

Message 001

Communication from the Commission - TRIS/(2026) 0276

Directive (EU) 2015/1535

Notification: 2026/0036/BE

Notification of a draft text from a Member State

Notification – Notificación – 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 - Nezahtuje 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 jiftaħ 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: 20260276.EN

1. MSG 001 IND 2026 0036 BE EN 27-01-2026 BE NOTIF

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4. 2026/0036/BE - C10P - Pharmaceuticals

5. Royal Decree amending the Royal Decree of 6 September 2017 regulating narcotic and psychotropic substances

6. This draft decree concerns active substances and preparations containing psychoactive substances, falling within the scope of narcotics and psychotropic substances, as regulated by the Royal Decree of 6 September 2017.

7.

8. This draft royal decree amends Annexes IA, IIB, III, IVB and IVC of the Royal Decree of 6 September 2017 regulating narcotic and psychotropic substances. It aims to:

- Include new psychoactive substances recently identified on the illicit market in the appropriate annexes;
- Reclassify certain known substances in order to adapt their level of control;
- Update the regulations applicable to preparations containing certain pharmaceutical active substances (pregabalin, gabapentin), in particular by setting dosage or concentration thresholds;
- Remove certain obsolete substances from the annexes when their reclassification is carried out elsewhere in the system.

9. This draft decree is motivated by several converging factors:

The rapid emergence of new psychoactive substances, particularly synthetic opioids of the nitazene family, which have a high potential for addiction and toxicity;

The increasing misuse of certain substances intended for medical use (notably gabapentin, pregabalin, and carisoprodol), used off-label and sometimes in combination with other substances;

The necessity of ensuring a high level of public health protection by promptly adapting the regulatory framework to developments observed in the drug market;

The obligation for the national authority to maintain the consistency and effectiveness of the narcotics and psychotropic substance control system, in accordance with the Act of 24 February 1921 and the Royal Decree of 6 September 2017.

These amendments thus make it possible to prevent health risks, strengthen the intervention capacity of the competent authorities, and avoid regulatory gaps in the face of newly identified substances.

10. References to basic texts: There are no basic texts

11. Yes

12. There is an immediate risk to public health linked to the circulation of highly potent substances (particularly nitazenes), associated with cases of serious poisoning and overdoses;

There is a rapid and unpredictable spread of new psychoactive substances, rendering the normal standstill period provided for by the TRIS procedure inadequate;

It is necessary to prevent circumvention of the existing legal framework, particularly through the marketing of substances chemically similar to those already controlled;

There is a need to ensure a swift and proportionate regulatory response, enabling enforcement and

monitoring authorities to act effectively.

Within this context, recourse to the emergency procedure provided for in Article 6(7) of Directive (EU) 2015/1535 appears justified in order to protect public health. These are harmful psychoactive substances; waiting three months means that these substances will be allowed to circulate freely in the meantime.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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