Message 001

Communication from the Commission - TRIS/(2025) 1388

Directive (EU) 2015/1535

Notification: 2025/0267/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: 20251388.EN

1. MSG 001 IND 2025 0267 BE EN 28-05-2025 BE NOTIF

2. Belgium

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4. 2025/0267/BE - C10P - Pharmaceuticals

5. Decision extending the submission of exports of medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, intended for the Belgian market, to prior authorisation

6. medicinal products categorised as GLP-1 analogues, whose authorisation includes the indication of type 2 diabetes mellitus, intended for the Belgian market

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.
In order to ensure continuity with the current unavailability decision, said draft will be published in the Belgian Official Gazette (Moniteur belge) on 01/09/2025.

10. References to reference texts: 2024/0614/BE

The basic texts were forwarded with an earlier notification:
2024/0614/BE

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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