

(English version)

**Question for written answer E-002281/24
to the Commission
Nicolás González Casares (S&D)
(28 October 2024)**

Subject: Monitoring and control of excessive national stockpiling of medicines

Medicine shortages are a critical issue in the EU. The reasons for these shortages are complex and involve many factors, such as the EU's loss of competitiveness vis-à-vis other markets and a lack of flexibility in regulatory procedures. In light of this situation, some Member States are demonstrating a lack of solidarity by stocking up on medicines to create national stockpiles large enough to cover demand over several months.

National stockpiling is not a solution for these shortages. In fact, it makes inexpensive and low-volume products less viable and creates a false sense of security, as well as making redistribution to other Member States impossible.

The Commission should monitor and regulate the disproportionate national stockpiling of medicines, which poses a risk to the free movement of goods within the EU internal market and to patients' health. The Commission should also actively discourage these practices and even consider imposing sanctions if necessary.

1. What measures will the Commission take to prevent Member States from hoarding medicines? How does the Commission plan to monitor compliance with EU internal market rules?
2. Is the Commission considering imposing sanctions in case of non-compliance?

Submitted: 28.10.2024

**Answer given by Mr Várhelyi on behalf of the European Commission
(7 January 2025)**

Several EU countries have recently imposed contingency stock requirements on supply chain actors. These national measures are taken in implementation of the current legislation on medicinal products which requires marketing authorisation holders and distributors to ensure appropriate and continued supplies in order to meet patient needs ⁽¹⁾.

Nevertheless, these measures should be justified on grounds of public health protection and be proportionate in relation to this objective.

As part of the Single Market Transparency Directive notification procedure ⁽²⁾, the Commission assesses the compatibility of the draft national technical measures notified by Member States with sectoral legislation and internal market rules to avoid the creation of obstacles to the internal market.

Furthermore, the Commission actively engages with Member States to foster exchanges of information and agree on common principles for national contingency stock requirements ⁽³⁾.

These common principles will focus on ensuring transparency, solidarity and proportionality of such measures to avoid negative impact on the availability of medicines in other countries.

Finally, as part of the revision of the EU pharmaceutical legislation ⁽⁴⁾, the Commission's proposal requires Member States to inform the European Medicines Agency (EMA) on national measures taken to mitigate critical shortages and ensure supply of critical medicines.

The Commission would also be empowered to take appropriate measures to improve the security of supply of critical medicines.

⁽¹⁾ Article 81 of Directive 2001/83/EC <http://data.europa.eu/eli/dir/2001/83/oj>

⁽²⁾ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1.

⁽³⁾ Human Pharmaceutical Committee — Meetings: https://health.ec.europa.eu/medicinal-products/pharmaceutical-committee-veterinary-pharmaceutical-committee-and-expert-groups/human-pharmaceutical-committee-meetings_en

⁽⁴⁾ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en