

Message 001

Communication from the Commission - TRIS/(2025) 2767

Directive (EU) 2015/1535

Notification: 2025/0570/DK

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 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: 20252767.EN

1. MSG 001 IND 2025 0570 DK EN 08-10-2025 DK NOTIF

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4. 2025/0570/DK - S00S - HEALTH, MEDICAL EQUIPMENT

5. Amendment to the Order on the manufacture, import and distribution of active substances for the manufacture of medicinal products

6. API, including cannabis API (Active Pharmaceutical Ingredient).

7.

8. The Order on the manufacture, import and distribution of active substances for the manufacture of medicinal products concerns the manufacture, import and distribution of active substances used in the manufacture of medicinal products for human use that are covered by a marketing authorisation.

The Ministry of the Interior and Health has assessed that the following provisions of the executive order should be notified: Sections 2, 4, 5, 6, 7, 9, 11, 12, 13, 14, 15, 17, 18, 19, 20 and 21.

Additionally, Section 13(2) has been added to the draft order, which enables the use of cannabis APIs in products under the Danish medicinal cannabis programme, cf. also the legislative proposal referred to below. Furthermore, Sections 11 and 15 have been added in order to describe the guidelines for manufacturers and distributors of active substances who wish to outsource manufacturing and distribution under contract.

With regard to impact assessments, reference is made to the legislative proposal amending the law governing the Medicinal Cannabis Pilot Programme, which includes a review of the economic and implementation consequences for the public sector, the economic and administrative consequences for the business community, etc. and the administrative consequences for citizens.

9. The Order on the manufacture, import and distribution of active substances for the manufacture of medicinal products is amended as a result of a political agreement on a permanent programme for medicinal cannabis entered into on 19 November 2024 between the government (Social Democratic Party, Liberal Party and Moderates), Green Left, Liberal Alliance, Red-Green Alliance, Danish People's Party and Alternative, and of a legislative proposal for a permanent programme for medicinal cannabis, which has also previously been notified.

Part of the legislative proposal concerned the possibility to use cannabis API in products under the programme, which is made possible by the addition of Section 13(2) to the order.

10. References in the basic text: No basic text available

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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