Message 001

Communication from the Commission - TRIS/(2025) 3445

Directive (EU) 2015/1535

Notification: 2025/0720/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: 20253445.EN

1. MSG 001 IND 2025 0720 DE EN 03-12-2025 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 114

4. 2025/0720/DE - C30P - Pharmacopoeias

5. German Pharmacopoeia 2026 - DAB 2026

6. Quality Specifications for Medicinal Products

7.

8. It is planned to amend the German Pharmacopoeia 2025 (DAB 2025, notification number 2024/0612/DE) in its current version and to implement the new version as the German Pharmacopoeia 2026. The announcement thereof will refer to the notification. The amendments requiring notification include the revised

monographs and reagent descriptions to be included in the German Pharmacopoeia 2026, as well as the deletion of monographs and reagents. The draft text is attached as an annex.

9. According to Section 55 of the German Medicines Act (AMG), the pharmacopoeia is a collection of recognised pharmaceutical rules concerning the quality, testing, storage, dispensing, and labelling of medicinal products and the substances used in their manufacture. The rules and labelling of the pharmacopoeia are adopted by the German Pharmacopoeia Commission, the European Pharmacopoeia Commission, or the German Homoeopathic Pharmacopoeia Commission, pursuant to Section 55, paragraphs 2 and 6 of the AMG. The Federal Institute for Drugs and Medical Devices publishes the pharmacopoeia in the Federal Gazette, indicating where to obtain the version and when the new version comes into effect. This is intended to ensure the safety of medicinal products in the market and in the interest of a proper supply of medicines.

10. Reference to the basic texts: No basic text available

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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