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Legal uncertainties and the re-use of health data: Clarify and harmonise to optimise

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Legal challenges impact secondary use of data

Lack of certainty and different GDPR implementation regimes amongst Member States in connection with health data can inhibit secondary use of data.

Legal uncertainty means that decisions are taken on the basis of interpretation and risk capacity of companies, as well as place of location of main premises (and thus the interpretation by country/local DPA). Research on health data for innovative medical technologies and care pathways to improve patient's health and improve healthcare systems' sustainability (including sharing of health data for such purposes) may therefore not be used to the fullest.

Opportunities for law to be clearer:

- Role of consent and validity of alternative Article 9 legal bases
- De–identification standards
- Concept of research by commercial companies (eg developing medical devices, obtaining reimbursement, responding to health authority requests etc)
- Data subject rights, exceptions and transparency
- Scope of compatibility

Opportunities for MS to align:

- Legal bases applied and required by MSs are currently different, for example the differing approaches to reliance on consent
- Approach to determination of a controller and processor differ in each MS and may differ, even in between HC providers in the same country
- Approach to public health purposes vary (as seen in the current global health pandemic DPA responses)

Industry views and recommendations

There needs to be alignment and harmonisation between EU and Member States if secondary use of health data is to be optimized.

This could be in form of

- Common agreed standards
- Code(s) of Conduct
- EDPB Guidance
- Policy

Action should cover fragmented rules and develop clear policies to address

- legal uncertainties and national differences
- in connection with the various purposes of such secondary use (including public health purposes, market approval, safety monitoring, product development, creation an EU Health Data Space, threats to public health)

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