EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2025/0032/ES (Spain)

Draft Royal Decree establishing the conditions for the preparation and dispensing of standardised master formulas for cannabis preparations.

Date received : 23/01/2025
End of Standstill : 24/04/2025 (closed)

Message

Message 001

Communication from the Commission - TRIS/(2025) 0176

Directive (EU) 2015/1535

Notification: 2025/0032/ES

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: 20250176.EN

1. MSG 001 IND 2025 0032 ES EN 23-01-2025 ES NOTIF

2. Spain

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación
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3B. Ministerio de Sanidad
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4. 2025/0032/ES - C00P - PHARMACEUTICAL AND COSMETICS

5. Draft Royal Decree establishing the conditions for the preparation and dispensing of standardised master formulas for cannabis preparations.

6. Elaboration and dispensing of standardised master formulas for cannabis preparations.

7.

8. Article 1 sets out the subject matter and scope of this Royal Decree.

Article 2 defines a series of terms necessary for the understanding of what is being legislated.

Article 3 sets out the conditions for the control of cannabis as narcotic substance listed in Schedule I to the Single Convention on Narcotic Drugs of 1961.

Article 4 establishes the conditions for the monograph to which the standardised master formulas for cannabis preparations must conform.

Article 5 sets out the obligations of pharmaceutical laboratories manufacturing standardised cannabis preparations.

Article 6 regulates the registration of standardised cannabis preparations.

Articles 7, 8, and 9 regulate the prescription of standardized master formulas for cannabis preparations, processing, and dispensing.

Article 10 regulates drug safety monitoring, establishing the need for health professionals to report suspected adverse reactions to the aforementioned master formulas to the Autonomous Centre for Drug Safety Monitoring corresponding to their field of care.

9. This draft Royal Decree establishes the conditions for the prescription, preparation, dispensing, and use of standardised master formulas for cannabis preparations. Likewise, it establishes a register for standardised cannabis preparations used in the elaboration of these master formulas, in order to guarantee their quality.
In the preparation of this draft, the different normative regulations on the regulation of medical cannabis in countries of the European Union (France, the Netherlands, the Czech Republic, Croatia, Portugal, Italy, Germany…) and in third countries (Switzerland, Israel, the United Kingdom, Canada…) have been considered. The review has been carried out considering its scientific basis, based on evidence published in scientific literature, the available information on the functioning of the different systems and their health effects, and the possibility its adaptation to the Spanish regulatory framework.

10. References to basic texts: There are no basic texts

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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