



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2023/0379/FR (France)

Order establishing the list of establishments, services or service providers who may supply foods for special medical purposes in accordance with the provisions of Article L. 5137-1 of the Public Health Code

Date received : 20/06/2023

End of Standstill : 21/09/2023 (closed)

Message

Message 001

Communication from the Commission - TRIS/(2023) 1859

Directive (EU) 2015/1535

Notification: 2023/0379/FR

Notification of a draft text from a Member State

Notification - Notificación - 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 késéset - Non fa decorrere la mora - Atidējimai 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: 20231859.EN

1. MSG 001 IND 2023 0379 FR EN 20-06-2023 FR NOTIF

2. France

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4. 2023/0379/FR - S00S - HEALTH, MEDICAL EQUIPMENT

5. Order establishing the list of establishments, services or service providers who may supply foods for special medical purposes in accordance with the provisions of Article L. 5137-1 of the Public Health Code

6. Foods for special medical purposes (FSMPs)

7.

8. Article L. 5137-1 of the Public Health Code, in its wording resulting from Law No 2023-171 of 9 March 2023, now provides that FSMPs, other than those presenting a serious risk to health in the event of misuse, may be issued only by: 'pharmacies for internal use in health establishments, army hospitals or the National Invalids' Institution, dispensing chemists or, under conditions guaranteeing effective medical supervision, by establishments, services or service providers, the list of which shall be drawn up by the Minister for Health.'

It is proposed that the notified draft decree should list the following establishments, services and providers: health cooperation groups with an in-house pharmacy, health establishments without an in-house pharmacy, certain medico-social establishments and services, social and medico-social cooperation groups and the service providers and equipment distributors referred to in Article L. 5232-3 of the Public Health Code.

It is also proposed that this decree shall specify that in healthcare establishments with an in-house pharmacy, the supply of such foods may be made, in connection with the in-house pharmacy, by a department of the establishment.

9. The consumption of FSMPs carries a number of risks and can have harmful health consequences if they are improperly consumed.

Indeed, the consumption of FSMPs can cause among others in the consumer: metabolic disorders, nutritional excesses or deficiencies or interactions with other substances if used incorrectly.

Therefore, subjecting the dispensation of FSMPs to the supervision of qualified health professionals appears to be necessary.

To that end, Article 2(2) of Regulation 609/2013 states that FSMPs may only be used under medical supervision, without however defining such supervision or specifying the conditions for the sale of these products.

Similarly, Article 5(2) of Regulation 2016/128 provides that such foods must contain a statement indicating that the product must be used under medical supervision. However, this obligation to notify does not appear to be sufficient to ensure that FSMPs are dispensed under medical supervision.

For this reason, the notified draft decree lists establishments, services and providers guaranteeing the dispensation of FSMPs under medical supervision.

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

11. No

12.



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13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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