Message 001

Communication from the Commission - TRIS/(2025) 2407

Directive (EU) 2015/1535

Notification: 2025/0498/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: 20252407.EN

1. MSG 001 IND 2025 0498 FI EN 04-09-2025 FI NOTIF

2. Finland

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4. 2025/0498/FI - C10P - Pharmaceuticals

5. Draft government proposal to Parliament for legislation to reform the pharmacy economy and enact pharmaceutical savings, and related amendment proposals to regulations.

6. Medicinal products.

7.
Directive (EC) No. 2006/123 on services in the internal market

Other
This part of the notification is issued on the basis of the qualification requirements (Section 9 of the Medicines Act) and the conditions to be granted a permit (Section 54f of the Medicines Act).

For example, Title VII of the Medicines Directive (Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use) contains important provisions that affect the organisation of pharmacies.

The retail sale and other release for consumption of over-the-counter medicinal products remains largely within the national legislative power of the Member States. EU legislation does not take a position on who is allowed to sell over-the-counter medicines in the Member States. A non-pharmacy operator may act as a retail distributor of medicinal products in a Member State. There is no obstacle to restrict the activity to pharmacies, as in the current regulation (Articles 1(17k) and 81 of the Medicines Directive, Article 103 of the Veterinary Medicinal Products Regulation).
In the current regulation of Finland, over-the-counter medicines, like all medicines, are generally only sold by pharmacies (Section 38a of the Medicines Act). The establishment of a pharmacy required a permit (section 40 of the Medicines Act) and the operations of a pharmacy are supervised by Fimea. The Medicines Act imposes operational obligations on pharmacies regarding medicinal and price advice (section 57), personnel and pharmacy facilities (section 56), and storage of medicinal products, opening hours, medicine quality, and marketing authorisations (section 55), among others. According to the proposal:

Section 9. The section provides for the responsible director of a medicinal product manufacturing plant and the qualified person. According to the provision in paragraph 2 of said section, the responsible director may not simultaneously be the responsible director of another company that has been authorised to manufacture medicinal products on an industrial scale. The responsible director shall also not be the responsible director for the pharmaceutical wholesale business of another company, nor a pharmacy licence owner, the manager of a hospital pharmacy or a pharmaceutical centre, the manager of a military pharmacy, or the manager of a pharmacy or a branch thereof. It is proposed to add that the responsible director should also not be the holder of a retail permit for over-the-counter medicinal products, a person belonging to the management thereof, or the person responsible for over-the-counter medicinal products. Subsections 1, 3 and 4 are not proposed to be amended.

Section 54f. This proposed section would be completely new. It provides for the retail permit and the conditions for the retail sale of over-the-counter medicinal products sold outside a non-pharmacy location. The section would enable the creation of new distribution channels under certain conditions. It describes the conditions for granting a permit precisely, one of which is that the applicant must not be a certain type of operator in the pharmaceutical sector, to prevent vertical integration (Sections 8, 32 or 34a).

The proposed measures would create additional distribution channels for over-the-counter medicinal products, to which both the qualification requirements (Section 9 of the Medicines Act) and the conditions for granting a permit (Section 54f of the Medicines Act) apply.

A limited range of over-the-counter medicinal products would be defined in the Medicines Act, the distribution channel of which the proposal would expand, consisting of categories of medicinal products with risks that are considered to be low and which are considered safe to provide without medicinal advice. Specifically, medicinal product categories would be defined by ATC group in the Medicines Regulation.

8. The draft proposal would amend the Medicines Act, the Act on Electronic Prescriptions, the Pharmacy Tax Act, and the Health Insurance Act. This notification concerns the first two. By way of derogation from the draft, preparation of regulations for online sales of over-the-counter medicinal products is ongoing and are not part of this notification.

The proposal is linked to the government programme of Prime Minister Petteri Orpo. A new regulation is proposed in the Medicines Act and the Medicines Regulation to define a limited range of over-the-counter medicinal products. Marketing authorisation holders may apply for an extension of sales channel regarding its range of over-the-counter medicinal products to sales at non-pharmacy locations, which could be granted under the conditions laid down in the Act. Sales at non-pharmacy locations would be based on retail licences for over-the-counter medicinal products issued to traders. The conditions of the permit, the permit application, the validity of the permit, the requirements imposed on the permit holder, and the duties of the responsible person would be laid down separately. In addition, the proposal would provide for supervision and penalties for non-compliance.

The proposal is also related to a point of the Government Programme, according to which the procedure for dispensing prescription medicines will be clarified so that the prescription may be adapted according to the availability and quantity of different pack sizes. The proposal would give pharmacies the right to deviate from a prescription and to correct an obvious error in the prescription in certain cases.

9. The Medicines Act would define a limited range of over-the-counter medicines, which would be composed of groups of medicinal products assessed as presenting a low risk, and which are expected to allow safe pharmacotherapy without medicinal advice. This solution is justified to ensure that the range of products sold at non-pharmacy locations remains meaningful. Market conditions for competing over-the-counter medicinal products with the same indications and similar safety profiles would remain as equal as possible. Companies would have equal opportunity to apply for an extension of the sales channel for their over-the-counter medicinal products to non-pharmacy locations.

Allowing the derogation from prescriptions would make broader use of the competence of pharmacy personnel as part of social welfare and healthcare. The proposal creates a framework to ensure access to pharmaceuticals and medication for customers, such as in the event of disruptions in the availability of medicines.

10. Basic text references: The basic texts have been provided in connection with an earlier notification: 2021/0371/FIN

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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