Message 001

Communication from the Commission - TRIS/(2026) 1617

Directive (EU) 2015/1535

Notification: 2026/0305/FI

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – 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 késéseket - 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: 20261617.EN

1. MSG 001 IND 2026 0305 FI EN 17-06-2026 FI NOTIF

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4. 2026/0305/FI - C10P - Pharmaceuticals

5. Draft Government Decree amending the Government Decree on mandatory stockpiling of medicinal products

6. Medicinal products

7.

8. It is proposed to amend the Government Decree on mandatory stockpiling of medicinal products. It is proposed to update the list of medicinal products covered by the obligation. Furthermore, it is proposed that the requirement for an auditor’s certificate be replaced by a requirement for a declaration from a director with executive responsibility or another person in a similar position. The Finnish Medicines Agency would be allowed to exempt the National Institute for Health and Welfare from the stockpiling obligation.

9. The objective is to ensure that the mandatory stockpiling of medicinal products continues to effectively secure the availability and security of supply of medicinal products. The objective is to have a flexible, balanced and up-to-date stockpiling system.

9a. The purpose of this regulation is to safeguard access to medicinal products and use thereof when it has become more difficult or impossible to provide medicinal products than normal. Expert and official knowledge has been drawn upon to prepare this document. Specifically, the proposal to update the List of Medicinal Products in the Decree contributes to the achievement of this objective.

9b. The proposed amendments do not have a significant impact on the internal market. Under existing legislation, the mandatory stockpile of medicinal products must be located in Finland. Statutory stockpiling ensures the security of supply of medicinal products more effectively than a system based on voluntary participation, for example. It is therefore necessary to consider mandatory stockpiling as a necessary measure to ensure the security of supply of medicinal products.

9c. The proposed amendments to the legislation on mandatory stockpiling of medicinal products are proportionate to the interest pursued. The Government Proposal examines the relationship between regulation and the free movement of goods. In this regulatory context, the pursued interest must be considered more important than the potential effects on the internal market. The failure to adequately safeguard the security of the supply of medicinal products is detrimental in light of its potential impact on the internal market.

10. Basic text references: The basic texts have been provided in connection with an earlier notification: 2026/0304/FI

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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