

Message 001

Communication from the Commission - TRIS/(2026) 0233

Directive (EU) 2015/1535

Notification: 2026/0025/BE

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 - 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: 20260233.EN

1. MSG 001 IND 2026 0025 BE EN 22-01-2026 BE NOTIF

2. Belgium

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4. 2026/0025/BE - C10P - Pharmaceuticals

5. Decision extending submission of the export of the medicinal product Visudyne 15 mg powder for solution for IV infusion 15 mg vial intended for the Belgian market to prior authorisation

6. Visudyne 15 mg powder for solution for IV infusion 15 mg vial

7.

8. The draft extends an authorisation requirement for the export of a specific medicinal product intended for the Belgian market in the event of unavailability, under the conditions laid down in the Royal Decree of 19 January 2023 implementing Article 12f, subparagraph 2, of the Law of 25 March 1964 on medicinal products, Article 4(1), (2), first subparagraph, and (3), first subparagraph. Prior authorisation for a specific period (i.e. the duration of the notified planned unavailability period), namely until 31 December 2026.

9. Fight against the unavailability of medicinal products in Belgium, in the swiftest and most efficient way possible, with a view to ensuring the protection of public health.

10. References to basic texts: 2025/0317/BE

The basic texts were forwarded with an earlier notification:
2025/0317/BE

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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