Message 001

Communication from the Commission - TRIS/(2026) 0112

Directive (EU) 2015/1535

Notification: 2026/0010/DE

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta’ dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20260112.EN

1. MSG 001 IND 2026 0010 DE EN 13-01-2026 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 121

4. 2026/0010/DE - C10P - Pharmaceuticals

5. Regulation amending the Regulations on the Operation of Pharmacies and other regulations

6. Dispatch and shipment of medicinal products within the meaning of Directive 2001/83/EC which are subject to sale in a pharmacy pursuant to Section 43(1) first sentence of the Medicinal Products Act (Arzneimittelgesetz) by a pharmacy using a logistics company to ship to the end consumer

7.

8. Under Section 17(2a) first sentence point 1 of the Regulations on the Operation of Pharmacies

(Apothekenbetriebsordnung), until now the director of a pharmacy has had to ensure, when dispatching a medicinal product subject to sale in a pharmacy and in accordance with Section 43(1) first sentence of the Medicinal Products Act, that the medicinal product is packaged, transported and delivered in such a way that its quality and effectiveness are maintained. This includes compliance with temperature requirements and, where necessary, provision of proof of this for temperature-sensitive medicines in particular. The basic obligation to ensure the quality-preserving dispatch remains in Section 17(2a) first sentence point 1 of the Regulations on the Operation of Pharmacies. The requirements will be specified in the new Section 35b of the Regulations on the Operation of Pharmacies. This includes specifications in the quality management system (paragraph 1), requirements for employees (paragraph 2), guidelines for compliance with temperature requirements (paragraph 3) and contractual safeguards in relation to the contracted logistics company (paragraph 4). In addition, Section 9a of the Regulation on the Trade of Medicinal Products (Arzneimittelhandelsverordnung) lays down requirements for quality-preserving transport, including any intermediate storage by the contracted logistics company.

9. The rules are intended to ensure that, even during the transport of medicinal products by mail order by pharmacies, the quality and efficacy of the medicinal products are maintained. To that end, on the one hand, the requirements for the pharmacy dispatching the medicinal products are specified in Section 35b of the Regulations on the Operation of Pharmacies and, on the other hand, the requirements for the transport company responsible for distribution are laid down in Section 9a of the Regulation on the Trade of Medicinal Products.

10. Reference to the basic texts:

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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