



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2024/0266/BE (Belgium)

Royal Decree amending the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances

Date received : 17/05/2024

End of Standstill : 21/08/2024

Message

Message 001

Communication from the Commission - TRIS/(2024) 1308

Directive (EU) 2015/1535

Notification: 2024/0266/BE

Notification of a draft text from a Member State

Notification – Notificación – 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 - Καμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéset - 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: 20241308.EN

1. MSG 001 IND 2024 0266 BE EN 17-05-2024 BE NOTIF

2. Belgium

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4. 2024/0266/BE - C00P - PHARMACEUTICAL AND COSMETICS

5. Royal Decree amending the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances

6. the supply of the products indicated in the Decree of the Regent – (pseudo)ephedrine and fusidic acid – subject to prescription

7.

8. An amendment to the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances in order to change the status of ephedrine- and pseudoephedrine-based substances from 'free supply: TF' or 'upon written request: TD' to 'with a medical prescription'.

9. The aim is to make the supply of the products indicated in the Decree of the Regent subject to prescription, for several reasons.

- For (pseudo)ephedrine, risks related to its use were identified.

- The above product may also be used as a drug precursor (psychotropic or narcotic drugs).

- For fusidic acid, the product is an important antibiotic, which is currently freely supplied for external use (ointments). This poses risks, given the fact that the product is used freely and bacteria develop resistance (AMR) to the product. It is therefore imperative to make its supply subject to prescription.

10. References to reference texts: There are no reference texts

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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