(English version)

Question for written answer E-004499/25
to the Commission
Anthony Smith (The Left)
(12 November 2025)

Subject: Risks posed by counterfeit medicines and medical devices from India

India's pharmaceutical industry has seen vigorous growth over many years. In 2024, it was worth EUR 50 billion, and it produced 20% of the world's generic medicines and 60% of all vaccines. According to India's Ministry of Commerce and Industry, Europe's share of the country's medicine exports was roughly 18.93% in 2024.

Despite the World Health Organisation having repeatedly called on the Indian Government to address the gaps in its health regulations, India continues to produce antibiotics without active ingredients and hazardous medical products. The latest scandal occurred in September, when a cough syrup contaminated with diethylene glycol — a highly toxic chemical — resulted in the deaths of around 20 children in the country. In 2023, similar cases claimed more than 140 victims in The Gambia, Uzbekistan and Cameroon.

In view of the above:

1. Can the Commission guarantee that medicines entering the EU market, especially those sold on the Internet, comply fully with its requirements, and that EU patients and consumers are safe?

2. Does it intend to take any action to bolster EU production of medicines, notably generic medicines, and medical devices?

Submitted: 12.11.2025

Answer given by Mr Várhelyi on behalf of the European Commission
(27 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.

All authorised medicines, whether authorised nationally or centrally, and regardless of whether they are innovative medicinal products, generics or biosimilars, must comply with the rigorous requirements for quality, safety and efficacy.

The EU has a strong legal framework for medicine manufacturing, centred around legally binding good manufacturing practice standards that safeguard the high quality of medicines placed on the EU market ([1]).

These standards apply regardless of where the medicines are manufactured. Compliance with these standards is verified through inspections carried out by EU competent authorities. Additional verifications also apply to imported products, including analytical tests on each batch in line with EU requirements.

The EU legislation ([2]) also foresees measures to prevent that falsified medicines enter the supply chain and reach patients. Its enforcement falls with Member States.

Furthermore, the illegal channels, offering potentially harmful medicines without proper medical supervision, are jointly tackled by customs authorities, police and medicines authorities.

Also, the European Anti-Fraud Office (OLAF) plays an active role in investigating fraudulent imports of illegal medicines including via e-commerce.

On the production in the EU, the Commission is putting forward actions specifically intended to improve the resilience of supply chains of medical products.

In particular, the proposal for a Critical Medicine Act ([3]) aims directly to strengthen Europe's manufacturing capacity for critical medicines and to reduce dependencies on third countries.

([1]) https://health.ec.europa.eu/medicinal-products/good-manufacturing-and-distribution-practices_en.
([2]) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0062.
([3]) https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/critical-medicines-act_en.