EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2020/278/FIN

Government proposal to the Parliament for an amendment of the Medicines Act, the Act on Mandatory Reserve Supplies and the Communicable Diseases Act

Date received : 06/05/2020

End of Standstill :

Message

Message 002

Communication from the Commission - TRIS/(2020) 01593
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2020/0278/FIN

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202001593.EN)

1. Structured Information Line
MSG 002 IND 2020 0278 FIN EN 06-05-2020 FIN NOTIF

2. Member State
FIN

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4. Notification Number
2020/0278/FIN - C10P

5. Title
Government proposal to the Parliament for an amendment of the Medicines Act, the Act on Mandatory Reserve Supplies and the Communicable Diseases Act

6. Products Concerned
Medicines and medical devices

7. Notification Under Another Act
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8. Main Content
It is suggested that the Medicines Act (395/1987) is amended as follows:
- if there is an interruption or a probable threat of an interruption in the availability of a medicinal product or medicine which is indicated for the prevention or treatment of a disease which is life-threatening or which would progress or significantly impair human health if left untreated with the medicinal product, or a medicinal product or medicine which is of great importance in terms of public health, the Ministry of Social Affairs and Health could, by a decision, restrict or target for a fixed period of time the distribution, sale or release for consumption of the medicinal product or medicine, or issue an order for prioritising the distribution of these medicinal products or medicines where necessary for the protection of public health. The Ministry of Social Affairs and Health could place conditions on the use of the medicinal products or medicines, on the duration of the restrictions or prohibition, on quantitative restrictions or other similar matters. The decision would be valid for a fixed period of time. Where necessary, the validity could be extended if the interruption or a probable threat of an interruption in availability continues. The decision may be appealed.
If the holders of marketing authorisations referred to under § 8, 21, 32, 38 a, 61 and 62 of the Medicines Act failed to comply with a decision issued under this section, the Finnish Medicines Agency Fimea could prohibit the holder of a marketing authorisation to continue or repeat this conduct or to otherwise order the holder of the marketing authorisation to meet the statutory obligations (§ 19 a and § 102(7) are added).
- the obligation of the holders of a marketing authorisation, a parallel import marketing authorisation and registration holders to provide information to the Finnish Medicines Agency Fimea shall be specified according to the Medicines Directive (amendments to § 27 of the Medicines Act)
- the obligation of the wholesale distribution of medicinal products to inform pharmacies ordering medicines of an interruption in the distribution of medicinal products ordered and the obligation to inform the Finnish Medicines Agency Fimea and all retail customers of significant disturbances and interruptions in the distribution of medicines shall be added (§ 37)
- the storage obligation of pharmacies shall be specified (§ 55)

Provisions on orders issued on pain of a fine by the Finnish Medicines Agency Fimea and an inspector would be added to the valid Act on Mandatory Reserve Supplies (979/2008). In addition, it would be suggested that the Act is specified so that the mandatory reserve supplies shall be located in Finland and that the Ministry of

Social Affairs and Health could decide to decrease the requirements for mandatory reserve supplies even under threat of an extensive availability issue.

It is suggested that the Communicable Diseases Act (1227/2016) is amended so that the right of the Ministry of Social Affairs and Health to temporarily restrict or grant rights to prescribe and sell medicines intended for the treatment of communicable diseases would be extended to cover medicines used for the prevention of communicable diseases and the treatment of the symptoms and complications related to communicable diseases. In addition, the proposal suggests an extension of the range of healthcare devices and supplies in terms of which a compliance assessment may be derogated from by Ministry of Social Affairs and Health Decree before making the devices available in the market.

9. Brief Statement of Grounds
The purpose of the proposals is to protect public health and to ensure the availability of medicines. Interruptions in the availability of medicines have increased globally. The Covid-19 pandemic has proven that the competences of the authorities included in applicable legislation are insufficient or ineffective in ensuring the availability of medicines in exceptional or normal circumstances under a threat of extensive interruptions in the availability of medicines, or during such interruptions. On an international scale, Finland's position on the pharmaceuticals market is vulnerable, since few medicines are manufactured in Finland, their manufacturing is highly centralised, and Finland is a small national market. The purpose of the suggested amendments is to permanently improve the equal availability and efficiency of medicines and to be prepared for future emergency situations under normal conditions and for potential exceptional circumstances.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Medicines Act 395/1987 https://www.finlex.fi/fi/laki/ajantasa/1987/19870395
Act on Mandatory Reserve Supplies 979/2008 https://finlex.fi/fi/laki/ajantasa/2008/20080979
Communicable Diseases Act 1227/2016 https://www.finlex.fi/fi/laki/ajantasa/2016/20161227

11. Invocation of the Emergency Procedure
Yes

12. Grounds for the Emergency
The rapid spread of the Covid-19 pandemic has unforeseeably increased the demand for certain medicines and caused problems in the production and logistics chains for medicinal products. These issues increase the immediate risk of interruptions in the availability of medicines required for the treatment of the coronavirus infection and also all other medicines. For instance, the spread of coronavirus infections in Finland in March 2020 led to an increase in the need for certain pharmaceutical groups among consumers. In addition, users of medicinal products acquired excessive amounts of certain medicines in pharmacies. These issues led to pharmacy inventories with temporary deficiencies in certain medicinal products, excessive orders from the wholesale distribution of medicinal products, and the difficulties of the wholesale distribution of medicinal products in delivering equal amounts of pharmaceuticals.

Due to the Covid-19 pandemic, it was declared on 16 March 2020 that Finland is in a state of emergency under the Emergency Powers Act (1552/2011). The exceptional competencies of the authorities related to medicines under § 87 of the Emergency Powers Act were adopted by an implementation decree. However, it is likely that the impact of the Covid-19 pandemic on the international pharmaceuticals market will be more prolonged and that the recovery of the pharmaceuticals market will continue in the period after the acute phase of the Covid-19 pandemic and the state of emergency. This has particular importance in Finland which is dependent on the import of medicines.

It has been estimated that after the state of emergency under the Emergency Powers Act, the authorities will not have sufficient and effective statutory competencies to deal with interruptions in the availability of medicines. The suggested amendments to legal provisions are justified in order to protect public health, since they are intended to safeguard the adequacy and availability of medicines immediately after the state of emergency. For instance, the purpose of the suggested new provision in the Medicines Act would be to intervene in situations where pharmaceutical companies are unable to import a sufficient quantity of medicinal products in the Finnish market in terms of the needs of the population. The decision would distribute the inadequate pharmaceutical inventory in the market equally to as many citizens in need as possible. These competences would be granted to the authorities in national legislation and could be implemented where necessary for the protection of public health.

In this unforeseeable situation, provisions shall be adopted as soon as possible in order to ensure the equal availability of medicines to those in need immediately after the state of emergency.

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
Yes

16. TBT and SPS aspects
TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

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European Commission

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