CPME MEDECINS EUROPEENS EUROPEAN DOCTORS

EPF European Patients Forum

PATIENTS' LEAFLET

What is the European Health Data Space (EHDS)?

The EHDS is a new EU law which sets out, among other, how patients can access and manage certain health data and permissions electronically for their own care across the European Union. It also sets rules for how health data can be used for future public health research. Visit the Data Saves Lives EHDS toolkit for more information.

The practical implementation will always depend on electronic health record system vendors and national solutions, where some variation between countries can therefore be expected.

What patient data will be affected?

- Patient summaries[1]
- Electronic prescriptions
- Electronic dispensations
- Medical imaging studies
- Medical test results
- Discharge reports

These rights apply to data processed electronically. The EHDS Regulation creates no obligation to digitise paper documents.[2,3]

Example: Maarja, a 45-year-old woman from Estonia living with chronic obstructive pulmonary disease (COPD), visits a new pulmonologist after her symptoms worsen. Her patient summary gives the specialist an overview of her diagnosis, allergies, vaccinations, current medicines and previous treatments. The doctor orders blood and lung function tests, whose medical test results and related reports are recorded electronically, as well as a chest CT scan, with the medical images and imaging report stored in her health record. Following these examinations, Maarja is briefly admitted to hospital for treatment. When she leaves, her discharge report records the care she received, changes to her treatment and the follow-up required. Her pulmonologist issues an electronic prescription for a new inhaler, which Maarja collects from her local pharmacy. The resulting electronic dispensation confirms that the medicine has been supplied, completing a digital record of her care pathway.

How does the EHDS benefit patients?

Access your electronic health records anytime, anywhere

View your medical history, prescriptions, and test results online → there is the potential of reducing the need to repeat tests or explain your medical history again when seeing a new doctor. Patients will be able to see the information in their own language but should bear in mind that the automated translations might be incorrect. Always confirm with the doctor relevant key information

[1,2] European Commission, Frequently Asked Questions on the European Health Data Space, Question 'For patients'

[3] This refers explicitly to electronic health data. Data that is not in a digital form is not in the scope of the Regulation.

Better & safer care across the EU

Doctors can access essential medical information during emergencies → Helps prevent medication errors, ensures higher safety and continuity of care.

More control over your health data

You can decide who can see your data, and you can add notes, request corrections, and track who accessed your records → Reduces mistakes and errors and increases adherence to treatment and patient safety.

Supports health research & innovation

Anonymised and pseudonymised data can be used for research to develop better care → You can still opt-out if you do not want your data used for secondary use.

What are patients' rights?

How can I control my data?

Right to access your own data

You will be able to access your electronic health data through a secure health data access service. In some cases, the data will only become available after a healthcare professional has explained it to you.[4,5] The right to obtain a paper copy of the electronic health data will remain. It is also important to note that if personal health data has not been collected electronically prior to the application of the EHDS regulation, Member States may decide not to convert it into an electronic format.

Right to report inaccuracies

If you find incorrect information in your electronic health record, you can ask your healthcare provider to check and correct it. However, you cannot change the information yourself.[6,7]

Right to add information

You can add your own health information to your electronic health record, such as data from compatible health or wellness apps (including blood glucose, blood pressure, heart rate, physical activity or sleep data). However, the information you add will be marked as provided by you and kept separate from information added by healthcare professionals.[8]

Right to opt-out of primary use

If your country introduces this option through national law, you can choose to opt-out of sharing your health data for primary use [the provision of healthcare] on your national electronic health data access service. Your country will define the rules of this opt-out mechanism. Healthcare providers will continue to record your health information, but neither you nor your healthcare professionals will be able to access your electronic health data through the EHDS, except in very limited circumstances. The decision made by patients is reversible.

[4] EPF's analysis of the European Health Data Space Regulation
[5,6] European Commission, Frequently Asked Questions on the European Health Data Space, Question 'For patients'
[7,8] EPF's analysis of the European Health Data Space Regulation

Example: Maria, a 52-year-old woman from Portugal living with systemic lupus erythematosus (SLE), uses a certified health app that automatically shares relevant health information with her electronic health record. She can also add information herself, such as details about symptom flare-ups, through her health data access service. This patient-provided information is clearly labelled as separate from records entered by healthcare professionals. When Maria notices that her patient summary still lists a medicine, she no longer takes, she submits a request to have the information corrected. Her healthcare provider reviews the request and updates the record where appropriate. During a routine check-up, Maria's blood tests reveal that her condition has significantly worsened. To avoid unnecessary distress, the results are not immediately displayed in her health data access service. Instead, her rheumatologist first discusses the findings, their implications and the available treatment options with her. Once this consultation has taken place, the test results become available for Maria to access, download and share like any other priority category of electronic health data.

How can I decide who can access my data?

Right to restrict access to your own data

You can choose to restrict healthcare professionals from accessing all or some of your health data. You can change your decision at any time. In exceptional circumstances, authorised healthcare professionals may temporarily access your restricted data if necessary to provide safe care. [9, 10]

Right to manage your proxy authorisations

You can authorise another person to act on your behalf in managing your electronic health data. For example, you can allow your spouse, another trusted person, or a legal guardian to access your health records, download prescriptions or help manage your healthcare. It must be possible to submit authorisations online or on paper.[11]

Right to opt out of secondary use

You can choose not to have your identifiable health data used for other purposes, such as research, innovation or policymaking. This is a separate choice from restricting access to your data for healthcare. If you want to do both, you need to choose each option separately. This right does not apply to anonymised data that can no longer be linked to you. In certain situations of public interest, such as a pandemic, countries may still allow your data to be used. Visit the Data Saves Lives EHDS toolkit – page 13 – for more information.

Example: Mateusz, a 45-year-old man from Poland living with pulmonary arterial hypertension, decides to take control of how his electronic health data are used. Through his health data access service, he temporarily restricts access to some of his medical information on sensitive issues such as mental or sexual health. He also appoints his wife as his proxy, allowing her to securely access his health records and prescriptions whenever he needs help managing his care. In addition, Mateusz chooses to opt out of the secondary use of his health data, meaning his information will no longer be included in newly approved research or health policy projects.

[9,11] European Commission, Frequently Asked Questions on the European Health Data Space, Question 'For patients'

[10] EPF's analysis of the European Health Data Space Regulation

Some of Mateusz's health data are already stored in a research database in a pseudonymised way, i.e. without information that directly identifies him. The hospital does not have to identify these records just to apply his opt-out. However, if the Health Data Access Body can identify his records when preparing data for a new research project, they will be excluded. If the records cannot be linked back to him, they may still be used, but researchers are not allowed to try to identify him.

How will patients be represented & How will patients' rights be protected?

European Health Data Space (EHDS) Board

The European Health Data Space (EHDS) Board will be the main body through which the European Commission and Member States cooperate on implementing the EHDS and exchange information[12]. At this stage, however, patient organisations are not permanent members of the EHDS Board. The Board may invite external experts where appropriate.

EHDS Stakeholder Forum

The EHDS Stakeholder Forum complements the work of the EHDS Board by bringing together a wider range of stakeholders, including patient organisations. It provides a platform to exchange information, share experiences and promote cooperation between the EHDS Board and relevant stakeholders. [13-14]

The EHDS Regulation foresees cooperation between **Health Data Access Bodies (HDABs)**, **Digital Health Authorities (DHAs)** and **patient organisations.**[15]

It is important to distinguish between being represented and being able to participate meaningfully. Meaningful involvement requires not only formally recognised rights, but also the political willingness to enable participation through active outreach, accessible information and sufficient support.

In what ways does this change the way patients consult with doctors?

The EHDS supports – but does not replace – the conversation with your healthcare professional.
Your electronic health record can help your healthcare professional understand your history and treatment. However, information may sometimes be incomplete, outdated, restricted or incorrectly translated. You and your healthcare professional should therefore continue to discuss relevant information and make treatment decisions together.

The European Health Data Space is coming! We invite you to get to know the initiative and encourage you to contact your national competent authorities for details on how it will work in your country. Information will be updated in line with national implementation and further regulation.

For more information:
www.eu-patient.eu
www.cpme.eu

[12, 13] European Commission, Frequently Asked Questions on the European Health Data Space, Question 'For patients'
[14] EPF's analysis of the European Health Data Space Regulation
[15] European Health Data Space Regulation