

Message 001

Communication from the Commission - TRIS/(2025) 0934

Directive (EU) 2015/1535

Notification: 2025/0185/SE

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 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

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1. MSG 001 IND 2025 0185 SE EN 31-03-2025 SE NOTIF

2. Sweden

3A. Kommerskollegium

3B. Socialdepartementet, Regeringskansliet

4. 2025/0185/SE - C10P - Pharmaceuticals

5. Ordinance amending the Ordinance (1992:1554) on Drug Control

6. Analgesics

7.

8. On the basis of the attached classification document, the Swedish Public Health Agency proposes that the substances cyclophosphine, isobutonitazene, secbutonitazene, fluetonitazene, N-pyrrolidino fluetonitazene (fluetonitazepyne), chlorphine and N,N-dimethyl etonitazene be classified as narcotic drugs under the

Narcotic Drugs Control Act (1992:860), and the Narcotic Drugs Act (1968: 64), and shall be included in the Ordinance (1992:1554) on Drug Control.

The substances are proposed to belong to the analgesics group. For all the substances, there is scientific documentation supporting the narcotics criteria. Two of the substances have been identified in Sweden. Cychlorphine is currently regulated as a hazardous product.

Classification will mean, inter alia, that this substance may not be imported or held in possession without special permission from the Swedish Medical Products Agency. Please note that only the substances listed next to a vertical line in the left margin of the draft Ordinance are additions to the attached ordinances. The other substances are already listed therein.

9. Given the danger posed to human health, the aim of the classification is to restrict the use of the substances listed in the Ordinances.

10. Reference(s) to basic text(s): No basic texts available

11. Yes

12. Risks to human life and health, and to public safety, mean that the regulatory amendments regarding the substance to be classified as a narcotic drug should be drawn up within a very short time frame.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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