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DATA PROTECTION & HEALTH RESEARCH GUIDE TO SECONDARY USE OF DATA

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SECONDARY USE OF HEALTH DATA
REVIEW OF CURRENT RULES

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Primary –v- Secondary Use of Health Data

- **Primary use** of health data generally refers to collection and use for **medical treatment** and part of patient's health record
- Health data can also be directly collected from patients expressly for health research purposes – GDPR rules apply directly, e.g. legal basis, transparency, etc.
- **Secondary use** of health data generally refers to use of **existing stored health data for other purposes**, including **later health/medical research**
  - E.g. Existing patient records in hospital or GP surgery
  - E.g. Existing/historic health screening or vaccination records
- Normal GDPR rules and how impacted by Data Protection (Health Research) Regulations 2018 (amended in 2019 and 2021) (**DPHRR**)

Reminder of “health research” under DPHRR

- “Health research” as defined by DPHRR, neutral on purpose, covers secondary use

(i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels
(ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury
(iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals
(iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system
(v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status

Current DP rules for secondary use

- Otherwise, A.5(1)(b) GDPR (rule on purpose limitation): further processing of personal data for scientific research (e.g. health research) purposes will not be considered incompatible with the initial purpose for which the personal data were collected (e.g. primary use of health data), as long as A.89(1) GDPR is complied with
- A.89(1) GDPR requires safeguards for health research: TOMs, data minimisation
- **BUT** for "health research" as defined by the DPHRR, the default legal basis for any research (including secondary use) is **explicit consent**
- Operates as effective derogation to other available legal bases and conditions set out in Articles 6 and 9 GDPR for health research (even noting guidance on other more suitable legal bases set out by EU Commission and EDPB); derogation permitted under A.9(4) GDPR

SECONDARY USE OF HEALTH DATA
PROPOSED NEW RULES UNDER EU HEALTH DATA SPACE REGULATION

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Proposed Health Data Space Regulation #1

- New EU Commission proposal for EU Regulation on European Health Data Space, May 2022
- See: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
- Only at early proposal stage, so could be number of years before finalised
- Number of measures, including:-
  - Electronic Health Record for patients across EU, mandatory, with technical parameters set by EU Commission, and
  - Mandatory system for access to health data for secondary use in health research
  - Data quality assurances by data holders of health data sets

Proposed Health Data Space Regulation #2

- Proposed secondary use rules
- Cover public sector and private sector electronic health data sets, including electronic health records, electronic health data from clinical trials and medical device investigations, and person-generated health data (e.g. from wearables)
- "Data holders" are obliged to make their health data sets available for "secondary use", via Member State-appointed "health data access bodies" via portals operated by bodies (gatekeepers of data, joint controllers)
- Researchers ("data users") can apply to health data access bodies for "data permit", i.e. access to data holders' health data sets, for specific purposes (set out in A.34, including health research) – these purposes are the secondary use purposes

Proposed Health Data Space Regulation #3

- Certain excluded purposes for the health data sets, e.g. using the data to take detrimental decisions against individuals or to exclude from insurance products or modify insurance premiums
- Proposes return of “enriched” health data set to data holders at end of secondary use
- Health data access bodies will have other obligations, including transparency obligations (legal basis, TOMs, rights of individuals and how they can be exercise, and outcomes of secondary uses) – not to individual data subjects, but on more general basis (publicly-available information)
- Preference for secondary uses on anonymised data sets, otherwise pseudonymised data sets

Proposed Health Data Space Regulation #4

- Proposed obligations on data users to make public the results of their research and inform of clinically significant findings that may affect health status of research subjects
- Possibility also for proposed data users to seek health data directly from single data holders; deemed to be joint controllers
- Provisions for cross-border access across EU and for mutual recognition of data permits across EU

Proposed Health Data Space Regulation #5

- Interaction with GDPR and specific national rules on processing of health data (e.g. in Ireland under DPHRR) unclear
- Health Data Space Regulation will be without prejudice to rights and obligations set out under GDPR and under Articles 7 and 8 of EU Charter of Fundamental Rights
- Proposed A.33(5) HDSR: "*Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in the HDSR to provide access to electronic health data*"
- Suggests that where the specific conditions of the HDSR apply, consent legal basis/consent requirements are overruled, and access to health data set will be permitted under HDSR
- Otherwise, GDPR and national rules (DPHRR) will apply

Q&A / Thank you

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