

Message 001

Communication from the Commission - TRIS/(2025) 3602

Directive (EU) 2015/1535

Notification: 2025/0749/BE

Notification of a draft text from a Member State

Notification – Notification – 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 - Nezahtuje 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 késésekét - 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: 20253602.EN

1. MSG 001 IND 2025 0749 BE EN 14-12-2025 BE NOTIF

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4. 2025/0749/BE - C10P - Pharmaceuticals

5. Royal Decree amending the Royal Decree of 21 January 2009 laying down instructions for pharmacists, the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use and the Royal Decree of 15 November 2017 on the materiovigilance contact point

6. The measure applies to antibiotics for human use, in solid oral form, in Class ATC J01.

7.

8. The measure concerns situations in which the packages available do not permit the exact quantity prescribed by the doctor to be dispensed, depending on the dosage and the duration of treatment. In order to avoid a surplus of unsold products in pharmacies and to limit economic and logistical losses, the following active substances, with their ATC codes, are excluded:

cefalexin (J01DB01)

lincomycin (J01FF02)

ofloxacin (J01MA01)

norfloxacin (J01MA06)

roxithromycin (J01FA06)

The draft introduces an obligation for dispensers to dispense the medicinal products concerned only in the quantity corresponding to the prescription. Where the prescription is issued under the international non-proprietary name (INN) and none of the packages available permit the exact quantity prescribed by the doctor to be supplied, dispensers shall be obliged to split the packages.

9. This measure pursues the following objectives, contributing to the fight against antimicrobial resistance (AMR):

- o to promote compliance with the prescription and proper adherence to treatment by the patient;
- o to prevent self-medication associated with the retention of leftover medication;
- o to reduce the presence of pharmaceutical waste in the environment.

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

European Commission

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