EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2023/0339/HU (Hungary)

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

Date received : 05/06/2023
End of Standstill : Not applicable (closed)

Message

Message 001

Communication from the Commission - TRIS/(2023) 1678

Directive (EU) 2015/1535

Notification: 2023/0339/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: 20231678.EN

1. MSG 001 IND 2023 0339 HU EN 05-06-2023 HU NOTIF

2. Hungary

3A. Igazságügyi Minisztérium
EU Jogi Megfelelésvizsgálati Főosztály - Műszaki Notifikációs Központ
H-1055 Budapest, Nádor utca 22.
E-mail: technicalnotification@im.gov.hu

3B. Belügyminisztérium
Nemzetközi és Európai Uniós Jogi Osztály
H-1051 Budapest V. József Attila utca 2-4.
Tel: (36 1) 999 4366
E-mail: judit.vera.acs@bm.gov.hu

4. 2023/0339/HU - C00P - Pharmaceutical and cosmetics

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

6. 10 unique new psychoactive substances (hexahydrocannabinol, acetyl-hexahydrocannabinol, hexahydrocannabiphorol, 4en-PDMB-4en-PINACA, ADMB-INACA, FUBIAT, fluorexetamine, rilmazafone, 5-MeO-TMT, 4F-MBZP) which may be abused

7.

8. The 10 unique new psychoactive substances (hexahydrocannabinol, acetyl-hexahydrocannabinol, hexahydrocannabiphorol, 4en-PDMB-4en-PINACA, ADMB-INACA, FUBIAT, fluorexetamine, rilmazafone, 5-MeO-TMT, 4F-MBZP), which are to be added to the List in Annex 3 of the Decree,
shall not be freely marketed in Hungary, and any activity carried out involving their use shall be subject to registration by 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 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 Section 27(4a) of Government Decree No 66/2012 of 2 April 2012 on licensed activities with narcotics and psychotropic substances, as well as new psychotropic substances, including the listing and amendment of the listing of these substances (hereinafter: 'the Government Decree'), the new task of the National Drug Focal Point is to monitor the list of suspected new psychoactive substances in foreign circulation on a monthly basis within the framework of information exchange. In this context, 9 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 addition, 1 new substance has been identified on the domestic market.

In accordance with Section 27(4)(c) and (4a) of the Government Decree, the National Drug Focal Point contacted the National Institute of Pharmacy and Nutrition (OGYÉI) and the National Food Chain Safety Office (NÉBIH) in connection with the above-mentioned 10 substances in order to verify whether the conditions specified in The provisions of Section 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, 10 unique new psychoactive substances are added to the List in Annex 3 of the Decree.

10. Reference(s) to basic text(s):
B-2023-0339-HU-01

11. Yes

12. The notification of the changes in the List of Annex 3 to the Decree (the addition of 10 unique new psychoactive substances) as a matter of urgency is justified both on grounds of public health and public safety. Further explanation can be found in the attached file.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

****
European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu