

Message 001

Communication from the Commission - TRIS/(2026) 1926

Directive (EU) 2015/1535

Notification: 2026/0378/DE

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – 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 késésekét - 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: 20261926.EN

1. MSG 001 IND 2026 0378 DE EN 13-07-2026 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Energie, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 511

4. 2026/0378/DE - S00S - HEALTH, MEDICAL EQUIPMENT

5. Law on Data and Digital Innovation in Healthcare

6. Healthcare information technology systems

7.

8. The Act aims in particular:

– to create essential technical conditions for the preparation of a digitally supported primary healthcare system;

- to make health data usable for care, research and the improvement of our healthcare system;
- to strengthen, in a flexible and legally sound manner, the innovative use of data held by health and long-term care insurance funds in the interests of the insured;
- to implement Regulation (EU) 2025/327 in Germany in a way that is free from red tape, meets deadlines and promotes innovation;
- to establish a health data ecosystem in Germany that is compatible with and interconnected with the rest of Europe;
- further to develop the interoperability process in healthcare and social care in a rigorous and cross-sectoral manner;
- further to develop the electronic patient record (ePA) for healthcare-related purposes in order to ensure the best possible and practical use of the ePA,
- to strengthen competition for applications that are easy to use and beneficial for the insured with varying levels of digital literacy, including those of advanced age, and to promote innovation within the ePA;
- to improve the operational stability of the telematics infrastructure; and
- to continue driving forward the digitalisation of communication between service providers in the health and care sectors.

9. The aim of the proposal is to bring the added value of digitalisation to the healthcare sector. At the same time, opportunities to use health data for research, innovation and care will be significantly improved.

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

9b. To improve the safety of medicine-based treatment and care, the compulsory development of the electronic patient record (ePA) and the improvement of the operational stability of the telematics infrastructure are necessary provisions for electronic communication between service providers. To this end, the necessary legal foundations will be put in place to provide digital pathways to outpatient care, which will also prepare for the introduction of the planned primary care system. One important tool is the e-transfer. In addition, a digital on-boarding process is being introduced: Insured persons can nationwide be directed via the ePA user interface (ePA app) to the national standardised initial assessment carried out by the appointment service centres of the Associations of Statutory Health Insurance Physicians and can then, if necessary, book an appointment online. In addition, existing data from the ePA will be made available for further use. As a concrete added value application, the digital vaccination overview is to be introduced as a precursor to the digitalised vaccination process based on billing data. The regulations governing the “Communication in Healthcare” (KIM) applications and the telematics infrastructure’s instant messaging service (TI-Messenger – TI-M) are being consolidated, refined and supplemented. The goal is comprehensive, interoperable and secure communication. Therefore, all TI-affiliated service providers will in future be obliged to use KIM for medical, nursing and administrative communication.

9c. Waiving these provisions is not a suitable alternative. Without further binding regulations on the digitalisation of information systems in the health sector, it is not expected that the existing shortcomings in the digitalisation of the health sector can be remedied.

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

European Commission

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