

Message 001

Communication from the Commission - TRIS/(2025) 0787

Directive (EU) 2015/1535

Notification: 2025/0155/FR

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 - 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 késésekét - 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: 20250787.EN

1. MSG 001 IND 2025 0155 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. 2025/0155/FR - C00P - PHARMACEUTICAL AND COSMETICS

5. Order laying down the technical arrangements for the holding, cultivation, import, export, transport and storage of the cannabis plant for medical purposes on national territory

6. Cannabis plant for medical purposes (raw material for pharmaceutical use)

7.

8. Article R. 5132-86 of the Public Health Code (CSP) regulates the specific field of cannabis, its plant and its resin. It lays down in I the principle of a general prohibition on all operations concerning them, but opens a derogation in II and III allowing the creation of a sector for the cultivation and production of cannabis for medical use on national territory.

In VI, the above-mentioned article calls for an interministerial order to specify the modalities of organisation of the operations of cultivation of the cannabis plant for medical purposes on national territory. This notified Order contains the following provisions:

- Reminder of the actors who may engage in the activity: pharmaceutical establishments authorised by the National Agency for the Safety of Medicines and Health Products (ANSM)
- Recall of the circuit of cultivation of the cannabis plant for medical purposes with an obligation of contract concluded between a grower and an aforementioned establishment;
- Content of the authorisation to be sent to the ANSM;
- Characteristics of cannabis cultivation buildings for medical use with a view to guaranteeing their safety and preventing malicious acts;
- Prohibition on leaving the place of cultivation and transporting plants, or parts of plants and reproductive material, except for the purpose of transport to an authorised establishment;
- Procedures for reporting any malicious acts or incidents;
- Possibility of requesting a security study, for each production site, from the security coordinator of the police or the national gendarmerie.

9. As part of the continuation of the experimentation on the medical use of cannabis, France has wished to enable the creation of a sector for the cultivation and production of cannabis for medical use. Decree No. 2022-194 of 17 February 2022 on cannabis for medical use, which was not subject to notification, thus amended Article R. 5132-86 of the CSP.

It has indeed appeared necessary to create such a supply chain in France, in order to consider the supply of medicinal products manufactured on national territory. Operators will also be able to produce raw materials for pharmaceutical use and medicinal products authorised in other Member States with a view to exporting them.

The purpose of the draft order is to specify the arrangements for the organisation of cultivation operations for the production of the cannabis plant for medical purposes on national territory. This will complete the mechanism to secure the crops that will be established on national territory.

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

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu