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[...] (2026) XXX draft

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

of XXX

laying down the minimum metadata elements and their characteristics to be provided by health data holders for dataset descriptions for the secondary use of electronic health data under Article 77(1) of Regulation (EU) 2025/327 establishing the European Health Data Space

(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.

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(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 77(4), first sentence, thereof,

Whereas:

- (1) Article 77(1) of Regulation (EU) 2025/327 requires health data access bodies to make publicly available dataset catalogues with description, in the form of metadata, of the datasets available for the secondary use of electronic health data, including information on the source, scope, main characteristics and nature of the electronic health data in the datasets and the conditions for making those data available.
- (2) For that purpose and in accordance with Article 60(3) of Regulation (EU) 2025/327, health data holders are to communicate to the health data access bodies such a description of the dataset they hold, irrespective of whether the datasets contain personal and/or non-personal electronic health data.
- (3) In accordance with Article 60(3) of Regulation (EU) 2025/327, health data holders are required to verify, at least annually, that dataset descriptions are accurate and up to date. This is essential to ensure the reliability and usability of dataset catalogues for the secondary use of electronic health data.
- (4) As provided for in Article 77(1) of Regulation (EU) 2025/327, dataset catalogues are to be standardised and machine-readable, in order to ensure semantic and technical interoperability across Member States. This is necessary to enable the interconnection of national dataset catalogues and dataset catalogues of authorised participants into the EU dataset catalogue established under Article 79 of that Regulation. Health data holders should therefore use a common approach to metadata for dataset descriptions when providing the minimum metadata elements and the characteristics of those elements.

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

- (5) It is appropriate that the HealthDCAT-Application Profile (HealthDCAT-AP) is used as that metadata framework. HealthDCAT-AP builds on the general DCAT-Application Profile, and is a technical specification developed and maintained by the Commission, specifically designed to support the description of health datasets made available for the secondary use of electronic health data. Those specifications are provided in accordance with the operational decisions of the relevant bodies established pursuant to Article 92 and 95, within the governance framework of the European Health Data Space.
- (6) 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,
- (7) This Regulation contributes to the interoperability of digital infrastructures supporting the European Health Data Space, including those related to cross-border data access. An interoperability assessment has been carried out and the resulting report will be published on the Interoperable Europe Portal upon adoption of this Regulation.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down the minimum metadata elements for dataset descriptions, and the characteristics of those elements, that health data holders are required to provide to health data access bodies pursuant to Article 60(3) of Regulation (EU) 2025/327 for the secondary use of electronic health data, as well as the metadata framework to be used for that purpose.
2. This Regulation also applies, where relevant, to authorised participants in HealthData@EU when providing dataset descriptions in accordance with Regulation (EU) 2025/327.
3. This Regulation shall not prevent health data holders from providing additional metadata elements and their characteristics on a voluntary basis, using for that purpose the metadata framework referred to in the first paragraph.

Article 2

Definitions

For the purposes of this Regulation, the definitions in the HealthDCAT-AP referred to in Part A of the Annex shall apply.

Article 3

Requirements for minimum metadata elements

The list of the minimum metadata elements that health data holders shall provide for dataset descriptions, and the characteristics of those elements, is set out in Part B of the Annex.

Health data holders shall express the minimum metadata elements listed in Part B of the Annex by using the definitions, structure, cardinalities and controlled vocabularies set out in the HealthDCAT-AP referred to in Part A of the Annex.

Article 4

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*.

It shall apply from 26 March 2029.

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

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