

Message 001

Communication from the Commission - TRIS/(2026) 1093

Directive (EU) 2015/1535

Notification: 2026/0193/DE

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – 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 - Nezahtuje 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 késésekét - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ 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: 20261093.EN

1. MSG 001 IND 2026 0193 DE EN 16-04-2026 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 114

4. 2026/0193/DE - C30P - Pharmacopoeias

5. Homoeopathic Pharmacopoeia 2026 – HAB 2026

6. Quality Specifications for Medicinal Products

7.

8. It is planned to amend the Homoeopathic Pharmacopoeia 2025 (HAB 2025, notification number 2025/0116/DE) in its current version and to implement the new version as the Homoeopathic Pharmacopoeia 2026. The announcement should refer to the notification. The amendments requiring

notification include the monographs to be included in revised form in the Homoeopathic Pharmacopoeia 2026. The draft text is attached as an annex.

9. According to Section 55 of the Medicinal Products Act [Arzneimittelgesetz] (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 designations 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 Medicinal Products Act (AMG). The pharmacopoeia is published in the Federal Gazette by the Federal Institute for Drugs and Medical Devices, indicating the source of the pharmacopoeia version and the start of validity of the new version. 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

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu