Message 001

Communication from the Commission - TRIS/(2025) 3209

Directive (EU) 2015/1535

Notification: 2025/0680/FI

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: 20253209.EN

1. MSG 001 IND 2025 0680 FI EN 12-11-2025 FI NOTIF

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4. 2025/0680/FI - C00C - CHEMICALS

5. Government Decree amending the Government Decree on narcotic substances, preparations and plants

One new substance, zuranolone, is classified as a narcotic.

6. Tsuranoloni (Zuranolone)
IUPAC name: 1-[2-[(3R,5R,8R,9R,10S,13S,14S,17S)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetra-deca-hydro-1H-cyclopenta[a]phenanthren-17-yl]-2-oxoethyl]pyrazole-4-carbonitrile (engl.)
CAS number: 1632051-40-1

7.

8. As a new substance, zuranolone has been approved for medicinal use in Finland and elsewhere in Europe in autumn 2025 (Zurzuvae). Zuranolone has been in medicinal use in the United States since 2023.

Finland intends to define this substance as a narcotic in accordance with the Narcotics Act (373/2008); as a result, the manufacture, import, export, sale and possession, among other actions, of the substance without a separate permit from the Finnish Medicines Agency will be prohibited.

Zuranolone is a new medicinal product and a potent positive allosteric modulator of the gamma-aminobutyric acid A
(GABAA) receptor. The medicinal product containing zuranolone has been authorised in the EU and Finland on 17 September 2025 and is intended for use in adults for the treatment of postpartum depression after childbirth. There are studies on the properties of zuranolone, and it has been used as a medicine since 2023 in the United States. The potential for substance misuse has been identified and, estimated to be similar to that of benzodiazepines when used in medicinal products. This is a new active substance for which misuse has not been observed.

Its classification as a narcotic will affect legitimate operators because medicinal products containing zuranolone will be subject to an import authorisation requirement. In addition, the classification entails additional obligations concerning the record keeping, storage and disposal of such medicinal products.

9. Zuranolone is a medicinal product within the meaning of Section 3 of the Medicines Act, which is currently not controlled under the Narcotics Act in Finland. Zuranolone is both used as a medical product and controlled as a narcotic drug in countries such as the United States, Germany and the United Kingdom.

Zuranolone acts similarly to benzodiazepines and has a similar potential for abuse. If the substance is subject to control, it may become an attractive alternative for users of controlled benzodiazepine medicinal products. The potential for abuse together with other agents acting on central nervous system poses a risk, especially in polysubstance use.

Based on the information gathered about the substance, the Finnish Medicines Agency concludes that the substance should, due to its properties and the severe adverse effects caused by them, be added to the Government Decree (543/2008) on substances, plants and products to be classified as narcotics (Annex IV).

10. Basic text references:

11. Yes

12. Protection of public health. The substance must be classified as a narcotic because there is a potential user base for abuse. When abused, the health risks of the substance are comparable to other benzodiazepines already on the narcotics list. The substance has not yet been observed on the illegal market. Based on the mechanism of action, it is expected that the substance can either be diverted to or will be directly manufactured for misuse. Zuranolone has been granted a marketing authorisation in the EU, and the processes for legal operators are facilitated by the fact that the classification of the substance as a narcotic is clear before it can be used as a medicine in Finland.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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