



The 2023 European Commission proposal and the 2024 European Parliament proposal for the EU pharmaceutical legislation: policy content analysis

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ARTICLE INFO

Keywords:

Pharmaceutical legislation
European Union
Innovation

ABSTRACT

A revision of the pharmaceutical legislation is ongoing at the European Level. The European Commission proposed a first draft in April 2023, and the European Parliament has adopted a position on the proposal in April 2024. The proposal consists of a new Directive and a new Regulation, with the aim of integrating different provisions that have been introduced over time. The proposal aims at encouraging the industry in conducting research and developing technologies that reach patients, while addressing market failures. We discuss both general and targeted incentives that are proposed, as well as the provisions to foster access to medicines for all patients in the European Union. Although the legislative process has not been completed yet, an analysis of the texts that have been debated in the early stages, vis-à-vis the legislation in force, can inform on the most relevant and debated issues and on the aspects the reform is most likely to affect.

1. Background

The year 2015 has marked the 50th anniversary of the first law on the authorisation of pharmaceuticals at EU level [1] and 20 years since the founding of the European Medicine Agency (EMA) and the first centrally authorised medicine for human use [2]. In the early 2000s, a set of directives and regulations was adopted that define the existing pharmaceutical legislation [3–6]. All relevant aspects of the medicines life cycle in the EU are considered, from development to marketing authorisation, manufacturing, use and related pharmacovigilance of medicines for human use. Specific instruments for orphan and paediatric medicines are regulated, as well as the role of EMA, which was strengthened over time [7].

This complex regulatory framework has allowed the achievement of remarkable results in terms of patient outcomes [8]. However, several challenges still need to be addressed. Access to medicines is not homogenous across the EU [9,10]. New medicines put pressure on pharmaceutical budgets, raising concerns about the affordability of innovative treatments [11]. Moreover, some therapeutic areas remain understudied, as private investments are linked to expected returns and

to the size of the market [12,13]. As a result, a partial misalignment may emerge between private industry's R&D priorities and public health goals [14]. A particularly serious threat is related to the combination of growing antimicrobial resistance (AMR) and insufficient innovation in the area of antimicrobials [15].

While some of these challenges have been known for some time, the COVID-19 pandemic highlighted additional weaknesses of the system, such as shortages -potentially due to a strong dependency upon the supply of active pharmaceutical ingredients by third countries-, the outsourcing of pharmaceutical production and parallel import [10].

To tackle these issues, in 2020 the European Commission (EC) adopted the "Pharmaceutical Strategy for Europe", which is based on four pillars: I) ensuring access to affordable medicines and addressing unmet medical needs (such as orphan diseases and AMR), II) supporting the competitiveness of the European pharmaceutical industry and promoting sustainable innovation, III) improving crisis preparedness, IV) promoting high standards of quality, efficacy and safety [16]. The Pharmaceutical Strategy for Europe includes several legislative and non-legislative measures, including a revision of the pharmaceutical legislation. In April 2023, the EC proposed to the European Parliament

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<https://doi.org/10.1016/j.healthpol.2025.105408>

Received 7 March 2024; Received in revised form 8 January 2025; Accepted 21 July 2025

Available online 25 July 2025

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(EP) and the Council a new Regulation [17] and a new Directive [18] to replace the existing legislation. In April 2024 the EP adopted some amendments to the texts proposed by the EC [19,20]. Following the Council's position, the next step is an informal interinstitutional negotiation bringing together representatives of the EP, the Council and the EC, aiming to reach a provisional agreement that must then be adopted by each of these institutions' formal procedures.

This article focuses on two aspects of the reform proposals, which are also pillars of the Pharmaceutical Strategy for Europe: incentives for innovation and mechanisms to improve patient access to affordable medicines. We provide a description of the measures included in the proposals of the EC (2023) and of the EP (2024) and compare them with the status quo. For a comparison with incentives provided in other geographic areas, see [21].

2. Incentives for access and innovation proposed

2.1. Data exclusivity and market protection

In addition to the protection granted by patents (and supplementary certificates), under the legislation in force, new medicines are entitled to regulatory data protection (hereinafter RDP) and market protection, which provide additional incentives for innovation for the industry.

RDP provides the beneficiary with the exclusive rights to use the results of preclinical tests and clinical trials for a given period. During this period, these data cannot be used by a third-party applicant in the application for marketing authorisation. The aim of this incentive is to protect the economic investment made by originator companies in carrying out preclinical and clinical trials. Under the legislation in force, RDP in the EU lasts eight years from the first marketing authorisation granted in a Member State and runs concurrently with 10 years of market protection, as well as with patent and supplementary patent protection [7, art. 14(11)].

During the period of market protection, a generic, hybrid or bio-similar cannot enter the market. However, market protection does not prevent distinct products for the same indication from entering the market, thus allowing originator-competitor competition. Market protection can be extended by one year in the case of authorisation of new therapeutic indications providing significant clinical benefit compared to existing therapies (the market authorisation must be obtained during the first eight years of protection). All in all, RDP and market protection can last for "8 + 2 + 1" years (see Fig. 1).

The EC and EP proposals introduce a modulated RDP to drive companies' innovation efforts, whereas the two additional years of market protection are maintained [18, art. 80–81]. The two proposals differ in

the length of the "standard" RDP: six years in the EC proposal and seven years and a half in the EP proposal [20, amendment 199].

In both proposals, extensions of the standard period of RDP are admitted under specific circumstances, with the aim of providing additional targeted incentives for the industry. In the EC proposal extensions can be gained (i) in case of EU-wide launch (two years), (ii) for products addressing an Unmet Medical Need (UMN) (six months), (iii) for products that underwent "comparator" clinical trials (six months), (iv) for products obtaining, during the RDP, an authorisation for an additional therapeutic indication, with significant clinical benefits compared to existing therapies (this extension can be granted only once). On the other hand, the length of market protection is fixed.

In the Parliament proposal, RDP extensions are admitted for products addressing UMN (one year), "comparator" trials (six months) or (new in [20]) when the R&D is conducted within the EU and in collaboration with public entities (six months) [20, amendments 200–202]. However, the maximum period of RDP is set to eight years and six months [20, amendment 206]. The Parliament's proposal re-introduces the one-year extension of market protection for new indications [20, amendment 196].

The RDP extension granted in the case of an EU-wide launch, proposed by the EC, has not been confirmed in the EP text. In the case of the Parliament, the same objective is pursued through the introduction of an obligation for the marketing authorisation holder to apply for pricing and reimbursement upon request of the Member States [20, amendment 174].

Fig. 1 shows the overall regulatory protection (RDP and market protection), with and without extensions, under the legislation in force (status quo), the EC and Parliament proposals. As already mentioned, regulatory protection does not prevent originator-competitor competition, which has been accelerating over time [22].

If some conditions are met, both in the EC and EP proposals, repurposed medicines (i.e., a medicine obtaining a new therapeutic indication not previously authorised in the EU) can also be granted four-year RDP [18, art. 84].

As a further novelty with respect to the current framework, both RDP and market protection shall be suspended in a Member State when a compulsory licence is granted [18, art. 80(4); 20, amendment 197].

2.2. Orphan drugs

In Europe, an orphan medicine is defined as one intended to treat a disease that is a) life-threatening or chronically debilitating, and that affects less than 5 people in 10,000 or that is unable to generate sufficient returns, and b) for which no satisfactory method of diagnosis,

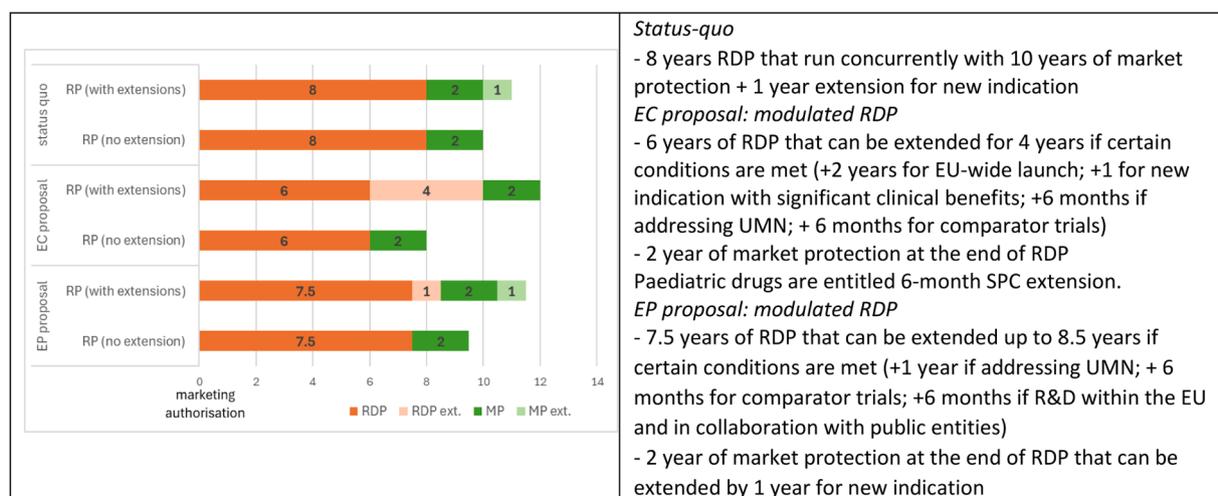


Fig. 1. Regulatory protection (RP): RDP and market protection for new drugs.

prevention or treatment is available in the EU or that offers significant advantages over existing options [6].

Since orphan diseases affect a “small” number of individuals, expected returns would not be sufficient to foster private R&D efforts in these areas. However, equity considerations would suggest that the same quality of treatment should be assured to rare disease patients as other patients. Specific provisions have, therefore, been introduced around the world to foster private research on rare conditions, to be added to the data exclusivity and market protection provided to all medicines [23].

The US first introduced orphan-specific regulations in 1983 (Orphan Drug Act, US-ODA, [24]). In Europe, Orphan Drug legislation was introduced in 2000 [6] and includes subsidies for protocol assistance, reduced application fees and 10 years of market exclusivity, which grants protection from similar medicines (i.e., medicines that rely on the same active substance, or on an active substance with the same principal molecular structural features and which acts via the same mechanism) targeting the same disease. The US-ODA also provides tax credits for R&D expenditures and subsidies for clinical trials. Within the EU, these additional incentives remain the responsibility of Member States.

Orphan drug provisions are considered successful in stimulating the development of orphan medicines (see, among others, [25,26]). However, they may have contributed to widening the gap in the availability of treatments among orphan diseases, by leading to a concentration of R&D investments toward rare diseases with comparatively high prevalence [23,25]. This tendency seems to be driven mainly by pull incentives, such as market exclusivity, the power of which grows with the size of the market [23]. The EC and EP proposals still rely on market exclusivity to incentivise innovation for orphan diseases. However, they introduce a modulated exclusivity period, which is set to nine years and reduced for active substances with well-established use (five years in the EC proposal, four years in the Parliament proposal). An extension of the exclusivity period is granted for orphan medicines addressing “high UMN” (ten years in the EC proposal, eleven years in the Parliament version) [17, art 71; 19, amendments 204–205], i.e. products treating a condition with no authorised medicine in the EU, or providing “exceptional therapeutic advancement” compared to other products with an indication for the same condition [17, art 70; 19, amendment 201–202].

In [17, art. 72], to support the launch and supply to all Member States, the nine- and ten-year market exclusivity period can be prolonged by one additional year if patients from all EU countries have access to the orphan medicine; this extension is not confirmed in [19]. As a measure to support further development of authorised orphan medicines, new indications (obtained at least two years before the end of the exclusivity period) are entitled to one additional year of exclusivity. However, this extension can only be granted twice [17, art. 72] to

prevent the possibility of ever-greening strategies (see e.g.,[27]). See Fig. 2 for a comparison of the EC and EP proposals with the legislation in force (status quo).

2.3. Antimicrobials and the emergence of antimicrobial resistance

AMR is becoming a pressing issue [28]. It is estimated that 25,000 patients die annually in the EU because of infections caused by resistant bacteria [29,30].

The Pharmaceutical Strategy for Europe calls for new incentives for the development of antimicrobials [16] and the EC and EP proposals introduce new tools for the development of priority antimicrobials. A priority antimicrobial is defined as an antimicrobial providing “significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics: (a) it represents a new class of antimicrobials; (b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union; (c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life-threatening infection.” [17, art. 40(3); confirmed in [19, art. 39 (new), amendment 147]].

To incentivise the development of priority antimicrobials, both the EC and EP proposals introduce an innovative incentive, the transferable data exclusivity voucher (TEV), which has never been used before. Indeed, in the US, vouchers are granted since 2007, but these are “priority review vouchers”, which provide access to an expedited review process for marketing authorisation [31]. The holder of a TEV could use it to extend RDP for any product in its portfolio or sell it to another marketing authorisation holder. The EC proposes one-year vouchers [17, art. 40], whereas the EP introduces different lengths based on the WHO classification of pathogens or equivalent list established at the Union level: 12 months if critical, 9 months if high and 6 months for medium [19, amendment 151]. TEVs can only be used or sold once [17, art. 41], and provisions are introduced to ensure competitors are able to predict in advance the timing of the expiry of the exclusivity period [17, art.41–42; 19, amendment 162]. The Parliament excludes products that already benefit from maximum RDP from voucher eligibility [19, amendment 159]. The use of the voucher is linked to obligations related to the supply of the product for which the TEV was granted in the EU [17, art. 40; 19, amendment 153]. To enhance transparency, the marketing authorisation holder is required to disclose the financial support for the development of the priority antimicrobial from any source worldwide (only direct support in [17, art. 40], also indirect financial support in [19, amendment 154]). Given the novelty of this incentive, an experimental phase is planned, involving a maximum of 10 products or 15 years, after which the measure will be assessed [17, artt. 40–43]. The

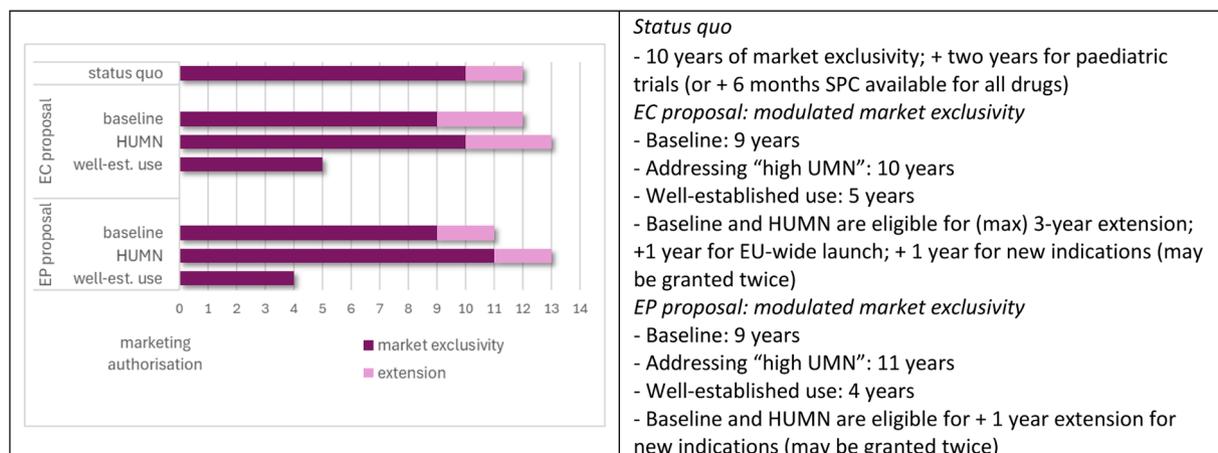


Fig. 2. Market exclusivity period for orphan drugs.

Parliament also plans a scientific evaluation of TEVs after five years [19, amendment 165].

The Parliament proposal also introduces milestone payments [19, amendment 147], prizes paid to the inventor when pre-defined development stages are completed. These prizes would take into account the costs of the development stage achieved and the anticipated cost of the next stage and are introduced as an alternative to TEVs (products receiving milestone payments cannot receive a TEV). Moreover, the EP proposal also introduces a subscription model for the joint procurement of antimicrobials [19, amendment 148], as suggested in a Commission Communication [32]. Subscription models involve buyers paying a lump-sum 'subscription' to the manufacturer for a set period, delinking revenues from the volume of drugs sold. Thus, this scheme provides an incentive to invest in drugs that would otherwise be unprofitable and may also promote appropriate antibiotic stewardship by de-linking payment from consumption and reducing companies' incentives to boost sales [33].

3. Discussion

The main pillars of the EU pharmaceutical legislation currently in force were designed in the early 2000s. Since then, several innovative medicines reached the market and a large number of EU patients had access to them, with positive impacts on health outcomes. Nonetheless, several challenges need to be addressed, including a growing pressure on healthcare budgets associated with innovation, the heterogeneous access to new medicines, the existence of UMN, the emerging threat of AMR. The ongoing process of revision of the EU pharmaceutical legislation aims to address these challenges. A description of and a comparison between the proposals of the EC and the EP can help identify the most debated or controversial issues, on which future health policy research will hopefully shed light.

The trade-off between the incentives to invest in R&D provided by patents and regulatory protection and access to medicines has been widely debated in the literature (see, among others, [34,35]). Moreover, establishing a precise link between the length of the protection period and innovation incentives is complicated [34]. Hence, it is no surprise to see that the EC (2023) and EP (2024) proposals differ on this dimension. Both of them, but especially the EC proposal, depart from the current model where the variability in the length of regulatory protection is very limited to move toward a model involving a reduced length of baseline protection, to be extended under certain circumstances. A reduced baseline regulatory protection may be a way to address the constant increase in pharmaceutical expenditure experienced over recent years, while using extensions to provide incentives with the aim of tackling some of the critical points that emerged from the current model, such as inequality in access across countries and the problem of UMN. Both the EC and the EP proposals include measures aimed at reducing the risk of inequality in access across Member States. However, they also adopt two rather different approaches, showing that no obvious solution to the problem exists.

The same approach of modulated incentives is proposed for rare diseases. Notably, the proposals seem to show awareness that not all UMN are the same, by introducing the new concept of highly UMN. However, for such small markets, where expected revenues per year are very low, relying solely on market rewards is unlikely to achieve the goal of providing at least one therapeutic option for these patients who currently have none. In these areas, more innovative tools involving the decoupling of revenues from volumes are needed.

Decoupling is even more important to incentivise the development of new antimicrobials, because the more targeted the product, the lower AMR risks, but this also implies limited revenues. It is interesting to note that the peculiarities of this challenge seem to have led to the introduction of innovative regulatory tools in the proposals. The EC proposal mainly relies on TEVs. Their adoption has raised concerns related to their financial impact on pharmaceutical expenditure (as TEVs may be

used on blockbuster drugs) and to the risk of overcompensating antimicrobial innovation [36,37]. In a recent assessment, Dubois et al. [38] argue that TEVs may be cost-effective. However, the final outcome depends on the buyers' market power and the degree of competition in the generics market. Concerns on the use of TEVs were expressed by several Member States [39,40], which may explain why both the EC and EP have placed restrictions on their use. In particular, the EP proposal is more restrictive on the use of TEVs, but introduces additional innovative tools, such as subscription models for the joint procurement of antimicrobials and milestone payments (not compatible with TEV for the same product). These regulatory innovations will be extremely important to learn more about the strengths and weaknesses of these new types of innovation incentives through real-world applications, although empirical evaluation of their impact will take time.

Finally, the proposed measures also push for greater coordination among countries in negotiation and tendering, which is one of the goals of the Pharmaceutical Strategy for Europe, expected to bring benefits in terms of patient access. It will be interesting to see if greater coordination, which was experimented during the pandemic emergency, is also feasible out of emergencies.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CRedit authorship contribution statement

Simona Gamba: Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Laura Magazzini:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Paolo Pertile:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization.

Declaration of competing interest

None.

Acknowledgments

The authors were commissioned by the STOA panel of the European Parliament to write a report on the reform of the European pharmaceutical legislation. The views contained in this article are solely those of the authors and in no way represent the views of the European Union institutions. We also acknowledge comments and suggestions from two anonymous reviewers.

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