EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2021/0383/S (Sweden)

Swedish Medical Products Agency’s regulations (HSLF-FS 2021:xx) on parallel imported human medicinal products

Date received : 28/06/2021
End of Standstill : 29/09/2021 (closed)

Message

Message 002

Communication from the Commission - TRIS/(2021) 02353
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2021/0383/S

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: 202102353.EN)
1. MSG 002 IND 2021 0383 S EN 28-06-2021 S NOTIF

2. S

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4. 2021/0383/S - C10P

5. Swedish Medical Products Agency’s regulations (HSLF-FS 2021:xx) on parallel imported human medicinal products

6. Human medicinal products that are subject to parallel imports, see further in the impact assessment and regulations.

7. - The proposal on parallel import of human medicinal products is a codification of the European Court of Justice’s case-

law based on the provisions of the Treaty on Free Movement. The proposal is largely a codification of the EU Court of Justice's case-law on free movement.

8. Requirements concerning the parallel import procedure of human medicinal products, e.g. labelling and package leaflet, as well as the procedure for granting authorisation to sell a human medicinal product that is subject to parallel import.

The requirements on human medicinal products that are parallel imported and presented in the regulations are largely a codification of the EU Court of Justice's case-law. The requirements that are set, including labelling and package leaflet, are deemed necessary to protect people's lives and health.

9. To maintain current rules on parallel imports of human medicinal products and thereby ensure that the medicinal products that are placed on the Swedish market are safe and correctly labelled.

The requirements on human medicinal products that are parallel imported and presented in the regulations are largely a codification of the EU Court of Justice's case-law. The requirements that are set, including labelling and package leaflet, are deemed necessary to protect people's lives and health.

10. No basic texts available

11. No

12. -

13. No

14. No

15. Yes

16. TBT aspect

No - The project 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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