



## EUROPEAN COMMISSION

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

eHealth-units

**14<sup>TH</sup> eHEALTH NETWORK 13 NOVEMBER 2018, BRUSSELS, BELGIUM**

**COVER NOTE BY eHEALTH NETWORK SECRETARIAT**

### **Agenda topic 1a: Review of the Implementing Decision on providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth (2011/890/EU)**

#### **Issue at stake**

Since the adoption of Commission Implementing Decision 2011/890/EU and to deliver on its objectives set by article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, the eHealth Network and the Commission worked towards the establishment of the eHealth Digital Service Infrastructure to enable healthcare providers through National Contact Points for eHealth to exchange patient data for the purposes of cross-border health care.

Commission Communication 2018(233) on the digital transformation of health and care proposed a review of the existing Commission Implementing Decision 2011/890/EU in order to clarify the role of the eHealth Network in the governance and functioning of the eHealth Digital Service Infrastructure. It would also clarify the existing rules governing the cross-border processing of personal data through the eHealth Digital Service Infrastructure, in accordance with the 2016 General Data Protection Regulation and Regulation 45/2001 (under review).

#### **Summary**

The eHealth Digital Service Infrastructure is a tool which can help to achieve the objectives of the eHealth Network regarding the interoperability of eHealth systems. For reasons of legal certainty and foreseeability, the role of the eHealth Network in the governance and functioning of the eHealth Digital Service Infrastructure should be clarified in an EU legal act.

Additionally, rules governing the cross-border exchange of electronic health data, rules providing definitions of certain elements of this exchange and a list of recommended actions that contribute to the Network's objectives could be introduced in the draft Implementing Decision, contributing to the legal certainty.

Moreover, the existing rules governing the cross-border processing of personal data through the eHealth Digital Service Infrastructure should be clarified in accordance with the 2016 General Data Protection Regulation and Regulation 45/2001, which is now under review to adapt its principles and provisions to the GDPR.

The initiative has been discussed with a sub-group of eHealth Network experts. For the eHealth Network meeting, the Commission will present its current thinking as set out in the document and would value feedback from Member States, with a view to further refining the proposal.

Subsequent to the discussions in the eHealth Network, on 13 November 2018, the initiative will also be tabled for informal discussion to the Cross-border Healthcare Committee's meeting scheduled to take place in December 2018, followed by a vote on the adoption of the act in February 2019.

**Format of procedure in the eHealth Network meeting**

The Commission will briefly introduce the topic of the draft Implementing Decision and explain why the existing Commission Implementing Decision 2011/890/EU needs to be repealed, as well as the advisory role of the eHealth Network in the process. The Commission co-chair will then hand over the presentation of this topic to Ioana-Maria Gligor who will present the reasons for the repeal of the existing Implementing Decision 2011/890/EU, the current thinking of the Commission concerning the new elements of the proposal, as well as the next steps.