Message 001

Communication from the Commission - TRIS/(2026) 1007

Directive (EU) 2015/1535

Notification: 2026/0174/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: 20261007.EN

1. MSG 001 IND 2026 0174 HU EN 02-04-2026 HU NOTIF

2. Hungary

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4. 2026/0174/HU - C00P - PHARMACEUTICAL AND COSMETICS

5. Amendment to Decree No 78/2022 of 28 December of the Ministry of Interior on controlled substances

6. 14 individual new psychoactive substances

7.

8. The 14 individual new psychoactive substances which are to be added to the List in Annex 3 of Decree No 78/2022 of 28 December of the Ministry of Interior on controlled substances (hereinafter: Decree) (namely CUMYL-PMINACA, MADMB-4en-PINACA, 2-allyl-delta-8-THC-O-acetate, 2-formyl-delta-9-THCP, delta-9-THCP-methylcarbonate, HHC-TBDMS, ADMB-FUBBIOCA, 2-allyl-delta-8-THC, delta-8-THC-methylcarbonate, protodesnitazene, tilmetamine, N-propyl ephenidine, avizafone, 2-allyl-8-THC-methylcarbonate) will not be allowed to be freely marketed in Hungary, and any activities involving their use may only be carried out after registration with the authorities. 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. In 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 'Medicines Act'), Section 15/B(1) stipulates that a substance or group of compounds may be classified as a new psychoactive substance after prior professional evaluation.

Pursuant to Section 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 substance or group of compounds poses a similar threat to public health than that attributed to drugs or the substances mentioned in Schedule 1 and 2 of the Psychotropic Substances in Annex 2 of the Decree of the Minister for Health on controlled substances.

Pursuant to Section 27(4a) of Government Decree No 66/2012 of 2 April on licensed activities with narcotics and psychotropic substances, as well as new psychotropic substances, including the listing and amendment of the lists of these substances (hereinafter: 'the Government Decree'), the National Drug Focal Point is responsible for monitoring the list of suspected new psychoactive substances in foreign circulation, on a monthly basis, within the framework of information exchange. In this context, 14 new substances were found that are included in the EU Early Warning System (EUDA Early Warning System) but are not subject to control in Hungary.

In accordance with Section 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 14 substances in order to verify if the conditions specified in the provisions of Section 15/B(3) of the Medicines Act are met. Based on the responses of NNGYK 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, 14 individual new psychoactive substances are added to the List in Annex 3 of the Decree.

The draft also serves to implement Commission Delegated Directive (EU) 2025/2062 of 14 October 2025

amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of drug, which classified 3 new substances (2-MMC, 4-BMC, NEP) as hazardous substances treated the same way as narcotic drugs. These psychotropic substances will be included in Schedule 1, meaning that, for the purposes of criminal law, they will be classified as drugs.

10. References to basic texts: The basic texts were forwarded with an earlier notification: 2026/0043/HU

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 14 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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