Notification Number : 2025/0143/BE (Belgium)

Decision extending subjection of the export of medicinal products Mimpara 30 mg film. tabl. 28 and Mimpara 60 mg film. tabl. 28 intended for the Belgian market to prior authorisation

Date received : 13/03/2025
End of Standstill :

Message

Message 001

Communication from the Commission - TRIS/(2025) 0725

Directive (EU) 2015/1535

Notification: 2025/0143/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: 20250725.EN

1. MSG 001 IND 2025 0143 BE EN 13-03-2025 BE NOTIF

2. Belgium

3A. SPF Economie, PME, Classes moyennes et Energie
Direction générale Qualité et Sécurité - Service Bureau de Liaison - BELNotif
NG III – 2ème étage
Boulevard du Roi Albert II, 16
B - 1000 Bruxelles
be.belnotif@economie.fgov.be

3B. Agence fédérale des médicaments et produits de santé
Avenue Galilée 5/03
1210 Bruxelles
Division législation et contentieux
ius@fagg-afmps.be

+32 2 528 40 00

4. 2025/0143/BE - C10P - Pharmaceuticals

5. Decision extending subjection of the export of medicinal products Mimpara 30 mg film. tabl. 28 and Mimpara 60 mg film. tabl. 28 intended for the Belgian market to prior authorisation

6. medicinal products Mimpara 30 mg film. tabl. 28 and Mimpara 60 mg film. tabl. 28

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 envisaged period of unavailability notified), notably until 29 September 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.

10. References to reference texts: 2024/0454/BE

The reference texts must be sent within the framework of the previous notification:
2024/0454/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. It will enter into force by publication in the Belgian Official Gazette on 1 April 2025, with a view to ensuring continuity of extension with the expiry of the old decision submitted to TRIS (2024/0454/B).

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

****
European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu