

Message 001

Communication from the Commission - TRIS/(2025) 0978

Directive (EU) 2015/1535

Notification: 2025/0192/PL

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 késésekét - 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: 20250978.EN

1. MSG 001 IND 2025 0192 PL EN 02-04-2025 PL NOTIF

2. Poland

3A. Ministerstwo Rozwoju i Technologii, Departament Obrotu Towarami Wrażliwymi i Bezpieczeństwa Technicznego,

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4. 2025/0192/PL - C00P - PHARMACEUTICAL AND COSMETICS

5. Regulation of the Minister for Health amending the Regulation on the list of psychotropic substances, narcotic drugs and new psychoactive substances.

6. Psychotropic substances, narcotic drugs, new psychoactive substances, including medicinal products containing substances that affect the central nervous system.

7.

8. On the basis of the decision of the Commission on Narcotic Drugs, amendments were made to Annex No. 1 — List of Psychotropic Substances (P), Annex 2 — List of Narcotic Drugs (N). These amendments concern:

- 1) the reassignment from group I-P to group II-P of the psychotropic substance: 3-CMC;
- 2) the expansion of group II-P to include the substance DIPENTYLONE;
- 3) the reassignment of the substance 2-FDCK from the list of new psychoactive substances to group II-P;
- 4) the expansion of group IV-P to include the substance BROMAZOLAM;
- 5) the expansion of group I-N to include the substance BUTONITAZENE.

Based on the recommendations of the Panel on the Assessment of the Risks to Human Health or Life related to the Use of New Psychoactive Substances, Annex 3 — List of New Psychoactive Substances (NPS) has been amended. These amendments concern:

- 1) the expansion of group II-P to include the substance LISDEXAMFETAMINE;
- 2) the expansion of the NPS group to include the following substances: delta-9-THCP, HHCP, GIDAZEPAM, MDMB-5Br-INACA, ADB-INACA, ADB-5Br-INACA, IBOTENIC ACIS, MUSCIMOL;
- 3) the inclusion in Annex 3 of Part '9. Benzimidazole derivatives — group VIII-NPS';
- 4) the expansion of the catalogue of new psychoactive substances described using the chemical formula of group III-NPS — synthetic cannabinoids (cannabinomimetics);
- 5) clarification of the chemical formula for group IV-NPS — fentanyl derivatives.

The Regulation has been corrected:

- 1) In Annex 1 — List of Psychotropic Substances (P), a different chemical name had been added for the substance alpha-PHiP.
- 2) In Annex 2 the substances dextromethorphan and dextrorphan have been literally excluded.

9. The substances substances delta-9-THCP, HHCP, GIDAZEPAM, MDMB-5Br-INACA, ADB-INACA, ADB-5Br-INACA, IBOTENIC ACIS, MUSCIMOL and substances belonging to the group of benzimidazole derivatives and synthetic cannabinoids, which are the subject of the regulation, not only pose a risk to human health and life, but also pose a high risk of poisoning, including fatal poisoning, and lead to the development of addictions. The aim of the draft Regulation is to allow for an effective protection of society against new psychoactive substances and the effects of the use thereof.

10. References to basic texts: 2023/0145/PL, 2024/0162/PL

Reference texts were submitted under the previous notification:

2023/0145/PL

2024/0162/PL

11. Yes

12. Protection of public health.

The Regulation has been drafted in response to the urgent need to contain the practice of placing substances on the market which affect the central nervous system and are dangerous to human life and health. Reducing the risks created by new psychoactive substances, which are increasingly highly toxic, is a serious public health challenge. If the use of a given substance is not prohibited, it may lead to the

misleading impression, especially among young people, that it is harmless. This Regulation responds to the rapid development of the market for new psychoactive substances, which pose a high risk of poisoning, including fatal poisoning, and the development of addiction.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission

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