

Message 001

Communication from the Commission - TRIS/(2026) 0750

Directive (EU) 2015/1535

Notification: 2026/0121/SE

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: 20260750.EN

1. MSG 001 IND 2026 0121 SE EN 10-03-2026 SE NOTIF

2. Sweden

3A. Kommerskollegium

3B. Socialdepartementet

4. 2026/0121/SE - C10P - Pharmaceuticals

5. Draft Act amending the Act (2009:366) on trade in medicinal products

6. Non-prescription medicinal products

7.

8. The new provisions in Chapter 2a, Sections 6d to 6f of the Act (2009:366) on trade in medicinal products mean that the Swedish Medical Products Agency may, on application, decide that a non-prescription medicinal product may be sold only after advice from a pharmacist. The medicinal products that may become

relevant are those for which advice is deemed necessary in order to ensure patient safety, the safety of animals or the person administering the medicinal product, or to reduce the risk of adverse effects on public or animal health, in particular with regard to the development of drug resistance.

The proposed addition to Chapter 2a, Section 6 stipulates that pharmacies open to the public must provide advice from a pharmacist when selling non-prescription medicinal products for which special advice is required.

The Draft Act also contains authorisations under which the Government, or the authority designated by the Government, may issue regulations on the specific advice to be given by a pharmacist and requirements for specific advice (Chapter 2a, Section 11).

Non-prescription medicinal products for which special advice is required will be available for sale at pharmacies open to the public, including online pharmacies. These medicinal products may not be sold through pharmacy agents (Chapter 2a, Section 5).

The other legislative proposals enable the proposal on selling non-prescription medicinal products with a requirement for specific advice from a pharmacist.

9. The proposed legal provisions are a consequence of Sweden's desire to enable more medicinal products to be sold without being subject to prescriptions. Therefore, it should be possible to make the sale of certain non-prescription medicinal products subject to the provision of specific advice by a pharmacist at the time of sale. The medicinal products which may become relevant are prescription medicinal products, but for which advice by a pharmacist is deemed to be able to be replaced by a prescription by an authorised health care professional or veterinarian in order to ensure patient safety, the safety of animals or the person administering the medicinal product, or to reduce the risk of adverse effects on public or animal health, in particular with regard to the development of drug resistance. The Draft aims to promote access to medicinal products while ensuring the proper, safe and effective use of medicinal products.

The Draft aims to promote access to medicinal products while ensuring the proper, safe and effective use of medicinal products. The Draft would allow medicinal products that would be classified as prescription-only to instead be classified as non-prescription with the requirement for specific advice.

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

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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