

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

eHealth-units

12TH EHEALTH NETWORK 28 NOVEMBER 2017, BRUSSELS, BELGIUM COVER NOTE BY EHEALTH NETWORK SECRETARIAT

Agenda point 5: Agreement for the exchange of health data

Issue at stake

The Agreement for the exchange of health data was adopted by the eHealth Network (eHN) in its meeting of 9 May 2016. At the same time the eHN decided to seek the Opinion of the Working Party under Article 29 of the Directive 95/46 on data protection. The General Data Protection Regulation (GDPR) will replace the Directive as from 25 May 2018. The Agreement includes an Annex listing the exemplary questions for the Working Party.

A Legal Task Force under the eHealth Member State Expert Group (eHMSEG) was set to followup the implementation of the Agreement and the requested Opinion. The initial observations from the Working Party indicate a number of data protection issues that need to be further clarified for the eHDSI to achieve a high level of trust and security. Other clarifications might also be necessary as regards the functioning of the Agreement in areas where MS legislation is variable, such as liability issues.

This agenda point aims to inform the eHealth Network about:

- The developments on the Agreement since the 11th eHealth Network meeting.
- Where in the process with the article 29 Working Party we are at the moment.

Summary

On behalf of the eHealth Network, a letter signed by the Member State co-chair accompanied with all relevant documentation was sent by the eHealth Network Secretariat to the Secretariat of the Article 29 Working Party (WP) on 16 June 2017. The Secretariat of the WP had forwarded the letter including the documentation to the chair of the WP on 29 June 2017. The request from the eHealth Network for an opinion was forwarded to the eGovernment sub-group under the WP. This sub-group is responsible to scrutinise the Agreement and develops the opinion which eventually will be adopted by the WP.

On 24 October 2017 the eGovernment sub-group convened and discussed among other things the request of the eHealth Network. Representatives of the Commission (DG SANTE) were invited to the meeting to answer any questions. The Commission had mentioned that for future meetings of the eGovernment sub-group, a representative of the Member States (eHMSEG Legal Taskforce) should be invited as well. The sub-group informed the Commission that they intend to provide the WP with an opinion in April 2018.

The meeting gave a clear understanding that many issues and questions remain unanswered. In order for the eGovernment sub-group to have a clear understanding of the Agreement, the questions and issues raised should be answered in an efficient and timely manner. The questions are both directed to the Service Provider (Commission) and the Member States. The Commission is working closely with the eHMSEG Legal Taskforce to provide the necessary answers to the questions and clarity to the issues raised.

Format of procedure in the eHN

The Member State co-chair opens the agenda point and gives the floor to the representative of the eHMSEG Legal Taskforce who will provide an update on the developments of the Agreement.

Furthermore, the eHealth Network will be given the floor to comment and ask questions.