



FACTSHEET

A European Health Data Space

Why does health data matter?

Everything related to our health, such as the latest ailments we had, our medical prescriptions or our blood pressure says something about the state of our bodies and minds. Medical and health records provide very useful information for doctors who diagnose us and can see what other doctors have prescribed, for governments looking into public health problems, or for researchers working to develop new treatments. Health records also help consumers understand their health conditions and the treatments they require. At the same time, health data is extremely sensitive and of enormous value to economic operators such as pharma companies and advertisers who want to sell us products or services.

How can this data be accessed?

At the moment, depending on where you live, health data gets treated differently. Some gets stored electronically on local databases, such as a hospital database, but might not get placed in a national registry. In other cases, the data is not available in a digital format. Data is also not available in different languages or across borders, meaning that medical imaging or exam results are not available if you spend time in another country, whether for work or holidays. This is where creating a health data space can be really useful, with strict rules about who can access data and how.

What is the European Health Data Space?

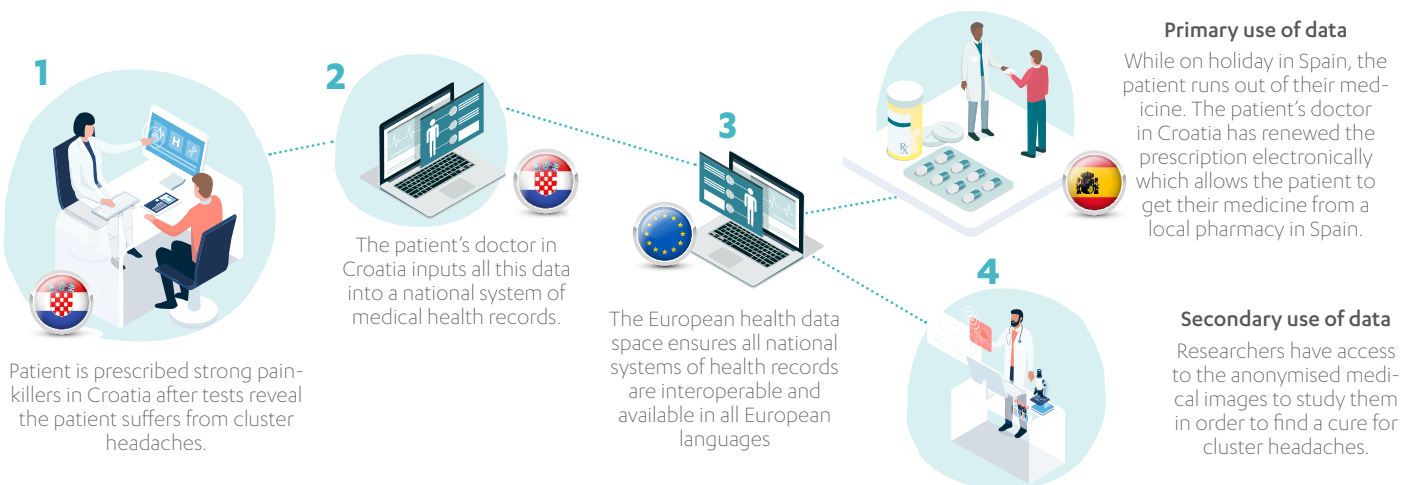
The European Commission proposed an EU health data space regulation in May 2022. National electronic health records would become interoperable and be accessible to healthcare professionals across countries. Consumers and patients would also have access to their data.

For example, it would allow a hospital to access data about an unconscious patient's allergies and the medication they are on when they are brought in.

Patients' health data would also be available for research, innovation, policy-making and regulatory activities. For example, a researcher would be able to access medical images to help develop a cure for a disease.

What the health data space would look like in practice

One of the cornerstones of the European Health Data Space is the distinction between primary and secondary use of health data. **Primary use** of data means data used to support healthcare delivery to the patient, while **secondary use** refers to uses such as scientific research, policy-making, regulatory purposes or public health monitoring.





What is the problem with the EU's Health Data Space proposal?

The objectives of the EHDS are worthy but the Commission's proposal is deeply flawed. It leaves many important questions unanswered and puts the protection of personal data and privacy at risk.

Excessively broad definition of health data

The definition of 'health data' proposed is immensely broad and includes all "data referring to determinants of health". Consequently, this definition opens up the scope of what can be collected to all kinds of socio-demographic categories of data such as nutrition, income, housing and energy consumption. This scope is too large and must be restricted. The definition must be fully in line with the General Data Protection Regulation, in other words health data relates to the physical or mental health of a natural person which reveals information about his or her health status.

Opt-out system for primary use

The proposal requires that data processed in electronic format is made available to healthcare professionals across the EU who are treating the patient. Individuals can restrict access to their data, but this requires effort from them and undermines their control over their own data in the first instance. This approach is inconsistent with a fundamental principle of EU data protection law, which is that individuals should have the authority to decide themselves when and within what limits their personal information is shared with others. This is even more important given the sensitivity of health data.

Such a system also heightens the risk from a data breach, with the potential misuse of sensitive personal data ranging from discrimination to exploitation of individuals.

Insufficient safeguards regarding secondary use

The proposal does not grant consumers the possibility to even opt out from having their data used for secondary purposes. It foresees that any person or entity can request access to health datasets that are pseudonymised or anonymised as long as there is a health or social reason for doing so. However, the purposes foreseen in the proposal are very broad and encompass even business innovation activities, AI systems training and personalised healthcare provision. Highly sensitive data could easily be exploited for purely commercial purposes.

Moreover, there are no specific obligations to ensure the robustness of the anonymisation or pseudonymisation required for sharing the data sets. This is particularly troublesome as genetic data cannot be anonymised and can reveal one's state of health, ethnic origin and family lineage. Furthermore, the proposal does not fully prevent the secondary use of data for purposes such as advertising or marketing, which are highly problematic.

The inclusion of data generated by medical devices, such as a blood sugar meter implant, or wellness apps, which measure sleep quality for example, also raises concerns. The low reliability and accuracy of wellness apps on the one hand, and the extreme intrusiveness of using data gathered by medical devices which might be inside a person's body, make them poor candidates for inclusion in the European Health Data Space proposal.

BEUC RECOMMENDATIONS

The European health data space has undeniable benefits but it must not compromise the protection of consumers' fundamental rights to data protection and privacy.

1. The legislation must **narrow the definition** of what constitutes health data and follow the definition used in the GDPR.
2. Consumers should **give their explicit consent** before their personal electronic health data is made available for primary use.
3. Consumers should have the **right to opt out** from having their data used for secondary purposes.
4. Lawmakers should **delete provisions that would enable businesses to access potentially unlimited amounts of health data** for very broadly defined purposes and it should not be possible to bypass control by health data access authorities to obtain access to the data.
5. There should be minimum quality **requirements for the anonymisation and pseudonymisation of data for secondary use**.
6. **Prohibitions on certain secondary uses of data must be strengthened**, particularly to prevent any use for marketing and advertising purposes, while neither genetic data nor data from lifestyle and wellness apps and medical devices should be made available for secondary use.