COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/EC/02022021/005_FINAL/EN

On 2 February 2021, the CPME Executive Committee adopted the 'CPME Statement on the Combined Evaluation Roadmap/Inception Impact Assessment on a European Health Data Space' (CPME 2021/005 FINAL).

CPME Statement on the Combined Evaluation Roadmap/ Inception Impact Assessment on a European Health Data Space

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME welcomes the development of a European Health Data Space to be used for health research and for improving health outcomes in relation to diagnosis and treatment of diseases.

CPME takes the opportunity to highlight the following points that the future legislative proposal needs to address:

1. The proposal should define criteria for what is to be considered 'innovation for the public good'. This is to avoid misuse and abuse when conducting innovative research.
2. Sector specific legislation for 'augmented intelligence' (AI) in the health area should exist. Training, testing and validation of AI in health require further consideration and, when a life of a human being is at stake, AI should always be intrinsically considered of high-risk.
3. In medical research, the principles of the Declarations of Helsinki[1] and Taipei[2] have to be complied with too. The General Data Protection Regulation (GDPR) is not sufficient to address the processing of health data for secondary purposes.[3] The Declarations are more exhaustive in relation to the right to information, the right to access the information about one's health data, and requirements for consent and respective withdrawal limitations. Feedback of

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[1] WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and as amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

[2] WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016.

[3] Processing health data for secondary purposes should be understood as processing patient data for other purposes than the purpose for which the data was originally collected, such as the treatment of the patient. Secondary purposes thus include health research, the development of new treatments, medicines, medical devices and services, and evidence-based health policy-making purposes.

findings to the data subject is also desirable for transparency reasons and it may help promote support about the research by the community at large. The combined evaluation omits these important specifications.

4. The use of genetic data for insurance, credit, criminal justice, education or employment purposes should never be allowed. No one should be discriminated because of their genome. Ethical objections from patients against certain private entities need to be taken into account. Proper assurances have to be provided that human dignity and other fundamental rights are always respected when using genetic and health data.
5. The costs for the interoperability of patient data should not be borne by physicians as it may be detrimental to the general access to healthcare and undermine the physicians' ability to provide the service.
6. Meaningless procedures that take time and resources should be avoided (e.g. introduction of new disease classification codes, adding to national and international ones). Coordination is required with national medical associations.

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