

Stakeholder coalition calls for legislative refinement of the EHDS

Pulmonary Hypertension Association Europe, as part of a large multi-stakeholder group, representing the entire spectrum of the healthcare ecosystem and consisting of 33 European patient organisations, medical associations, health research infrastructures and health industry associations, have issued a joint statement to alarm bells about the significant legislative shortcomings and uncertainties in the proposed Regulation for a European Health Data Space (EHDS).

The multi-stakeholder group is issuing this joint statement in advance of the plenary vote in the European Parliament scheduled on 13 December 2023. In addition, the group is raising its concerns ahead of a COREPER meeting on 6 December 2023 in the hope that Member States will make much-needed changes to the legislative text before reaching general approach.

There remain serious legislative problems with the EHDS, which is now being fast-tracked through both the European Parliament and Council. Stakeholders are concerned that if these problems are not addressed, then the legislation could generate more risks than benefits. The significant degree of legal ambiguity and uncertainty could pose risks for the protection of patient data as well as health research collaborations. As it stands, the potential effects of some of the key provisions in the EHDS are the opposite of what the original policy objectives were aiming for.

Specifically, the key concerns are:

The EHDS must set forth clear and coherent definitions – The lack of clarity about the scope of key definitions (e.g. ‘electronic health data’, ‘data holder’) would lead to implementation problems from the outset.

The EHDS should clarify its interaction with other legal frameworks – The EHDS could generate legal uncertainty as it leaves considerable room for interpretation about its interaction with other legal frameworks (such as the GDPR, Data Governance Act, Data Act, Database Directive, AI Act, Cyber Resilience Act, Medical Devices Regulation, In Vitro Diagnostic Medical Devices Regulation, Clinical Trials Regulation).

The EHDS should specify the scope of electronic health data categories for secondary use – There is a need for clarity about the scope of electronic health data that data holders will be required to make available for secondary use (e.g. public health, health research) purposes under the EHDS. It would be also important that such data are scientifically validated, and that it is clarified how existing safeguards aimed at protecting the scientific or technological potential of researchers and innovators would apply in the new framework.

The EHDS should avoid excessive data localisation and international health data transfer requirements – The introduction of legal requirements without any impact assessment poses significant risks for vital international health collaborations, or in the face of a future pandemic. If Member States are allowed to set their own conditions, then this would lead to fragmentation and different degrees of legal protection for data subjects across the EU.

Keep stakeholders involved in the EHDS governance – It would be critical that those who actually work with patients and fight diseases are able to have a meaningful role in the governance of the EHDS. The active engagement of a broad range of stakeholders would facilitate responsible, trustworthy and impactful implementation of the EHDS. The co-legislative procedure has highlighted the complexity of creating the EHDS, and the risks that it may generate if experts are not involved properly.