

Message 001

Communication from the Commission - TRIS/(2025) 0658

Directive (EU) 2015/1535

Notification: 2025/0131/FR

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: 20250658.EN

1. MSG 001 IND 2025 0131 FR EN 10-03-2025 FR NOTIF

2. France

3A. Ministères économiques et financiers

Direction générale des entreprises

SCIDE/SQUALPI - Pôle Normalisation et réglementation des produits

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3B. Ministère de la santé et de l'accès aux soins

Délégation au numérique en santé

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4. 2025/0131/FR - S00S - HEALTH, MEDICAL EQUIPMENT

5. Order concerning applicable criteria for referencing digital services and tools in the service catalogue of

the digital health space.

6. Public or private publishers developing digital solutions in connection with 'Mon espace santé (My Health Space)'.

7.

8. Law No 2019-774 of 24 July 2019 on the organisation and transformation of the health system, known as "OTSS", created the digital health space ('Mon espace santé (My Health Space)') which includes services necessary for people benefiting from health insurance in France to manage their health.

This draft Order is made pursuant to Articles R.1111-37 and R.1111-38 of the Public Health Code.

This digital environment, 'Mon espace santé (My Health Space)', offers a catalogue 'referencing' digital tools or services already available on the market by public or private operators, which are then 'referenced' by the public authorities, enabling them to be used in confidence should the insured person decide to install the tool or service. The referencing of a digital tool or service in the catalogue is preceded by an initial assessment, with regard to its compliance with the ethical, technical, security and GDPR criteria referred to in Article R.1111-37 of the Public Health Code and defined by the Order of 23 June 2022 (<https://www.legifrance.gouv.fr/loda/id/JORFTEXT000046014336/2023-04-17/>) previously notified under reference 2022/083/F).

9. The purpose of this Order is to submit a proposal to amend the current Order of 20 November 2023 on the criteria applicable to the referencing of digital services and tools to the service catalogue of the digital health space. It allows the following:

1. The implementation of two simplified referencing pathways in Mon espace santé (My Health Space) for Digital Medical Devices (DMN) and tele-consultation companies (STLC) together with a certificate of compliance outlining the specific requirements of the sectoral benchmarks applicable to them.
2. Streamlining the criteria relating to referencing in Mon espace santé (My Health Space) in the light of the experience gained on referencing, the feedback from publishers and furthermore the recommendations made by the High Authority of Health.
3. The modification of the evaluation procedure for the aforementioned 'optional' criteria, which are now systematically verified as part of their ongoing monitoring.

10. References to reference texts: 2022/0083/F

The reference texts are to be appended to the previous notification:
2022/0083/F

11. No

12.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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