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*On 8 April 2021, the CPME Executive Committee adopted the 'CPME Statement on Shaping the Healthcare Sector Interoperability Policy' (CPME 2021/024 FINAL).*

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## CPME Statement on Shaping the Healthcare Sector Interoperability Policy

*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.*

The European Commission's Communication on [Shaping Europe's digital future](#)<sup>1</sup> set out as one of the key actions to implement, the development by 2021 of 'a reinforced EU governments interoperability strategy', to ensure coordination and the adoption of common standards for public sector data flows and services. To this end, the European Commission launched a public consultation on "[Shaping the future public sector interoperability policy](#)" gathering stakeholders' views on possible objectives and policy actions for enhancing interoperability in the public sector in the EU. It also intends to understand the economic, social, environmental and fundamental rights impact that such policies could have. The results will feed into the impact assessment on a future interoperability policy.

The public consultation is very broad and the questions do not allow contextualising interoperability in the healthcare sector. With this statement, CPME intends to address the major challenges and particularities of interoperability in the healthcare sector, offering few recommendations.

CPME highlights the following:

1. Security by design, privacy by design, medical confidentiality and ethical principles, i.e. the World Medical Association Declarations of Helsinki<sup>2</sup> and Taipei,<sup>3</sup> must be considered as fundamental principles of an interoperability policy in the healthcare sector.
2. Caution should exist concerning interoperability between healthcare sector and other sectors of the public administration. For example, using health data for other purposes than those consented to by the patient, or expected, at the moment of collection by the patient.

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<sup>1</sup> COM(2020)67 final, 1-16.

<sup>2</sup> WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18<sup>th</sup> WMA General Assembly, Helsinki, Finland, June 1964 and as amended by the 64<sup>th</sup> WMA General Assembly, Fortaleza, Brazil, October 2013.

<sup>3</sup> WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53<sup>rd</sup> WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67<sup>th</sup> WMA General Assembly, Taipei, Taiwan, October 2016.

3. The requirements of healthcare professionals and patients should be assessed and taken into account when designing interoperable processes. Moreover, the design of technical systems in healthcare settings must be driven by the needs of the healthcare system itself and healthcare professionals, and not by the needs of the industry.
4. The healthcare system is highly dependent on the software industry, especially in the “last mile” concerning information systems used by doctors and hospitals. The adoption of standards is associated with substantial costs and effort, both for the software industry and for the healthcare system. Even if healthcare systems adopt reasonable digital technologies, software companies usually do not have a motivation to invest in interoperability. There are even cases of information systems blocking information exchange as a strategy to defend or expand market shares, allowing connectivity only between software products of the same vendor.
5. Healthcare systems must not shift, or reduce, their financial resources intended for clinical care to attain interoperability.
6. A future public sector interoperability policy should address the above-mentioned issues, and be combined with a legal framework (i.e. a Directive on minimum interoperability requirements) that enforces interoperability for the software industry and foresees specific financial funding.
7. CPME believes that a Directive would be very positive to improve i) the quality of the healthcare services provided by public administration; ii) research and healthcare innovation in the EU; and, iii) access and quality of basic healthcare products.

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