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

Pranešimo numeris : 2025/0156/FR (France)

Arrêté pris en application du 4° de l’article L. 5121-1 du code de la santé publique fixant les spécifications des médicaments à base de cannabis ainsi que les indications thérapeutiques dans lesquelles ils seront utilisés.

Gauti duomenys : 19/03/2025
Status quo pabaiga : 20/06/2025

Message

Message 001

Communication from the Commission - TRIS/(2025) 0790

Directive (EU) 2015/1535

Notification: 2025/0156/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: 20250790.EN

1. MSG 001 IND 2025 0156 FR EN 19-03-2025 FR NOTIF

2. France

3A. Ministères économiques et financiers
Direction générale des entreprises
SCIDE/SQUALPI - Pôle Normalisation et réglementation des produits
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3B. Ministère du travail, de la santé et des solidarités
Direction générale de la santé
Sous-direction politique des produits de santé et qualité des pratiques et des soins (PP)
Bureau du médicament (PP2)

14, Avenue Duquesne
75007 PARIS

4. 2025/0156/FR - C00P - PHARMACEUTICAL AND COSMETICS

5. Order adopted pursuant to Article L. 5121-1(4) of the Public Health Code laying down the specifications of cannabis-based medicinal products and the therapeutic indications in which they will be used.

6. Cannabis-based medicinal products

7.

8. Taken at the proposal of the National Agency for the Safety of Medicines and Health Products (ANSM), this order takes over the framework of the specifications for medicinal products as well as the indications of the experimentation.
It sets the scope of use of cannabis-based medicinal products to the five therapeutic indications of the experiment for which efficacy and safety profile are presumed to be favourable on the basis of the available data.
It also lays down specifications for future cannabis-based medicinal products: characteristics, composition, pharmaceutical form and quality control processes. The level of requirement is conformant in particular with the expectations of the European Cannabis Flower Monograph.
It should be clarified that pharmaceutical forms such as dried flowers in their raw form are excluded to avoid confusion between medicinal and recreational cannabis. However, authorisation for the use of flowering tops in fast-acting forms packaged in tamper-proof, secured and non-refillable single-dose cartridges is permitted in order to ensure patients' access to fast-acting pharmaceutical forms.

9. In France, experimentation with the medical use of cannabis was authorised pursuant to Article 43 of Act No. 2019-1446 of 24 December 2019 on the financing of social security for 2020. It was launched on 26 March 2021 and ended on 31 December 2024.
In line with its continuity, France has wished to regulate the medical use of cannabis. However, medicinal products used within this context are currently not eligible for the existing regulatory statuses. Indeed, the level of clinical evidence does not correspond to the requirements of the marketing authorisation. For this reason, it is proposed to create an appropriate temporary status for cannabis for medical use.
The proposed mechanism is proportionate. As during experiments, the prescription of a medicinal product based on medical cannabis will be possible only in the absence of an available or suitable proprietary medicinal product, guaranteeing the primacy of proprietary medicinal products with a marketing authorisation.
Furthermore, access to cannabis for medical use will be strictly restricted at the last line of treatment, on initial hospital prescription in exhaustively defined clinical indications and situations for which effectiveness could be presumed by ANSM.
In addition, these medicinal products will be subject to authorisation based in particular on a literature review for toxicological, pharmacokinetic and pharmacodynamic data to replace the findings of preclinical and clinical trials.
Finally, to make the connection with this last point, our proposal is of a temporary nature because the authorisation is limited to a period of five years.

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

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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