

Message 001

Communication from the Commission - TRIS/(2025) 2686

Directive (EU) 2015/1535

Notification: 2025/0552/DE

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 - Nezahtuje 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 - 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: 20252686.EN

1. MSG 001 IND 2025 0552 DE EN 02-10-2025 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 122, 53107 Bonn

4. 2025/0552/DE - C00P - PHARMACEUTICAL AND COSMETICS

5. First Act amending the Medicinal Cannabis Act

6. The Federal Republic of Germany intends to enact a ban on the remote prescription of and mail order sales of cannabis flowers for medical purposes.

7.

8. The First Act amending the Medicinal Cannabis Act aims, first, to provide that cannabis flowers can only be prescribed for medical purposes after an in-person consultation between a doctor and the patient at the

doctor's surgery or as part of a home visit. This excludes treatment exclusively via video consultation. In addition, changes are to be made to distribution channels. Sales of cannabis flowers by mail order are to be excluded. Due to the many particularities associated with cannabis flowers for medical purposes, there are comprehensive information and counselling obligations that must be fulfilled during in-person consultation at a pharmacy. Education on addiction and its health risks is needed. The placing on the market of cannabis flowers by mail order is not appropriate from the point of view of patient safety.

9. The import of cannabis flowers for medical purposes already increased by 170 % between the first and second halves of 2024. In the same period, however, the prescriptions of cannabis flowers for medical purposes funded by the statutory health insurance (GKV) increased by only 9 %. This inconsistency suggests that the rising import figures are primarily serving to supply an increasing number of private prescriptions from self-payers outside the statutory health insurance system. At the same time, telemedicine platforms are increasingly active on the market and allow cannabis flowers to be acquired for medical purposes without in-person doctor-patient contact or without any doctor-patient contact at all.

When treating patients with cannabis flowers for medical purposes, in-person contact with the person being treated is advisable and necessary, among other things because of the risk of addiction and other health risks, side effects and undesirable drug reactions. Cannabis flowers for medical purposes do not have medicinal product approval for a specific indication. Due to the absence of approval, there are heightened duties of care for the prescribing doctor to ensure safe and effective use for the patient. A comprehensive medical history, physical examination, counselling and informed consent should be obtained during in-person doctor-patient contact as part of on-site medical treatment and counselling when prescribing cannabis flowers for medical purposes.

Due to the many particularities associated with cannabis flowers for medical purposes, there are also comprehensive information and counselling obligations that must be fulfilled during in-person consultation at a pharmacy. It is essential to inform patients about the risks of addiction and health hazards associated with cannabis flowers for medical purposes. Due to the risks and hazards involved, the placing on the market of cannabis flowers by mail order is not appropriate from the point of view of patient safety. Likewise, patients on site must be advised and informed by pharmacy staff about the correct use of cannabis flowers, possible side effects or interactions, proper storage and disposal, and the dangers of misuse, for example by children, adolescents and young adults.

10. Reference to the basic texts: Basic texts have been sent within the framework of a previous notification: 2023/0199/D

11. Yes

12. From the perspective of the federal government, the amendment to the Medicinal Cannabis Act is urgent for reasons of protecting the health of the population and individuals from the risks of addiction and health hazards associated with cannabis flowers for medical purposes. Cannabis flowers for medical purposes are a medicinal product that carries an addiction risk and other health risks, particularly affecting brain development in young people. Cannabis flowers for medical purposes can be marketed without pharmaceutical approval and are therefore prescribed exclusively under non-label use, lacking the scientific

evidence from clinical trials on patients that has been verified as part of the approval process. The unpredictable increase in imports, and the simultaneous increase in telemedicine platforms offering prescription and delivery of cannabis flowers for medical purposes without prior physical examination or counselling, create unacceptable incentives and therefore make a legislative amendment urgently necessary.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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