CPME 2026/077 FINAL	ADOPTED
AUTHOR: CPME BOARD	7 MAY 2026

Feedback on Commission Implementing Regulation 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

CPME welcomes the opportunity to comment on the draft implementing legislation. Building on the CPME response to the TEHDAS2 M5.1 Draft guidelines on data description, we ask to take into consideration the following feedback:

- Doctors' primary task is diagnosing and treating patients and maintaining health records to this end. The possible duties for healthcare professionals related to data descriptions and data transfers under the secondary use regime of the EHDS Regulation are seen as a discretionary aspect of work and diminishes clinical time spent on patient care.
- Considering the current health workforce crisis, healthcare professionals' time cannot be exhausted in preparing, including the anonymising or pseudonymising, data for third parties including those which pursue private and commercial interest. CPME supports the 'once-only principle'.
- Healthcare software manufacturers need to support healthcare professionals by automating the creation and provision of metadata descriptions for health data access bodies. Data holders should be able to describe metadata in free text format which is translated by the health data access body into the appropriate standard.
- The maturity and capability of health data holders is different, and this difference is not addressed in the draft implementing Regulation. The role of health data intermediaries is not addressed.
- Requesting health data holders, which includes healthcare professionals, to provide dataset descriptions in the HealthDCAT-AP standard, and update the information regularly, is disproportionate. Healthcare professionals should not be burdened with this standardisation task. Mandatory metadata descriptions should be minimal.

- The additional costs for healthcare software manufacturers, health data holders (which may be health professionals) and health data access bodies must be covered by national health authorities and not by health professionals and/or patients.
- If, despite these amendments, there will be extra workload, either temporarily or permanently, it has to be remunerated and taken into account considering the total workload.

Amendment 1 – Recital 2	
Commission proposal	**CPME amendment**
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.	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 ***upon request*** such a description of the dataset they hold, irrespective of whether the datasets contain personal and/or non-personal electronic health data. ***Member States shall require in their national law that health data intermediation entities carry out the duties of certain categories of health data holders in relation to these activities, with the objective of avoiding a disproportionate burden on health professionals and professional associations. Natural persons and microenterprises should be as a general rule, exempted from the obligations on health data holders.***

Amendment 2 – Recital 3	
Commission proposal	**CPME amendment**
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.	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. ***Member States shall require in their national law that health data intermediation entities carry out the duties of certain categories of health data holders in relation to these activities, with the objective of avoiding a***

	disproportionate burden on health professionals and professional associations. Natural persons and microenterprises should be as a general rule, exempted from the obligations on health data holders.

Amendment 3 – Article 3	
Commission proposal	**CPME amendment**
	(new) Member States shall provide training on the use and implementation of the HealthDCAT-AP to health data holders. ***The European Commission shall establish a reporting mechanism on the use and implementation of the HealthDCAT-AP for health data holders and produce an annual review.***