

Message 001

Communication from the Commission - TRIS/(2025) 0252

Directive (EU) 2015/1535

Notification: 2025/0053/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 - Atidējimai 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: 20250252.EN

1. MSG 001 IND 2025 0053 BE EN 27-01-2025 BE NOTIF

2. Belgium

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4. 2025/0053/BE - C10P - Pharmaceuticals

5. Decision extending the requirement for prior authorisation for the export of the medicinal product Bleomycine Sanofi 15000 IU intended for the Belgian market

6. the medicinal product Bleomycine Sanofi 15000 IU

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 2 March 2026.

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: 2024/0171/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. On Monday, 6 January 2025, the end date of the unavailability of Bleomycin Sanofi 15000 IU sol. inj. (pdr) i.m./i.perit./i.tumour./i.v./i.pleur./i.artér./s.c. vial 15000 UI has been extended by Sanofi Belgium until 02.03.2026.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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