Message 001

Communication from the Commission - TRIS/(2025) 2642

Directive (EU) 2015/1535

Notification: 2025/0542/BE

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: 20252642.EN

1. MSG 001 IND 2025 0542 BE EN 26-09-2025 BE NOTIF

2. Belgium

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4. 2025/0542/BE - C10P - Pharmaceuticals

5. Decision extending submission of the export of the medicinal products Zypadhera 405 mg prolonged release suspension for IM injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial [...]

6. The medicinal products Zypadhera 405 mg prolonged release suspension for injection (pulv. + solv.) vial 405 mg + 3 ml, Zypadhera 300 mg prolonged release suspension for IM injection (pulv. + solv.) vial 300 mg + 3 ml and Zypadhera 210 mg prolonged release suspension for IM injection (pulv. + solv.) vial 210 mg + 3 ml

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 31/03/2026.

9. Controlling the unavailability of medicinal products in Belgium, in the swiftest and most efficient way possible, with a view to ensuring public health protection.
This draft will enter into force through its publication in the Moniteur belge (national gazette) on 01/01/2026 in order to ensure continuity with the decision notified under 2025/0137/B, which expires on 31/12/2025.

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

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European Commission

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