

Message 001

Communication from the Commission - TRIS/(2026) 0255

Directive (EU) 2015/1535

Notification: 2026/0032/ES

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 - 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: 20260255.EN

1. MSG 001 IND 2026 0032 ES EN 23-01-2026 ES NOTIF

2. Spain

3A. Subdirección de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y de Medioambiente.

Dirección General de Coordinación del Mercado Interior y otras Políticas Comunitarias.

Secretaría de Estado para la Unión Europea.

Ministerio de Asuntos Exteriores, Unión Europea y Cooperación.

Plaza Marqués de Salamanca, 8 28006 Madrid.

3B. Dirección General de Inspección y Ordenación Sanitaria

Consejería de Sanidad de la Comunidad de Madrid

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4. 2026/0032/ES - S00S - HEALTH, MEDICAL EQUIPMENT

5. Draft decree of the Governing Council partially implementing Law 13/2022 of 21 December 2022 on pharmaceutical care and management in the Community of Madrid, covering opening hours, out-of-hours

and holiday services, personalised dosage systems, pharmaceutical care and dispensing, etc.

6. Retail pharmacy opening hours, out-of-hours and holiday services

Personalised dosage systems (PDS)

Pharmaceutical care and dispensing with informed delivery to the home,

Dispatch authorisation regime for retail pharmacies

7.

8. The purpose of the draft decree is to regulate the opening hours, out-of-hours and holiday services of retail pharmacies, the conditions and requirements for preparing and delivering personalised dosage systems, providing pharmaceutical care and dispensing medicinal products and medical devices to the home on behalf of pharmacy offices, the non-face-to-face dispensing by hospital pharmacy services of medicinal products whose dispensing is restricted to the hospital environment, as well as to regulate the procedure for authorising dispatches from retail pharmacies.

9. The reference draft decree includes technical specifications that fall within the scope of the Directive and Chapter 3 thereof regulates characteristics specific to pharmacies, as well as those relating to the preparation, preservation, storage and delivery of personalised dosage systems (PDS), which affect both pharmaceutical establishments and the provision of their services.

The need to approve this regulation addresses the general interest of guaranteeing the safety and quality of pharmaceutical care for the population of the Community of Madrid, meeting the demands of users and the sectors involved. This regulation makes it possible to achieve this objective by regulating the various aspects of pharmaceutical care described in the previous sections, thus complying with the principles of necessity and effectiveness.

10. References to the basic texts:

11. No

12.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission

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