

(English version)

**Question for written answer E-002706/26
to the Commission
Michalis Hadjipantela (PPE)
(30 June 2026)**

Subject: Implementation of new pharmaceutical legislation

The reform of EU pharmaceutical legislation represents a major shift in how the EU will regulate medicine. Predictability regarding the implementation of this new framework is essential to promote the competitiveness of the EU's pharmaceutical ecosystem and provide clarity regarding measures to improve patient access to transformative therapies. Ahead of the publication of the new directive and regulation in the Official Journal of the European Union, I would like to ask:

1. Could the Commission provide clarity regarding when the various provisions will apply?
2. Bearing in mind Article 180(7)(a), what is the application of provisions related to orphan drug incentives, especially under Article 72 of the new regulation? This proposal will represent a major change to how rare disease therapies are developed.

Submitted: 30.6.2026

**Answer given by Mr Várhelyi on behalf of the European Commission
(3 September 2026)**

The new EU pharmaceutical Directive ⁽¹⁾ ('the directive') and Regulation ⁽²⁾ ('the regulation'), would, as a general rule, apply 24 months after their entry into force, with some exceptions.

Without prejudice to the outcome of the ongoing legislative procedure, adoption and publication in the Official Journal of the European Union are expected in the fourth quarter of 2026 ⁽³⁾.

Some provisions of the regulation would apply from its entry into force: on transferable exclusivity vouchers for priority antimicrobials and a voluntary subscription model, regulatory sandboxes, security of supply, Member States' exemptions from security of supply, European Medicines Agency's (EMA) international regulatory cooperation and EMA's awarding of grants.

Monitoring and shortage management provisions of the regulation will apply six months after its entry into force. The access provision for new medicines of the directive would apply 12 months after entry into force. Provisions on the register of designated orphan medicines of the regulation would apply six months after the date of application.

A prioritisation programme for the Environmental Risk Assessment (ERA) for legacy products (authorised before 2005 and identified as potentially harmful to the environment) should be established 30 months after entry into force of the directive.

The provisions on regulatory incentives for orphan medicines in Chapter VI of the regulation would apply 24 months after entry into force. However, transitional provisions may apply, such as Article 180(7) (a) of the regulation.

⁽¹⁾ COM/2023/192 final.

⁽²⁾ COM/2023/193 final.

⁽³⁾ As the procedure is still being finalised, this answer does not refer to specific articles, as their numbering may change in the final legal acts after adoption.