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

Notification Number : 2024/0240/DE (Germany)

Health IT Interoperability Governance Regulation

Date received : 02/05/2024
End of Standstill : 05/08/2024 (05/09/2024) (closed)

Message

Message 001

Communication from the Commission - TRIS/(2024) 1183

Directive (EU) 2015/1535

Notification: 2024/0240/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: 20241183.EN

1. MSG 001 IND 2024 0240 DE EN 02-05-2024 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Klimaschutz, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 512

4. 2024/0240/DE - S00S - HEALTH, MEDICAL EQUIPMENT

5. Health IT Interoperability Governance Regulation

6. Health information technology systems

7.

8. The tasks of the Health Interoperability Competence Centre and the procedures (accreditation, conformity assessment, proposal for mandatory definition) necessary for the interoperability process are regulated in general.

In concrete terms, the Implementation Guideline ‘Primary Systems – Electronic patient records (ePA)’ for the implementation of the relevant requirements for interoperability between the ePA file systems and primary systems is made mandatory with regard to the implementation of the Electronic Medication List (EML) and is then to be implemented in the primary systems.

9. The Competence Centre will thus become the central actor in creating interoperability in the health sector. The Competence Centre is given essential tasks, such as the central prioritisation of needs, commissioning third parties to develop specifications and providing a single quality-assuring comment and standardisation process, as well as a conformity assessment procedure. Only by creating such a central actor can it be ensured in a sustainable manner that the existing continuing challenges in promoting interoperability can be addressed effectively.

10. Reference to the basic texts: No basic text available

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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