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

Notification Number : 2025/0154/FR (France)

Decree on medical cannabis

Date received : 19/03/2025
End of Standstill : 20/06/2025

Message

Message 001

Communication from the Commission - TRIS/(2025) 0784

Directive (EU) 2015/1535

Notification: 2025/0154/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: 20250784.EN

1. MSG 001 IND 2025 0154 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
Bât. Sieyès -Teledoc 143
61, Bd Vincent Auriol
75703 PARIS Cedex 13

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. 2025/0154/FR - C00P - PHARMACEUTICAL AND COSMETICS

5. Decree on medical cannabis

6. Cannabis-based medicinal products

7.

8. Article 78 of Law No 2023-1250 of 26 December 2023 on Social Security financing for 2024 (LFSS) provides for the creation of a temporary status for the use of medical cannabis. These medicinal products will be subject to an authorisation limited to 5 years, renewable for a period of 5 years, issued by the National Agency for the Safety of Medicines and Health Products (ANSM).
The legislative proposal refers to a decree made after hearing the Council of State, intended to define the framework for the future system more precisely (authorisation application, ANSM evaluation, pharmacovigilance, circuit, etc.).
The content of the application file submitted by pharmaceutical establishments to obtain the temporary authorisation for use is similar to that for proprietary medicinal products with a marketing authorisation, apart from the requirement to produce the results of pre-clinical and clinical trials, which do not appear to be available for cannabis-based medicinal products. The available toxicological, pharmacokinetic and pharmacodynamic data (in the form of a literature review) must be provided in the application file. The draft Summary of Product Characteristics (SPC) must be provided and written up in accordance with the rules in force for the marketing authorisation.
Pharmaceutical establishments are also not required to provide a risk management plan (RMP), based on non-clinical and clinical studies conducted on the medicinal product, but a risk management system to prevent or minimise the risks associated with the use of the medicinal product.
In the same way, the means of giving or obtaining evidence available to the Director-General of ANSM when examining the application are the same as for the marketing authorisation. The time limit for examining the file is 210 days and is the same as that for the marketing authorisation and for registration.
In accordance with Article 78 of LFSS 2024, the authorisation is issued by ANSM for a period of 5 years, based on evaluation of the quality and safety criteria, in the absence of clinical data. Effectiveness is in fact presumed for the indications exhaustively established by ministerial order adopted on a proposal from ANSM (which is the subject of a separate notification). Authorisation will thus be refused if it appears that the requested indication is not included in that Order.
As with the marketing authorisation, the authorisation will lay down the conditions for prescription and dispensing in relation to the classification in the lists of poisonous substances and in one of the categories of medicinal products subject to restricted prescription.
It may also be accompanied, along the lines of the marketing authorisation, by appropriate conditions, in particular the obligation to carry out post-authorisation safety or efficacy studies.
Post-authorisation, a level of health security requirement comparable to that for the marketing authorisation will apply to cannabis-based medicinal products.
As with the marketing authorisation, pharmaceutical establishments will be obliged to take account of scientific and technical progress and to communicate any new data that might lead to amendment of the authorisation (notably all of the results of safety and efficacy studies and the results of human clinical research).
ANSM will be able to require studies (efficacy, safety, etc.) to be carried out post-authorisation and may amend the authorisation on public health grounds or at the request of the Minister.
ANSM will be able to amend, ex officio, suspend or withdraw the authorisation if it appears that the safety and quality conditions of the authorisation are no longer guaranteed.
The rules applicable in the event of a change of authorisation holder are identical to those for the marketing authorisation.
The authorisation renewal procedures will be based on the same requirements (updated where appropriate) as the initial evaluation. The time limit within which the holder must submit its application is identical to that for the marketing authorisation (9 months).
As regards pharmacovigilance, the level of requirements is the same as for proprietary medicinal products.
Pharmaceutical establishments will be required to record all suspected adverse reactions and report them to ANSM. A periodic safety report, including the safety data and a review of the literature, will be sent to ANSM annually.

Concerning the training of prescribers on the specificities of cannabis-based medicinal products, it provides that prescription will be conditional on prior training.
The provisions relating to manufacturing and wholesale distribution have been supplemented to refer to the specific authorisation of cannabis-based medicinal products and apply the same requirements as for the marketing authorisation. In particular, the cannabis authorisation, like the marketing authorisation, will be equivalent to an import authorisation.
The provisions relating to poisonous substances have been amended to allow the prescription and supply of these medicinal products classified as narcotics. The text also provides for the authorisation by ANSM of operations, notably including cultivation and import, permitting the manufacture of an authorised medicinal product. ANSM may also authorise these operations for raw materials for pharmaceutical use and medicinal products authorised in other Member States that do not comply with the specifications laid down at national level with a view to their export.
In addition, the requirement that these export operations pertain to pharmaceutical establishments authorised by ANSM is maintained, as for any type of narcotic (growers will not be able to export directly).

9. In France, experimentation with the medical use of cannabis was authorised pursuant to Article 43 of Law No 2019-1446 of 24 December 2019 on Social Security financing for 2020. It was launched on 26 March 2021 and ended on 31 December 2024.
By way of continuation, France has wished to regulate the medical use of cannabis. However, the medicinal products used in this context are not currently 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 that an appropriate temporary status be created for medical cannabis.
The proposed instrument is proportionate because, as during the experimentation, it will only be possible to prescribe a medical-cannabis-based medicinal product in the absence of an available or suitable proprietary medicinal product, thus guaranteeing the primacy of medicinal products with a marketing authorisation

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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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu