

Message 001

Communication from the Commission - TRIS/(2025) 0828

Directive (EU) 2015/1535

Notification: 2025/0167/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 - 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 késésekét - 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: 20250828.EN

1. MSG 001 IND 2025 0167 BE EN 23-03-2025 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. 2025/0167/BE - C10P - Pharmaceuticals

5. Royal Decree amending the Royal Decree of 21 January 2009 laying down instructions for pharmacists

6. Naloxone-based nasal sprays

7.

8. The purpose of the draft is to allow pharmacists to dispense nasal sprays to doctors in charge of reception centres for 'drug addicts' (a term still used in our legislation), upon presentation of an order form.

The products in question are subject to prescription in Belgium, and can normally only be dispensed to patients who are known in advance. Here, we clarify the content of the doctor's 'emergency kit' by specifically mentioning the product in question, in order to permit dispensing directly to the prescriber.

9. The draft concerns the rules for the dispensing, by pharmacists, of medicinal products subject to medical prescription. In addition, the draft is limited to use of the doctor's emergency kit. Also, as the product is subject to medical prescription (in the broad sense), its intra-European trade is already severely limited (requirement for a written prescription or request, prohibition of Internet sales) and prescription can, with the exception of the minimum content of individual prescriptions, be regulated at national level.

Thus, we are not imposing any measures that have an impact on trade, but we are only explicitly allowing trade, at national level, to take place on the basis of an 'order form' (which should be understood to mean a medical prescription without mention of an individual patient).

10. References to basic texts:

11. No

12.

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

