Message 001

Communication from the Commission - TRIS/(2026) 1720

Directive (EU) 2015/1535

Notification: 2026/0323/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: 20261720.EN

1. MSG 001 IND 2026 0323 FI EN 01-07-2026 FI NOTIF

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4. 2026/0323/FI - C10P - Pharmaceuticals

5. Draft government proposal to Parliament on amending the Medicines Act and related legislation, and as part of the same legislative package, draft Government Decree amending the Medicines Decree with a draft explanatory memorandum

6. The proposed legislative and regulatory amendments concern pharmaceuticals, medical devices and hospital pharmacies, including their branch offices and dispensaries.

7.

8. It is proposed to lay down procedures to regulate the decision-making and implementation of international assistance concerning medicinal products in the Medicines Act. A provision would be introduced to the Act concerning the duties of the National Institute for Health and Welfare regarding pharmaceutical preparedness. It is proposed to amend the regulation of hospital pharmacies and dispensaries to establish it through the wellbeing services counties' responsibility for organising services. It is proposed to clarify the definition of wholesale trade in medicines, and to define the general distribution of medicines and medicinal products in national law. On that basis, provisions would be laid down regarding the right of hospital pharmacies, dispensaries and branch offices of hospital pharmacies to supply medicinal products. The Ministry of Social Affairs and Health would be given the right to decide on exceptional arrangements for the distribution of medicines in certain disruptions of normal conditions and states of emergency. It is proposed to introduce provisions to the Medicines Act concerning the right of emergency medical service vehicles and military units to import and export medicines for their own operations. Amendments are proposed to the regulations governing the preparation of medicines in pharmacies, relating to hospital pharmacies, military pharmacies and medicinal gases. It is proposed to amend the Act on Medical Devices to allow for the reprocessing and reuse of single-use medical devices, subject to the conditions laid down in the Act. It is proposed to make amendments to the Medicines Decree as a result of the legislative changes. The Acts and Decree are intended to enter into force on 1 January 2027.

9. The proposal is based on the provisions of Prime Minister Petteri Orpo's Government Programme regarding the receipt and provision of international aid, NATO membership obligations, ensuring the availability of medicines and medical products, and the development of Nordic and European cooperation, among others.
The draft proposal is submitted to the notification procedure because it contains legislative proposals with international implications. These include the right of military forces from NATO partner countries and domestic military forces, as well as vehicles belonging to emergency services, to import and export medicines, as well as regulations governing international aid relating to medicines. In addition, the proposed regulation of hospital pharmacies may have an impact on the national pharmaceutical market and some of the proposed provisions are based on national regulatory leeway in EU legislation.

9a. The proposed provisions on medicines and medical devices will help to achieve the objective of the Government Programme to ensure the availability of essential medicines and medical products in Finland and to strengthen Nordic and European cooperation.
The proposals regarding international assistance for medicinal products and for exceptional supply of

medicinal products between wellbeing services counties will improve preparedness for disruptions to normal conditions and states of emergency. They safeguard the continuity of pharmacotherapy and thus, indirectly, the functional capacity of healthcare services, were there a disruption in the availability of medicines. According to observations by the national medicines authority, the Finnish Medicines Agency (Fimea), medicine shortages have become more common (see section 9c). Furthermore, there are a number of different measures under way in the EU to safeguard the availability of medicines. In 2025, the European Commission issued a proposal for an EU regulation on critical medicines (Critical Medicines Act, CMA). In addition, in 2023, the Commission established an interim voluntary solidarity mechanism for Member States. The proposals will have a positive impact on the well-being and health of the population, as it will be possible to safeguard the availability of medicines more effectively than before. They reduce the risk of patients not receiving essential medicines. In a crisis, timely medicinal assistance can save lives. At the same time, it is ensured that the medicinal assistance provided from Finland is proportionate and does not jeopardise the domestic pharmaceutical stockpile.

It is not considered that the medicinal aid received by Finland would compromise patient safety, as the authorities assess the quality of the batches of medicinal products and prevent counterfeits from entering the supply chain. The use of medicinal products requires a marketing authorisation, a special permit or exemption, which ensures their safety and efficacy.

The stronger role proposed for the Ministry of Social Affairs and Health will enable the overall management of the pharmaceutical supply system to allocate medicinal products regionally in line with the needs of healthcare. This will ensure functioning health care if an individual county’s reserves are insufficient.

The reprocessing of single-use medical devices supports device availability, especially during disruptions and emergencies. It reduces dependence on international supply chains and supports the continuity of healthcare when there is increased demand or reduced availability. This measure is based on the EU Medical Devices Regulation (EU) 2017/745, under which reprocessing is permitted provided that the safety and performance of the device are retained at the original level. Reprocessing also provides significant benefits in terms of security of supply and the environment, as it reduces material waste and can help ensure the availability of critical medical supplies.

However, risks to patient safety have been identified during the preparation process, such as infections due to inadequate cleaning or changes in the technical features of the device. These risks can be managed by setting strict requirements for reprocessing, ensuring staff competence and requiring appropriate self-monitoring. It is estimated that reprocessing could introduce significant economic benefits, such as in the case of catheters, where the savings potential is around EUR 4.36 million per year.

Russian aggression against Ukraine, the experience of the COVID-19 pandemic, and tensions in global politics underline the importance of societal resilience. The number of medicine shortages also highlights the need for new regulatory measures. Overall, the regulations improve the protection of public health and the security of supply. In the event of a crisis, reliance on international assistance would be temporary and entail lower risks than if access to essential medicines or equipment were to be interrupted.

9b. The current general regulation does not allow for effective international assistance for medicinal products, nor does it allow for a clear division of competences, considering the specificities of the supply of medicinal products. The proposed regulation affects the internal market, in particular with regard to the distribution of medicinal products and cross-border trade, insofar as it concerns the import, export and distribution of medicinal products in the context of international assistance. However, the effect would be limited, as the measure is based on the existing harmonised EU system for the distribution of medicinal

products (incl. wholesale authorisation requirements and the marketing authorisation system). The proposed model uses existing structures; it does not create new barriers for entering the market and is only suitable for states of emergency
The preparation process examined alternatives in which separate regulations are not provided, relying instead on the current general legislation. This was found to be insufficient due to lack of competence and lack of clarity in implementation. In addition, various implementation models were assessed (the National Institute for Health and Welfare (THL) acting alone, a decentralised model), of which the chosen solution strikes a balance between efficiency, oversight and security of supply, while minimising the impact on the internal market as far as possible.
The number of parties involved in the implementation was restricted as, during the preparation of the proposal, it was identified that the implementation would require a medicine wholesaler's authorisation. However, in order to safeguard the continuity of care, it was considered justified that the task could alternatively be assigned to one or more hospital pharmacies belonging to a university hospital or the HUS Group, in addition to THL. The proposed solution would allow the supply of medicines from pharmaceutical wholesalers to hospital pharmacies. This was considered to be an adequate, given the exceptional nature of international assistance and interregional supplies of medicinal products.
The impact of the proposal on medical devices on the internal market relates to the regulation of use and placing on the market of medical devices. Reprocessing may have an impact on the device market, as it reduces demand for new devices in certain respects. However, the impact is limited and mainly concerns internal use within the public healthcare system.

9c. The proposed regulation is proportionate to the objectives of protecting public health and ensuring the security of supply. Risks of medicine shortages can lead to significant harm, including discontinuation of treatment and serious harm to population health. In these situations, the severity of the risk is high, and the likelihood of it materialising has increased in recent years. Medicine shortages have become more common across Europe in recent years. In 2025, Fimea received a total of 2,783 notifications of shortages from pharmaceutical companies (Holthöfer, Lehtinen: Mitä lääkkeiden saatavuus näytti vuonna 2025, Sic! Series, 5 January 2026. Link retrieved on 15 June 2026:
https://www.julkari.fi/items/601ac03c-d98b-4680-a799-93ad9b10e751).
The impacts of the reuse of medical devices have been weighed against the possible benefits. There are risks associated with reprocessing (e.g. risk of infection, change in the technical features of the device), but these risks can be minimised by strict regulation (quality requirements, monitoring, documentation). Therefore, the impact on the internal market is minor and indirect. Furthermore, the regulations are in accordance with EU law.
The restrictions imposed by these measures on the internal market and on businesses are limited, as the measures are based on existing authorisation schemes; new obligations mainly apply to public sector operators, and no significant new barriers to market entry are imposed on private operators.
The financial and administrative implications are relatively minor compared with the possible benefits. If the public interest objective is not achieved, the result may be considerably more harmful than the restrictions imposed by regulation. The proposed regulation does not impose a disproportionate burden; rather, its benefits in terms of public health and security of supply clearly outweigh the restrictions it imposes, which must be regarded as minor.
The public interest objectives (public health, security of supply and environmental protection) clearly outweigh the potential harm caused by the measures.

10. Basic text references: 2021/0371/FIN

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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