

(English version)

**Priority question for written answer P-001402/25
to the Commission
Christine Anderson (ESN)
(7 April 2025)**

Subject: Comprehensive overview of EU legislation on the manufacturing and importation of medicines

In the context of ongoing discussions on pharmaceutical security and the recently proposed critical medicines act, it is essential to take stock of the existing legal framework governing the production and importation of medicinal products within the EU.

Can the Commission answer the following questions:

1. What current EU legislation is regulating the manufacture of medicinal products within the EU, including relevant regulations, directives and delegated and implementing acts?
2. What current EU legislation is governing the importation of medicinal products from non-EU countries into the EU, including applicable procedures, quality control requirements and oversight mechanisms?

Submitted: 7.4.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(2 July 2025)**

As regards the regulatory requirements for the manufacturing and importation of medicinal products for human use the main legal acts are: Directive 2001/83/EC ⁽¹⁾ on the Community code relating to medicinal products for human use, Commission Directive (EU) 2017/1572 ⁽²⁾ on the principles and guidelines of good manufacturing practice for medicinal products for human use, and Delegated Regulation (EU) No 1252/2014 ⁽³⁾ on principles and guidelines of good manufacturing practice for active substances for medicinal products for human use.

Specific manufacturing rules for investigational medicinal products are established in Regulation (EU) 536/2014 ⁽⁴⁾ on clinical trials and Delegated Regulation (EU) 2017/1569 ⁽⁵⁾ on good manufacturing practices for investigational medicinal products.

All these legal acts are complemented by guidelines on good manufacturing practice for medicinal products and active substances, published by the Commission on its website (Eudralex volume IV) ⁽⁶⁾.

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

⁽²⁾ Commission Directive (EU) 2017/1572 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use.

⁽³⁾ Delegated regulation (EU) No 1252/2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use.

⁽⁴⁾ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

⁽⁵⁾ Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and the guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections.

⁽⁶⁾ EudraLex — Volume 4: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en.