

Message 001

Communication from the Commission - TRIS/(2025) 1986

Directive (EU) 2015/1535

Notification: 2025/0405/BE

Notification of a draft text from a Member State

Notification – Notifikation – 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 késések - Non fa decorrere la mora - Atidėjimai 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: 20251986.EN

1. MSG 001 IND 2025 0405 BE EN 23-07-2025 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. 2025/0405/BE - C10P - Pharmaceuticals

5. Extract from the preliminary draft Law laying down various provisions on the processing of personal data, in the context of medicinal products and health products

6. Veterinary medicinal products: Collection of antimicrobial data and communication to the EC (Art. 57 Regulation (EU) 2019/6)

7.

8. Chapter 5 replaces Section 23/1 and provides the legal basis for data processing in the context of data collection and reporting to the European Commission on the use of antimicrobial medicinal products in animals. This data collection is mandatory and stems from Article 57 of Regulation (EU) 2019/6. The Regulation provides for a step-by-step process for this data collection (and communication).

The new articles replace, in accordance with the GDPR legislation, the current legal basis for this data processing under European obligations.

It defines in particular the purposes of data processing, the controller, the categories of data collected, the retention period, etc. and covers all the processes covered by the Regulation.

9. The current provisions have been rewritten and divided into several articles, in order to ensure consistency and uniformity with other provisions on data processing and to improve their readability.

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

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu

