MEDECINS EUROPEENS
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FEEDBACK

CPME 2026/078 FINAL	ADOPTED
AUTHOR: CPME BOARD	7 MAY 2026

Feedback on Commission Implementing Regulation on MyHealth@EU

CPME welcomes the opportunity to comment on the draft implementing legislation. We ask to take into consideration the following feedback:

- CPME underlines that, while this Implementing Regulation is primarily technical, its requirements will directly shape the clinical use of MyHealth@EU. It is therefore essential to ensure that the requirements catalogue and technical specifications are informed by clinical use cases and prioritise clinically relevant information. This should include safeguards to avoid unnecessary complexity, excessive data volumes and increased documentation burden for health professionals.
- The security, confidentiality and protection of patient data must be central to the implementation of MyHealth@EU. This must be accompanied not only by compliance checks, but accessible and effective and deterrent consequences to critical incidents detected, for example in case of unauthorised access.
- To this end, CPME asks the European Commission to clarify the scope and legal basis of the technical requirements to be developed with the steering group as described in Article 4 (3). CPME also asks the European Commission to make public the security plan and risk assessment to ensure transparency and build trust. This must include the option for stakeholder feedback and correction mechanisms.
- While ensuring a high level of security, confidentiality and data protection, it is equally important that MyHealth@EU is designed to be fast, stable and usable in clinical practice. The system should not delay access to relevant health data or create friction in the provision of care[1].
- Complete integration in EHR is a prerequisite. The costs of implementing and maintaining this must be covered by national health authorities, not health professionals and/or patients.

Amendment 1 – Article 15 (h)	
Commission proposal	**CPME amendment**
They shall communicate any personal data breaches with regard to processing operations in MyHealth@EU to the competent data protection supervisory authorities and, where	They shall communicate any personal data breaches with regard to processing operations in MyHealth@EU to the competent data protection supervisory authorities and~~, where~~

[1] Implementing a 'user-friendly' European Health Data Space: Guiding the integration of an intuitive electronic health record , March 2025

required, to data subjects, in accordance with Articles 33 and 34 of Regulation (EU) 2016/679.	~~required,~~ to data subjects, ***and as appropriate health professionals accessing the personal data***, in accordance with Articles 33 and 34 of Regulation (EU) 2016/679.

Amendment 2 – Article 16 paragraph (e)	
Commission proposal	**CPME amendment**
It shall put in place the necessary measures to ensure a level of security of personal data processed in the central secure communication service appropriate to the risks. These measures shall be documented in a security plan, which shall be kept up to date. The measures shall include:	It shall put in place the necessary measures to ensure a level of security of personal data processed in the central secure communication service appropriate to the risks. These measures shall be ***set out*** in a security plan, ***which shall be developed with the involvement of the Health Cybersecurity Advisory Board and presented for public consultation. This security plan*** shall be kept up to date. The measures shall include: