Message 001

Communication from the Commission - TRIS/(2026) 1424

Directive (EU) 2015/1535

Notification: 2026/0263/DE

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: 20261424.EN

1. MSG 001 IND 2026 0263 DE EN 26-05-2026 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 512

4. 2026/0263/DE - S00S - HEALTH, MEDICAL EQUIPMENT

5. Third Ordinance amending the Health IT Interoperability Governance Ordinance

6. Health information technology systems

7.

8. The aim of this Ordinance is to establish binding requirements for the interoperability of information technology systems in the healthcare sector by introducing an interoperability standard for a digitally supported medication plan. By implementing clear technical and organisational requirements, the aim is to

create uniform standards that increase the safety of medication-based treatment, improve cross-sectoral healthcare and safeguard the sustainable quality of medication data. More specifically, Annex 1 to the IOP Governance Ordinance introduces the mandatory applicability of the use of the digitally supported medication process, thereby establishing the electronic medication plan in the electronic patient record system.

9. By establishing binding, uniform technical and organisational requirements, the aim is to create uniform standards that increase the safety of medication-based treatment, improve cross-sectoral healthcare and safeguard the sustainable quality of medication data.

9a. By establishing binding, uniform technical and organisational requirements, uniform standards are created that increase the safety of medication-based treatment, improve cross-sectoral healthcare and safeguard the sustainable quality of medication data (see above for a brief explanation of the reasons).

9b. In order to improve the safety of medication-based treatment and to ensure ongoing, quality-assured medication documentation, it is necessary to introduce the digitally supported medication plan (dgMP) as a standalone application that must be made mandatory. To this end, we propose to establish the legal foundations necessary to make the dgMP an integral part of healthcare in the electronic health record system (ePA). The dgMP builds on the already existing electronic medication plan (eMP) in the ePA and provides a structured overview of the patient’s currently prescribed medications, including, for example, structured dosage information and instructions for use for the respective medications.

9c. It is not a suitable alternative to forgo the introduction of the eMP as a component of the dgMP or to make exclusive use of the electronic medication list that already exists in the ePA, since doing so would breach the legal requirements. The function of the electronic medication list is essentially only of a documentary nature, and it does not ensure consistent accountability for its maintenance, nor does it guarantee quality-assured, continuous updating of medication data. In the absence of further binding regulations for integration into the healthcare processes and in absence of requirements for the data structure, it cannot be expected that the existing deficiencies regarding the completeness, up-to-date status and reliability of medication information will be remedied, nor that intersectoral cooperation in the dgMP can be ensured.

10. Reference to the basic texts: Basic texts have been forwarded under a previous notification: 2024/0240/DE

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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