Message 001

Communication from the Commission - TRIS/(2025) 0250

Directive (EU) 2015/1535

Notification: 2025/0052/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: 20250250.EN

1. MSG 001 IND 2025 0052 BE EN 27-01-2025 BE NOTIF

2. Belgium

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4. 2025/0052/BE - C10P - Pharmaceuticals

5. Decision extending the subjecting of the export of the medicinal products Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. vial 20 ml and 100 ml and Fluracedyl 50 mg/ml i.v./i.arter. sol. for inj. 100 ml intended for the [...] market

6. The medicinal products Fluorouracil Accord Healthcare 50 mg/ml i.v./i.arter. sol. for inj./inf. vial 20 ml and 100 ml and Fluracedyl 50 mg/ml i.v./i.arter. sol. for inj. 100 ml

7.

8. The draft extends an authorisation requirement for the export of a specific medicinal product intended for the Belgian market in case of unavailability, under the conditions laid down in the Royal Order of 19 January 2023 implementing Article 12f, subparagraph 2, of the Law of 25 March 1964 on medicinal products, Article 4(1), (2), subparagraph 1, and (3), subparagraph 1. Prior authorisation for a certain period (i.e. the duration of the notified planned unavailability period), in particular until 23 June 2025.

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

10. References to reference texts: The reference texts should be sent as part of the previous notification: 2024/0291/BE

11. Yes

12. In order to avoid the 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 is applicable as soon as possible. + Annex

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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