Message 001

Communication from the Commission - TRIS/(2025) 1492

Directive (EU) 2015/1535

Notification: 2025/0290/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: 20251492.EN

1. MSG 001 IND 2025 0290 BE EN 10-06-2025 BE NOTIF

2. Belgium

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4. 2025/0290/BE - C10P - Pharmaceuticals

5. Decision extending the requirement for prior authorisation for the export of the medicinal products Zypadhera [...] intended for the Belgian market

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 obligation for the export of a specific medicinal product intended for the Belgian market in the event of unavailability, under the conditions laid down by the Royal Decree of 19 January 2023
implementing Article 12f(2) of the Law of 25 March 1964 on medicinal products, Article 4, §1, §2(1) and §3(1). Prior authorisation for a certain period (i.e. the duration of the notified envisaged period of unavailability), namely until 31/12/2025.

9. Countering the unavailability of medicinal products in Belgium, in the most effective and fastest way possible, with a view to ensuring the protection of public health. A further extension of unavailability was notified to the FAMHP during the standstill period of a standard TRIS notification - 2025/0166/B

10. References to basic texts:

11. Yes

12. In order to avoid worsening of the unpredictable unavailability following the distribution of the medicinal product intended for the Belgian market to other Member States, it is essential that the measure be applicable as soon as possible + annex

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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European Commission

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