

EPF's position on establishing an opt-out system for the secondary use of health data

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The European Patients' Forum (EPF) welcomes and supports the proposal to establish a European Health Data Space (EHDS) and the objectives put forward by the Commission in relation to the primary and secondary use of data. We believe that a harmonised and well-functioning framework for the exchange and reuse of health data can support healthcare delivery and facilitate research, innovation, and policy making, with the objective of bringing tangible benefits to patients and society.

EPF is closely following the ongoing legislative discussions and would like to comment on the provisions regarding consent in the context of the secondary use of data that are currently being debated in the European Parliament and the Council of the EU.

We believe that a consent framework should be shaped keeping into consideration the objective described in Article 1(2)(a) of the proposed regulation, namely, to strengthen the rights of individuals regarding the availability and control of their electronic health data. We therefore advise the co-legislators to agree on an **EU-wide opt-out** mechanism that would allow patients and citizens to actively object to the secondary use of their data.

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.

EHDS should aim to facilitate a more coherent approach to reuse of health data by establishing coherent and **EU-wide rules** and mechanisms, including the opt-out system. We, therefore, advise against a national opt-out system which could lead to a lack of harmonisation in the application and interpretation of the proposed mechanism, especially in view of the already existing rules, structures, and processes which differ greatly across the EU Member States. A national patchwork would also complicate patients' access to, exercise, and understanding of their rights, leading to inequalities, while also potentially affecting the access and cross-border sharing of data.

We are aware of concerns that a consent mechanism could lead to less representative data. However, denying patients and citizens the right to control access to their data might lead to even worse consequences such as diminished trust in healthcare professionals and governments, and healthcare avoidance. Allowing patients to decide if they want to object to data processing for specific purposes, combined with information to patients on what this processing means, can on the contrary boost their trust

in healthcare systems, and their willingness to share the data. A high level of awareness among patients is set to lead to higher engagement and empowerment.

We have heard concerns that patients may opt-out “by default” due to low levels of (digital) health literacy among the EU population. However, we would like to stress that addressing health literacy is essential not only in the context of the EHDS but should be seen as the crucial prerequisite for all informed decisions about health. Lack of trust and of digital health literacy is precisely why an opt-out mechanism is needed. We call on EU institutions and Member States to provide sufficient funding for initiatives aimed at **improving (digital) health literacy** for both patients and healthcare professionals. An easily accessible, understandable, and actionable consent mechanism could therefore become an important instrument for shared decision-making and patient empowerment which, together with transparent information campaigns on the benefits and possible risks of the secondary use of health data, could improve digital health literacy among patients and citizens.

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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