European Commission | Assessment of Member State Rules on Health Data in Light of GDPR

On 12 February 2021, the European Commission's DG Health and Food Safety (the ***Commission***) published an assessment of the EU Member State rules governing health data in the light of the General Data Protection Regulation (EU) 2016/679 (***GDPR***). The study's objective was to examine possible differences between Member States and identify elements that might affect the cross-border exchange of health data in the EU for the purposes of healthcare, research, innovation and policy-making. The European Commission concluded that the existing fragmented approach of national rules governing health data between Member States hampers cross-border co-operation in the provision of healthcare, the administration of healthcare systems and research carried out so as to further public health objectives.

VARIATIONS IN NATIONAL LAW LINKED TO IMPLEMENTATION IN THE AREA OF HEALTH

The study discusses the use of health data for primary purposes (patient care) and for secondary use in public health and for scientific or historical purposes. For each of these uses, the study analyses the legal bases for processing the data under the GDPR and inquires whether local legislation provides for alternatives to the use of consent as a legal basis.

The Commission thus found that various legal bases are available under national law to provide patient care. By contrast, newer forms of patient care, such as those involving apps and specific devices, usually relied on the patient's consent.

The Commission found differences in the implementation of the GDPR in the area of health. The resulting fragmented approach can have a negative impact on cross-border co-operation for the provision of care, healthcare system administration, public health, and research. The study showed that the implementation of the law is complex for researchers at national level, while patients do not always find it easy to exercise the rights granted to them by the GDPR. In this regard, the evidence gathered through the study demonstrated strong interest in the prospect of a European Health Data Space that would allow access to health data under a sound level of legal and operational governance and support digital health services' free movement. The study highlighted the need for operational governance and wide-spread implementation of technical standards so as to ensure data interoperability and build trust in data governance amongst EU citizens.

With its study, the European Commission also included an overview of "Country Fiches", discussing, for each Member State, the relevant legal framework for the subjects discussed in the study as well as the practical regulation of health records and technical standards.

POTENTIAL ACTIONS AT EU LEVEL

In response to the challenges identified, the study suggested actions at EU level to support the European Health Data Space and ensure the best possible use of health data. These include:

- Stakeholder-driven Codes of Conduct;
- New sector-specific EU level legislation;
- Non-legislative measures, including guidance and policy actions; and
- Practical Measures to support a European Health Data Space

The Commission advocated establishing a Code of Conduct on the use of health-related data at EU level as a strong tool to support the use and re-use of trusted health data. However, this could involve quite a lengthy path from initial idea to final adoption through an EU level implementing act. The study also favoured an additional international assessment of the EU Member State rules on health data in the light of the GDPR so as to seek legal interoperability across countries and regions, both within and outside the EU. According to the Commission, the GDPR rather than other weaker data protection laws should be the basis for this exercise.

The Code of Conduct could be given legal status through a legally binding act that enables the Commission to set conditions that ensure that EU rules are applied uniformly. Other legal instruments could harmonise health data processing, address data governance principles, and promote the responsible use of health data and health data accessibility.

As regards non-legislative measures, the study highlighted the need for harmonised digital skills and capacity-building for primary and secondary use of health data. Patients should act as active agents in both their health and their care and have the maximum ability to exercise their health data related rights. These factors can be regarded as pillars of trust necessary to enhance the development of a European Health Data Space. In this regard, the study addresses the legal framework for patient care, data subjects' rights, and data governance strategies, including the promotion of data altruism. Data altruism means data that is made available without reward for purely non-commercial usage that benefits communities or society, such as the use of mobility data to improve local transport.

Furthermore, the study showed that co-operation between the EU Member States is crucial. Such co-operation should draw on the work of national data protection authorities that come together as the European Data Protection Board, as well as on the numerous national and EU level bodies that represent patients, patients of specific disease groups, healthcare professionals, researchers, and industry. The COVID-19 pandemic has fostered the willingness for such co-operation and provides many new models for rapid, responsive, and impactful action.

A copy of the study can be consulted here. The annex containing "country fiches" with an overview of Member States' rules on health data in the light of the GDPR can be found here.

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