

EDPS Formal comments on the draft Commission Implementing Regulation on MyHealth@EU

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 MyHealth@EU ('the draft Implementing Regulation').
2. The draft Implementing Regulation would be issued pursuant to Article 23(4) and (8) of Regulation (EU) 2025/327² ('EHDS Regulation'), also in view of the Commission's obligation to establish a central interoperability platform for digital health ('MyHealth@EU') to provide services to support and facilitate the exchange of personal electronic health data between the national contact points for digital health of EU Member States ('NCP-DH').³
3. The objective of the draft Implementing Regulation is to lay down the rules regarding the requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management of the MyHealth@EU platform. The draft Implementing Regulation would also provide the necessary measures for the technical development of the MyHealth@EU platform, detailed rules concerning the security, confidentiality and protection of personal electronic health data and the

¹ OJ L 295, 21.11.2018, p. 39.

² 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>.

³ Article 23(1) EHDS.

conditions for compliance checks necessary to join and remain connected to the MyHealth@EU platform.⁴

4. The EDPS and the European Data Protection Board ('EDPB') issued a Joint Opinion pursuant to Article 42(1) EUDPR of Regulation 2018/1725⁵ ('EUDPR') on the Proposal for a Regulation on the European Health Data Space.⁶ The EDPS recalls the recommendations issued in relation to MyHealth@EU in that Joint Opinion.
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 such consultation in Recital 23 of the draft Implementing Regulation. The EDPS also positively notes that he was already informally consulted on a previous draft.
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 acts⁷.
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. The EDPS welcomes the specification that the personal data to be exchanged via the MyHealth@EU platform would be limited to the categories of data mentioned in Article 14(1) EHDS and the personal data necessary to manage MyHealth@EU.⁸
9. The EDPS also welcomes the detailed list of responsibilities that the draft Implementing Regulation would establish for the NCP-DH in their capacity as joint controllers as provided under Article 23(7) EHDS.⁹ The EDPS recommends assessing

⁴ Article 1 of the draft Implementing Regulation.

⁵ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons 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, OJ L 295, 21.11.2018, p. 39.

⁶ [EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space](#), Adopted on 12 July 2022

⁷ 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.

⁸ Article 14 of the draft Implementing Regulation.

⁹ Article 15 of the draft Implementing Regulation.

how additional elements concerning the processing of personal data, such as the implementation of general data protection principles, the carrying out of data protection impact assessments and the organisation of contact with supervisory authorities should can be addressed by the joint arrangement.¹⁰ Alternatively, the recitals of the draft Implementing Regulation could clarify that the list of responsibilities contained in Article 15 may need to be reflected in and complemented by an arrangement pursuant to Article 26(1) of Regulation (EU) 2016/679¹¹ ('GDPR') between the NCP-DH.

10. The EDPS notes that, pursuant to Article 23(7) EHDS, the Commission shall act as processor in relation to the personal electronic health data communicated through MyHealth@EU, which it would process only on behalf and under the instructions of the NCP-DH acting as joint controllers. This is reflected in Article 16 of the draft Implementing Regulation, which would lay down the Commission's responsibilities in its capacity as processor.
11. The EDPS notes that the draft Implementing Regulation aims at ensuring compliance with Articles 28 GDPR and 29 EUDPR by setting out the subject-matter, duration, nature and purpose of the processing, as well as the obligations and rights of the Commission as processor in a binding legal act.¹² The EDPS welcomes that the list of responsibilities in Article 16 of the draft Implementing Regulation would broadly reflect the requirements of Articles 28 GDPR and Article 29 EUDPR, but notes that, as a processor, the Commission would be obliged to notify the NCP-DH acting as joint controllers - and not the EDPS - of detected personal data breaches.¹³ The EDPS recommends amending Article 16(h)(vi) of the draft Implementing Regulation accordingly. In the same vein, and for the avoidance of doubt, the EDPS recommends clarifying in Article 16(i) of the draft Implementing Regulation that the patient information notices to be published by the Commission should be agreed by the NCP-DH acting as joint controllers and communicated to the Commission for publication.
12. Furthermore, the EDPS stresses that all elements of Articles 28(3) GDPR and Article 29(3) EUDPR should be included in the legal acts governing the processing by a processor. In this context, the EDPS notes that the draft Implementing Regulation allows the Commission to engage sub-processors to fulfil its responsibilities as a processor. The EDPS stresses that the NCP-DH acting as joint controllers must have detailed knowledge of the processing that is delegated by the Commission to sub-processors, including about the personal data that is shared, the purposes of the

¹⁰ [EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 2.1](#), Adopted on 07 July 2021, paragraphs 161 to 170.

¹¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, pp. 1–88.

¹² Recital 19 of the draft Implementing Regulation.

¹³ Article 34(2) EUDPR.

sharing, the specific sub-processors engaged, where they are located, and the safeguards that are to be applied by each sub-processor.¹⁴

13. Under Article 28(2) GDPR and Article 29(2) EUDPR, the processor may not engage another processor without specific or general written authorisation of the controller. To serve as a general authorisation, a list of potential sub-processors agreed by the NCP-DH acting as joint controller should be provided for. The EDPS therefore recommends including in the draft Implementing Regulation an initial list of authorised sub-processors that the Commission can engage, or an obligation for the NCP-DH acting as joint controllers and the Commission to agree on that initial list prior to the processing.¹⁵
14. Furthermore, the EDPS finds it necessary that Article 16 of the draft Implementing Regulation provides for a procedure for the Commission to inform the NCP-DH of any intended changes concerning the addition or replacement of sub-processors, and for the NCP-DH to object to such changes.¹⁶
15. The EDPS notes that Article 16 of the draft Implementing Regulation does not provide for how requests from data subjects should be handled and notified by the Commission to the NCP-DH acting as joint controllers. The EDPS recommends amending Article 16 of the draft Implementing Regulation to include obligations for the Commission as processor to notify and to assist the joint controllers, insofar as this is possible¹⁷, with the fulfilment of their obligation to respond request related to data subject rights laid down in Chapter III GDPR. In line with Article 29(3) EUDPR, the EDPS also recommends describing in the draft Implementing Regulation the duration of the processing, the types of personal data and categories of data subjects either explicitly or by inserting cross-references to the relevant provisions in the EHDS.¹⁸
16. The EDPS invites the Commission to consider whether the temporary suspension of the exchange of personal electronic health data should be a default consequence of a

¹⁴ [EDPB Opinion 22/2024 on certain obligations following from the reliance on processor\(s\) and sub-processor\(s\)](#), Adopted on 7 October 2024, paragraphs 39 and 55.

¹⁵ [Commission Implementing Decision \(EU\) 2021/915 of 4 June 2021 on standard contractual clauses between controllers and processors under Article 28\(7\) of Regulation \(EU\) 2016/679 of the European Parliament and of the Council and Article 29\(7\) of Regulation \(EU\) 2018/1725 of the European Parliament and of the Council \(Text with EEA relevance\) C/2021/3701, OJ L 199, 7.6.2021, pp. 18–30](#), Clause 7.7.(a), Option 2.

¹⁶ Article 28(2) GDPR and Article 29(2) EUDPR.

¹⁷ According to the information provided by the Commission, due to the architecture of the system, the Commission may not be able assist the controllers in replying to data subject requests. The EDPS notes that the obligation for the Commission to assist the joint controller only exists where it is possible for Commission to offer the relevant assistance. Absent further information on the technical architecture of the system, the EDPS recommends including the obligation for the sake of completeness.

¹⁸ The description of the processing operations to be carried out by the Commission is provided throughout the text of the draft Implementing Regulation, e.g. in Articles 3 (task to provide e.g. the secure communication network), 5 (tasks in operations) and 16 (detailed list of tasks and responsibilities). In accordance with Article 23(7) EHDS, the Commission provides MyHealth@EU as a processor. Hence, the description of the functions of MyHealth@EU is the description of the processing. The purpose of the processing is also defined in Article 23 EHDS.

refusal of an authorisation under Article 12(1) of the draft Implementing Regulation, instead of only a possible mitigation measure under Article 12(2).

17. Finally, the EDPS recommends recalling by way of a Recital that processing of personal data in MyHealth@EU must comply with the requirements of the GDPR and the EUDPR, as applicable.

Brussels, 18 May 2026

(e-signed)

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