

EHDS and secondary use of data – end of legal fragmentation?

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EHDS regulation – background and aims

[European strategy for data](#) (2020) – aim to create of Common European Data Spaces in a number of strategic fields: **health**, agriculture, manufacturing, energy, mobility, finance, public administration, skills, the European Open Science Cloud, and the green deal.

Together, data spaces shall form the single market for data.

EHDS regulation – background and aims

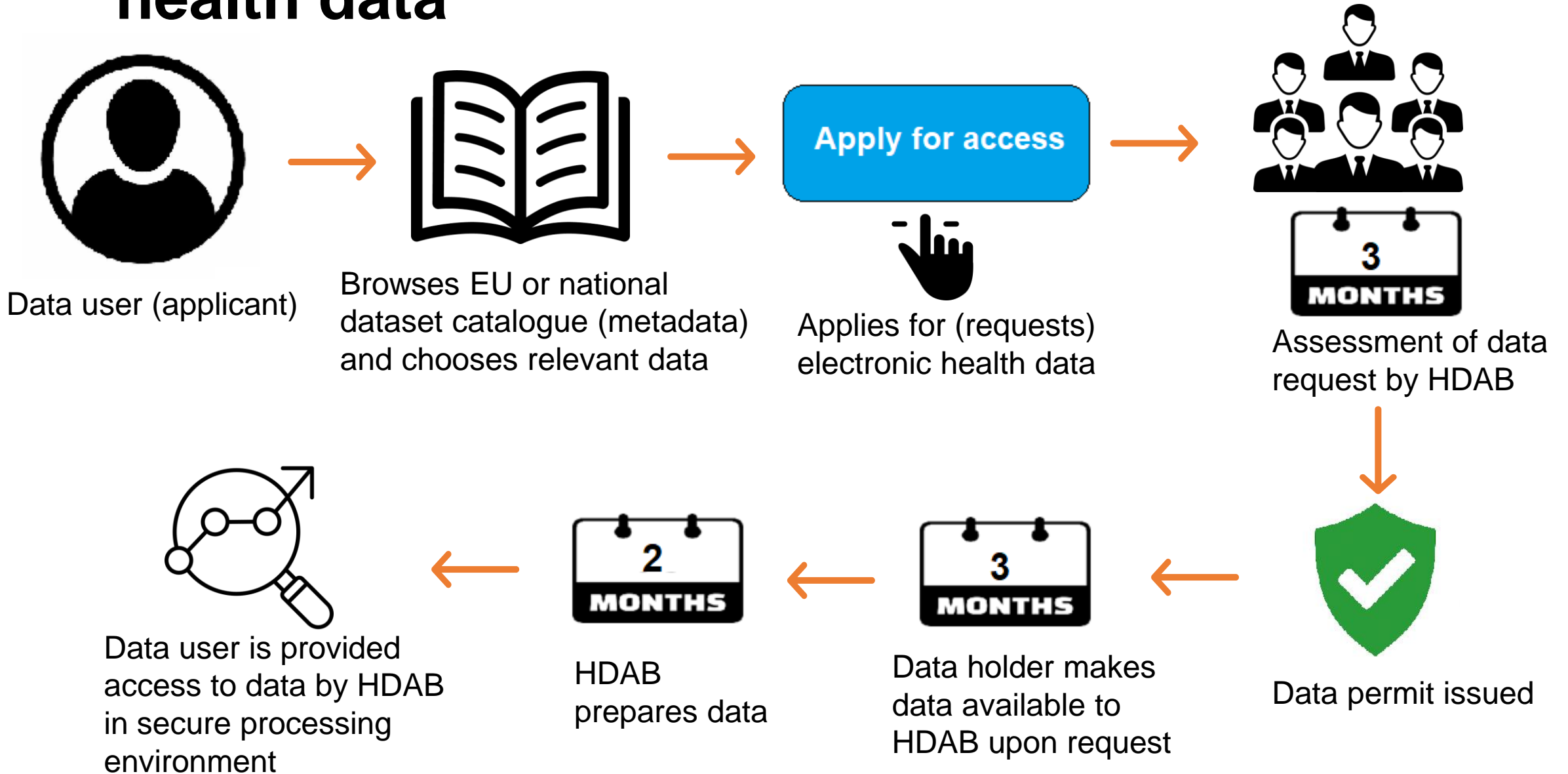
EHDS is first of common data spaces created pursuant to [European strategy for data](#) (2020), dedicated to sector of health, specifically electronic health data.

Current fragmented legal rules governing use of health data make cross-border cooperation in health care or research difficult (DG Health and Food Safety: [Assessment of the EU Member States' rules on health data in the light of GDPR](#)).

Aim of regulation is to **establish harmonised legal framework** for primary and secondary use of electronic health data within the European Union.

Secondary use purposes include inter alia **scientific research** (most discussed), education, policymaking, public health surveillance, statistics.

EHDS mechanism for secondary use of electronic health data



EHDS regulation – background and aims

This presentation is focused on secondary use of electronic health data under EHDS, analysing its key instruments:

- EHDS as legal act **providing legal basis (bases)** for stakeholders involved (data holder, health data access body, data user)

and

- **opt-out mechanism**

It will describe interplay of these instruments with existing data protection law (GDPR) and potential problems which may complicate establishment of truly harmonised legal framework.

EHDS as legal basis

Rec. 52 EHDS

EHDS provides **legal basis and safeguards for data holders** to make personal health data available based on data permit:

Legal basis	Exemption for special category of data
Art. 6/1 c) – legal obligation	art. 9/2 i) GDPR - public interest in area of public health
	art. 9/2 j) GDPR - scientific research, statistic purposes

EHDS as legal basis

Rec. 52 EHDS

EHDS also provides **legal basis and safeguards for HDABs** to process personal health data pursuant to EHDS:

Legal basis	Exemption for special category of data
art. 6/1 e) GDPR (task carried out in public interest)	art. 9/2 g) GDPR (substantial public interest)
	art. 9/2 h) GDPR (health or social care)
	art. 9/2 i) GDPR -public interest in area of public health
	art. 9/2 j) GDPR - scientific research, statistic purposes

EHDS as legal basis

EHDS PROVIDING LEGAL BASIS FOR HEALTH DATA USERS?

Rec. 52 EHDS: secondary processing of data under EHDS mechanism requires one of legal bases under art. 6/1 together with exemption in art. 9/2 GDPR.

Possible legal basis for data user under art. 6/1

6/1 a) consent

6/1 c) legal obligation

6/1 e) task in public interest

6/1 f) legitimate interest

Rec. 52 continues with statements that EHDS provides for legal basis for secondary processing of health data including safeguards for under art. 9/2 g) to j) GDPR (...) and that health data applicants should also demonstrate a legal basis referred to in Article 6 GDPR that allows them to request access to electronic health data.

Safeguards required under art. 9/2 g) to j) GDPR seem to be clearly provided by EHDS (e.g. trusted governance, data permit, secure processing environment).

Providing legal basis for data users under 6/1 GDPR is not clear from normative text of EHDS.

EHDS as legal basis

EHDS PROVIDING LEGAL BASIS FOR HEALTH DATA USERS?

Art. 67/4 EHDS names as obligatory part of health data request „*description on how processing would comply with applicable EU and national data protection law, specifically art. 6/1 GDPR*“.

We assume that EHDS itself does not provide legal basis for health data users and that it is data user's obligation to demonstrate its existence in data request.

EHDS as legal basis

Nevertheless EHDS does not contain details on how legal basis should be demonstrated by health data users.

[TEHDAS draft of „Guideline for Health Data Access Bodies on the procedures and formats for data access“](#) (text before public consultation) is also not much detailed on this.

Assessment, whether legal basis demonstrated by health data applicant is lawful, seems to be left to HDAB discretion.

In our opinion further guidance on this topic would be useful (if not necessary).

Example: Data request is made for health data held by data holders from more member states. Such request is submitted to one HDAB which forwards it to others. Is it sufficient to demonstrate legal basis to the HDAB to which data application is submitted? Or is data user obliged to demonstrate legal basis in each member state separately?

EHDS and opt-out right – interplay with GDPR

- Art. 71 EHDS: natural person at any time and without demonstrating reason has right to opt-out from processing his/her personal electronic health data for secondary use.
- Opt-out is sector specific mechanism and right related to electronic health data.






EHDS and opt-out right – interplay with GDPR

OPT OUT ≠ WITHDRAWAL OF GDPR CONSENT

OPT-OUT	GDPR CONSENT WITHDRAWAL	✓
AT ANY TIME, WITHOUT REASON		✗
REGARDLESS OF LEGAL BASIS	ONLY WHEN CONSENT IS LEGAL BASIS	✗
ONLY FOR ELECTRONIC HEALTH DATA UNDER EHDS	FOR ALL PERSONAL DATA	✗
REVERSIBLE	NOT ALWAYS REVERSIBLE	✗
PROSPECTIVE EFFECT (PROCESSING PURSUANT TO DATA PERMITS ISSUED BEFORE OPT-OUT IS NOT AFFECTED)	PROCESSING MUST STOP AND PERSONAL DATA SHALL BE ERASED (IF NO OTHER LEGAL BASIS EXISTS) –“RIGHT TO BE FORGOTTEN“	✗

EHDS and opt-out right – interplay with GDPR

OPT OUT ≠ GDPR RIGHT TO OBJECT TO DATA PROCESSING

OPT-OUT	GDPR RIGHT TO OBJECT	
REGARDLESS OF LEGAL BASIS	AGAINST PROCESSING BASED ON ART. 6/1 E) (PUBLIC INTEREST) OR F) (LEGITIMATE INTEREST) OR 9/2 J) GDPR (SCIENTIFIC RESEARCH)	
AT ANY TIME, WITHOUT REASON	ON GROUNDS RELATED TO DATA SUBJECT'S PARTICULAR INFORMATION	
ONLY FOR ELECTRONIC HEALTH DATA UNDER EHDS	FOR ALL PERSONAL DATA	
ALWAYS REVERSIBLE	NOT ALWAYS REVERSIBLE	
PROSPECTIVE EFFECT - PROCESSING PURSUANT TO DATA PERMITS ISSUED BEFORE OPT-OUT IS NOT AFFECTED	PROCESSING MUST STOP AND DATA SHALL BE ERASED, UNLESS DATA CONTROLLER DEMONSTRATES GROUNDS WHICH OVERRIDE RIGHTS, INTERESTS AND FREEDOM OF DATA SUBJECTS OR IF NEEDED FOR EXERCISE, ESTABLISHMENT AND DEFENCE OF LEGAL CLAIMS OR FOR RESEARCH CARRIED OUT IS IN PUBLIC INTEREST	

EHDS and opt-out right – interplay with GDPR

OPT OUT RELEVANCE OUTSIDE OF EHDS FRAMEWORK?

- Opt-out is specific mechanism and right under EHDS. EHDS is sectoral regulation. Hence opt-out is not relevant outside of EHDS Framework.
- National states could possibly address opt-out relevance outside of EHDS framework in their national laws.

EHDS and opt-out right – interplay with GDPR

GDPR CONSENT WITHDRAWAL AND RIGHT TO OBJECT - RELEVANCE FOR EHDS FRAMEWORK?

- GDPR is *lex generalis* (horizontal regulation) and EHDS *lex specialis* (sector specific regulation with relation to electronic personal health data).
- *Lex specialis derogat legi generali* – where EHDS and GDPR rules overlap, the specific rule supersedes general rule (for example EHDS specifically states that member states are not allowed to implement stricter rules pursuant to art. 9/4 GDPR with exception of particularly sensitive data).
- Art. 1/2 a) EHDS explicitly states that EHDS specifies and complements the rights laid down in GDPR in relation to the use of their personal electronic health data.
- **Right to opt-out is not *lex specialis* to right to object or to right to withdraw consent.**

EHDS and opt-out right – interplay with GDPR

- Right to object and right to withdraw consent (if consent is legal basis demonstrated by data user) shall apply also in EHDS Framework.
- This could in practice weaken EHDS function as tool enhancing secondary use of health data.

Examples:

- Health data user is given data permit based on legitimate interest. Data subject may object to data processing based on his/her current situation. Objection may affect processing based on issued data permit (in contrast opt-out is relevant only for future processing).
- Health data user is given data permit based on consent (consent is demonstrated as legal basis in data request). Data subject may withdraw consent under GDPR at any time which may affect processing based on issued data permit.

EHDS and opt-out right – national implementation

- EHDS does not set unified rules for opt-out mechanism implementation on national level.
- Pursuant to [TEHDAS draft on Guideline to Health Data Access Bodies “How to implement opt-out from secondary use of electronic health data”](#) (text before public consultation) member states have flexibility to design opt-out granularity as they deem appropriate.

At the same time guideline states that as health data flows increasingly across borders there is a growing need to align opt-out frameworks across the EU, ensuring they are interoperability, transparency and intelligibility not only to institutions but also to individuals.

- Member states may also implement law enabling overriding opt-out if data is requested by a public health body or Union institution for "scientific research for important public interest".

EHDS and opt-out right – particularly sensitive data

Last but not least:

Art. 51/4 EHDS - data of particular sensitivity (e.g. genetic and omics data, biobank data) may be subject to stricter measures and additional safeguards in national laws.

Measures and safeguards may include:

- **Opt-in** – explicit consent with secondary use
- **Ethics committee approval**
- **Obligatory research ethics assessment** – for example assessment of compliance of intended use described in application with ethics informed consent of data subject

Conclusion

Although EHDS principles represent strong tools for harmonizing rules for secondary data processing, there can be identified some issues which may be an obstacle to reaching its goal.

EHDS provides legal basis for secondary use of electronic health data for stakeholders, but this is not case of health data users who must demonstrate one of legal bases under art. 6/1 GDPR.

We identify need for more detailed guidance on how legal basis shall be demonstrated by data users to ensure harmonised approach of HDABs, particularly if requested data are held by data holders from more member states.

Conclusion

Opt-out as special mechanism and right in EHDS framework does not derogate or supersede data subject rights under GDPR like right to object or to withdraw consent. Exercising of right to object or to withdraw consent and its consequences can possibly weaken EHDS role as tool enhancing secondary use of health data.

Opt-out implementation (e.g. level of granularity, introduction of right to override opt-out) is subject to member states discretion which may lead to lack of harmonisation, transparency and interoperability.

Right of member states to introduce stricter measures and additional safeguards for particularly sensitive data by member states may be another source of legal fragmentation.

Clear guidelines for stakeholders are one of essential steps to unlock EHDS regulation's full potential.

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Thank you for your attention!