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Answer given by Mr Várhelyi
on behalf of the European Commission
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The European Health Data Space (EHDS)[1] Regulation establishes provisions for strengthening the single market of electronic health record (EHR) systems, reducing costs and barriers to entry. By harmonising rules for EHR systems, the compliance costs get lower for new entrants, including small and medium-sized enterprises. For example, the Regulation lays down a self-certification procedure for EHR systems limiting certification costs and administrative burdens for EHR systems manufacturers of all sizes, including small and medium-sized enterprises.

Regarding use EU citizens' health data by entities from third countries, the EHDS Regulation sets out a mechanism[2] of reciprocal access that will serve to assess the rules in third countries to ensure that only entities from third countries recognised as providing similar rules will be able to apply for access. Transfers of personal data to third countries can only take place subject to the conditions and limitations set out in Chapter V of the General Data Protection Regulation (GDPR)[3], notably the need to ensure a level of protection in the third country that is essentially equivalent to the one guaranteed within the EU[4].

When it comes to risks of digital exclusion among older populations, the EHDS promotes inclusive design usable for all, including older adults, enabling them to exercise their rights under the Regulation.

[1] 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*.
[2] See Articles 75(5) and 91 EHDS Regulation.
[3] 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 (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.
[4] See also recitals 35 and 81 EHDS Regulation.