

EN

E-003022/2026

Answer given by Mr Várhelyi
on behalf of the European Commission
(24.9.2026)

Under Article 71 of Regulation (EU) 2025/327 on the European Health Data Space, (EHDS)¹, Member States must provide ‘accessible and easily understandable’ mechanisms for natural persons to exercise their right to opt out from having their personal electronic health data being made available for secondary use. Member States may provide for exceptions to the right to opt out under limited circumstances restricted to cases where data access is requested by public bodies for critical public interest (e.g., health threats) and rigorous justification is required. These exceptions must in particular be necessary and proportionate, maintaining all safeguards of Chapter IV of the EHDS Regulation like re-identification prohibitions.

The Commission has provided EU-wide cost estimates in the EHDS impact assessment accompanying its proposal². While no estimate specific to Poland is available, implementation costs are expected to broadly scale with population, with some economies of scale (i.e. degressive costs). EU funding may support implementation through relevant Union programmes, such as the EU4Health programme, subject to their conditions.

Pursuant to Better Regulation guidelines³, ex-post evaluation requires data on the application of the legislation over a period of at least three to four years, as results and impacts take time to materialise. Given the application timelines of the EHDS, an overall review is scheduled for 2035, and a targeted review, including on the opt out for secondary use mechanism, for 2033, in accordance with Article 102 of the EHDS Regulation.

¹ <https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng>.

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0131>.

³ https://commission.europa.eu/law/law-making-process/better-regulation/better-regulation-guidelines-and-toolbox_en.