

Reaction to European Parliament's adoption of the EHDS report

13 December 2023

The European Patients' Forum (EPF) welcomes the adoption of the report on the European Health Data Space at today's plenary session.

We believe that the Parliament's report improves the Commission's proposal to empower European patients and citizens to access and control their personal healthcare data in an electronic format and facilitate secure sharing for research and altruistic purposes.

We particularly welcome the changes to Article 33 which include an opt-out mechanism for sharing health data for secondary use. We suggest that health data access bodies provide an accessible and easily understandable mechanism for natural persons to express their objection against all or part of their personal electronic health data being processed for some or all purposes for secondary use listed in Article 34, with the exception of public health emergencies and regulatory purposes.

We also very much welcome the increased focus on digital health literacy of patients and citizens. In this regard, we especially welcome calls on Member States to create targeted national digital literacy and social inclusion programmes, and patient-centric guidance on the access to and use of electronic health records and the exercise of consent mechanisms. We would like to recall the importance of leveraging patient organisations' reach and expertise and of involving them in the development of these programmes.

While we welcome the increased importance given to cooperation with stakeholders, we regret that the report does not give patients and patient representatives a clear role in the governance and decision-making structures of the EHDS board, national digital health authorities, and health data access bodies. The concrete and meaningful involvement of patients in the governance of the EHDS is essential to ensure transparency, build a high level of trust, and make sure that patient's needs are fully taken into consideration. Should the co-legislators

agree on establishing a stakeholder advisory board, as foreseen by Parliament's report, a balanced composition and meaningful participation need to be ensured.

The provisions on judicial remedies of patients and citizens whose rights have been infringed are a very welcome addition to the text of the Regulation, as well as the prohibition of automated individual decision-making and re-identification of natural persons.

Moreover, we also welcome the provisions on uptake of real-world data and real-world evidence, application of digital health ethical principles, prevention of conflict of interest in EHDS governance and decision-making structures, and penalties for any infringement of the Regulation.

As this plenary vote marks the beginning of the trialogues, we urge the co-legislators to endorse these important provisions in the final text and to reach an agreement that will pave the way for a patient-centric EHDS.

ABOUT EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease-areas. Our 79 members include disease-specific patient groups active at EU level and national coalitions of patients representing 21 countries and an estimated 150 million patients across Europe.

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