EUROPEAN COMMISSION

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

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2023/0429/BE (Belgium)

Law on raw materials used by pharmacists

Date received : 10/07/2023
End of Standstill : 11/10/2023

Message

Message 001

Communication from the Commission - TRIS/(2023) 2084

Directive (EU) 2015/1535

Notification: 2023/0429/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: 20232084.EN

1. MSG 001 IND 2023 0429 BE EN 10-07-2023 BE NOTIF

2. Belgium

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4. 2023/0429/BE - S00S - HEALTH, MEDICAL EQUIPMENT

5. Law on raw materials used by pharmacists

6. Raw materials used by pharmacists to prepare magistral and officinal preparations

7.

8. The draft aims to regulate raw materials, i.e. active substances and excipients intended for use by pharmacists in officinal or magistral preparations. The draft successively regulates the way in which a raw material can be manufactured, marketed and used, as well as the obligations of the various market players, namely the manufacturer, the distributor and the pharmacist.

9. The bill therefore aims to update the regulations on raw materials used by pharmacists with current practice in the field. This takes particular account of the European environment which Belgium forms a part of.
The bill redefines, clarifies and harmonises requirements, quality and control standards to offer the patient, at the end of the chain, raw material of the highest possible quality, on the basis of which the pharmacist will prepare the magistral or officinal preparation for them.

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

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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European Commission
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