Message 001

Communication from the Commission - TRIS/(2025) 0562

Directive (EU) 2015/1535

Notification: 2025/0116/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: 20250562.EN

1. MSG 001 IND 2025 0116 DE EN 27-02-2025 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Klimaschutz, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 114

4. 2025/0116/DE - C30P - Pharmacopoeias

5. Homeopathic Pharmacopoeia 2025 – HAB 2025

6. Quality specifications for medicinal products

7.

8. It is planned to amend the current version of the German Pharmacopoeia 2024 (DAB 2024, notification number 2024/0170/DE) and to implement the new version as the German Pharmacopoeia 2025. The publication thereof will refer to the notification. The amendments requiring notification cover the monographs

to be included in the Homeopathic Pharmacopoeia 2025 in revised form. The draft text is enclosed as an attachment.

9. According to § 55 of the Medicinal Products Act [Arzneimittelgesetz – AMG] the Pharmacopoeia is a collection of recognised pharmaceutical rules regarding the quality, testing, storage, dispensing and naming of medicinal products and the substances used in their manufacture. Pursuant to § 55(2) and (6) of the AMG, the rules contained in and the name of the Pharmacopoeia are decided by the German Pharmacopoeia Commission or the European Pharmacopoeia Commission or the German Homoeopathic Pharmacopoeia Commission. The Pharmacopoeia is published by the Federal Institute for Drugs and Medical Devices in the Federal Gazette, indicating the Pharmacopoeia version that is the reference source and the commencement of the validity of the new version. The aim is to ensure safety in the circulation of medicinal products in the interest of a proper supply of medicinal products.

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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