Message 001

Communication from the Commission - TRIS/(2025) 1790

Directive (EU) 2015/1535

Notification: 2025/0359/FR

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: 20251790.EN

1. MSG 001 IND 2025 0359 FR EN 08-07-2025 FR NOTIF

2. France

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4. 2025/0359/FR - S00S - HEALTH, MEDICAL EQUIPMENT

5. Draft decree amending Decree No 2022-100 of 31 January 2022 on the unit-dose dispensing of certain medicinal products in retail pharmacies

6. Medicinal products eligible for unit-dose dispensing

7.

8. The draft decree amends the labelling rules for the new packaging of medicinal products that may be dispensed by unit in retail pharmacies. The list of information that must appear on the new outer packaging is simplified, by removing the patient's name and surname, the duration of treatment and the dispensed date.

9. Unit-dose dispensing ('UDD') pursues the objective of combating drug waste and antibiotic resistance. This dispensing method also makes it possible to monitor the evolution of drug prescription recommendations.
Since Law No 2020-105 of 10 February 2020 on combating waste and on the circular economy, the so-called "AGEC Law", pharmacists are authorised to dispense certain medicinal products individually when the packaging characteristics so allow. The draft decree aims to relax the regulatory framework laying down the dispensing rules (Articles R. 5132-42-1 to R. 5132-42-7 of the Public Health Code).
The information that must appear on the outer packaging of medicinal products is simplified, by removing the obligation to record the patient's name and surname, the dispensed date and the number of units dispensed to the patient. This information is already mentioned on the prescription kept by the patient and does not currently appear on the medicine boxes. In addition, the pharmaceutical form of the medicinal products eligible for unit-dose dispensing is set out in an Order.
The draft decree would simplify and facilitate the procedure for dispensing individual medicinal products for retail pharmacies, making this practice more efficient by simply providing the information necessary for the monitoring of the treatment by patients while ensuring the protection of public health.

10. References to the basic texts:

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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