Message 001

Communication from the Commission - TRIS/(2025) 1740

Directive (EU) 2015/1535

Notification: 2025/0348/HU

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: 20251740.EN

1. MSG 001 IND 2025 0348 HU EN 03-07-2025 HU NOTIF

2. Hungary

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4. 2025/0348/HU - C00P - PHARMACEUTICAL AND COSMETICS

5. amending Ministry of Interior Decree No 78/2022 of 28 December 2022 on controlled substances

6. 20 unique new psychoactive substances susceptible to abuse

7.

8. In Decree No 78/2022 of the Ministry of Interior of 28 December 2022 on controlled substances (hereinafter: the Decree) 20 individual new psychoactive substances (N-desethyl protonitazene, delta-8-THC-O-acetate, delta-8-THCB-O-acetate, delta-8-THCM, delta-9-THCP-O-acetate, clonazafone desglycyl, diclazafone desglycyl, fluetonitazepyne, αMPip-isohexanophenone, 3'-Me-PHP, delta-9-THC-methylcarbonate, 10-OH-HHC, 10-OH-HHC-P, Ro 07-3953, 1P-AL-LAD, desnitroclonitazene, cyclorphine, homomazindol, 3,4-EtPV, 3,4-EtMC) to be included in the List of Annex 3 thereto, will not be freely marketed in Hungary and all activities carried out with their use will only be carried out after official registration. Due to the above, health risks will be reduced, as it will be made more difficult for substance users to gain access to these substances.

9. 15/B. § (1) of Act XCV of 2005 on medicinal products for human use and on the amendment of other regulations related to medicinal products (hereinafter referred to as: the Medicines Act) stipulates that a substance or group of compounds may be classified as a new psychoactive substance after prior professional evaluation.

Pursuant to 15/B. § (3) of the Medicines Act, such preliminary professional evaluation should verify that, concerning the given substance or group of compounds, the Hungarian authorities and expert institutions are not aware of any information
a) that would indicate the pharmaceutical use of the substance or the group of compounds, and
b) which rules out the possibility that that substance or group of compounds poses a similar threat to public health than that attributed to drugs or the substances mentioned in List 1 and 2 of the Psychotropic Substances in Annex 2 of the Decree of the Minister for Health on controlled substances.

Pursuant to 27. § (4a) of Government Decree No 66/2012 of 2 April 2012 on activities that can be carried out in relation to narcotic drugs, psychotropic substances, new psychoactive substances, as well as the listing of these substances and amendment of such lists (hereinafter referred to as: Government Decree) the task of the National Drug Focal Point is to monitor on a monthly basis, within the framework of information exchange, the list of suspected new psychoactive substances that are released abroad. In this context, 20 new substances were found that are included in the European Early Warning System (EMCDDA Early Warning System) but are not subject to control in Hungary.

In accordance with 27. § (4) c) and (4a) of the Government Decree, the National Drug Focal Point contacted the National Centre for Public Health and Pharmacy (NNGYK) and the National Food Chain Safety Office (NÉBIH) in connection with the above-mentioned 20 substances in order to verify if the conditions specified in the provisions of 15/B. § (3) of the Medicines Act are met. Based on the responses of OGYÉI and NÉBIH as well as its own further investigation, the National Drug Focal Point concluded that these substances are suspected of being abused and black marketed, which justifies their classification as new psychoactive substances.

Accordingly, 20 new individual psychoactive substances are added to the List in Annex 3 of the Decree.

10. References to basic texts:

11. Yes

12. Notification of the amendments to the List in Annex 3 of the Decree, as a matter of urgency, is justified both on grounds of public health and public security. As long as the 20 compounds concerned are not included in the List, the Hungarian authorities are not authorised under law to intervene and are unable to prevent such substances with unpredictable effects from claiming new victims. Inclusion in the List entails several months of procedure. This enables distributors to sell these substances to consumers with impunity during this period.

The rapid entry into force of the amendment could ensure that there is a veritable chance for real-time response on behalf of the authorities once a new psychoactive substance already present in another Member State appears in Hungary, instead of resorting to the tool of following up the changes in the market supply of illegal substances, which could force the country to allow the marketing of such substances without prosecution in the absence of the necessary legal prohibition. Recent experience has shown that it does not take long for any new psychoactive substance appearing in a Member State to also reach Hungary.

Any delay in this matter risks more young people falling victim to these new psychoactive substances.

Our experience shows that these substances are, if possible, even more dangerous for consumers than traditional drugs or new psychoactive substances that have emerged in the past because their mechanism of action and its consequences are unpredictable.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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