

EPF's response to the European Commission's call for feedback on the European Health Data Space

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The European Patients' Forum (EPF) welcomes the ambition to establish an overarching framework for the exchange and sharing of health data. Appropriate use of health data can improve health systems' sustainability, increase the quality, safety and patient-centredness of healthcare, and transform care into a more participatory process.

The success of the European Health Data Space (EHDS) lies in its ability to reach out to patients and citizens, to be shaped with them, to be accepted by them and to respond to their needs. This is a unique opportunity for EPF and its members to play an enabling role in data quality and trust.

EPF therefore calls for a regulation on the European Health Data Space shaped with and for patients:

1. Patients must be in control of their electronic health data

Mandating a common MyHealth@EU data format in which patients receive their data will help patients manage their care between providers and their self-management, and support patients' use of their data to improve care and outcomes. This is needed for daily care, primary data quality and patients' trust, not only for travel. A standardised data format will also enable patient organisations to scale up education to empower patients on how to best make use of their data. In the context of secondary use, national health data access bodies should inform patients about who has had access to their data, on what basis and for what purpose, in accordance with national law. Patients must also be fully informed of their rights, the consequences and potential consequences of sharing and exchanging health data.

2. Safeguards should be in place for the re-use of electronic health data

Patients are generally willing to share their data for research, policy and public services, particularly if they feel that there is a public benefit in doing so and if they are able to control and monitor access to their data. However, they are generally less inclined to share for the purposes of vaguely defined innovation, especially when private companies are involved.

In this sense, the common European purposes for re-use, as defined in Article 34, are too broad and should be clearly defined by focusing on benefits for patients and society. There should also be transparent and proportionate fines for unwanted use and sharing of patient data. Without these elements, it would be difficult to build trust, which would ultimately impact the acceptance of the EHDS.

3. Patient organisations should be part of the governance of the EHDS

Patient representatives should have a clear role in the governance of the EHDS Board, not only through ad hoc participation in some meetings. The unique expertise that patients can bring is fundamental to ensuring effective implementation of the EHDS. Patient representation is also critical to ensuring trust. Similarly, the common tasks of national digital health authorities and health data access bodies should include the representation of patient organisations in their governance and decision-making. This is already the case in the French health data access body, the Health Data Hub, where the vice-president is the president of the national platform of patient and health system user organisations.

4. The functioning of the EHDS with pre-existing mechanisms should be clarified

The risk of fragmentation of the application of the EHDS at national level is a concern in a cross-border context and may hamper patients' rights. It will be essential to ensure alignment between the new and existing regulations, in particular, the General Data Protection Regulation.

Ultimately, patients need reliable, ethical, safe and inclusive data sharing infrastructure and governance for better care and innovation for the benefit of patients' health and citizens in general. The implementation of the EHDS should also be accompanied by EU and national funding to address underlying issues of health literacy, access to digital means, and digital skills, among others.

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