

Message 001

Communication from the Commission - TRIS/(2026) 2231

Directive (EU) 2015/1535

Notification: 2026/0434/AT

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 - 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 késések - Non fa decorrere la mora - Atidėjimai 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: 20262231.EN

1. MSG 001 IND 2026 0434 AT EN 17-08-2026 AT NOTIF

2. Austria

3A. Bundesministerium für Wirtschaft, Energie und Tourismus

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3B. Bundesministerium für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz

Sektion VI – Humanmedizinrecht

Abteilung 4 – Rechtsangelegenheiten Arzneimittel, Medizinprodukte, Apotheken, Krankenanstalten, übertragbare Krankheiten

4. 2026/0434/AT - C10P - Pharmaceuticals

5. Ordinance of the Federal Minister for Labour, Social Affairs, Health, Care and Consumer Protection on the 91st Addendum to the Pharmacopoeia

6. Pharmaceutical products

7.

8. Entry into force of the Official Edition 2026 of the Austrian Pharmacopoeia and abrogation of the Official Edition 2025 thereof.

(See 2022/807/A, inter alia)

9. In order to comply with Austria's obligations under the Convention on the Elaboration of a European Pharmacopoeia, Federal Law Gazette No. 181/1979, from the 2012 Pharmacopoeia Act, Federal Law Gazette I No. 44/2012, and EU Directive 2001/83/EC, the Austrian Pharmacopoeia, Official Edition 2026, shall be brought into force by way of Ordinance as the 91st Addendum to the Pharmacopoeia.

9a. The Pharmacopoeia is a collection of recognised pharmaceutical rules concerning the definition, manufacture, quality, composition, posology, designation, storage, dispensing and testing of medicinal products, as well as the characteristics of their containers and packaging. It is made up of the European and the Austrian Pharmacopoeia.

The primary function of the Austrian Pharmacopoeia is to cover special national requirements.

9b. The Federal Minister in charge of public health shall, by order, declare those provisions of the Austrian Pharmacopoeia which are not superseded by the European Pharmacopoeia to be binding as the 'Austrian Pharmacopoeia, Official Edition', taking into account the current state of scientific knowledge and the specific requirements for Austria.

The measure does not impose any restrictions on the single market and has no impact on cross-border trade.

9c. The project is in the public interest. The measures are taken on the basis of the recommendations of a specialist commission (the Pharmacopoeia Commission). Only changes that take specific national requirements into account and are in line with the current state of scientific knowledge will be implemented.

10. Reference to the basic texts: 2022/0807/A

Basic texts have been forwarded under a previous notification:
2022/0807/A

11. No

12.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission

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