

Message 001

Communication from the Commission - TRIS/(2026) 1614

Directive (EU) 2015/1535

Notification: 2026/0304/FI

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 késések - 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: 20261614.EN

1. MSG 001 IND 2026 0304 FI EN 17-06-2026 FI NOTIF

2. Finland

3A. Työ- ja elinkeinoministeriö
Työllisyys ja toimivat markkinat -osasto
PL 32
FI-00023 VALTIONEUVOSTO
Puhelin +358 (0)295 16001
Faksi +358 1606 2160
maaraykset.tekniset.tem@gov.fi

3B. Sosiaali- ja terveystieteiden ministeriö
Turvallisuus- ja terveys -osasto
PL 33
FI-00023 VALTIONEUVOSTO
Puhelin +358 (0)295 16001
Faksi +358 2951 63415
kirjaamo.stm@gov.fi

4. 2026/0304/FI - C10P - Pharmaceuticals

5. Draft Government proposal to Parliament for an act amending the act on mandatory stockpiling of medicinal products

6. Medicinal products

7.

8. The Government's proposal would amend the act on the mandatory stockpiling of medicines. The proposal would update the categories of medicinal products subject to the stockpiling obligation. Under the proposal, the Finnish Medicines Agency could, upon application, grant authorisation to fall short of the stockpiling obligation when the consumption of a product subject to the obligation on behalf of the party responsible for stockpiling decreases to a significant extent. It is proposed that the right of those subject to stockpiling obligations to fall short of their storage obligations independently be extended.

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 medicines 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 act. 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:

11. No

12.

13. No

14. No

15. Yes

16.

TBT aspects: No

SPS aspects: No

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu