

(English version)

Question for written answer E-004761/25
to the Commission
Gerald Hauser (P/E)
(2 December 2025)

Subject: Personal health data

Under the General Data Protection Regulation (GDPR), the processing of personal health data is strictly prohibited unless the data subjects have expressly consented to the processing of their personal data for one or more specified purposes. In Austria, from 1 January 2026, all doctors will be required to digitally transfer all personal health data, including the ICD-10 code, into the country's electronic health record system (ELGA). The Austrian Ministry of Health has mandated that every patient treated or cared for in the Austrian health system must participate in ELGA, although this participation can be revoked at any time. The German Ministry of Health states that patients in Germany are entitled to refuse to be included in the electronic patient record in Germany if they wish their data and diagnoses to remain secret. Nevertheless, press articles have claimed that not all patients in the EU may prevent their health data from being forwarded.

1. Do patients in the EU have the right to prohibit the doctors treating them from forwarding their health data, including diagnoses?
2. Has the right of patients in the EU to opt out of the processing and transfer of their health data been revoked or is it to be revoked in the near future?
3. What exactly happens to the health data collected in all EU Member States which is subsequently transferred to the EU's European Health Data Space (EHDS)?

Submitted: 2.12.2025

Answer given by Mr Várhelyi on behalf of the European Commission
(27 February 2026)

Under Regulation (EU) 2016/679 (GDPR) ⁽¹⁾ personal health data can be lawfully processed using any of the legal bases in its Article 6 combined with any of the exceptions in its Article 9.

Article 9(2)(h) provides an exception for processing that is 'necessary for [...] medical diagnosis, the provision of health [...] care or treatment or the management of health [...] systems and services on the basis of Union or Member State law' and subject to professional secrecy or an obligation to secrecy ⁽²⁾.

Exchanges of such data in the Austrian electronic health record system (ELGA) or the German electronic patient file are based on such Member State law.

National law regulates the registration of health data in country-wide electronic health record systems, including the rights of patients to opt out from the use of such systems.

On the other hand, the relevant provisions of Regulation (EU) 2025/327 on the European Health Data Space (EHDS Regulation) ⁽³⁾, once applicable, will enable the cross-border exchange of health data for the provision of medical treatment to a patient in another Member State (primary use).

Such exchanges will happen between the healthcare providers involved, via the respective national contact points and the MyHealth@EU infrastructure.

The EHDS Regulation contains rules on restricting access to data and opting out in this context, including an option for Member States to provide for an opt-out.

The EHDS Regulation also enables the re-use of certain categories of health data for research and certain other purposes. Such re-use will only happen on pseudonymised or anonymised data, and with strict safeguards, including a possibility to opt out, set out in Chapter IV of the EHDS Regulation.

⁽¹⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, *OJ L 119*, 4.5.2016, pp. 1-88, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>.

⁽²⁾ Article 9(3) of the General Data Protection Regulation.

⁽³⁾ Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, *OJ L*, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.