

Question for written answer E-004896/2025
to the Commission
Rule 144
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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?

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