22nd eHealth Network meeting Summary Report

7 November 2022

Location: Albert Borschette Conference Centre, Brussels, Belgium

Participants : Representatives of DG SANTE, DG CNECT, HaDEA, Members of the eHealth Network (AT, BE, BU, CR, CY, CZ, DK, DE, EE, EI, FI, GR, ES, FR, IS, IT, LV, LI, LU, HU, MT, NL, NO, PL, RO, SE, SV), invited experts: Stefanie Weber (eHN subgroup on Semantics), Vincent van Pelt (eHN subgroup on Technical interoperability), Klara Jirakova (eHMSEG Chair), David Novillo Ortiz (WHO), Maria Sotiriou (WHO), InfEurope staff.

Chairs:

EC co-chair Fulvia Raffaelli, Head of Unit, SANTE C1, European Commission

MS co-chair Ron Roozendaal, Ministry of Health, Welfare and Sports, the Netherlands

Opening and approval of agenda:

The MS Co-Chair opened the meeting and welcomed the participants.

The agenda is presented to the participants and was adopted by the participants.

The EC Co-Chair presented herself and wished participants good cooperation for this 22nd meeting of the eHealth Network.

ES pointed out that there were simultaneous eHMSEG and eHN Tech SG meetings on the 2022-10-10. Some decisions were made in that eHN Tech SG meeting which would have been challenged by persons who could not attend, since they were in the eHMSEG meeting. For many Member States the representatives in these groups are the same, and they cannot attend two meetings at the same time.

ES thus asked all the actors involved (chairs of the eHN, eHMSEG and eHN sub-groups) to make sure that high-level decision making does not overlap: the eHMSEG and eHN Tech SG (or eHN Semantics SG, or any other eHN subgroup) must not take place at the same time, unless this is agreed to between all the stakeholders involved.

1. Interoperability

1.1. Patient Summary Guidelines update (for adoption)

The MS Co-Chair of the Subgroup on Semantics provided an update on the work on the eHN Guidelines, namely the Patient Summary guidelines, the Medical images guidelines and the Hospital Discharge Report guidelines.

Following the eHealth Network adoption of the release 3 of the General Guidelines and ePrescription guidelines and the release 1 of Laboratory Reports guidelines, it was identified the need to perform a minor update into the Patient Summary guidelines.

This minor update in Patient Summary Guidelines release 3.1 should align the format of guidelines and move some of the general provisions from the Patient Summary Guidelines to the "General guidelines" to ensure consistency across domains. This minor update should not add additional information elements nor change fundamentally provisions in the guidelines chapter.

The next steps rest in delivering by June 2023 a reflection and possible adaptation of existing vaccine code systems and issues pertaining to rare disease fields as they are not yet included in Patient Summary Guidelines.

The Semantics SG requested adoption of the Patient Summary Guidelines release 3.1. The Co-Chair of the Semantics SG clarified that their mandate was to fix the layout, resulting in outstanding items (vaccine code systems and rare disease fields) being placed on hold.

The Patient Summary Guidelines version 3.1 were adopted by the eHealth Network.

With regards to the outstanding items not included in PS, the Semantics SG proposed that they address this issue through a mandate given by the eHN. There were no comments or objections and the Semantics SG was awarded the mandate.

ES highlighted that it is important to clarify if these guidelines will set a precedent for the * national * scope of primary use cases proposed in the EHDS draft legislation (all clinical software of the EU that use the data categories of the art 5 EHDS proposal), or if the work on guidelines will only focus on cross-border use cases. Given the current scope of work of the eHN, ES understood that this is only for cross-border use cases. ES underlined that it is important to ensure coordination between the eHN Tech IOP subgroup (and its subgroup on HL7 HFIR and CDA) and eHN Semantics SGs, the eHMSEG new use cases WG, X-eHealth and Joint Action 09 on primary use cases.

1.2. Hospital Discharge Report Guidelines Readiness and Action Plan (for decision)

According to the eHN Common Semantic Strategy and the mandate given to the Semantics SG in June 2022, an assessment has been performed on the readiness and action plan towards eHN Guidelines on Hospital Discharge Report(HDR). The purpose was to assess: (1) the maturity of specifications to be used in the development of eHN guidelines; and (2) the readiness of MS to implement any such guidelines. Thanks were given to the X-eHealth project, the readiness assessment having made use of results of the X-eHealth project and the EC study on "Interoperability of Electronic Health Records in the EU (2020)".

The Semantics SG requested that the eHN clarifies the scope that they should have for the first version of the Hospital Discharge Reports Guidelines. The Semantics SG also requested clarifications on whether or not any distinctions should be made between possible use cases identified, namely if there should be any recommendation for implementation indicated in MyHealth@EU. Consideration should be given to the implementation burden and Member States' readiness in how the dataset should be described in these Guidelines. More specifically, it should be considered if section level datasets with indication of preferred code systems or if a more detailed description equivalent to level of detail in other eHN guidelines are necessary. Members should carefully weigh the implications of a common European standard.

The Semantics SG proposed to adopt a two-step approach for the preparation of the HDR Guidelines. The first step (ready by June 2023) would be the outline of the Guidelines including candidate content in some of the key chapters resulting from and initial consultations with key stakeholders. The second step - the consolidated Guidelines (including a wider stakeholder

consultation) - would be available by November 2023. The second step would be performed by the Joint Action on primary use.

The Semantics Subgroup requested guidance from the eHN on : a) the scope (Discharge report or hospital discharge report); b) distinction between possible use cases identified; and c) the two-step approach.

Concerning a) Scope: The floor was opened to questions and comments. Member States agreed with these Guidelines being prepared. ES, DE, and CZ noticed that, due to complexity of these guidelines, maintaining the scope to only in-patient stays and Hospital Discharge Report (HDR) would be preferable. Following no objections, the scope of HDR Guidelines was defined to be only relevant for HDR.

Concerning b) Possible distinctions between use cases identified: it was clarified that the purpose of this question was to determine how the information in the HDR should be handled (i.e. what direction should be addressed). The Semantics SG recommended looking at the use case scenario of information being sent from the Country of Treatment (B) to the Country of Affiliation (A). PT mentioned that there are many different versions of (hospital) discharge reports and noted that it would be useful to have HDR available in relation to diagnoses found in PS (in-patient stays). CZ, on the other hand, offered to consider all possible use cases because they determine the content of the report. It was added that in emergency cases, the patient summary can be of some use, but the HDR summarises the diagnostics. The eHN decided, with the majority of the members opting for a broader general description, that the HDR Guidelines should remain flexible for the future inclusion of other use cases.

With regards to c) two-step approach: no objections were expressed for the two-step approach.

ES had several questions and recomendations.

Q“a) What scope should be adopted for the first version of this guidelines: i) hospital discharge reports or ii) discharge report?” A: Due to the complexity it seems that it would make more sense to focus only on Hospital Discharge Reports

Q: “b) Should there be any distinctions between the possible use cases identified, namely should there be indicated any recommendation for implementation in MyHealth@EU?” A: it would be better *not* to include implementation details especially now that the use of FHIR is being considered. The guideline should be implementation-independent.

Q: “c) Considering the implementation burden, how should the dataset be described in the guidelines: a) section level datasets with indication of preferred code systems or b) detailed description equivalent to level of detail in other eHealth Network guidelines?” A: it’s better to leave this up to further work, especially in a context of discussions on the general standardization approach.

Q: “d) Considering the complexity of the dataset and interplays of this guidelines but also its importance for implementation projects (i.e. Myhealth@EU), it is recommended to adopt a 2 step approach for the preparation of this guidelines. The first step (ready by June 2023) would be the outline of the guideline including candidate content in some of the key chapters and some consultation with key stakeholders. The second step - the consolidated guidelines (including a wider stakeholders consultation) - would be available by Nov 2023).”

1.3. Imaging Study and Report Guidelines Readiness and Action Plan (for decision)

The X-eHealth project and the EC study on "Interoperability of Electronic Health Records in the EU (2020) also proved useful with regards to this matter, the main findings being that the imaging domain is well characterized, with key interoperability challenges identified. There were two distinct information sets: those of the Imaging Study and the Imaging Report. Primary use case is the main ability for Professionals in the Country of Treatment being able to access Imaging Studies and Imaging Reports (from Country of Affiliation). Concerning Member States readiness, a few States are willing to proceed for Imaging Study, but fewer are ready for Imaging Reports. As a note, there is a potential overlap with the Results section of the Patient Summary dataset.

The Semantics SG recommended to the eHN a two-step approach for the preparation of these Guidelines similar to the proposed outline for the implementation of Hospital Discharge Reports. Considering the technical nature of some of the interoperability challenges (i.e. medical images formats and standards, file sizes and bandwidth implications), a joint effort is proposed between the Semantics and Technical SGs of the eHN. Considering that the need for metadata to describe clinical documents is horizontal to the different type of documents (i.e. Patient Summary, ePrescription, Laboratory results, Imaging Reports, Imaging Studies), it is recommended to reflect on how to provide guidance on metadata (i.e. include in General Guidelines, prepare specific guidelines document on metadata for clinical documents) and how (by subgroups or Joint Action) and when such guidelines should be prepared. The eHN was requested to take action and provide guidance on proposals a) to c).

On the topic a) two step-approach: the eHN stated that adding the conditions to distinguish between use-cases, standards, and conducting an analysis of needs, they agree to have the SG proceed with a two-step approach.

Concerning proposal b) making these Guidelines a joint effort between the Semantics and Technical Interoperability Subgroups, no objections were voiced and the action was approved.

Regarding c) guidance for metadata: the SG on Semantics mentioned having the Joint Action taking the lead. ES opined that the Semantics SG is doing a good job and has access to the qualified stakeholders. The EC mediated that since the Joint Action (JA) will not begin until next year, the Semantics SG could begin the work and then transfer it to the JA. PT and SI agreed with this two-step proposal. The eHN decided to begin the discussions within the Semantics SG and then transfer the work to the Joint Action.

2. MyHealth@EU

2.1. State of Play, Key Performance Indicators and Roadmap (for information)

An update was given on MyHealth@EU. Eleven Member States are currently live in the system, including CZ, EE, ES, FI, FR, HR, LU, MT, NL, PL, and PT. CY, EL, IE, AND HU are planning to go live in 2022; BG, IT, LT, LV, SE, and SI are planning to go live in 2023; and SK is planning to go live in 2024. Currently, applications from AT, DE, DK, IS, NO, and RO are under review. Within the MyHealth@EU system, six Member States are utilising ePrescriptions and nine are using Patient Summary.

Concerning KPI's, the number of ePrescriptions are rising while the use of Patient Summary is much lower, with numbers for 2022 being especially low. The points of care that are connected through

the National Contact Points for eHealth is stable as are the number of citizens who can benefit from the service.

98% of ePrescription transactions are between Estonia and Finland. Q1 and Q2 are in line with expectations. As for PS transactions, there is a need to understand why these numbers are so low, expressing hope that the numbers will nevertheless pick up in the future.

A timeline was presented to update members on the main policy initiatives. These are: on-going EHDS negotiations; the Joint Action on Primary use; new eHN Guidelines and new services; a capacity building project on primary use; direct grants to Member States to implement MyHealth@EU services; the Patient Access Project; and the development of new services based on EUDCC technology.

The floor was opened to comments and questions. ES brought up the point that in the case of patient access, a challenge could be the licensing of the translation. They asked for clarifications on possible solutions for how this legal challenge could be solved. EC stated that one of the very reasons why the pilot was launched was to explore this question in more detail. They specify that even if translations are not readily available in the language of the country in question, it could be translated in English. PL pointed out that the Digital Identity Wallet pilot led by HU is missing from the above timeline. The EC made a note to add this pilot to the timeline.

2.2. Future Strategy: Increasing the value for end users (for discussion)

Contextual background on the MyHealth@EU initiative was provided. Its services have been in operation since 2019. Two services are currently in routine operation, the use of the ePrescription service is growing (currently over a thousand dispensations per month), while the number of transactions in the Patient Summary service remains rather low (less than 10 exchanges in a month). More feedback should be collected from end-users to understand possibilities for improvement/development of services. Closer involvement of patients and healthcare professionals in the service design would promote commitment and ownership by end users of the services.

Feedback from end users is also currently being discussed for the selection of the future use cases. It's important to analyse the business value of the proposed new use cases before launching the development of corresponding technical specifications. The involvement of end users may also allow for reflection on existing foundational design principles of MyHealth@EU (document-based approach, focus on fully structured data in all situations, translation of coded information only). This reflection should be driven by a value-based approach and avoid the trap of choosing what is easily implementable and should steer investments over the coming years at EU and national level, also in respect to the expansion and evolution of MyHealth@EU services.

Within the current deliberations on increasing the value for end-users, the governance structure of the MyHealth@EU services is being reconsidered. Key questions are posited around the provision of services and how there is a collaboration for the delivery of these services between the eHN and the end users. To strengthen business involvement and representation of the voice of end users, possibly some governance changes could be considered, such as: (1) stronger involvement of end users at the strategic level; (2) stronger involvement of end users at the operational/tactical level; (3) different organization of the eHN and eHMSEG subgroups; (4) service design approach and business value driven prioritisation. The whole design of user engagement should be reflected upon with a particular focus on how it should be strengthened.

CZ and NO remarked on the importance of marketing and ensuring that end users are aware that these services exist. FR also added that it was also important to analyse the cases in which KPIs indicate that there is use as well as the cases where there are not, so as to have a more complete understanding of the root causes for success/lack of realization. The NL iterated that in order for the eHN to have an impact, it is critical to involve end-users. Therefore, they agree with FR that the role of end-users needs to be better defined. PL stressed that all end users' voices are important to consider and that the group should avoid letting the loudest, biggest organisation set the agenda for end user input. The EC noted the feedback and thanked the members for their input and advice on the matter.

The eHealth Network Subgroups and the eHMSEG are asked to work on a proposal regarding potential ways of strengthening end user involvement in their work, the result of which would be presented in the next eHealth Network meeting in June 2023. The Semantics SG was mandated to contribute to the creation of a white-paper alongside a "Coalition of the Willing" of the Member States: NL, ES, CZ, NO, DE, FR, IT, and PT.

2.3. Preparation of an Action Plan for implementation of New Use Cases (for discussion)

The X-eHealth project has delivered building blocks for the introduction of new use cases: the Laboratory results and reports, Medical images and Medical imaging reports, Hospital Discharge Reports and Rare disease scenarios as part of the Patient Summary.

Considering the eHN Guidelines are available since July 2022, they foresee two possible scenarios in the eHN Guidelines on Laboratory Results:

1) Scenario 1A: Request for Laboratory summary from Country A
2) Scenario 1B: Request for Laboratory result reports from Country A

Considering in 1A, a Laboratory summary might include links to laboratory reports documenting how and where the specific observations were obtained, and that in 1B, the metadata on laboratory result documents might contain some basic information on observations, the two scenarios may be combined.

Questions were asked if 1A, 1B or a combination of both options should be implemented in MyHealth@EU. Although a Change Proposal has been submitted to propose to implement 1B, a decision regarding the summary element should be made prior to the start of the implementation, as from a user perspective 1B is perhaps not the best serviceable option. It was also remarked that a decision regarding the summary element should be made prior to the start of the implementation.

With regards to Medical Images and Medical Imaging Reports, there are no eHN Guidelines available yet. Exchange of medical imaging reports (and medical images) as PDF documents is currently available in MyHealth@EU (OrCD service). A Change Proposal has been submitted, suggesting to implement only the use case scenario that involves the transfer of images from Country A to Country B. To note, this does not apply for the retrieval of Imaging Studies, the use case being specific to imaging reports.

Regarding medical images, ES stated that we should try to stick with existing standards and try to avoid reinventing the wheel. From a technical perspective, both the TESTA network and the openNCP software seem inadequate for the exchange of medical images, and are likely to be major challenges for practical implementation.

On the topic of (Hospital) Discharge Reports, there are also no eHN Guidelines on the use case that are currently available. A Change Proposal has also been submitted, suggesting to implement the use case specific for the transference from Country A to Country B. This change proposal differed from the discussions held previously with the Semantics SG request for a mandate for compiling HDR Guidelines.

These new use cases being introduced in the MyHealth@EU domain has prompted discussions in both the eHN subgroups. Of particular interest to the Tech IOP SG are the technical implications for Laboratory Results, Medical Images and Medical Imaging Reports, as well as Hospital Discharge Reports. It was specified that the technology choice for MyHealth@EU system is based at present on HL7 CDA documents. Nonetheless, some Member States are mentioning an increase in the use of HL7 FHIR in their national infrastructure. The implementation of new services could in principle be based on a new technology. Support for both CDA and FHIR for the same service would, however, increase complexity. Patient Summary and ePrescription could continue on CDA until further notice, as the change of technology for these services could disrupt ongoing developments. A choice is required to be made for each new service (either CDA or FHIR) and avoid implementing both options. For medical image exchange, DICOM support needs to be introduced.

A preliminary draft comparison between CDA and FHIR was presented. Of note, no further developments are expected for HL7 CDA. The commonalities between both technologies are that technically, they are both possible to implement. IHE profiles exist for both technologies and are currently used in MyHealth@EU for CDA and may be used for FHIR if so decided. The implementation of the new use cases will consume time and resources in any case, and trainings and knowledge exchange is required for both, especially when it comes to new team members.

The Technical IOP SG proposed the following timeline: to receive a mandate to prepare a non-paper to submit for informational use to Member States; to compile a Survey to identify national preferences and willingness/readiness to implement; a submission of a revised non-paper to the eHN for decision; implementation of new use cases in MyHealth@EU.

The Technical Interoperability and Semantics SGs proposed to divide the responsibilities accordingly, with the Tech IOP SG leading the creation of a non-paper on the choice of technology (CDA vs. FHIR) while the Semantics SG creates multiple Task Forces to prepare for the decision regarding Laboratory Result Reports, Medical Image and Imaging Reports, as well as Hospital Discharge Reports within the eHN Guidelines, while also providing a minor update in the Patient Summary Guidelines that includes the integration of the X-eHealth Rare Disease Scenarios.

The eHN came to the conclusion that considering this is such a fundamental discussion, the SGs should present the non-paper and survey results through written procedure at the Coordinated Actions meeting. PL and NL agreed that this question requires thorough consideration, and therefore a strategic discussion by the eHN needs to take place. FR agreed that there was a strong value to do the non-paper and survey to help the eHN in its strategic discussions and guide Member States in their decision-making.

The eHN provided the mandate to the Tech IOP SG to create a non-paper and conduct a survey on MS willingness and ability to transition from CDA to FHIR for new use cases.

ES made a general comments on point 2.3 (focusing on cross-border use cases only, which is the scope of discussions of the eHN), regarding the discussion on technology:

1) for current primary use cases of the EHDS, i.e. Patient Summary (PS) and ePrescription/eDispensation (eP/eD), the current CDA-based implementation (or a generally-compatible one) should be kept as long as possible.

There is very significant investment in many MS in the current technical specification of PS and eP/eD, based on CDA: 11 EU Member States are in production. For many of these, the standardization work performed in PS and eP/eD dates back to the ePSOS project (which dates back to 2008) and are only now seeing the benefits of this decade-long work. Most other EU Member States will be in production in these services by 2025-2026.

Most of the EU MS have legally binding Grant Agreements with the EU funding agency INEA/HaDEA, some dating up to 2025 (which will probably extend beyond that date), to implement PS and/or eP/eD services under the assumption of the current specification of these services, which is based on CDA. It is important to provide certain stability in the technical specification of PS and eP/eD in order to allow these MS to join these services, and also to allow MS to reap some benefits after implementation, without radical changes.

2) HL7 FHIR should be considered for future primary use cases of the EHDS (i.e. lab results, medical images and reports and hospital discharge reports) for several reasons: in these new primary use cases, the new citizen rights of art 3 of the EHDS proposal seem to be aligned with certain functionalities of HL7 FHIR. The user experience for the health professional in some of these use cases, such as laboratory results, could be much better with HL7 FHIR (for instance, it would allow extraction of relevant pieces of information from several lab results for a single patient, thus presenting the information in an evolution graph; the document-based approach would lead to the need of accessing several lab results documents one by one).

3) So far, openEHR is out of the debate at the EU level. We think it should be included. HL7 FHIR and openEHR are mostly complementary standards. HL7 FHIR is more oriented towards information exchange and openEHR is more oriented towards persistence (mostly, towards building EHRs which avoid vendor lock-in and are highly interoperable between each other at the clinical level). OpenEHR is much less extended than HL7 FHIR, but has potential, and is used in some EU Member States, including Spain, Italy, Sweden and Slovenia: https://www.openehr.org/deployments/jurisdictions/.

ES added that right now, HL7 FHIR and openEHR are generally compatible, and there is a collaboration, crosspollination of ideas, etc between the entities working on both standards. We believe that it's important to maintain compatibility between HL7 FHIR and openEHR in the standardization work we perform in the EU, and that it would be important to include it in the non-paper. If the EU adopts HL7 FHIR as a standard for all of its healthcare software, we will have a very large weight in the decision-making process in HL7 FHIR, and it's important to keep the existing collaboration that HL7 FHIR has with openEHR at the standardization level. Our proposal would be to stick with HL7 FHIR for the new use cases of the EHDS, but to also make sure that we keep the existing compatibility between HL7 FHIR and openEHR in the process.

2.4. MyHealth@EU Work Plan 2023 (for adoption)

A brief explanation of MyHealth@EU Work Plan 2023 was presented. It described the key actions the Commission (Policy owner, Solution Provider) will address in 2023 in relation to the core service implementation and support to the National Contact Points for eHealth. It also listed the management and governance, requirements and specifications, configuration services, terminology services, NCPeH reference implementation, test and compliance check services, communication and collaboration, operations management, and support to the NCPeHs and hosting.

Considering the eHealth Member State Expert Group (eHMSEG) has adopted and endorsed the Work Plan 2023 in October 2022, the eHN adopted (upon hearing no objections) the MyHealth@EU Work Plan 2023.

ES commented that funding foreseen for 2023 seems to be clearly insufficient (26 M€ only for secondary use) and does not seem aligned, for instance, with the ambition of the EHDS Proposal at its current drafting. Some funding calls are also non-applicable in practice as they would risk breaching the double-funding rule: for instance, DI-g-23-75 (Direct grants to Member States' authorities: increase health data semantic interoperability and build national capacity on health terminologies). The funding for the deployment of the new services for primary use Dl-p-23-74 (medical images, HDR, etc) is just 5 M€, whereas the funding to cover the costs of expansion to these new services would be at least 10 times that amount.

3. COVID-19

Due to time constraints, agenda item 3 was removed from the schedule and postponed to be discussed at the following Coordinated Actions meeting. DE is currently debating whether it is necessary to have test certificates enshrined as a mandatory solution, as well. The Tech IOP SG welcomed their suggestions and took them into account. The matter will be further discussed in the Coordinated Actions meeting.

ES intervened regarding point 3.2 of the agenda (EFGS), many MS have completed the off-boarding of EFGS, including Spain. What is the practical use of the EFGS at this point? What is the value it provides? Perhaps, we should consider the closure of the EFGS Gateway infrastructure at the EU level, and these resources could be used for long-term usage of the EU DCC Gateway.

ES commented on point 3.1, most likely Regulation (EU) 2021/953 will not be extended any further after the 30th of June 2023. After that, there will be no legal basis for the cross-border usage of the EU DCC in the EU/EEA. In ES' opinion the Gateway can continue to be operated by COM nevertheless and some MS and some third countries can continue to use it on a voluntary basis. This would be the preferred option. The cost of 6M€ seems reasonable to keep the service running by COM. In the EU Gateway (or a different Gateway), several challenges would remain:

- how to make sure that the validity of the EU DCCs is coherent with the validity of DSCs. As we have seen, it's not an easy problem.

- how to inform other countries (especially non-EU countries) about falsified DCCs. Identifiers would be personally-identifiable information (PII), and the GDPR would apply, etc.

For the first problem, the "third state" of the vaccination DCC can be introduced: "DCC was valid while the DSC was not expired". For the second problem, we still have not come to a reasonable solution due to art 10 of the EU DCC Regulation (COM as processor).

4. Election of Member States Co-Chair (for decision)

Since November 2020, the elected Member State Co-chair has been Ron Roozendaal of the Dutch Ministry of Health. His two-year term ends at this eHN meeting. The EC Co-Chair thanked him for the leadership of the eHN on behalf of the Member States and the work done by him and his team. Therefore, a new Member State Co-Chair will be elected for a period of 2 years, until November 2024. Currently there are 2 candidates: Bianca Rouwenhorst, Director Information Policy at the Netherlands Ministry of Health and Raphael Beaufret, co-head of the Ministerial Delegation for Digital Health, French Ministry of Health and Prevention. Following a description of the voting

process, the candidates were given the floor. Thereafter, voting took place, with one vote being accorded per Member State.

The results were communicated at the end of the day: the vote was a tie, with 12 votes for each candidate. Consequently, a new vote was launched until Wednesday, November 9, 2022 at 18:00 CET (Brussels) with Member States sending in their votes via written procedure.

5. Update on EHDS

An update was given on the EHDS negotiations, specifying that there will be a longer update provided at the Council meeting.

Regarding the EHDS Proposal, it was noted that within the EU Parliament, ENVI and LIBE committees will be the lead, with the first formal exchange being held on November 8, 2022. The IMCO and ITRE Committees will also provide their opinions. The Budget Committee was also asked to give an opinion but they chose not to. The LIBE rapporteur is from IND (far-right group), with the ENVI rapporteur being from EPP. It was noted that the Parliament will begin first to establish its own position on the matter.

The Council's work on the EHDS Proposal was a bit more advanced, with an article-by-article read-through of the proposal in the Public Health Council Working Party. Initial discussions were started on the Czech Presidency compromise text for Chapters II and III.

A summarized update on MyHealth@EU was given, having already presented this in the morning. The reference architecture was explained of the MyHealth@EU sister project, HealthData@EU, which focuses on the secondary use of data. It follows a similar pattern to MyHealth@EU, with national contact points being the health data access bodies. The novelty is that the EMA and ECDC can participate as well in the data sharing infrastructures. It was specified that the Commission's role in the HealthData@EU project will be to provide central services, enabling the infrastructure to work.

The HealthData@EU Pilot has two projects: the EHDS2 Pilot being divided within Nodes Service (Project 1) and Central Services (Project 2). The first project is led by the Pilot Consortium, whereas the second is managed by the EC, Solution Provider and Contractor. The Pilot will run from October 2022 until September 2024. The first year will be dedicated to developing the Pilot, then a scale-up phase will follow based on the lessons learned during the piloting period so as to improve its functioning in countries across Europe.

6. Funding

6.1. EU4Health (for information)

Relevant actions for the EHDS under EU4Health were presented. This included a brief overview of actions that are currently ongoing or under preparation from work programme 2022 of EU4Health. The actions that are most relevant for primary uses of health data include the Direct Grants for the expansion of expand MyHealth@EU services and the work towards implementing the EHDS through the Joint Action on primary use.

An overview was given on the funding offered under Connecting Europe Facility and the Digital Europe Programme that is relevant for the EHDS. It was noted that 2022 was an important year as the direct grant amounts have doubled from 2021, with EUR 30 million being allocated to MyHealth@EU and EUR 4 million to the Joint Action on primary uses of health data.

The objective of the MyHealth@EU grant is to have additional Member States implement MyHealth@EU services and to have those already live to expand their services to new data domains. The Joint Action has the objective to enhance cooperation amongst Member States on the primary use of health data and to conduct preparatory work for the implementation of EHDS.

The NL asked for an update on the eHN Workshop results in Paris concerning the improvement of funding applications. The EC responded that one of the outcomes of the Paris eHealth Network Workshop was to provide more support and assistance to Member States in their funding applications. Competent Authorities were invited to a dedicated workshop in October 2022 on direct grants and joint actions. Further help and assistance is offered by the Commission should the Member States need it.

6.2. Funding: Relevant action under Connecting Europe Facility, Digital Europe Programme and Horizon Europe (for information)

A brief presentation was given of the Digital Europe Programme (DEP).

The eHN was reminded of the structure of the DEP, its purpose being the progress in the digital transformation of the EU and the deployment of advanced digital technologies, including edge-to-cloud and high performance computing capabilities. The co-funding rate is 50% except for specific calls where the co-funding rate for SMEs is 75%.

Since October 1, 2022, the Data Spaces Support Centre is in place. It is an important horizontal Coordination and Support action for all data spaces, including the European Health Data Space. It will provide support on common requirements for data spaces and knowledge exchanges and it will work on creating a network of stakeholders to support the deployment of data spaces.

In relation to the Health Data Space, there are two major federated European infrastructures: one on genomics data and another one on cancer images data. Additionally, proposals are currently under evaluation for the Digital Identity Framework and grant agreements are under preparation for a Testing and Experimentation Facility for Health. These actions are further complemented by Coordination and Support Actions on the uptake for digital solutions and the uptake for digital twins in Health.

Concerning Cybersecurity in health, DEP will support cybersecurity resilience of hospitals and other entities through specific grants.

While Digital Europe Programme (DEP) focuses on the deployment of digital technologies, Connecting Europe Facility II (CEF2) is about deploying digital infrastructures, and in this case interconnection.

The Work Programme for CEF-DIG 2021-2023 includes among others a 140 million euro grant for backbone networks for pan-European cloud federations. A backbone network connects data centres facilitating a consistent performance of bandwidth, latency, and performance in time.

The Commission invited the eHealth Network members to reflect whether their corresponding digital health related services have the necessarily underlying infrastructure.

A call was opened for funding in October 2022 for three EUR 1 million studies related to developing new and/or significant upgrade of cloud interconnections. The deadline is end of February 2023, and health is one of the key sectors that could be included. The study proposals can to be cross-border and/or national. The co-financing rate of 50%. Final beneficiaries of the connectivity should be the

public sector or services of general interest, although private sector actors are welcomed to participate in Consortiums.

7. Czech presidency and Swedish presidency

The Czech Presidency provided an update on what they have achieved throughout their presidency. They briefly mentioned hosting the joint meeting of the Technical Interoperability and Semantics Subgroups in Prague at Emauzy Monastery. It was a busy two-days and a pleasure to be able to host.

The main work conducted by the Czech Presidency was on the EHDS Regulations. Following the FR presidency, they continued the discussions on the EHDS Regulation. In total, they had 16 meetings of the Working Party of the Council dedicated to the proposal for EHDS, with at least three more meetings to follow.

The EC thanked the CZ Presidency for their devoted work on the legislative proposal of EHDS.

The SE Presidency representatives assured the members of the eHN that they would do their best to keep the work moving forward. The main tasks during the Presidency will be to chair meetings in the Council and its preparatory bodies as well as lead and drive forward the Council's work on EU legislation. This is the third time that SE has held the Presidency and preparations are well under way. However, it was noted that national parliamentary elections were held on September 11, 2022, and so the SE government will only have the chance to present its budget tomorrow (November 8, 2022). As a result, the new government has not had a chance to be involved yet, but will be in the near future. The SE Presidency priorities and work programme will therefore be communicated later this year.

In terms of preparations, the general political direction of the SE Presidency is: to provide security for EU citizens and strengthen the EU's role in the world; to stop organized crime; speed up the green transition; to strengthen the EU's competitiveness for jobs of the future and to safeguard Europe's fundamental values.

They have a heavy agenda for Spring 2023 due to SE having small ministries dealing with large agencies. The SE representative assured that the understaffed situation will be fixed. In regards to health, there are many legislative files on the table such as the continuation of the EHDS Regulation Proposal, revising pharmaceutical legislation, and work on regulation on substances of human origin.

More than 2,000 meetings in total are planned during the SE Presidency, with around 150 planned in Sweden and 11 informal ministering meetings in total. The Ministry is planning for: an informal EPSCO Health meeting in May; a High-Level meeting on Health in February; and for two presidency expert conferences on health. They are also looking at hosting the 23rd eHN meeting in June 2023.

8. WHO Europe: Digital Action Plan

An update on the WHO Digital Europe Action Plan was given, since the Digital Health Plan was recently adopted by the WHO General Committee in September 2022.

The WHO Regional office for Europe covers 53 countries with nearly one billion people. The three main challenges related to health in the region are suicide, mental health problems and alcohol consumption amongst others. The COVID-19 pandemic is also an on-going health challenge for the region. Within this context, there is also a digital health fever around health data.

The WHO is promoting the Action Plan for multiple reasons, namely because there was a launch of a global digital health strategy signed by 194 member countries in 2020. This Action Plan is the

instrument to implement this global strategy at the regional level. During COVID-19, many digital solutions have been implemented and therefore an investment plan is needed.

The purpose of the Action Plan is to promote digital health systems to improve health at scale by leveraging and scaling up digital transformation and aligning digital technology investments with health system needs. This Action Plan was developed with the support of 38 Member States and their active contribution to the resolution. It was adopted alongside eleven important partners, including the European Commission.

Four strategic objectives, eighteen key regional focus areas (to be implemented between 2023-2030), and twenty-one illustrative actions (to be executed in the next two years) are included in the Action Plan. The four strategic objectives are: setting norms and developing technical guidance (i.e. guidelines); assist country capacity and strengthen digital health literacy; building networks and promoting dialogue in knowledge exchange; and look at what is working from a digital solution point of view and scale it up globally. A survey was completed to gain input from Member States on how they would like to be assisted – the results are to be published mid-November 2022.

The key illustrative actions for Member States that will be prioritized in the next two years are: to develop a digital health strategic resource kit; to identify core competencies of digital health literacy; to promote and contribute to the assessment of infrastructural needs and the review of national laws and policies to drive successful digital transformation; to strengthen countries' capacities to leverage the full potential of big data; and to continue promoting the alignment with EU, OECD and other international organisations. The Action plan is thus trying to operationalise the WHO global strategy, to enhance country capacities to better govern digital transitions in the health sector, and to continue to implement these illustrative actions as necessary.

The EC co-Chair thanked the WHO representative for this presentation and stressed the continued need for alignment between the WHO and EC/DG SANTE. An open channel of communication with regular updates between the WHO and the EC would be welcomed.

Any other business:

Digital decade indicators for eHealth:

An update was provided by DG CNECT on the Digital Decade monitoring framework and policy development. They presented the preparatory work for the adoption and implementation of the Digital Decade Policy Programme (DDPP) and the support needed from Member States in the design of the Digital Decade monitoring framework in relation to the measurements of advancing towards the health target. The target is to assure 100% health data access to all citizens in the EU. This information was all communicated during the Digital COMPASS Communication in 2021.

The Digital COMMUNICATION 2021 will be followed by the DDPP that will set up the monitoring and operational mechanism to achieve the objectives and targets. It proposes a series of elements of governance mechanism like annual reports and a digital health decade board.

The State of the EU Digital Decade Annual Report will be central to the governance framework as it will provide an annual snapshot of the advancement towards the targets across Member States and the EU, as well as identify significant gaps/shortages to be addressed through recommendations of policies, measures or actions to be taken by Member States. The Annual Report will be presented to the European Parliament and Council and will also give rise to dialogue with Member States on follow-up measures.

How the progress for each target will be measured and the preparatory work being done at the moment will be reported across Member States through an expert group and then adopted via formal comitology procedure. What follows would be an implementing act for the implementation of the DDPP. Union-level trajectories will be designed to have a reference for Key Performance Indicators (KPIs) that should follow, as well as provide guidance to Member States to establish national roadmaps and common elements.

The next procedural step is that the Programme will enter into force in early January 2023. EC together with Member States will develop KPIs to measure the progress towards targets in preparation of the Annual Report of the Digital Decade. This work will be supported by the Contractor who will help in designing a set of indicators based on developed methodology to measure progress and ensure that the assessment criteria is common across countries.

In order to develop a proper and sufficient monitoring framework, Member States are encouraged to be a part of this project. The Contractor will facilitate a structured survey or conduct interviews to receive comments on methodology and indicators composition. The aim is to have this done by the Coordination Support meeting of November 2023 and include in the results of the second Annual Report. Should Member States want more details, they are encouraged to contact DG CNECT.

With no other AOB, the meeting was adjourned.