

Message 001

Communication from the Commission - TRIS/(2026) 0117

Directive (EU) 2015/1535

Notification: 2026/0011/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: 20260117.EN

1. MSG 001 IND 2026 0011 BE EN 13-01-2026 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. 2026/0011/BE - C10P - Pharmaceuticals

5. Decision extending the submission for export of the medicinal products Creon 25,000 300 mg gastro-resistant gel capsules 200 and Creon 35,000 420 mg gastro-resistant gel capsules 200 intended for the Belgian market with a prior authorisation.

6. medicinal products Creon 5000 601.2 mg/g gastro-resistant granules 20 g, Creon 10,000 150 mg 20 and 100 gastro-resistant gel capsules, Creon 25,000 300 mg 100 gastro-resistant gel capsules, Creon 35,000 420 mg 100 and 200 gastro-resistant gel capsules 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 in the Royal Decree of 19 January 2023 implementing Article 12f, Paragraph 2, of the Law of 25 March 1964 on medicinal products, Article 4 Section 1, Section 2 and Section 3, Paragraph 1. A prior authorisation for a certain period (i.e. the duration of the notified expected shortage period), specifically until 15/01/2027.

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

10. References to basic texts: 2025/0420/BE,2024/0063/BE,2024/0637/BE

The basic texts were forwarded with an earlier notification:

2025/0420/BE

2024/0063/BE

2024/0637/BE

11. Yes

12. In order to prevent the worsening of unforeseeable unavailability following the distribution of the medicinal product intended for the Belgian market to other Member States, the measure must take effect as soon as possible. Furthermore, in order to ensure continuity with the previous publication, this must be published in the Belgian Official Gazette on 16 January 2026. + see Annex A.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

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European Commission

Contact point Directive (EU) 2015/1535

email: [grow-dir2015-1535-central@ec.europa.eu](mailto:grow-dir2015-1535-central@ec.europa.eu)