Message 201

Communication from the Commission - TRIS/(2026) 1537

Directive (EU) 2015/1535

Notification: 2026/0010/DE

Forwarding of the response of the Member State notifying a draft (Germany) to of European Commission.

MSG: 20261537.EN

1. MSG 201 IND 2026 0010 DE EN 14-07-2026 09-06-2026 DE ANSWER 14-07-2026

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 121

4. 2026/0010/DE - C10P - Pharmaceuticals

5.

6. Notification No 2026/0010/DE
Ordinance amending the Pharmacy Operating Ordinance and other ordinances

Re: Detailed opinion of the European Commission in accordance with Article 6(2) of Directive (EU) 2015/1535 of 10 April 2015 (C(2026) 2506 final)

The Federal Government has the honour to notify the European Commission of the following:

It follows from the opinion of the European Commission that the rules addressed to transport service providers are not sustainable under European law, as they would lay down disproportionate requirements.

The draft ordinance, which has been notified, amending the Pharmacy Operating Ordinance and other ordinances, aims to enhance further patient safety with regard to the rules governing the mail-order sale of medicines. Article 85c(2) of Directive 2001/83/EC allows Member States to impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services. The power granted to Member States to determine the content of the ‘conditions for retail distribution justified on grounds of public health protection’ was also recently reaffirmed by the Court of Justice of the European Union in Case C-604/24 with regard to the arrangements for the distribution of medicinal products to the public, i.e. the conditions governing activities relating to the retail supply of medicinal products within their territory (ECJ, judgment of 21 May 2026, Farmakeio YZ & Sia, C-604/24, ECLI:EU:C:2026:418, para. 33).

In the meantime, it has been examined whether the objective of improving patient safety in mail order sales can also be achieved with less intrusive and thus proportionate measures. The review concluded that this is possible. Following the European Commission's advice, the responsibility for the quality and efficacy of dispatched medicinal products should remain entirely in the hands of the dispatching pharmacy. On the one hand, it has the relevant technical expertise to plan the entire transport operation. On the other hand, according to the associations involved, it has at all times all relevant information on the progress of the transport at its disposal.

The requirements previously set out in Section 9a of the Medicinal Products Trade Ordinance of the draft of an ordinance amending the Pharmacy Operating Ordinance and other ordinances relating to logistics companies involved – including the provision for administrative fines in Section 10(4) of the Medicinal Products Trade Ordinance – as well as the corresponding provisions in Sections 17(2a), first sentence, point 1, 35b(4) of the Pharmacy Operating Ordinance, are therefore deleted from the draft ordinance. The draft ordinance maintains that the requirements for the pharmacy of dispatch will be specified. It, as part of risk-based transport planning, must select transport packaging that is suitable for the medicinal product in question (taking into account the specific medicinal product as well as factors such as the outside temperature and the duration of transport; see Section 35c(1)). For prescription-only medicinal products, it is clarified that they may be delivered only against written or electronic acknowledgement of receipt (point 2 of the first sentence of Section 17(2a)). A specific obligation to keep medicines cool continues to apply to those that must be kept cool and those subject to cold-chain requirements; in such cases, the pharmacy may decide whether to meet this obligation by including cooling packs (‘passive cooling’) or by using specially temperature-controlled vehicles (‘active cooling’) (Section 35c(3), second sentence, point 1). In the case of medicinal products supplied under passive cooling, the pharmacy must specify a maximum transport time; if this is exceeded, the product must not be dispensed (Section 35c, sentence 3). In addition, it is stipulated that medicinal products requiring refrigeration or refrigeration chains may not be deposited in automated collection stations (Section 35c(3), second sentence, point 3). The changes compared with the preliminary draft of January 2026 are set out in detail in the attached summary.

The Bundesrat must approve the draft ordinance. A review of the project is planned in the near future. In light of this, the Federal Government would be grateful for a prompt response as to whether the proposed amendments will address the European Commission’s concerns. Please do not hesitate to contact the Federal Ministry of Health for further clarification.

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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu