

Message 001

Communication from the Commission - TRIS/(2025) 0268

Directive (EU) 2015/1535

Notification: 2025/0058/FI

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: 20250268.EN

1. MSG 001 IND 2025 0058 FI EN 29-01-2025 FI NOTIF

2. Finland

3A. Työ- ja elinkeinoministeriö
Työllisyys ja toimivat markkinat -osasto
PL 32
FI-00023 VALTIONEUVOSTO
maaraykset.tekniset@gov.fi
PUHELIN +358 29 504 7261

3B. Lääkealan turvallisuus- ja kehittämiskeskus (Fimea)
Mannerheimintie 166, PL 55
FI-00034 FIMEA

Puhelin +358 29 5223422

4. 2025/0058/FI - C00P - PHARMACEUTICAL AND COSMETICS

5. The Finnish Medicines Agency Fimea's (2025/xx) Decision on the List of Medicinal Products

6. Medicinal products and substances

7.

8. The Decision is intended for the supervisory authorities, particularly to facilitate the monitoring of imports and to provide clarification for the public as to what substances are deemed to be medicinal products. Fimea has updated the substances in the annexes and added substances relevant for control purposes to the previous list.

The list of medicinal products is drawn up taking into consideration the provisions of sections 3 and 5 of the Finnish Medicines Act.

The most important changes to the annexes of the previous list of medicinal products are:

Annex 1. 2938 medicinal substances, of which a total of 152 are new medicinal substances

Annex 1 A. 99 medicinal substance analogues and prohormones, 7 of which are new

Annex 2. 392 medicinally active herbal substances

9. The definition of a medicinal product under the Finnish Medicines Act is written in full in the Decision. The Decision states that the list is neither absolute nor exhaustive. The Decision states the difference between substances and preparations as regards their medicinal properties.

The substances and herbal products listed in Annexes 1 and 2 either have been or still are used for medicinal purposes, or may have a medicinal application.

The substances listed in Annex 1A are medicinal substance analogues and prohormones which will be brought under supervisory control.

10. Basic text references:

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