

## Initial Feedback on the Commission initiative “Digital health data and services – the European health data space”

The European Hospital and Healthcare Federation (HOPE) welcomes the European Health Data Space (EHDS) legislative proposal and its key objectives as a logical next step in the digital transformation of health and care. However, based on our preliminary analysis, a number of legal and technical clarifications will be required — in particular regarding some of the terminologies, operational requirements and standards, and links with other legislation (e.g., data protection, data governance, Artificial Intelligence) — to ensure that the hospital and healthcare sector will be able to reap tangible benefits. To attain a high level of trust and uptake, the EHDS should generate better-quality services and improved health outcomes for patients, provide support for healthcare professionals, enhance hospital administrative processes and continuity of care as part of health systems strengthening.

Currently, the digital technology budgets of most hospitals and healthcare facilities are rather low. In addition, under pandemic conditions, hospitals are operating under significant resource limitations affecting the recruitment and retention of healthcare workers and specialised health data professionals essential for the EHDS implementation. Nonetheless, the sector has seen increased investment in data infrastructures and digital tools as part of national and regional initiatives and strategies to create health data spaces. Hence, it will be important to ensure that systems already in place and serving specific aims can be smoothly incorporated into the EHDS and that EU funding will support the transition. The initial costs of implementing the EHDS, pertaining to setting up IT infrastructures and ensuring semantic and technical interoperability, are believed to be very significant, and they are likely to further exacerbate the economic pressure experienced in our sector. Hence, the projected savings derived from the primary and secondary uses of personal health data estimated by the Commission are not convincing.

The proposal foresees the integration of personal health data from a wide range of sources, including health and wellbeing apps, which calls for establishing unambiguous data quality standards and inclusion criteria. In turn, realising this ambition depends on a high level of interoperability and standardisation to facilitate the meaningful use of personal health data in healthcare and in research. Moreover, for public health and decision-making functions, existing data silos (e.g., between health and social data repositories) need to be broken down, and many member states would need to introduce legislative changes to provide comprehensive data sets giving insights into various determinants of health.

The research realm of the EHDS must safeguard the highest viable levels of personal data protection and fundamental rights, while being subject to strong ethical governance. It should allow for effective exchanges with close research partners including the UK.

The ownership of the EHDS must be in the hands of healthcare stakeholders not the IT industry to make sure that the actual needs of patients, professionals, and health systems are met. The right to access and contribute health data must be tied to concrete opportunities for co-creation and investments in digital health literacy to ensure that all people in Europe will benefit from the EHDS. Therefore, the composition of the EHDS Board should reflect the diversity of interests in this space or it should consult a larger group of stakeholders.

Finally, the EHDS proposal could benefit from a clearer focus: for example, by ensuring the successful EU-wide implementation of only some of the priority categories of personal health data for primary use, rather than simultaneously describing a much broader vision that may not be realistic to attain within the envisaged timeframe and could result in further fragmentation and slowing down the negotiations.

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*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.*