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DG HEALTH AND FOOD SAFETY
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

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**COVER NOTE BY SECRETARIAT**

**Topic 3: Cross-border exchange of patient data – multilateral legal agreement**

## Issue at stake

A stable legal framework is an important condition for the eHealth Digital Service Infrastructure (eHDSI) to become a reality. High level political support is necessary to bring this development to a successful end in time.

The appointed team of legal experts have been working on creating this legal framework since November 2014. After starting as the eHealth Network subgroup, the group merged with the JAseHN as the Task 5.6 Group.

The Commission in its part has made a legal analysis on the way Member States could enter into a multilateral legal agreement in context of the EU data protection legislation.

## Summary of document

Article 10 of the Cross-border Healthcare Directive foresees exchange of information between Member States and calls for the Commission to "encourage Member States, particularly neighbouring countries, to conclude agreements among themselves". Such an agreement may in principle cover all issues necessary for patient data exchange, except those already covered by the EU law.

Such an exchange can only happen in accordance with Data Protection Directive (95/46/EC) and its implementing legislation in each Member State, either on the basis of the patient's consent or, on another ground for lawful processing of personal data (i.e. with no consent), such as preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services (Article 8(3) of Directive 95/46/EC).

One of such grounds could be the legal basis of the national legislations implementing the Cross-border Healthcare Directive (notably Article 10). In all cases the patient needs to be informed about the processing in accordance with Directive 95/46/EC.

## Format of procedure in the eHN

The Member State co-chair opens the topic and highlights the importance of this topic.

The chair of the team of legal experts (Task 5.6 Group) provides the state of play of the group's work.

DG JUST gives presentation on the new Data Protection Regulation (2016/679/EU) focusing on health issues. Member States may send questions in advance to the Network Secretariat.

The Members are invited to discuss the legal issues highlighted in the Commission's legal analysis.

The Members are invited to report any administrative, legislative or other reasons, which might stand in the way of the described exchange of information on the basis of such an agreement.

24.05.2016

# Exchange of patient data across borders

# – EC legal analysis –

## The legal framework

The Crossborder Healthcare Directive (2011/24/EU) recognizes the importance of the work on interoperability and encourages Member States to facilitate the establishment of cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient cross-border healthcare. Article 11 of the Directive lays down measures to facilitate the recognition of medical prescriptions issued in another Member State, and foresees the exchange of such data.[1]

The CBHC Directive (Article 14) establishes the eHealth Network, whose task is to achieve high level of trust and security with regard to European eHealth systems and service and interoperable applications. In its meeting in November 2014, the eHealth network decided to set up a legal sub-group to create a multilateral agreement to enable cross-border exchange of patient data for the purposes of patient data summaries and ePrescriptions through NCPs (national contact points).

The CBHC Directive does not include detailed provisions to exchange patient data across borders. Instead, according to its Article 2 the Directive applies without prejudice to Directive 95/46/EC on data protection. However, the Directive provides basic rules for the mutual assistance and co-operation in cross-border healthcare. Article 10 of the Cross-border Healthcare Directive foresees exchange of information between the Member States and calls for the Commission to "encourage Member States, particularly neighbouring countries, to conclude **agreements** among themselves".

Such an agreement may in principle cover all issues necessary for patient data exchange, except those already covered by the EU law.[2]

Therefore, Member States may agree, for example, to define precise purposes/use scenarios for such exchange of data and to designate a national contact point (NCP) for those purposes.

As the EU legislation already covers such an exchange of data to a large extent on the interstate level, such an agreement should take the form of an executive agreement between the NCPs.

## Data protection

Such an exchange can only happen in accordance with Data Protection Directive (95/46/EC) and its implementing legislation in each Member State, either on the basis of the patient's consent or on any other of the grounds for lawful processing of personal data (i.e. with no consent). [3]

[1] Commission Directive 2012/52/EU lays down implementing rules for such recognition of prescriptions.

[2] Such as data protection, as laid down in Directive 95/46/EC and Regulation (EU) 2016/679.

[3] Article 8(2),(3) and (4) of Directive 95/46/EC.

One of such grounds could be the legal basis of the national legislations implementing the CBHD (notably Article 10). In all cases the patient needs to be informed about the processing in accordance with Directive 95/46/EC.

Directive 95/46/EC on data protection regulates the rules and principles relating to data processing, in particular as regards quality, information of the data subject, right of access, right to object, as well as confidentiality and data security, and data protection supervisory authorities. The Member States cannot limit the free flow of personal data between them for the reasons connected with data protection.[4]

Member States do not have competence to make agreements in so far as they would affect the EU data protection rules or overlap with them. But Member States may agree on details in so far as this is within the limits and in compliance with the EU rules, as foreseen in Article 10 of the CBHC Directive. These issues might include specification of the persons authorized to process data, systems to validate their identity and accreditation, maximum retention period and the details of further processing.

**Liability and choice of law**

These issues are already harmonised within the EU. It is suggested that this agreement will not address the issue of liability and the choice of law/jurisdiction. Further attempts may be made in order to clarify and give guidance on the applicable rules.

**Governance**

The governance should happen within the existing structures, most conveniently through the eHealth Network, within which a Governing Board could be set up to monitor the implementation and the review needs of the agreement.

**Question**

The members of the eHN are invited to report any administrative, legislative or other reason which might stand in the way of the described exchange of information on the basis of such an agreement.

[4] Article 1(2) of Directive 95/46/EC and Article 1(3) of Regulation (EU) 2016/679.