

EHDS regulation will provide researchers with access to large-scale health data for scientific purposes

On 3 May 2022, the European Commission (EC) published its proposal for the European Health Data Space (EHDS) (1). The EHDS proposal was crafted in the aftermath of the COVID-19 pandemic (2–4). EHDS is the only project of its kind in the world to date (2,5). The aim is to make the EU a common Health Data Space. EHDS regulation in European Union Member States (EU-MS) is already in effect since 26 March 2025. According to the EC, trust is a fundamental enabler in the success of EHDS (1,6). EHDS is an ecosystem of national health data spaces which can interact through EU level platforms (7).

EHDS will provide patients with fast and free access over their own electronic health data, easy sharing of health data with health professionals (including across borders), more control over their own electronic health data (with a possibility to add personal health information), the ability to restrict access to specific parts of their record or to specific persons, view who accessed their data, ask for correc-

tions if errors are found and the right to view health data in a standard European format. In addition, patients will have security and privacy protections by default and opt-out rights from secondary use of their own electronic health data. Many of these are already real and live in Finland.

Importantly, researchers will get access to large-scale health data for scientific purposes, a clear and structured system to discover what data are available, where data are located and its quality, and more cost-efficient access to high-quality health data. These data will be available in a European Electronic Health Record exchange format (8).

One of EHDS central objectives is to enhance patient control over health data (2,9). EHDS partially builds and expands on the rights and obligations set out in the General Data Protection Regulation (GDPR) (10). EHDS seeks to create a legal obligation on data holders (such as pharmacies) to share electronic health data for secondary purposes (4).

EHDS distinguishes between two uses of

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health data: primary use and secondary use (1,11). To ensure the functioning of these two pillars, rules, common standards and practices, infrastructure, and governance framework are prescribed. Quality of data that flows into EHDS will determine the value of the insights generated and health solutions developed through its secondary use (5).

Pharmacies and EHDS

Pharmacies are expected to play a crucial role in EHDS, as more and more patients are expected to ask their community pharmacies for advice on interpreting their health data (3). Furthermore, pharmacies are pivotal in the exchange of and access to different types of electronic health data such as electronic prescriptions. Under EHDS regulation, pharmacies are data holders, since a pharmacy is an entity within healthcare (Directive 2011/24/EU). The inclusion of hospital pharmacies in EHDS is vital for the comprehensive digitalization of healthcare data. In addition, EHDS regulation explicitly includes online pharmacies, recognizing that online pharmacies must be allowed to take part in the EHDS infrastructure.

Pharmacies must have access to electronic prescriptions issued in other EU-MS via the EHDS's MyHealth@EU infrastructure, and pharmacies must accept these electronic prescriptions for medicine dispensations. When medicine has been dispensed based on an electronic prescription issued in other EU-MS, the pharmacy must inform via MyHealth@EU infrastructure these medicine dispensations to the national contact point of the EU-MS in which the electronic prescription was issued.

EHDS implementation and adoption in Finland

The national implementation of EHDS regulation in Finland requires amendments to leg-

islation (12,13). The Ministry of Social Affairs and Health (MSAH) is currently preparing two government proposals related to the regulation that are scheduled to be submitted to Parliament in 2025 and 2026. In addition to the implementation of EHDS regulation, the MSAH is working on a legislative project to amend the Act on the Secondary Use of Health and Social Data.

EHDS is a new and currently already mandatory regulation in EU-MS who have started its implementation and adoption efforts. In Finland, a set objective is that the central EHDS regulation requirements will be implemented and adopted in a cost-effective fashion by utilizing already extant nationwide data systems, such as Kanta Services (Kanta-palvelut).

However, EHDS will bring changes to Kanta Services of Finland. For example, EHDS regulation has set rights for persons or their representatives to add data and information into their electronic patient records, but these persons cannot directly change electronic health information recorded by healthcare professionals. Adding information into the electronic patient records will be realized via MyKanta (OmaKanta) of Kanta Services in due time. In addition, the EHDS regulation and its appropriate transitional provisions will also change the current set of Kanta Services: the nationwide Kanta Personal Health Record (Omatietovaranto) service will be removed from Kanta Services as it is a duplicate service that already exists in EHDS.

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Tiivistelmä

EHDS-asetus tarjoaa tutkijoille pääsyn laajamittaisiin terveystietoihin tieteellisiä tarkoituksia varten

Euroopan Unionin komission asetus eurooppalaiseksi terveystietoalueeksi (European Health Data Space, EHDS) tuli voimaan 26.3.2025. Parhaillaan Suomessa muutetaan kansallista lainsäädäntöä vastaamaan pakottavan EHDS-asetuksen vaatimuksia. Tavoitteena on mahdollisimman pitkälle säilyttää nykytila ja hyödyntää jo tehtyjä toteutuksia (kuten Kanta-palvelut). EHDS-asetuksella vahvistetaan yhteiset säännöt ja mekanismit terveystietojen ensisijaista ja toissijaista käyttöä varten, perustetaan rajat ylittävät käytön infrastruktuurit koko unionissa sekä kansallisen ja unionin tason hallinto- ja koordinoitumekanismit.

OmaKanta toimisi EHDS-asetuksen mukaisena sähköisten terveystietojen käyttöpalveluna. Luonnollisilla henkilöillä tai heidän edustajillaan on oikeus lisätä tietoja sähköiseen potilaskertomukseen selvästi erottuvalla tavalla, eikä terveydenhuollon ammattihenkilöiden syöttämiä sähköisiä terveystietoja ja niihin liittyviä tietoja voi muuttaa suoraan. EHDS-asetuksen kanssa päällekkäiset Kanta-

palvelujen Omatietovaranto ja ammattilaisen käyttöliittymä sähköisten lääkemääräysten käsittelyyn ehdotetaan lakkautettavaksi. Apteekkien tietojärjestelmissä tulee pystyä käsittelemään eurooppalaisen vaihtoformaatin mukaisia lääkemääräysten ja lääketoitustusten tietoja.

Maaliskuussa 2027 komissio hyväksyy henkilökohtaisten sähköisten terveystietojen tekniset eritelmät ja muun muassa eurooppalaisen sähköisten terveystietojen vaihtoformaatin. Yhteen toimivuuden takaava vaihtoformaatti mahdollistaa unioninlaajuisten tietojen käytön myös tutkimustarkoituksiin.

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