



25TH EHEALTH NETWORK MEETING 28 NOVEMBER 2023, BRUSSELS

COVER NOTE

12. Update on Proposal for regulation on EHDS

Cover note/background

1) Introduction

On 3 May 2022, the European Commission adopted the proposal for a Regulation on the European Health Data Space (EHDS), which was accompanied by an impact assessment and a communication. It is the first proposal for a common European data space following the communication ‘A European strategy for data from 2020, which announced the creation of nine sector- and domain-specific data spaces.

The proposal aims to improve individuals’ access to and control over their personal electronic health data (primary use of data), including at national and EU level, and to facilitate data re-use (secondary use of data) for research, innovation and public policy purposes across the EU. It also aims to improve the functioning of the single market, in particular for the development, marketing and use of digital health services and products (e.g. electronic health record systems).

2) Issue at stake

The Commission is giving a short overview of the negotiations with both co-legislators – see below.

3) Summary

Both co-legislators are aiming to have an agreement during this mandate of European Parliament.

Council intends to have a negotiation mandate at the beginning of December 2023. On European Parliament side ENVI/LIBE committee vote is foreseen on 28.11.2023 and plenary vote on 13.12.2023.

4) Format of procedure in the meeting

No action required from eHN members, point for their information.