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European Health Data Space: Council and Parliament strike deal

The Council of the EU and the European Parliament have reached a provisional agreement on a new law making it easier to **exchange and access health data** at EU level. The agreement will now need to be endorsed by both the Council and the Parliament.

The proposed regulation for a **European Health Data Space (EHDS)** aims to improve individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes. It provides for a **health-specific data environment** that will help foster a single market for digital health services and products.

Currently, **cross-border access to health data varies** across the EU. The new rules aim to make it possible for a Spanish tourist to pick up a prescription in a German pharmacy, or for doctors to access the health information of a Belgian patient undergoing treatment in Italy.

After months of hard work and dedication, we have a deal that will strongly support patient care and scientific research in the EU. The new law agreed on today will allow patients to access their health data wherever they are in the EU, while also providing scientific research for important reasons of public interest with a wealth of secure data that will greatly benefit the development of health policies.

— Frank Vandenbroucke, Belgian Deputy Prime-Minister and Minister of Social Affairs and Public Health

Easier access to health data for individuals

Under the new rules, individuals will have **faster and easier access to electronic health data**, regardless of whether they are in their home country or another member state. They will also have **greater control over how that data is used**. EU countries will be required to set up a **digital health authority** to implement the new provisions.

Greater research potential

The EHDS will also provide researchers and policy-makers with access to specific kinds of **secure health data**, enabling them to tap into the vast potential provided by the EU's health data to inform scientific research in the public interest.

Ensuring interoperability

Currently, the level of digitalisation of health data in the EU varies from one member state to another, making it more difficult to share data across member-state borders. The proposed regulation requires all electronic health record (EHR) systems to comply with the specifications of the **European electronic health record exchange format**, ensuring that they are interoperable at EU level.

Key elements of the provisional agreement

The provisional agreement reached today between the Council and the Parliament amends the Commission's original proposal in a number of key areas, including:

- **opt-out:** member states can allow patients to opt-out on the use of their health data being accessed, whether by a healthcare professional (primary use) or for further use (secondary use, always under strict conditions), except for purposes of public interest, policy making, statistics and research purposes in the public interest
- **restricted information:** if patients choose to restrict information, healthcare professionals will only be able to access restricted health data in situations of vital interest
- **sensitive data:** member states may put in place stricter measures governing access to certain kinds of sensitive data, such as genetic data, for research purposes
- **trusted data holders:** in order to reduce the administrative burden, member states may establish trusted data holders that can securely process requests for access to health data
- **clinically significant findings:** if researchers inform health data access bodies (HDABs) about findings that may impact the health of a patient whose data was used in the scientific research, the HDAB may inform the trusted data holder who has to inform the patient or the relevant treating health professional about these findings

Next steps

The provisional agreement will now have to be endorsed by the Council and the Parliament. It will then be formally adopted by both institutions after legal-linguistic revision. The regulation will enter into force 20 days after publication in the EU's Official Journal.

Background

On 3 May 2022 the European Commission published a proposal for a regulation creating a European Health Data Space (EHDS). The proposal is the first of nine European sector- and domain-specific data spaces set out by the Commission in its 2020 communication, 'A European strategy for data'. The Council agreed on its mandate for negotiations on 6 December 2023.

The aim of the EHDS is to make it easier to access and exchange health data across borders, both to support healthcare delivery ('primary use of data') and inform health research and policy-making (re-use of data, also referred to as 'secondary use of data'). It is considered a key pillar of the European Health Union.

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