

HOPE contribution to the European Commission Call for Evidence “Digital Fitness Check”

HOPE thinks that great care must be taken that simplification measures, primarily requested by technology companies to reduce administrative and cost burdens, do not generate detrimental effects (privacy, liability, safety, security, uncertainty) for the institutions and individuals charged with overseeing and using advanced digital tools in healthcare, including hospital staff, healthcare workers, and patients. They are the ones dealing with the consequences, with persons in vulnerable situations and/or low levels of digital literacy most affected.

Carefully balancing the needs of digital end users and innovation actors is critical. The proposals contained in the Digital Omnibus regulations and potential follow-up initiatives should not put potentially short-lived competitiveness objectives before the health, safety and fundamental rights of people. In the EU healthcare sector, this is of utmost importance because comprehensive yet empowering regulation is essential to avoid the misuse of highly sensitive personal electronic data, made possible through advanced AI tools, with potentially devastating consequences for health systems while eroding public trust in digitalisation.

HOPE agrees that the digital legislative framework is becoming progressively complex; in healthcare, each regulation adds similar and overlapping legal obligations. At the same time, the refinement and endorsement of these obligations during the EU policymaking process reflects the need to establish clear responsibilities for the distinct circumstances governed by each law.

Stress-testing the complementarity, efficiency and effectiveness of the EU’s digital rulebook is nonetheless worthwhile. The Digital Fitness Check (DFC) is an opportunity to identify areas where legal obligations are so similar in practice that the associated administrative and reporting tasks could de facto be combined. In healthcare, several intersecting obligations arise from the interplay between the EU AI Act and the Medical Devices / In Vitro Diagnostics regulations, as well as from tensions between the GDPR and the ambitions of the European Health Data Space and Data Act, to which multiple cybersecurity obligations for devices and IT infrastructures must be added. Many data-relevant definitions appear to be unclear or inconsistent. Both deployers (including hospitals and healthcare services) and technology providers anticipate an augmentation of time-consuming bureaucratic tasks.

From this perspective, HOPE encourages the Commission to further develop highly secure and user-friendly, multi-purpose platforms and tools. These should be sufficiently smart and versatile to enable compliance with different EU legal acts while also taking into account national obligations. The removal of repetitive, duplicate duties is helpful as long as it does not undermine existing rights and protections.

HOPE acknowledges the Commission's assertion that it "set the gold standard for the highest level of protections for fundamental rights, consumer safety and the protection of our values". Yet this high standard can be easily undone by bowing to market pressures in the name of competitiveness in the current volatile geopolitical environment. Rather than vying with global competitors on their terms, the human-centric EU approach to digitalisation should be maintained. Enshrining data protection, privacy and fundamental rights in EU digital law provides a powerful lure for innovation companies in search of democratic values and stability.

Hence HOPE is concerned that the further loosening of legal provisions is premature, especially those designed to ensure the transparency and accountability of AI system providers, protect privacy and fundamental rights. Since the digital rulebook has not even been fully applied in healthcare, statements about the cumulative impact of obligations are largely speculative rather than empirical.

HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 36 organisations coming from the 27 Member States of the European Union, as well as from the United Kingdom, Switzerland and Serbia as observer members. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.