



EDPS Formal comments on the draft Commission Implementing Regulation on an interoperable, cross-border identification and authentication mechanism for natural persons, health professionals and healthcare providers for the purposes of the cross-border exchange of personal electronic health data

THE EUROPEAN DATA PROTECTION SUPERVISOR,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ('EUDPR')¹, and in particular Article 42(1) thereof,

HAS ADOPTED THE FOLLOWING FORMAL COMMENTS:

1. Introduction and background

1. On 8 April 2026, the European Commission consulted the EDPS on the draft Commission Implementing Regulation on an interoperable, cross-border identification and authentication mechanism for natural persons, health professionals and healthcare providers for the purposes of the cross-border exchange of personal electronic health data ('the draft Implementing Regulation').
2. The objective of the draft Implementing Regulation is to lay down the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons, health professionals and healthcare providers for the purposes of cross-border exchange of electronic health data² through the MyHealth@EU platform referred to in Article 23(1) of the Regulation (EU) 2025/327 on the European Health Data Space³ ('EHDS Regulation').
3. The draft Implementing Regulation is adopted pursuant to Article 16(2) of the EHDS Regulation.

¹ OJ L 295, 21.11.2018, p. 39.

² Article 1 and recital 1 of the draft Implementing Regulation.

³ Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.



4. The EDPS and the European Data Protection Board ('EDPB') previously issued a Joint Opinion on the Proposal for a Regulation on the European Health Data Space⁴.
5. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) of EUDPR. The EDPS welcomes the reference to this consultation in Recital 6 of the draft Implementing Regulation.
6. These formal comments do not preclude any additional comments by the EDPS in the future, in particular if further issues are identified or new information becomes available, for example as a result of the adoption of other related Implementing or Delegated acts⁵.
7. Furthermore, these formal comments are without prejudice to any future action that may be taken by the EDPS in the exercise of his powers pursuant to Article 58 of the EUDPR and are limited to the provisions of the draft Implementing Regulation that are relevant from a data protection perspective.

2. Comments

8. Pursuant to Article 2(2) of the draft Implementing Regulation, 'attribute' means attribute as defined in Article 3, point (43), of Regulation (EU) 910/2014⁶. Article 2(1) of the draft Implementing Regulation defines 'healthcare attribute' as an attribute that is used for the identification of a natural person for the purposes of cross-border exchange of electronic health data. Regulation (EU) 910/2014 contains the definition of 'attribute' in Article 3, point (43) but does not contain the definition of 'healthcare attribute'.
9. Since the identification data used in the various Member States differ, one of the aims of the draft Implementing Regulation is to require Member States to determine the identification data that are to be used to identify natural persons for the purposes of the cross-border exchange of personal electronic health data and to notify them to the Commission in view of their publication⁷.
10. The EDPS notes that the term 'healthcare attribute' could easily be understood as referring to any electronic health data (e.g., the priority categories of personal electronic health data for primary use under Article 14 of the EHDS Regulation). For the sake of legal clarity and certainty, the EDPS recommends replacing the term

⁴ [EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space](#), adopted on 12 July 2022.

⁵ In case of other Implementing or Delegated acts with an impact on the protection of individuals' rights and freedoms with regard to the processing of personal data, the EDPS would like to remind that he needs to be consulted on those acts as well. The same applies in case of future amendments that would introduce new or modify existing provisions that directly or indirectly concern the processing of personal data.

⁶ Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257, 28.8.2014, pp. 73–114.

⁷ Recital (2) and Article 3 of the draft Implementing Regulation.

‘healthcare attribute’ with another term (e.g., ‘health identification attribute’ or similar).

11. The EDPS welcomes that the Annex to the draft implementing regulation sets out in an exhaustive manner the mandatory identification data for health professionals.
12. The EDPS welcomes that, as from 26 March 2032, the electronic identification means used by natural persons, health professionals and healthcare providers shall provide the assurance level ‘high’ referred to in Article 8(2), point (c), of Regulation (EU) No 910/2014. For the period between 26 March 2030 and 26 March 2032, the EDPS notes a slight discrepancy between, on the one hand the assurance level applicable to individuals⁸ and, other hand healthcare professionals and healthcare providers on the other hand⁹. As the justification for allowing entities to authenticate using the assurance level ‘substantial’ between 2030 and 2032 is justified by the reference to the need to allow sufficient time for the full rollout of electronic identification means in the Member States¹⁰, the EDPS recommends aligning the relevant provisions and to impose the assurance level high on all entities as soon as possible.
13. For the sake of completeness, the EDPS recommends recalling by way of a recital the applicability of the GDPR and the EUDPR to the personal data processing under the draft Implementing Regulation.

Brussels, 5 May 2026

(e-signed)

Wojciech Rafał WIEWIÓROWSKI

⁸ According to Article 4(2) of the draft Implementing Regulation, individuals must use electronic identification means that provide the assurance level “high” as of 26 March 2030,

⁹ According to Article 6(3) of the draft Implementing Regulation, health professional or healthcare provider must use electronic identification means that provide the assurance level “high” as of 26 March 2032.

¹⁰ See recital (3) of the draft Implementing Regulation.