protection: Current: 10 years Proposed: 13 years

(1) Where the marketing authorisation is valid within 2 years after authorisation (3 years for SMEs and not-for-profit entities).

(2) 5 years for medicines authorised on the basis of scientific literature.

(3) Considering that all orphan medicines are considered unmet medical need.

(4) For an already authorised orphan medicine (up to 2 years).

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

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The Debate

While the reform aims to strike a balance between incentivizing innovation and ensuring timely access to medicines, some argue that reducing Regulatory Data Protection (RDP) and orphan market exclusivity could hinder investment in life sciences in Europe. Comparisons with the more attractive regulatory data protection system in the US are also relevant.

What objections against the proposal have been raised by EU stakeholders?

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European Federation of Pharmaceutical Industries and Associations

- RDP is crucial for EU's competitiveness.
- Emphasizes the financial benefits for patients, the EU, and member states.
- Concerns about reducing new medicines availability in Europe.
- Argues against the Commission's cost estimate of €1.2 billion/year, suggesting €2 billion/year instead.
- Highlights the importance of R&D attractiveness, especially for advanced therapies.
- Notes the US has a more attractive RDP (12 years for biologics, 6-7 years for small molecules).

medicines for europe
better access. better health.

- Warns of potential misunderstanding about RDP extensions.
- Concerned about extended RDP durations exceeding Supplementary Protection Certificate (SPC) (up to 18 years), delaying generics/biosimilars entry.
- Estimates significant budget impacts (€2.5-5.35 billion for France, Germany, Spain; up to €99.5 billion for EU).
- Emphasizes dual track of pharmaceutical incentives (regulatory and patent/SPC).

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- Criticizes high costs of RDP extensions on public budgets.
- Argues RDP extensions distort competition and delay patient access.
- Supports a 6-year standard RDP with limited extensions.
- Proposes alternative incentives for developing new antibiotics.
- Calls for a balanced reform, ensuring generic competition to treat more patients at lower costs.

JURI Committee (EU Parliament)

- Stresses the need for balance between innovation and rapid access to essential products.
- Recommends clarifying "crisis" definitions and ensuring proportionate measures.
- Suggests Union compulsory licenses as a last resort, with a max duration of 12 months.
- Proposes clearer definitions for necessary manufacturing know-how and advisory board roles.
- Emphasizes rights-holders' involvement in licensing processes and fair remuneration.

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Around the World

How are regulatory protections, also known as regulatory exclusivities, assigned around the world? Let's compare Europe with the competitiveness of USA, and with Japan having an interestingly different approach to data exclusivity system.

The United States

In the United States, the term "regulatory exclusivity" typically refers to a period during which the Food and Drug Administration (FDA) grants approved drugs protection from competing applications for marketing approval. While FDA exclusivity primarily relates to market exclusivity, it may also result in data exclusivity for a certain duration. Below is a short overview table summarizing the various types of FDA exclusivities:

Table 2 – US FDA exclusivities

21	Duration	Key Conditions
New Chemical Entity (NCE)	Up to 5 years	No ANDAs or s 505(b)(2) applications accepted for the same active moiety during this period.
	4 years	If ANDA or s 505(b)(2) application includes a certification of patent invalidity/non-infringement.
	5 years	If ANDA or s 505(b)(2) application does not include such a certification.
Orphan Drug Exclusivity (ODE)	7 years	For diseases affecting fewer than 200,000 people in the US (or more than 200,000 without cost recovery prospects).
Other Exclusivity (New Clinical Investigation)	3 years	For new indications, combination products, or changes to existing products based on new clinical investigations (other than bioavailability).
Paediatric Exclusivity	Additional 6 months	Granted if paediatric studies are conducted and submitted in response to FDA request. This period can be extended to any existing exclusivity period.
GAIN* Exclusivity	Additional 5 years	For products designated as Qualified Infectious Disease Products (QIDP).
First Generic Exclusivity	180 days	For the first ANDA applicant challenging a listed patent. Begins with first marketing or court decision.
Biologics Reference Product Exclusivity	12 years (plus 6 months paediatric)	No 351(k) applications accepted for 12 years from first licensure (plus an additional 6-month period for paediatric indication). Submissions allowed 4 years after first licensure.

* GAIN: Generating Antibiotic Incentives Now

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Japan

Unlike other countries, Japan does not have a data exclusivity system. Instead, generics are delayed by the re-examination period in pharmaceutical regulations and patent terms. Price listing under the national insurance system may also be relevant. Japan's approach differs from regions like the US and EU, which have specific data exclusivity laws. In Japan, the re-examination period, a post-marketing surveillance system designated by the Minister of Health, Labour, and Welfare, effectively acts as data exclusivity. During this period, additional data is collected, and safety and efficacy are re-evaluated after its expiration. See the table below for re-examination period durations.

Table 3 – Duration of re-examination period in Japan

	Types of New Drug	Column A: range	Column B: maximum	Column C: general principle
1.1	Orphan drugs; and Other drugs specified by the Ministry of Health Labour and Welfare as requiring more than six years of re-examination.	Six to 10 years	10 years	10 years
1.2.1	New indication drugs (excluding 1.1 and 1.2.2); and New dosage drugs and new administration drugs (excluding 1.1 and 1.2.2).	Not exceeding six years		4 years
1.2.2	If the indications of the prior approved drug are those of orphan drugs so designated under the PMD Act, but include no other indications: drugs with new indications; and drugs with new dosages and drugs with new administrations.			5 years and 10 months
1.3	New drugs other than 1.1, 1.2.1 and 1.2.2: drugs with new active ingredients; and drugs with new administration routes.	At least six years		8 years *(drugs with new active ingredients)* 6 years *(drugs with new administration routes)*

There is no specific categorisation for paediatric medicines in this regard, but the re-examination period may be extended (not exceeding 10 years) as per the necessity to collect clinical data required for the re-examination of dosage or administration for child use.

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Conclusion? Not reached yet...

The ongoing debate surrounding the proposed changes to European Regulatory Data Protection and Market Protection within the context of European Pharmaceutical legislation reform centres on striking a balance between incentivizing innovation and ensuring timely access to affordable medicines while keeping up with the competitiveness and attractivity of other markets around the world. As discussions continue and stakeholders provide input, the European Parliament's position will play a crucial role in shaping the final legislation. Harmonizing the perspectives is crucial to creating a regulatory framework that supports patient welfare and industry growth.

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