

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.

Report on the General Data Protection Regulation

Response to the call for evidence of the European Commission

European Doctors welcome the European Commission's initiative to consult a wide range of stakeholders to submit their views on the application of the General Data Protection Regulation (GDPR), in view of the second evaluation and review report due by mid-2024.

Although the timeline to offer comments is very short to be able to conduct a thorough survey among our members' members (that is individual doctors), CPME highlights the following points which relate to its scope of activity:

- *Question 3 – b) Have the guidance and tools provided by data protection authorities and the EDPB in recent years assisted SMEs in their application of the GDPR?*

CPME Response: The EDPB 'Guidelines on the processing of personal data for scientific research purposes' are still missing. These guidelines have been promised since 2021, to ensure proper harmonisation, but have never been delivered (please see also "EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research", <https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaire_research_final.pdf>). The interpretation of the GDPR is very important for the digitisation of the healthcare system and patient empowerment. Multinational multi-centric studies are difficult to carry out due to the different interpretations of the GDPR in Member States;

- *Question 5 – c) – Are DPAs following up on each complaint submitted and providing information on the progress of the case?*

CPME Response: Data protection authorities (DPAs) lack resources to carry out its activities, and legislation is only increasing with additional competences for these entities (e.g. European Health Data Space, Artificial Intelligence Act, Data Governance Act, etc.). They need to be properly resourced and staffed. DPAs should also provide more training and guidance to Data Protection Officers, in particular in the healthcare sector due to the processing of special categories of personal data;

- *Question 14 – b) – Please provide your views on the interaction between the GDPR and new initiatives under the Data Strategy (e.g., Data Act, Data Governance Act, European Health Data Space etc.)*

CPME Response: The interplay between the European Health data Space and the GDPR need to be clarified, for example the definitions of the EHDS on ‘non-personal data’ and ‘electronic health data’; the terminology on ‘further processing’ in the GDPR which is not used in the EHDS but rather the term ‘secondary use’; professional secrecy and ‘consent-requirements’ obligations in secondary use (interplay with Articles 9(4) and 7 of the GDPR); data altruism and right to withdraw consent; consequences of Article 38(2) of the EHDS on data subject rights under the GDPR.
