



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 077

Communication from the Commission - TRIS/(2025) 2029

Directive (EU) 2015/1535

Notification: 2025/0061/EE

Message further to the dialogue between the Commission and the Member States following recourse to the official reactions expressly laid down by Directive (EU) 2015/1535.

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1. MSG 077 IND 2025 0061 EE EN 02-05-2025 29-07-2025 COM DIALOG 02-05-2025

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2025/0061/EE - C00P - PHARMACEUTICAL AND COSMETICS

5.

6. The Commission services would like to thank the Estonian authorities for their answer of 9 June 2025 to the Commission's comments on the draft "Act amending the Medicinal Products Act" (hereinafter 'the notified draft'), notified to the Commission on 30 January 2025 under number 2025/0061/EE.

In its comments, the Commission invited the Estonian authorities to ensure that the provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use on wholesale distribution of medicinal products are complied with in the notified draft and its implementation.

In their answer, the Estonian authorities recall that the notified draft seeks to grant hospital pharmacies the right to procure medicinal products not only from wholesalers operating in Estonia, but also from wholesalers of other Member States, whereas imported medicinal products must meet the requirements for medicinal products authorised to be marketed in Estonia. The Estonian authorities explain, in particular, that a hospital pharmacy is a structural unit of a medical institution for the supply of medicinal products to a hospital and does in their view not engage in the wholesale distribution of medicinal products and that procurement of medicinal products in this context is allowed only for the supply of medical institutions. They also point out that the notified draft does not allow hospital pharmacies to engage in parallel distribution of medicinal products. In their opinion, the procurement of medicinal products by hospital pharmacies for the purpose of providing healthcare services is not wholesale distribution but a supply to the public as defined in Directive 2001/83/EC. The Estonian authorities also mention that there is no intention to manufacture medicinal products in hospital pharmacies under the notified draft but only to prepare medicinal products of active substances and for administration, subject to the prescription of the attending physician, to patients remaining in a medical institution.

The Commission services take note of the answer of the Estonian authorities and the explanations it contains.

The Commission services refer to the Commission's comments of 2 May 2025 on the notified draft and draw the attention of the Estonian authorities to the provision of Article 5(2) of Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. Under that provision, The Estonian authorities are required to take the Commission's comments into account as far as possible in the subsequent preparation of the notified draft.



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