EU Health Data Space: more efficient treatments and life-saving research

- Citizens will have access across the EU to an electronic health record containing prescriptions, imagery and lab tests
- Anonymised health data to be shared for research e.g. into rare diseases
- Strong privacy safeguards governing how and for what purpose sensitive data are shared

MEPs approved the creation of a European Health Data Space, improving citizens’ access to their personal health data and boosting secure sharing in the public interest.

On Wednesday, MEPs voted with 445 in favour and 142 against (39 abstentions) to approve the inter-institutional agreement on establishing a European Health Data Space. It will empower patients to access their health data in an electronic format, including from a different member state to the one in which they live, and allow health professionals to consult their patients’ files with their consent (so-called primary use), also from other EU countries. These electronic health records (EHR) would include patient summaries, electronic prescriptions, medical imagery and laboratory results.

The law will make it possible to transfer health data safely to health professionals in other EU countries (based on MyHealth@EU infrastructure), for example when citizens move to another state. It will be possible to download the health record free of charge.

Data-sharing for the common good with safeguards

Additionally, the Health Data Space would unleash the research potential of health data in an
anonymised or pseudonymised format. Data including health records, clinical trials, pathogens, health claims and reimbursements, genetic data, public health registry information, wellness data and information on healthcare resources, expenditure and financing, could be processed for public interest purposes, including research, statistics and policy-making (so-called secondary use). Data could, for example, be used to find treatments for rare diseases, where small datasets and fragmentation currently prevent advances in treatments.

Secondary use will not be allowed for commercial purposes including advertising, assessing insurance requests or lending conditions or making job market decisions. Access decisions will be made by national data access bodies.

Robust privacy safeguards

The law ensures people will have a say in how their data are used and accessed. Patients will be able to refuse their health data being accessed by practitioners (except where this is necessary for protecting the vital interests of the data subject or another person) or processed for research purposes, apart from certain public-interest, policy-making or statistical purposes. Patients will also have to be informed each time their data are accessed, and will have the right to request corrections to incorrect data.

Quotes

Tomislav Sokol (EPP, Croatia), Environment Committee co-rapporteur, said: "The Health Data Space can help us to leverage the data we have in a safe and secure manner, giving vital research into new treatments a major boost. It will prevent gaps in treatment by making sure health professional can access their patients’ records across borders. At the same time, opt-outs will ensure that patients have a say, and that the system is trustworthy. It will be a major step forward for digital healthcare in the EU."

Annalisa Tardino (ID, Italy), Civil Liberties Committee co-rapporteur, said: “The Health Data Space will boost everyone’s access to healthcare. In future, doctors can be authorised to access their patients’ health records and laboratory results in other regions, or even other EU member states, saving money, resources and providing better cures. We also secured opt-outs to ensure that patients have a say in how their data are used. Although we would have preferred even stronger measures, we were able to find a position that can be accepted by a majority."

Next steps

The provisional agreement still needs to be formally approved by the Council. Once published in
the EU’s Official Journal, it will enter into force twenty days later. It will be applied two years after, with certain exceptions, including primary and secondary use of data categories, which will apply four to six years later, depending on the category.

By adopting the law, Parliament is responding to the demands of citizens put forward in the conclusions of the Conference of the Future of Europe. These include proposal 8(1), which explicitly recommended the creation of a health data space to facilitate exchanges, and proposals 35(7) and 35(8) on data and artificial intelligence.

Further information
Agreed text
Procedure file
EP Research Service briefing
Committee on the Environment, Public Health and Food Safety
Committee on Civil Liberties, Justice and Home Affairs

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