



Freie Ärzteschaft



Innovationsverbund
Öffentliche Gesundheit

BUKO
Pharma-Kampagne



Brussels, 8 February 2024

We, the undersigned organisations and trade unions and organisations representing patients, medical professionals, persons with disabilities, consumer and digital rights, urge you to **uphold European patients' fundamental rights and agree on the right for opting out of the primary and, in particular, secondary use of medical records in the EHDS for all people in the EU.**

The European Parliament's report of 13 December 2023 rightly recognises that: *"A relationship of trust between patients, health professionals, healthcare providers and other holders of personal health data is a paramount element of the provision of health or social care or treatment"* and therefore patients must *"have a say in the processing of their health data for secondary use in the form of a right to opt-out of the processing of all or parts of their health data for secondary use."*¹

The EHDS claims to give individuals more control over their private information, but without a right to opt out in all Member States it does the exact opposite: it completely deprives them of that control. In the original proposal by the Commission, patients would have no say over the sharing and commercial exploitation of their data and would not even be informed about who receives it or what is done with it.

¹ Amendments adopted by the European Parliament on 13 December 2023 on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)).

As a result, the proposal overrides the long-established principle of doctor-patient confidentiality and blatantly undermines the most fundamental principles of privacy established by GDPR, namely that the collection and processing of health data requires the data subject's consent, with the exception of narrowly defined circumstances.

Instead of acknowledging and safeguarding the special protections afforded to our medical records by GDPR and the European Courts' highest jurisprudence, an EHDS without opt-out right in all Member States would legally compel physicians and hospitals to betray that confidentiality and share sensitive medical information for purposes unrelated to their patients' medical treatment.



The undersigned organisations therefore urge you to agree on the wording proposed by the European Parliament for Articles 33(5) and (5a).

Those provisions establish the crucial right for patients to opt out of the secondary use of their medical records in part or in full, and require patients' consent for the secondary use of health information that is impossible to anonymise.²

Such a right to opt out can only provide effective choice to patients, however, if they know about its existence and can use it in practice. The EHDS should therefore prescribe that patients be systematically and pro-actively presented with neutral and accessible information about their rights upon their visit to their health care provider.

If the European Health Data Space truly is about giving people control over their medical data and building trust in Europe's new digital health infrastructure, it must earn this trust first.

SIGNATURES

AIDS Action Europe (regional network),
Germany

AK EUROPA (Federal Chamber of Labour
Brussels Office), Austria

Berufsverband Deutscher Psychologinnen und
Psychologen e.V.

BUKO Pharma-Kampagne, Germany

European Digital Rights, EU

European Disability Forum, EU

European Public Service Union, EU

European Sex Workers' Rights Alliance, EU

Epicenter.works – for digital rights, Austria

Freie Ärzteschaft e.V. (Association of
Independent Doctors), Germany

Global Health Advocates, France

Health Action International, Netherlands

Innovationsverbund Öffentliche Gesundheit
(Public Health Innovation Alliance), Germany

medConfidential, UK

Mental Health Europe, EU

² Those particularly intimate types of health information include extracts from human genetic, genomic and proteomic data, such as genetic markers as well as data from biobanks and dedicated databases.