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

Uimhir an Fhógra : 2019/0484/CZ (Czechia)

Draft Act amending Act No 378/2007 on pharmaceuticals and on amendments to certain related acts (Pharmaceuticals Act), as amended, and Act No 48/1997 on public health insurance and on amendments to certain related acts, as amended

An dáta ar a bhfuarthas é/í : 02/10/2019
Deireadh leis an Tréimhse Neamhghníomhaíochta : 03/01/2020 (withdrawn)

Message

Message 002

Communication from the Commission - TRIS/(2019) 02726
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2019/0484/CZ

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: 201902726.EN)
1. MSG 002 IND 2019 0484 CZ EN 02-10-2019 CZ NOTIF

2. CZ

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4. 2019/0484/CZ - C10P

5. Draft Act amending Act No 378/2007 on pharmaceuticals and on amendments to certain related acts (Pharmaceuticals Act), as amended, and Act No 48/1997
on public health insurance and on amendments to certain related acts, as amended

6. Medicinal products for human use according to the definition under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

7. -

8. The purpose of the draft Act is to contribute to better availability of pharmaceuticals to Czech patients through a combination of interrelated measures:
- a mechanism for extreme cases where a shortage of a medicinal product is detected, such as provision for the possibility of importing and using a medicinal product even if some of the formal requirements, which do not affect the quality and safety of the medicinal product, have not been duly met (§ 11 of the attached draft),
- prevention of uncoordinated exports from the Czech Republic in the case of a predefined, identifiable and justifiable group of medicines, which should concern medicinal products that are covered by public health insurance and dispensed on prescription,
- introduction of an 'emergency medicine ordering system', which should be compulsorily set up and operated by every manufacturer of a medicine covered by public health insurance and dispensed on prescription (§ 33a to § 33c of the attached draft).
Manufacturers and marketing authorisation holders will assume responsibility for ensuring that supplies cover market needs, while they will continue to be free to compete.
The attached measure under the Act on public health insurance addresses situations where, in the interest of ensuring the availability of a medicinal product, the maximum price at which it can be marketed in the Czech Republic or the amount of reimbursement for the product from health insurance need to be changed for a limited period during which it is expected to be unavailable.

Keywords: medicinal products for human use, availability of medicinal products

9. The previous amendment supplemented the Act with measures against undesirable distribution outside the Czech market of medicinal products intended for Czech patients.
The objective pursued by the Czech Republic through this draft is to amend the legislation so that patients have access to the necessary medicinal products that have been prescribed to them, while not distorting the market and the rules of competition beyond the level that is strictly necessary.
The proposed amendment affects the rights and obligations of the holders of marketing authorisations for medicinal products and distributors of pharmaceuticals.
The provisions are partially harmonised with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. The proposed provisions are compatible with this Directive and the mechanisms for ensuring the availability of medicinal products on the Czech market are fully compatible with Article 81 of the Directive. The draft further specifies the obligations of holders of marketing authorisations for medicinal products and distributors of pharmaceuticals that are already imposed on them by EU law (see the provisions mentioned above) and Czech law (in particular § 33(3) of Act No 378/2007 on pharmaceuticals).
The proposed mechanisms partially interfere with the free movement of goods, but only to the extent permitted by primary law on the basis of Article 36 of the Treaty on the Functioning of the European Union.

10. Reference(s) to basic text(s): Act No 378/2007 on pharmaceuticals and on amendments to certain related acts
Act No 48/1997 on public health insurance and on amendments to certain related acts
The basic texts were forwarded with an earlier notification: 2016/278/CZ

11. No

12. -

13. No

14. No

15. Yes

16. TBT aspect

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

SPS aspect

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

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

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European Commission

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