Message 001

Communication from the Commission - TRIS/(2026) 1313

Directive (EU) 2015/1535

Notification: 2026/0239/CZ

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: 20261313.EN

1. MSG 001 IND 2026 0239 CZ EN 12-05-2026 CZ NOTIF

2. Czechia

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4. 2026/0239/CZ - S10S - Medical devices

5. Draft Act amending Act No 375/2022 on medical devices and in vitro diagnostic medical devices, as amended

6. New mechanisms are being introduced to ensure the protection of patients' health. Where manufacturers foresee an interruption of supply, it imposes an obligation to inform the relevant entities. At the same time, the Institute is given the competence to request information and investigation of availability.

7.

8. The draft Act implements Regulation (EU) 2024/1860, with the aim of ensuring the health and safety of patients through newly introduced mechanisms. Where manufacturers anticipate an interruption or cessation of supplies of medical devices or in vitro diagnostic medical devices, and the resulting situation represents serious harm or a risk of such harm to patients or public health in one or more Member States, they are required to inform the relevant entities to which they supply the devices directly. At the same time, the authority of the State Institute for Drug Control (SÚKL) is entrenched at a national level to request, in stipulated cases, information regarding the availability of a device important for the provision of healthcare services, as is the authority of the Ministry of Health to regulate the handling of devices whose availability is at risk.

Transposition of Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulation (EU) 2017/745 and (EU) 2017/746 as regards the phased implementation of the Eudamed database, the obligation to provide information in the event of a suspension or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

Keywords
Medical devices, in vitro diagnostic medical devices, protection of the health of patients and users of medical devices

9. The draft Act implements Regulation (EU) 2024/1860, with the aim of ensuring the health and safety of patients through newly introduced mechanisms. Where manufacturers anticipate an interruption or cessation of supplies of medical devices or in vitro diagnostic medical devices, and the resulting situation represents serious harm or a risk of such harm to patients or public health in one or more Member States, they are required to inform the relevant entities to which they supply the devices directly. At the same time, the authority of SÚKL is entrenched at the national level to request, in stipulated cases, information regarding the availability of a device important for the provision of healthcare services, as is the authority of the Ministry of Health to regulate the handling of devices whose availability is at risk.
We are attaching the basic text, namely Act No 375/2022, which was the subject of the previous notification 2022/0142/CZ.

9a. The new Article 10a, which, in view of the impact that shortages of certain medical devices and in vitro diagnostic medical devices may have on patient safety and public health, establishes a prior notification mechanism designed, in particular, to enable competent authorities and healthcare providers to take mitigating measures where necessary to safeguard the health and safety of patients.

9b. At the national level, there are no mechanisms in place to require manufacturers to report interruptions, discontinuations or impending interruptions in the supply of medical devices or in vitro diagnostic medical devices. The aim of the EU legislation is to safeguard the health and safety of patients, and the draft Act

addresses this by, inter alia, establishing the powers of SÚKL and the Ministry of Health, which may request information or take measures in the event that the availability of a device is at risk. Only then can the protection of patients' life and health be ensured.

9c. The factual assessment did not reveal any undue burden that was not strictly necessary to ensure the security of supply and, consequently, to prevent any potential risk to the health or harm to the health of patients and users resulting from a disruption in the supply of medical devices.

10. Reference(s) to basic text(s): 2022/0142/CZ

The basic texts were forwarded with an earlier notification:
2022/0142/CZ

11. Yes

12. There are no mechanisms at the national level to oblige manufacturers to report the interruption or discontinuation of the supply of medical devices or in vitro diagnostic medical devices. However, even impending unavailability of a device is capable of endangering patients' lives and health. The aim of the EU legislation is to safeguard the health and safety of patients, and the draft Act addresses this by, inter alia, establishing the powers of SÚKL and the Ministry of Health, which may request information or take measures in the event that the availability of a device is at risk. Only then can the protection of patients' life and health be ensured. Without the prompt adoption of the draft Act, it will not be possible to effectively protect the lives of patients, which, as a result, can lead to deaths that could be prevented by the new legislation.

13. No

14. No

15. Yes

16.
TBT aspects: No

SPS aspects: No

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