The European Health Data Space from a patient perspective

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On 3 May, the European Commission presented a proposal for a regulation setting up the **European Health Data Space** (EHDS) together with a Communication. This initiative aims to provide a common framework across the Member States for the sharing and exchange of health data to support healthcare delivery (i.e. primary use of data) and facilitate health research, policymaking, and legislation (i.e. secondary use of data).

The EHDS builds upon the possibilities and rights offered by the **General Data Protection Regulation** (GDPR), such as the rights of access and transmission of data. The proposal aims to strengthen these rights and safeguards while expanding the use of electronic health data, including in research and public health.

Key points relevant to patient organisations

- Patient and patient representatives are **not part of the governance of the European Health Data Space Board**.
- Patient and patient representatives may actively cooperate with the **digital health authority** and the **health data access body** set up by the Member States, but their participation in the governance is not mandatory and depends on national law.
- Measures to improve **patient health literacy** are fundamental to achieving an adequate acceptance of the EHDS at the patients' level.
- Researchers, companies and public institutions can **only access and process non-identifiable data**, as long as the permit is in line with the purposes set out in the regulation
- The re-use of health data is not subject to **individual patient consent**.
- Patients' rights **to check information on who has had access to their data, on what basis and for what purposes** in the context of secondary use of data is not satisfactory.

The primary use of data

The proposal covers the primary use of data in two main areas: **patients' rights** and **digital health services and products.**

The proposal foresees that **minimum categories of health data** will be integrated into the EHDS, such as patient summaries, electronic prescriptions or laboratory results. These data will be integrated in stages with transition periods of one or three years. The proposal provides for and enforces **several rights for patients** with regard to these categories of health data, such as:

- the right to **add data** for themselves;
- the right to **object** to the processing of health data;
- the right to **request rectification** of data;
- the right to **obtain information** on the healthcare professionals and providers who have accessed their electronic health data.

The supervisory authority, already established in the Member States, responsible for the processing of personal data, will monitor the application of these rights and issue fines in case of non-compliance.

Member States will also have to set up a **digital health authority** charged with implementing and enforcing the primary use of data. This authority may actively collaborate with patient representatives, but their participation in the governance is not mandatory and depends on national law.

With regard to **digital services and products**, the draft regulation contains provisions on the interoperability of certain health-related datasets and further outlines specific requirements for the Electronic Health Record systems, the software used to store and share health records. The proposal also reinforces cross-border infrastructures to support and facilitate electronic health data exchange between Member States, with mandatory participation in MyHealth@EU[1] by 2025.

Overall, the draft regulation supports the **uptake of digital health products and services** and **the integration of telehealth** through authorisation and interoperability schemes and the development of cross-border infrastructures.

However, for the EHDS to be well accepted by patients, underlying issues of **health literacy and access to digital means** must also be addressed. While the communication on the EHDS mentions funding under the EU4Health programme to help patients get their health data on their smartphones, measures to improve patient health literacy are conspicuous by their absence.

In addition, the absence of some key measures will impede the deployment of digital health in the EU. There is a need for a more **European approach and guidelines towards reimbursement and assessment of digital health**. A harmonised approach would ensure that all patients in Europe can have the same level of access to digital health services and products and would limit the risk of exacerbating already existing differences in the digitalisation of health and care systems. Similarly, the proposal does not provide for a **transparent, easily accessible and clear repository of digital health products**, which would both facilitate reimbursement decisions and increase transparency towards patients.

Last but not least, the proposal adopts a **one-size-fits-all approach** that does not mention the current different levels of digitalisation of health systems. Although this is a national competence, these differences and inequalities should be carefully considered in the deployment of the EHDS to avoid increasing disparity and exacerbating existing inequalities between Member States.

The secondary use of data

The EHDS aims to **facilitate the reuse of health data for research, innovation, policymaking and regulatory purposes**. The proposal defines a set of data types that can be reused for defined purposes, such as research and development and innovation activities. It also prohibits certain purposes, such as commercial advertising. Member States will have to set up a **health data access body** charged with granting access to these electronic health data for secondary use and ensuring that the data is made available by data providers for data users. As long as the request is in line with the purposes set out in the regulation, the data user can be public or private. In addition, researchers, industry or public institutions may only access **non-identifiable data.**

[1] Cross-border digital infrastructure for the exchange of health data to ensure continuity of care when travelling abroad in the EU.

Access to data is not subject to patient consent. Consent is only required for specific categories of data under national law. Many patients will agree to their data being used for research, policy and public services, particularly if they feel that there is a public benefit in doing so and if they are able to control and monitor access to their data. However, they are generally less inclined to share for the purposes of vaguely defined innovation, especially when third parties and private companies are involved. In this sense, the common European purposes for reuse, as defined in Article 60, are very broad and leave a substantial leeway for interpretation.

The proposal is also unsatisfactory as regards **patients' rights to check information on who has had access to their data, on what basis and for what purpose**. The competent bodies set up by the Member States are not obliged to provide individual information to each person. They only have to provide information concerning the conditions under which secondary use of electronic health data is made accessible, the technical and organisational measures taken to protect individuals' rights, and the results of the research project. In addition, Member States may regularly inform the public about the role and benefits of health data access bodies but they are not obliged to do so.

Once again, the EHDS takes a **one-size-fits-all approach** to the secondary use of data. The proposal does not take into account the 27 Member States with their own rules and context. Disparities and inequalities should be taken into consideration in the deployment of the EHDS.

In addition, the proposal contains very limited provisions on **data altruism in health** (i.e. people voluntarily donating their data for the public good). While the harmonisation of the definition between the EHDS and the Data Governance Act, which was the first to introduce this concept, is welcome, the proposal does not elaborate on the protocols and procedures for the practical exercise of this voluntary transfer of data.

Governance

One of the novelties of the EHDS is the creation of the **European Health Data Space Board**. It will be responsible, among other things, for adopting guidelines to ensure consistency in the application of the Regulation, for promoting collaboration between the competent bodies or for advising the Commission.

However, patients and **patient representatives are not part of the Board's governance** and may be invited to attend the Board's meetings, depending on the topics discussed and their degree of sensitivity. Concrete and meaningful involvement of patients in the governance of the EHDS is key to ensuring that patients' needs are fully taken into consideration and that patient safety is ensured at all levels.

Next steps

The **target date for the deployment of the EHDS is 2025**, both for primary and secondary use of data. The draft regulation will now be discussed by the EU co-legislators, the European Parliament and the Council of the EU. The discussions are expected to start in the second half of 2022. In the European Parliament, the file was already attributed to the Committee on Civil Liberties, Justice and Home Affairs (LIBE). The regulation will apply 12 months after it enters into force, with different transitional periods. In addition, the Commission may adopt implementing and delegated acts on the EHDS.

EPF will engage with its membership to explore patients' perspectives on key issues of the EHDS with the aim of developing a **position statement to engage with relevant stakeholders** throughout the legislative process.