Message 001

Communication from the Commission - TRIS/(2025) 1316

Directive (EU) 2015/1535

Notification: 2025/0248/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: 20251316.EN

1. MSG 001 IND 2025 0248 BE EN 22-05-2025 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. 2025/0248/BE - C10P - Pharmaceuticals

5. Extract of a draft bill amending the Law of 7 May 2017 on clinical trials of medicinal products for human use.

6. To regulate the dispensing of investigational medicinal products and auxiliary medicinal products to those taking part in clinical trials.

7.

8. This draft bill will be revised so as to be included in a bill laying down various provisions. In order to facilitate the analysis of the measures concerned and to respect the standstill period of the TRIS procedure. We are already introducing the bill in its current form. This will be amended to be included in a broader legislative bill.

9. The purpose of the bill is to regulate the dispensing of investigational medicinal products and auxiliary medicinal products to those taking part in clinical trials, which has not thus far been regulated by the Law of 7 May 2017. Two ways of dispensing investigational medicinal products and auxiliary medicinal products are thus possible: in-person delivery and remote delivery, via a delivery service. This latter possibility follows developments in the organisation of clinical trials and is based on the principles of the recommendation paper on decentralised elements in clinical trials by the HMA (Heads of Medicines Agencies) Clinical Trials Coordination Group.

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
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu