



Joint Public Statement on the need for better safeguards in the European Health Data Space

Amsterdam, 26 February 2024

Civil society coalition urges EU Member States and the European Parliament to put the interests of patients and EU citizens at the heart of the European Health Data Space.

We, the undersigned civil society organisations and trade unions, working in the fields of consumer and digital rights, global health, access to medicine, and human rights, call upon the Belgian EU Council presidency and the European Parliament rapporteurs to uphold the fundamental rights of European patients and citizens in the trilogue negotiations on the Regulation for a European Health Data Space (EHDS).

While we welcome the intention of the EHDS to promote health data and patient record sharing within the frame of direct medical treatment of patients (primary use), it is essential to include strong and meaningful safeguards regarding the use of health data for secondary purposes, such as research and product development by companies, and policy-making by governments.

Although the EHDS aims to improve EU citizens' access to, and control over, personal electronic health data, it currently does the opposite: due to the absence of a consent requirement in the EHDS proposal, patients lose control over the sharing of their own medical data. An EHDS that obliges healthcare providers to share patient data without consent violates the principle of doctor-patient confidentiality and undermines the fundamental principles of privacy set out in the EU General Data Protection Regulation (GDPR).

Moreover, with the EHDS proposal, the EU is rolling out the red carpet for Big Tech companies such as Amazon, Google, and Microsoft, which are becoming increasingly active in the healthcare sector. The EHDS offers Big Tech an unprecedented opportunity to use EU citizens' health data – perhaps the most personal and sensitive form of data – to expand its already problematic monopolistic market power into the health sector. This does not align with the efforts of EU governments to counter the growing power of Big Tech, e.g. through the Digital Services Act and Digital Markets Act.

The undersigned organisations therefore urgently call upon EU negotiators to ensure the following points regarding the use of the patient data and digital health infrastructures are included in the final design of the EHDS:

- The right for patients across the EU to at least opt-out from the use of their health data for primary and secondary purposes.
- The requirement for companies to charge fair prices and ensure widespread accessibility of the products and services that were developed using EU citizens' health data, so that EU citizens and health systems actually benefit from the data they provide.
- The inclusion of the voice of EU citizens in the decisions on who is granted access to their health data and under what conditions. Health Data Access Bodies must be governed in a transparent, democratic, and independent manner. Industry representatives who may have an interest in accessing patient data for secondary use should not be allowed to partake in the governance of these data access bodies.
- Governments and market regulators must act against the growing monopolistic market positions of Big Tech companies. Governments and national health systems should invest in public and transparent digital health infrastructures.

Signatories

- Access to Medicines Ireland
- AIDS Action Europe
- Asociación por un Acceso Justo al Medicamento
- Centre for Research on Multinational Corporations (SOMO)
- Consilium Scientific
- Corporate Europe Observatory
- Defend Democracy
- Electronic Frontier Norway
- epicenter.works
- European Public Services Union (EPSU)
- Global Health Advocates
- Health Action International
- ICCL Enforce
- Open Future
- Patiëntenfederatie Nederland
- Pharmaceutical Accountability Foundation
- Wemos

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