Message 001

Communication from the Commission - TRIS/(2025) 0855

Directive (EU) 2015/1535

Notification: 2025/0170/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: 20250855.EN

1. MSG 001 IND 2025 0170 BE EN 24-03-2025 BE NOTIF

2. Belgium

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4. 2025/0170/BE - C10P - Pharmaceuticals

5. Decision extending the requirement for pre-clearance for the export of injectable medicinal products containing etoposide as an active pharmaceutical ingredient intended for the Belgian market

6. Injectable medicinal products whose active pharmaceutical ingredient is etoposide

7.

8. The project 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 paragraph 2 of the Act of 25 March 1964 on medicinal products, Article 4, §1, §2 paragraph 1 and §3 paragraph 1. Prior authorisation for a certain period (i.e. the duration of the notified planned period of unavailability), namely until 19/01/2026.

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.

10. References to reference texts: 2024/0551/BE

The reference texts must be sent under case-law notification:
2024/0551/BE

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 Grounds for urgency. The old decision expires on 30/04/2025. The project submitted to TRIS will be published in the Moniteur belge on 01/05/2025 with a view to ensuring continuity of the extension.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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