PHARMACEUTICAL LEGISLATION REFORM

Proposal COM(2023) 193 of 26 April 2023 for a **Regulation** of the European Parliament and the Council **laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency**

Proposal COM(2023) 192 of 26 April 2023 for a **Directive** of the European Parliament and the Council **on the Union code relating to medicinal products for human use**

cep**PolicyBrief** No. 2/2024

SHORT VERSION [Go to Long Version]

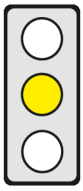
Context | Objective | Interested Parties

Context: An ageing society, worldwide competition, dependencies, and the fragmented progress of digitalisation show that a renewed regulatory basis is needed to ensure a future-proof European Health Policy. For this, the Commission proposes two laws, a regulation [COM (2023) 193, "Regulation Proposal"] and a directive [COM (2023) 192, "Directive Proposal"]. The Commission tries to ensure that patients have access to affordable medicines EU-wide while stimulating innovation and keeping a balance between protecting intellectual property and ensuring competition.

Objective: The Commission tries to reach several goals at once, ranging from ensuring "affordability", "access" and "availability" of medicines, while at the same time fostering innovation in Europe.

Interested Parties: Patients, healthcare professionals and providers, pharmacies, and the pharmaceutical sector.

Brief Assessment



Pro

- Reducing the period of time in which an innovative company's regulatory data is protected from being used by competitors to seek authorisation for their medicine will stimulate competition as competitors can rely on it sooner thereby enabling earlier market entry of generics and biosimilars.
- The proposed transferable Data Exclusivity Voucher is a proportionate means to incentivise the development of new antibiotics at EU level in order to address the public health threat of antimicrobial resistance.

Contra

- Reducing the period of time in which an innovative company's regulatory data is protected from being used by competitors to seek authorisation for their medicine will reduce the incentive to bring innovative medicines to the market.
- The obligatory refusal of an authorisation for a new medicine based on an "insufficient" Environmental Risk Assessment may hinder patient access to new safe and effective medicines.
- The Commission will later be empowered to introduce electronic-only packaging leaflets – rather than keeping non-digital formats –but this is a public health policy decision which should remain with the Member States and made in their country-specific context.
- The Commission's power to amend environmental risk assessment requirements is a violation of the principle of reserving "essential elements" of law for the EU Parliament and Council.

Regulatory Data Protection [Long Version A.4.1 and C.1.1]

Commission proposal: Data submitted to obtain an authorisation for a new medicine can be used by others after regulatory data protection (RDP) has lapsed. A cumulative RDP system is introduced which will reduce the length of the basic RDP from 8 to 6 years. In addition to the basic RDP, more time can be earned by launching and continuously supplying a new medicine in all Member States (2 years), addressing an unmet medical need (6 months), conducting comparative clinical trials (6 months), and obtaining an additional therapeutic indication (1 year) – in theory totaling up to 10 years.

cep-Assessment: The proposed approach is generally appropriate but has several practical weaknesses. For instance, certain conditions such as "continuous supply" are unclear and must be clarified right away. On average the total RDP period will decrease. This will facilitate needed competition within the EU. However, in order to remain globally competitive, the basic RDP period should be set to 7 years.

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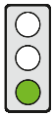
Data Exclusivity Voucher [Long Version A.4.4 and C.1.2]

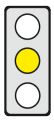
Commission proposal: A transferable data exclusivity voucher ("voucher") will reward the developer of a "priority" antimicrobial (e.g., an antibiotic). To be classified as such, it must have a significant clinical benefit with respect to antimicrobial resistance (AMR) and must meet at least one other strict criterium. This incentive system is limited to 10 vouchers over 15 years. The voucher allows for an additional 12 months of RDP for a medicine. The developer can use it for the new antimicrobial, for another medicine in his portfolio or sell it. A voucher can be transferred only once.



cep-Assessment: New antimicrobials are an important way to combat AMR and are urgently needed. Yet, the developmental pipeline is dry. All incentive systems have their advantages and disadvantages. For instance, it is very likely that a voucher will be sold and used for a commercially successful medicine thereby prolonging the ability to charge a monopoly price. However, as the voucher system is restricted in several ways, it is a proportionate method and should be implemented.

Environmental Risk Assessment (ERA) [Long Version A.5.2 and C.1.3]

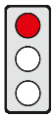
Commission proposal: As part of the authorisation application, an Environmental Risk Assessment (ERA) must be conducted to evaluate and eventually reduce the impact on and risks of pharmaceuticals in the environment. This is foreseen under current legislation too. However, the Commission is unhappy that compliance with the requirements cannot be enforced. Therefore, an authorisation must now be refused if ERA requirements are not "sufficiently" met.



cep-Assessment: Compliance with ERA requirements is important and should be part of an authorisation procedure but it could result in new medicines, with a positive health-related benefit-risk-balance, being refused authorisation on grounds of environmental concerns. Rather than introducing obligatory grounds for refusal with possible negative impact on patient access to new medicines, a more targeted approach should be taken, such as a phased, proportionate, and post-authorisation enforcement mechanism.

Powers Delegated to the Commission [Long Version A.5.2 and C.2.2]

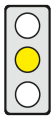
Commission proposal: The reform contains a plethora of delegations of power to the Commission to make important legislative decisions via delegated acts. The power to change the criteria of the Environmental Risk Assessment (ERA) by directly amending the legal text of Art. 22 Directive Proposal, which contains the ERA requirements, [Art. 213 Directive Proposal] stands out in this regard.



cep-Assessment: Changes to the requirements of an ERA will most certainly have far-reaching effects because they may concern a decisive factor, especially given the fact that an "insufficient" ERA must lead to the refusal of an authorisation. The Commission will be able to decide on its own what constitutes a "sufficient" ERA. Therefore, delegating this decision is a violation of the concept of reserving "essential elements" of a law for the EU legislator, i.e., the EU Parliament and the Council. This specific delegation of powers must be scrapped.

Preventing Shortages [Long Version A.6 and C.1.4]

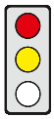
Commission proposal: The Commission tries to prevent future shortage situations by, e.g., obligating authorisation holders to report a temporary disruption in the supply of a medicine six months ahead of time. They must also have in place a shortage prevention plan for all medicines. Further obligations arise for "critical" shortages, meaning shortage situations which cannot be solved nationally. For this, a "list of critical shortages" is adopted at EU level, which, inter alia, allow for EU level recommendations to authorisation holders and Member States.



cep-Assessment: The new notification requirements follow a rigid planning approach and cannot help to prevent shortages substantially. The reporting period for temporary disruptions may lead to precautionary overreporting to avoid liability which would trigger unnecessary control mechanisms at EU and national level. It should therefore be set to 2 months. A shortage prevention plan for all medicines is inappropriate and will lead to further regulatory burden. This obligation should only apply to critical medicines.

Electronic Packaging Leaflets [Long Version A.8 and C.1.7, C.2.2]

Commission proposal: A packaging leaflet is and remains mandatory for all medicines. The reform foresees that the Member States can decide if it is to be provided electronically, in paper format, or both [Art. 63 (3) Directive Proposal]. However, about 6 years after the reform enters into force, the Commission can make the electronic-only version of the packaging leaflet compulsory via a delegated act [Art. 63 (5) Directive Proposal].



cep-Assessment: Packaging leaflets aim to empower the patient as self-care relies heavily on sufficient and high-quality information. Its form affects patients directly and differently due to a generational digital divide. Also, due to the varying levels of digitalisation, the decision can be dealt with most effectively by Member States and should therefore be left to them to make it in their country-specific context [as Art. 63 (3) Directive Proposal foresees]. Consequently, the deferral of power to the Commission [Art. 63 (5) Directive Proposal] must be scrapped.