Message 001

Communication from the Commission - TRIS/(2026) 0806

Directive (EU) 2015/1535

Notification: 2026/0134/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: 20260806.EN

1. MSG 001 IND 2026 0134 BE EN 13-03-2026 BE NOTIF

2. Belgium

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4. 2026/0134/BE - C10P - Pharmaceuticals

5. Royal decree amending the Royal Decree, of 9 October 2017, implementing the Law, of 7 May 2017, on clinical trials of medicinal products for human use

6. Investigational medicinal products, unauthorised ancillary medicinal products and authorised ancillary medicinal products subject to a modification that does not require a marketing authorisation

7.

8. This draft royal decree makes the distribution of investigational medicinal products, unauthorised ancillary medicinal products and authorised ancillary medicinal products subject to a modification that does not require a marketing authorisation, used in the context of clinical trials, subject to an authorisation for distributors established in Belgium. It regulates the conditions and procedures for obtaining and maintaining the authorisation. The draft decree also establishes the rules to be followed by the distributor established in Belgium or in another Member State. This notification follows the amendment of the draft submitted under procedure TRIS 2025/0323/BE.

9. Regulate the distribution and distribution requirements for the medicinal products concerned.

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

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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