

(English version)

**Question for written answer E-004896/25
to the Commission
Loucas Furlas (PPE)
(10 December 2025)**

Subject: Pharma package

The Commission has presented the so-called ‘pharma package’ as the biggest pharmaceutical reform of the last twenty years.

However, the following weaknesses are noted:

- Its proposals provide for the possibility of extending data protection for pharmaceutical companies up to 12 years, under conditions such as making the medicine available in all Member States, while the Commission does not guarantee that this will actually lead to real access in countries with lower purchasing power.
- Despite widespread shortages and dependence on non-EU countries (particularly India and China), the package does not include mandatory production mechanisms within the EU or binding targets for the sufficiency of essential medicines.
- Finally, it remains unclear how ‘unmet medical need’, which is directly linked to tax and regulatory incentives for companies, will be assessed.

In view of the above, the Commission is asked:

1. How does the Commission ensure that the extension of protection periods does not act as a tool to prolong monopolies, especially to the detriment of the national health systems of Member States with limited resources?
2. Why does the pharma package not include explicit obligations for domestic production of critical medicines for reasons of strategic autonomy?
3. What scientific and transparent criteria will be used to identify ‘unmet medical needs’, and what mechanism will prevent them being abused by companies to extend privileges?

Submitted: 10.12.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(23 February 2026)**

The political agreement on the EU pharmaceutical legislation⁽¹⁾ introduces an obligation for supply. Member States may require companies to launch and supply a medicine on their national market which will increase access to medicines either through the earlier launch of innovative medicines or with earlier generic, biosimilar entry.

The enhanced ‘Bolar’ provision enables day-one entry for off-patent medicines, further improving access. Details can be found in the press releases of the co-legislators⁽²⁾.

In March 2025, the Commission proposed a Critical Medicines Act⁽³⁾ which aims at reducing EU dependencies on third countries and single suppliers.

This Act proposes to incentivise domestic production of critical medicines through the fast-tracking of administrative procedures, facilitated access to financial support and demand-side measures that will favour EU production in public procurement procedures of certain critical medicines.

The concept of ‘unmet medical needs’, which already exists to some extent in current rules, was further developed in the Commission’s proposal through objective, scientific criteria to help regulators identify medicines that bring significant medical progress for patients suffering from serious diseases.

⁽¹⁾ COM/2023/193 final and COM/2023/192 final.

⁽²⁾ Deal on comprehensive reform of EU pharmaceutical legislation; European Parliament <https://www.europarl.europa.eu/news/en/press-room/20251209IPR32110/deal-on-comprehensive-reform-of-eu-pharmaceutical-legislation>; ‘Pharma package’: Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector; Council: <https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>.

⁽³⁾ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest and amending Regulation (EU) 2024/795.

These criteria are applied following an independent scientific assessment of each medicine by the European Medicines Agency or national competent authorities. The provisional political agreement of the co-legislators follows the same logic.
