



15TH EHEALTH NETWORK 11-12 JUNE 2019, BUCHAREST, ROMANIA

COVER NOTE BY EHEALTH NETWORK SECRETARIAT

Topic 10.1. Regulatory gaps of new and disruptive technologies in the field of digital health

Issue at stake

The annual work plan 2019 of the Health Programme foresees a study examining the legal and regulatory gaps and challenges in the field of digital health, especially in a cross-border context. The main ideas and question are put on the agenda of the eHealth Network for your information and discussion. It will give you the opportunity to ask questions concerning the scope, objectives and deliverables and to provide suggestions concerning the uncovered areas.

Summary

The study will consist of five subject issues. Each of these issues will be examined separately from the others, always within the context of digital health and the provision of digital cross-border health services.

1. Data protection and ownership of health data

The study will focus on the implementation of the GDPR in the health sector and will try to shed light on issues like the Member States' national legislation related to the secondary use of data, the requirements for health research or the patients' consent when used as a legal basis for the processing of health data.

2. Liability issues

Here the focus will be on rules defining the liability, especially in the context of new developments (AI, autonomous healthcare application) and their application in a cross-border context.

3. Administrative practices

This topic will concern reimbursement, applicable legislation etc. of digital health services when provided in a cross-border setting.

4. Artificial Intelligence in healthcare

The study will examine legal questions arising from the application of AI technology in healthcare especially in relation to the EU legislation on product liability and medical devices.

5. Interoperability in healthcare

Applicable standards will be mapped.

For each of the subject issues presented above, the study will analyse the existing laws and policies of the EU Member States, and assess whether there are legal and regulatory gaps that might need to be addressed when digital health services are provided in a cross-border context or digital health data are exchanged across borders.

Format of procedure in the eHealth Network meeting

The Commission co-chair introduces the topic shortly and opens the floor to the questions of the eHealth Network.

After the discussion, the Commission co-chair will summarise the discussion and close this agenda topic.