



# 7. Czech Presidency of the European Council



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## Joint eHN WG meeting in Prague

- *2 days workshop of SGS and TIO was held on 10 – 11. October at inspiring Emauzy Monastery in Prague*
- *~ 30 on-site participants on both days*
- *many on-line participants on Webex*
- *8 hours of busy program each day and many informal talks during joint dinners*
- *According to feedback received from participants it was very successful, inspiring and efficient event*







7 November 2022 Brussels

**22<sup>nd</sup> eHN Meeting**



# Proposal for a Regulation on the European Health Data Space (EHDS)



## Development and current status of the proposal

- CZ PRES followed FR PRES and continued the first reading of the proposal from Article 14 from July 2022.
- 16 meetings of the working party in the Council to this date dedicated to proposal for Regulation on EHDS, at least 3 other meetings will follow (9.11., 18.11. and 29.11.)
- All 72 articles of the first proposal have already been discussed during first reading.
- Part of the meetings were devoted to horizontal topics (i.e., legal bases, the relation of the proposal to the GDPR, EHDS governance ).



## Examination of the proposal and objectives of CZ PRES

- Compromise proposal of **Chapter II** (Primary use of electronic health data) and **Chapter III** (EHR systems and wellness applications ) was shared on 7 October.
- Compromise was based on the comments of the MS and other important entities in EU such as EDPB and EDPS.
- Second reading has started on 18 October with discussion on legal bases of the proposal and exchange of view on the Article 3.
- The aim of CZ PRES: present **progress report** on the EPSCO Council on 9 December.
- The negotiations will continue during SE PRES in the first half of 2023.



# **Discussions on the proposal and main issues**

**Discussions of the proposal are thorough, but constructive and cooperative. A significant part of the comments is made up of requests to clarify the wording in various articles.**

## **Main issues:**

- Legal bases of the Regulation
- Alignment with the GDPR
- Possible interference with healthcare systems in MSs
- Balancing the administrative burden for MS
- Involvement of MSs in subsequent legislation processes – Implementing/delegated act, Advisory/examination procedure
- Investment needed and time frame for implementation of the Regulation
- In general, more issues arise regarding secondary use of health data





## Examples of particular issues to be further discussed

- Definitions (art. 2), incl. EHR
- OPT-OUT / OPT-IN for individuals (both in primary and secondary use of data)
- Restriction of access to EHR for HC professionals (determined by the patient)
- Patients inserting data in their EHR systems
- Burden on existing or new public bodies and healthcare providers
- Implementation time and extent (date for applicability of the Reg., categories of EHR and detailed scopes of primary categories for primary and secondary use of the data)
- Telemedicine in the context of cross-border healthcare (Art. 8)
- Data from wellness apps
- Issues not clearly covered in the proposal (e.g., legacy EHRs, citizen and ethical values)
- Fees and economic sustainability of the infrastructure for secondary use of data
- Data sharing and access of third countries
- Penalties





# Questions?

## Further information

**eHealth Network**

[https://ec.europa.eu/health/ehealth/policy/network\\_en](https://ec.europa.eu/health/ehealth/policy/network_en)

**All events**

[https://ec.europa.eu/health/ehealth/events\\_en#anchor0](https://ec.europa.eu/health/ehealth/events_en#anchor0)