

(English version)

**Question for written answer E-004447/25
to the Commission
Ioan-Rareş Bogdan (PPE)
(11 November 2025)**

Subject: Clarifications on the double standard for medicinal products

Many eastern European citizens call on family members living in Belgium, France, Germany and other EU countries in the west of the continent to obtain for them essential medicines — anti-inflammatory drugs, cold formulae, painkillers, and plant cures that have the same content but of different efficacy. People seek out doctors in those countries to procure from them prescriptions for medicines needed to treat chronic conditions, but under the law their attempts to do so prove fruitless. The explanation for doing this is that people have noticed that the medicines produced and sold in western countries are of greater efficacy.

1. I have heard the explanations for the double standard for food, but could the Commission state whether it is aware of the double standard for medicine?
2. If the Commission is aware of such a double standard, could it inform me of the legal basis for this or, if there is no such standard, of what measures it plans to take?

Submitted: 11.11.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(26 January 2026)**

In the EU, all medicinal products must be authorised, either at national or at EU level, before they can be marketed and made available to patients.

There are no double standards for the authorisation and monitoring of medicines. All authorised medicines, whether authorised nationally or centrally, and whether reference medicinal products, generics or biosimilars, must comply with the same requirements for quality, safety and efficacy.

International standards, called good clinical practice ⁽¹⁾, apply to the study design, recording and reporting to ensure that studies supporting a marketing authorisation are conducted according to the EU requirements.

The type of evidence needed to determine the benefits and risks of a medicine are defined by EU legislation and are valid for authorisation and monitoring in all EU Member States. Inspections are conducted nationally and can also be requested by the European Medicines Agency to verify compliance with these standards.

Furthermore, the EU has a strong legal framework for the licensing, manufacturing, centred around legally binding good manufacturing practice standards ⁽²⁾, and distribution of medicines.

In this respect, the directive on falsified medicines for human use ⁽³⁾, ensures that only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including legitimate sale via the Internet.

⁽¹⁾ <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice>.

⁽²⁾ Good manufacturing practice <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice>.

⁽³⁾ Falsified medicines https://health.ec.europa.eu/medicinal-products/falsified-medicines_en.