



EUROPEAN
COMMISSION

Brussels, XXX
[...] (2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

**laying down the necessary measures for the establishment and operation of the
European Health Data Space Board**

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

laying down the necessary measures for the establishment and operation of the European Health Data Space Board

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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) 2024/2847¹, and in particular Article 92(11), first sentence, thereof,

Whereas:

- (1) Regulation (EU) 2025/327 establishes the European Health Data Space Board (the ‘EHDS Board’) as a body responsible for promoting the consistent application of that Regulation. The EHDS Board is to serve as a forum for cooperation and exchange of information both between Member States and between them and the Commission.
- (2) The EHDS Board is a key part of the governance mechanisms under the EHDS Regulation. It builds on the experience gained with the eHealth Network established under Commission Implementing Decision 2019/1765 on a network of national authorities responsible for eHealth². The eHealth Network will cease to exist on 26 March 2031³. Until then, the EHDS Board should cooperate with the eHealth Network, as well as with the eHealth Member States Expert Group, ensuring an orderly transition to the new governance framework, including at subgroup level. As different parts of the EHDS Regulation will start to apply, for example on the exchange of the first group of priority categories, the Board will start its activities on those topics, gradually taking over from the eHealth Network.
- (3) The general tasks of the EHDS Board are set out in Article 94(1) and (2) of Regulation (EU) 2025/327. While the substance of the EHDS Board’s tasks is regulated in those provisions, it is appropriate to detail the types of actions the EHDS Board may take when performing its general tasks to ensure consistent application of Regulation (EU) 2025/327. Written contributions, including in the form of non-binding guidelines issued by the EHDS Board can provide useful guidance to national authorities and other stakeholders involved in implementing the European Health Data Space (EHDS).

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¹ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

² Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU (OJ L 270, 24.10.2019, p. 83, ELI: http://data.europa.eu/eli/dec_impl/2019/1765/oj).

³ See Article 103 Regulation (EU) 2025/327

- (4) The EHDS Board may provide written contributions in relation to technical specifications in accordance with the EHDS Regulation, supporting the access to and exchange of electronic health data, in the form of technical implementation guides and other documentation. The EHDS Board may also provide written contributions for the purpose of addressing common implementation challenges, proposing coordinated responses or joint road maps for the Member States and EHDS communication strategies. Other written contributions can provide useful information on the implementation of the EHDS, including any issues that may arise during the implementation of the EHDS Regulation. Exchanges of best practices are expected to foster mutual learning and best practice adoption among national authorities as well as the cooperation of the EHDS Board with different relevant bodies, authorities and agencies invited to attend the meetings of the EHDS Board in accordance with Article 92(3) of Regulation (EU) 2025/327.
- (5) Similarly, the EHDS Board should cooperate with other fora set up to support the implementation of the EHDS, such as the Community of Practice of Health Data Access Bodies and cross-border interoperability of public services in general, the Interoperable Europe Board established through Regulation (EU) 2024/903 and the AI Board established through Regulation 2024/1689.
- (6) The EHDS Board should adopt, every two years, a work plan to detail the activities that it will carry out to perform its general tasks. That two-year plan may be adapted to changing circumstances. The Commission, as secretariat of the EHDS Board, should provide support to the EHDS Board's activities, including by providing secure collaboration tools.
- (7) As Regulation (EU) 2025/327 provides that the EHDS Board is to be co-chaired by a representative of the Member States and a representative of the Commission, rules on the designation of the Member State co-chair should be laid down. With the Commission providing the secretariat of the EHDS Board, the representative of the Commission on the EHDS Board should not be entitled to vote.
- (8) EHDS Board members should not be remunerated by the Commission for their participation in the activities of the EHDS Board. However, the Commission should reimburse their travel and subsistence expenses incurred for participating in the EHDS Board's activities, following the approach for other similar bodies.
- (9) Given that, in the course of their work, EHDS Board members, invited experts and observers may obtain access to sensitive information, they should be subject to the obligation of professional secrecy.
- (10) As the Commission provides the secretariat of the EHDS Board, documents held by the secretariat of the EHDS Board should be subject to Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁴.
- (11) The work of the EHDS Board should be transparent. For this reason, information about its membership should be publicly available, and key documents should be published on a dedicated website.

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⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: <http://data.europa.eu/eli/reg/2001/1049/oj>).

- (12) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council⁵ and delivered an opinion on XX XX 20XX.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 98(1) of Regulation (EU) 2025/327,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the necessary rules for the establishment, the management and the functioning of the European Health Data Space Board (the ‘EHDS Board’).

Article 2

Activities of the EHDS Board

1. When carrying out its tasks listed in Article 94(1) and (2) of Regulation (EU) 2025/327, the EHDS Board may take the following actions:
 - (a) issue written contributions relating to technical specifications and other relevant matters in accordance with the EHDS Regulation, supporting the access to and exchange of electronic health data, particularly in the form of implementation guides;
 - (b) issue written contributions, including in the form of non-binding guidelines to support the implementation of Regulation (EU) 2025/327 for example, identifying common implementation challenges and proposing coordinated responses or joint road maps for the Member States, as well as EHDS communication strategies;
 - (c) facilitate thematic exchanges among its members, the Commission, and with relevant bodies, agencies and authorities invited to attend the EHDS Board meetings in accordance with Article 92(3) of Regulation (EU) 2025/327, including through workshops, peer learning and mutual assistance on best practices, technological tools and lessons learned in relation to the implementation of Regulation (EU) 2025/327 and the operation of the EHDS;
2. Every two years, the EHDS Board shall adopt a work plan detailing the activities that it will carry out to perform the tasks assigned to it under Article 94 of Regulation (EU) 2025/327. This two-year plan may be adapted to changing circumstances to ensure that it remains relevant.
3. The EHDS Board shall cooperate with the steering groups established by Article 95(1), first sentence, of Regulation (EU) 2025/327 to ensure consistency between their respective activities.

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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, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).

4. To support the activities of the EHDS Board, the Commission shall provide secure collaboration tools.

Article 3

Membership of the EHDS Board

Member States shall notify the Commission in writing of the names of their representatives on the EHDS Board and to which Member State authorities they are affiliated and, without undue delay, of any changes thereof.

Article 4

Representative of the Commission

The representative of the Commission referred to in Article 92(2) of Regulation (EU) 2025/327 shall be designated by the Commission's Director-General for Health and Food Safety.

Article 5

Chair

1. The EHDS Board shall be co-chaired by the representative of the Commission referred to in Article 4 and by a representative of a Member State elected among the Member States' representatives by absolute majority of all Member States for a term of two years.
2. If the representative elected among the Member States' representatives is no longer available to fulfil the role of co-chair, the EHDS Board shall elect a new Member State co-chair.

Article 6

Decision-making

1. As far as possible, the EHDS Board shall adopt its positions, written contributions, opinions, recommendations and reports by consensus.
2. If a consensus cannot be reached, a vote shall be taken if any EHDS Board member or EHDS Board co-chair so requests. In the event of a vote, the outcome of the vote shall be decided by a majority of two thirds of the Member States present when the co-chairs proceed to the vote. Each Member State shall have one vote.
3. Member States absent from EHDS Board meetings may delegate their vote to another Member State to vote on their behalf.
4. The representative of the Commission referred to in Article 4 shall not be entitled to vote.

Article 7

Expenses

1. EHDS Board members participating in the activities of the EHDS Board shall not be remunerated by the Commission for their participation.

2. The Commission shall reimburse travel and subsistence expenses incurred by EHDS Board members for participating in the activities of the EHDS Board. Those expenses shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for allocating resources in accordance with the provisions in force within the Commission.

Article 8

Professional secrecy and handling of classified information

EHDS Board members, invited experts and observers are subject to the obligation of professional secrecy, which, by virtue of the Treaties and the rules implementing them, applies to all members of the institutions and their staff. They are also subject to the Commission's rules on security regarding the protection of Union sensitive non-classified and classified information, laid down in Commission Decisions (EU, Euratom) 2015/443⁶ and (EU, Euratom) 2015/444⁷. Should EHDS Board members, invited experts and observers fail to respect these obligations, the Commission may take all appropriate measures.

Article 9

Access to documents

Requests for access to the EHDS Board's documents shall be handled in accordance with Regulation (EC) No 1049/2001. It is for the Commission to take a decision on requests for access to those documents. That decision shall be taken in accordance with Commission Decision (EU) 2024/3080⁸. If requests for access to the EHDS Board's documents are addressed to a Member State, Article 5 of Regulation (EC) No 1049/2001 shall apply.

Article 10

Transparency

1. The Commission shall publish the following information on a dedicated website:
 - (a) the names of the Member State authorities to which EHDS Board members are affiliated;
 - (b) the rules of procedure and the code of conduct of the EHDS Board;
 - (c) meeting dates, agendas, minutes, adopted written contributions, guidelines, and activity reports of the EHDS Board.
2. Access to that website shall not be subject to user registration or any other restriction.
3. The agenda and other relevant background documents referred to in paragraph 1, point (c) shall be published in due time ahead of EHDS Board meetings, followed by timely publication of minutes and adopted documents after the meetings.

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⁶ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41, ELI: <http://data.europa.eu/eli/dec/2015/443/oj>).

⁷ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53, ELI: <https://eur-lex.europa.eu/eli/dec/2015/444/oj>).

⁸ Commission Decision (EU) 2024/3080 of 4 December 2024 establishing the Rules of Procedure of the Commission and amending Decision C(2000) 3614 (OJ L, 2024/3080, 5.12.2024, ELI: <https://data.europa.eu/eli/dec/2024/3080/oj>).

4. The information referred to in paragraph 1, point (c) shall not be published where it is deemed that the disclosure of that information would undermine the protection of a public or private interest referred to in Article 4 of Regulation (EC) No 1049/2001.

Article 11

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN