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Health systems and products
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Final summary minutes, 2nd eHealth Network meeting 7 November 2012

Introduction

These draft summary minutes are prepared by the Secretariat of the eHealth Network and are organised around the points of the agenda of the meeting. They will be posted on the European Commission dedicated web page[1], once adopted in written procedure.

The agenda was adopted unanimously in the beginning of the meeting.

All Member States, except one, were represented. Croatia and Norway were observers. Switzerland was present on an ad-hoc basis. The meeting was chaired by Paola Testori-Coggi, Director General SANCO (the Commission Co-Chair of the Network) and Clemens Auer, Director General for Health Austria (the Member State Co-Chair).

No conflict of interest was declared by any of the experts accompanying the Members.

The Directive 2011/24/EU on patients' rights in cross-border healthcare[2] is referred to in these minutes as "the Directive".

1. POINT 1 OF THE AGENDA: STRATEGIC PRIORITIES FOR 2012-2014

1.1. Presentation of EU initiatives on eHealth

Paola Testori-Coggi recalled the overall objective of Article 14 of the Directive, and pointed out that the Network should aim at facilitating cross- border care, notably through two eHealth services: electronic cross-border exchange and access to a set of patients' summary data and ePrescription.

She gave a brief overview of the following EC initiatives related to eHealth, which could impact the work and priorities setting of the eHealth Network.

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[1]   http://ec.europa.eu/health/ehealth

[2]   http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

1.1.1. *Work on ePrescription under article of the Directive 2011/24*

The Commission Co-Chair explained that the upcoming (vote on 28 November, entry into force planned by end of year) Commission implementing directive on measures for improving the recognition of prescriptions in another Member State (Article 11(2)(a), (c) and (d) of the Directive) should define a minimum obligatory set of prescription elements. This set would apply regardless of medium used (paper or electronic prescription).

The future interoperability guidelines on ePrescriptions, referred to in Article 11(2)(b), which are to be endorsed by the eHealth Network, should build on the minimum data set agreed in the Implementing act.

Some Network Members pointed out the need to ensure compatibility at early stage between the minimum set of prescription elements and the set applied by EPSOS.

The Commission Co-Chair advised the Members to liaise with their national representatives in the Cross-Border Health Committee of the Directive. Once adopted the Implementing act will be sent to the Network.

1.1.2. *eHealth Action Plan 2012-2020*

The upcoming eHealth action plan 2012-2020 is expected to be published by the end of 2012 (6 December). The action plan emphasized that the Network will be the key strategic governance mechanism for eHealth interoperability in the EU.

The eHealth Action plan will be send to the Network.

1.1.3. *The Connecting Europe Facility 2014-2020*

The Connecting Europe Facility (CEF) is a new EU financial instrument and therefore a key mechanism to implement and scale up cross-border eHealth services. Up to 2 billion euros are foreseen to finance public digital services and infrastructure, e.g. for eHealth. The CEF is planned to be operational from 2014 until 2020.

The CEF governance is in preparation by the Commission. The eHealth Network will be consulted in the next meeting in May 2013.

1.1.4. *The ICT multistakeholders platform on standardisation*

The platform is created by the new Standardisation regulation adopted in June 2011. The Commission and Member States will be able to suggest priority use cases and corresponding ICT specifications, for their evaluation and identification by the Platform This will allow Member States' public authorities to use identified interoperability specifications in public tenders and thereby foster and support interoperability, for instance on eHealth.

A legal study shall be launched in February 2013 under the EU Health Programme 2013. It aims at examining how national laws on electronic health records (e.g. e Prescriptions) interact with cross-border provision of eHealth services and cross-border exchange of health data. The results of the study will be used as a basis for discussion with Members' legal experts to explore the way forward for creating a sustainable and supportive legal environment for cross-border eHealth services. Some Member States confirmed their request to be involved before the launch on the study description of work and criteria.

1.2. Network's strategic priorities in the Multi annual Work Programme 2012-2014

The MS Co-Chair introduced the suggested strategic priorities of the Network as included in the draft Multiannual Work Programme 2012-2014. He strongly encouraged commitment at EU level to make progress and ensure certainty and guidance for national policies and investments.

The EC Co-Chair recalled the priorities specified by the Directive and pointed out that there was a window of opportunity to develop interoperability and it should not be missed. She invited the Members to be ambitious and to commit to the suggested programme. She pointed out that as a matter of principle the Network and the implementation of its results are voluntary, and also those who would like to move ahead should be supported.

The Members shared the opinion that it is of utmost importance that they actively participate in decisions on interoperability to ensure the sustainability of national investments. They expressed the view that a stronger harmonisation and integration on eHealth, e.g. agreement on standards, is needed to achieve interoperability.

It was highlighted that national investments should be open to interoperability, instead of locked by proprietary solutions. It was emphasised that while addressing interoperability, the Network should not reinvent the wheel but align and build on existing work and experience, for example the EPSOS project. It was also noted that the multiannual programming should have some flexibility and allow for adjustments.

Conclusion: The Network Members expressed strong support and commitment to the strategic priorities suggested in the Multiannual work programme 2012-2014 and endorsed it unanimously.

2. POINT 2 OF THE AGENDA: SEMANTIC INTEROPERABILITY

The Member States Co-Chair introduced the semantic interoperability paper prepared by the eHGI, outlining the challenges and benefits, main principle and recommendations to handle semantic interoperability for eHealth in Europe. He pointed out that semantic interoperability issues were handled already within the EPSOS project but the Network's discussion is the first attempt to work towards an agreement at a governmental and policy level on this issue.

He mentioned that semantic interoperability is one of the key preconditions for enhancing online access to medical information. Difficulties in semantic interoperability were revealed by the Member States' responses to the eHGI questionnaire last summer, namely a huge complexity due to the use of an exceptional number of standards and coding systems in Members States.

Some Members mentioned that despite the availability of some universal coding systems, standards or interoperability guidelines, which could be used, such as ICD, HL7, IHE, the reality in Member States is different and further work is needed to enhance interoperability. SNOMED was reported to be used by some Member States, also aligned with other standards.

Various views were expressed on possible approaches to narrow down this diversity, in order to facilitate interoperability by mastering costs.

Some Members called for an agreement on a common European terminology, a list of priority terminology fields, a common information model and a structure of data. Others called for restricting the number of coding and classification systems as well as standards used.

Finally, some claimed that given the complexity, the use of a single system is not feasible and a long-term convergence and interoperability should be aimed for.

One Member asked if it would be possible to have a common European contract for buying a terminology referential. The Commission welcomed the idea and reported that such contract is being tested for joint procurement of vaccines.

Another Member highlighted the need to make such coding systems operational for users first. Finally, it was highlighted that the suggested use case based approach (in the semantic paper) is appropriate to test semantic interoperability but a broader strategy is needed to achieve it.

The Commission presented the *SemanticHealthNet* project[3], aimed to develop a scalable and sustainable pan-European organisational and governance process for the semantic interoperability of clinical and biomedical knowledge. The project will run until November 2014.

Conclusions: The Network's Members endorsed unanimously the paper on semantic interoperability as a first commitment at policy level towards semantic interoperability.

The eHGI initiative was requested to refine the policy options and to roadmap steps and milestones regarding semantic interoperability for the next meeting of the Network in Dublin in 2013.

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[3] http://www.semantichealthnet.eu/

3. POINT 3 OF THE AGENDA: EIDENTIFICATION FOR EHEALTH PURPOSES

The Commission Co-Chair opened the discussion on electronic identification by underlining that the work on common identification and authentications measures is one of the priorities of the eHealth Network.

Robert Madelin, Director General at DG CONNECT, gave an overview of the regulatory framework of electronic identification and authentication in the health sector, underlining the complementarity of the draft regulation on electronic identification [4] and Article 14 of the Directive. He also presented the next steps towards common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

He recalled that the draft regulation, whose adoption is expected in 2013, is based on the principles of voluntary notification and mutual recognition of electronic identification means. This means that while Member States are free to decide which electronic identification means they want to notify, they must accept all notified electronic identification means of other Member States. The legislation will in particular enable the cross-border and cross-sectorial use of electronic identifications but does not specify any technical or procedural requirement to harmonise the security of technical systems at national level.

He also presented the results of the mapping exercise on electronic identification and authentication practices for the health sector prepared by the Network's Secretariat. This mapping showed that while 8 Member States have an e-card with health functionality, 16 Member States have a cross-sector identification means.

He emphasised the arguments for a cross-sectorial approach within the Member States as it entails a series of advantages, such as economies of scale, citizen's convenience, interoperability of electronic identification means.

He also recalled the conclusions of the Network at its first meeting on "eIdentification EU Governance for eHealth Services" and welcomed the fact that the eHealth Network has started the work on their implementation.

On the security aspect, he emphasised that while health data are sensitive and therefore need to be fully secure, one has to acknowledge that security standards have improved overall and that not all data exchange in health requires the same degree of security. He also emphasised activities that the Commission will launch to strengthen security online: the European cyber-security strategy and the proposal for a Directive on network and information security (January 2013).

Finally, Robert Madelin underlined the value of the epSOS results in establishing a circle of trust for identification and authentication based on mutual recognition. He said these results could also be very valuable in relation to security aspects and he concluded by calling on the Member States to support a European approach of electronic identification for health.

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[4]   Draft regulation on electronic identification and trust services for electronic transactions in the internal market http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0238:FIN:EN:PDF

This vision was shared by the Commission Co-Chair who asked Members if they were ready to support a cross-sectorial approach to electronic identification and authentication for eHealth services[5].

A few Members expressed the view that it is crucial that the framework chosen is flexible enough to enable the coexistence of both the cross-sectorial approach and the sector specific one within the Member States.

Robert Madelin clarified that the Commission is not dissuading Member States from opting for a health card but emphasised that there would be economies of scale and lowering of costs if one card, whose security standards are high, is used by many sectors. He also made it clear that rapid technological progress may result in mobile solutions also in the eHealth sector, solving the potential problems of hardware interoperability for on the spot identification.

He also recalled the importance of taking into account the citizen centricity and user-friendliness that could be undermined by sector specific solutions that prevent a really seamless and cross-border experience. Finally, he recalled that the identification step, which is covered by the draft regulation, is based on the principle of mutual recognition. This means whether a card is sector specific or cross-sectorial, it has to be accepted by other Member States.

One Network Member expressed the view that currently decisions are mainly taken with a short term vision while underlining that the choice of a multi-sectorial or sector specific approach is crucial on the longer term.

Another Member requested a clarification on whether the proposed Regulation could provide a legal basis for the adoption of common security level in the health sector. Robert Madelin replied that its article 8 could accommodate such request from Member States. He recommended that the Member States coordinate internally to ensure interoperability of electronic identifications for eHealth purposes under the Regulation.

In **conclusion**, the Commission Co-Chair stressed the importance of progress on electronic identification for health. She recalled that the work programme foresees the adoption of an electronic identification position paper in May 2013 and of a roadmap giving a strategic approach to common measures on electronic identification for health in November 2013.

The Member States Co-Chair proposed that the eHealth Governance Initiative organises for the Members a workshop on electronic identification to provide a clearer vision of what is at stake and prepare for the next meeting of the Network in Dublin in May 2013.

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[5] The proposed eID Regulation foresees that any notified eIdentification systems - a generic one or a specific one – can be used in all EU countries in a cross-sectorial way, for identification in any sector.

4. POINT 4 OF THE AGENDA: DISCUSSION PAPER ON THE DATA PROTECTION REGULATION

As an introduction, the Commission Co-Chair stressed that the proposed Regulation for Data Protection aims to achieve a high level protection and privacy of personal health data and harmonised criteria for the lawful processing of personal data for research purposes.

The MS Co-Chair presented the Discussion paper on Data Protection drafted by the eHealth Governance Initiative (eHGI). The paper raises questions for discussion on eHealth related aspects. The concerns highlighted in the paper included: definitions, consent, right to be forgotten and implementation (delegated acts). He invited Members to discuss the nomination of the eHealth Network Rapporteur on data protection.

Paul Nemitz, Director in DG Justice, responded to the issues raised in the Discussion paper. He highlighted that the Regulation is proposed to keep data protection rights up with the challenges of the 21st century. The Commission carried out public consultations for two years before proposing the law.

The negotiation schedule:

- The European Parliament should present a report on the text before December 2012. The health (ENVI) committee is not involved in the discussions.
- Negotiations are on-going in the Council.
- The Data Protection Regulation is high on the agenda of Irish presidency of the Council (1st semester 2013)
- The proposal provides for a 2 year period for the implementation, after adoption of the Regulation.

The eHealth Network Members welcomed the update on the proposal and asked several questions:

Definition of personal data

> There is no major change in the proposed Regulation compared to the current Directive 95/46/EC. Genetic data are now explicitly included in the definition and therefore fall under the Regulation.

Consent

> The proposed Regulation clarifies the requirements for valid consent but does not as such represent a change as it merely codifies existing law under Directive 95/46/EC.

> Member States have the possibility to lay down by national law the rules for processing data without consent.

> Members noticed that they apply divergent rules on consent. These do not seem to be always compatible with the definition as provided by the Regulation. As different definitions coexist, the Regulation requiring explicit provisions could cause some problems.

The issue of consent is important when Member States set up Electronic Health Records systems.

In order to make a progress on this issue, a clear vision of the European Union and clear legal requirements are needed.

Right to be forgotten and to erasure

The right to be forgotten is a right to have the data deleted. However Paul Nemitz highlighted that in case there is a legal obligation to keep and process the data, notably on a long term, the right to be forgotten does not apply (article 17(3)(b) provides exceptions).

Some Members informed that the deletion of data in the electronic systems would "not be possible" as the data are to be kept forever due to the nature of electronic systems.

Sector specific legislation

Some Members expressed the need for a sectorial approach on data protection. Others informed about their ongoing national revision of legislation on data protection and problems in the area of healthcare. They questioned the diverging opt-in / opt-out approaches to consent for access and storage of data in electronic health.

Paul Nemitz suggested that the eHealth Network asks the opinion of the Working Party 29 on possible issues on data protection.

Delegated acts

Paul Nemitz stressed that delegated acts, supporting the adaptation of the legislation to the technical developments, help the implementation of the Regulation. He recalled that Member States are key actors in the decisions made under these acts, the Council has the right to block them, and Member States have no interest to leave important issues to non-legislative implementing instruments such as codes of conducts.

Some Members highlighted that the delegated acts must apply only to the non-essential elements of the article. Paul Nemitz fully agreed and noted that the Legal Service of the European Parliament concluded that none of the delegated acts proposed by the Commission concern essential elements. He stated however that the Commission's Vice President Reding agreed to potentially drop the number of the proposed delegated acts by up to 40%.

Some Members questioned that the proposed Regulation applies equally to public and private sector. Paul Nemitz said that the fundamental right to the protection of personal data as recognised in Article 8 of the EU Charter of Fundamental Rights does not differentiate in intensity and binding force for the private and public sector: the same level of data protection level has to be in principle ensured in both sectors.

General comments

> Some Members called for more harmonisation of the data protection rules on EU level. They expressed concern that the current situation and the reference to the Member States law in the proposed Regulation would cause a 'moving target' situation that should be avoided.

> Both the Commission Co-Chair and Paul Nemitz indicated that the eHealth Network could come up with a proposal for a more specific text on data protection in the area of health in the future based on the Regulation, once adopted.

Rapporteur on Data Protection

> The MS Co-Chair asked the opinion of the Network about the proposal by the eHGI to appoint a Rapporteur on Data Protection.

> One Member said that it is too early to speak with one voice but supported option 2 of the eHGI paper (adoption of an "awareness raising report" by the Network). Others underlined that good communication is needed between the Ministries of Health and EU institutions.

Conclusions: The MS Co-Chair concluded that the future steps on the proposed Regulation will be discussed again by the eHealth Governance Initiative and possibly re-discussed in the Network's next meeting in Dublin.

The Commission Co-Chair stressed that it would be worthwhile to safeguard the opportunity for a delegated act to implement the Article 81 in case it would be needed in the future instead of specific secondary EU law and called on Network's Members to advocate this in the Council negotiations. One Member objected to this.

5. POINT 5 OF THE AGENDA: INTEROPERABILITY OF DATABASES OF MEDICINAL PRODUCTS

The Commission Co-Chair introduced the item recalling the objectives pursued: 1) to give an overview of the on-going work to the Network's Members and 2) to decide how the Network can contribute to this issue.

This point had been suggested by Belgium and endorsed by the first meeting of the eHealth Network. The Secretariat provided a background note, having consulted the eHealth Governance Initiative.

Representing views of Member States, Vanessa Binamé from the Belgian Federal agency for medicines and health products described various existing national and EU level databases and pointed out their incompatibilities.

She presented the concept for a European Authentic Source (EAS) of Medicines, which could be an EU-supported initiative. She mentioned that the implementation of article 57 (2) of the pharmacovigilance regulation 1235/2010 could be a basis for the EAS. She briefly introduced the Common European Submission platform (CESP) and finally gave a short overview of the equivalent issues at stake as regards the identification of medical

devices. In this field, the work on identification will be addressed by the recent Commission proposal for a Regulation on medical devices.

From the European Medicines Agency (EMA), Luc Verhelst gave a comprehensive overview of the on-going work on interoperability of databases of medicinal products, in the context of the new pharmacovigilance legislation. He gave a clear message that progress on the implementation of interoperable international standards will depend on the willingness of competent authorities to use them. He shared the vision that such databases will be open source and shared with all health players and stakeholders, notably for the purpose of eHealth services (e.g. ePrescriptions) as well as for pricing and reimbursement decisions on pharmaceutical products. He also confirmed the vision that Member states and EMA should evolve to a common portal.

Some Members argued that these databases should also serve the purpose of identifying products interactions. Vanessa Binamé agreed that the EAS should contain such a function; an e-SPC project (Electronic Summary of Product Characteristics) could contribute to this kind of identification.

Another Member asked if the draft decision on cross-border recognition of paper prescriptions is compatible with the plans for implementing ePrescriptions as suggested by epSOS. Both types of cross-border exchange should be implemented under the Directive on cross-border healthcare. The Co-Chair replied that the two processes are mutually supportive but emphasized the need to keep them formally separated.

Thanking the speakers for informing the Network on the on-going work by the national and European authorities on medicinal products, the Co-Chair suggested:

- The Network should be kept continuously informed of the further progress.

- The Network Members should liaise with their national colleagues in charge of regulatory issues on medicinal products, to raise their awareness on the need to pursue building databases interoperable between the Member States and with the EMA.

- The Network should study the use of medicinal databases to promote other eHealth services, such as the ePrescription.

Members, except one, did not object to this.

6. CONCLUSIONS

The Co-Chairs recalled the rules of procedures of the Network which require summary minutes and no mention of the individual positions.

They gave the preliminary information as regards the 3rd meeting of the Network:

− It will take place in Dublin, in the margin of the eHealth week 2013, on 13, 14 or 15 May 2013

− Some draft agenda points will derive from the outcomes of this 2nd meeting and from the adopted multi annual work programme, namely:

    o eID for eHealth: adoption of a position paper on the Commission proposal for a regulation recognition on eID and eSignature

    o Interoperability: adoption of a roadmap on semantic and technical interoperability

    o Sustainability: adoption of a Network's recommendation on the governance of the Connecting Europe Facility

    o First discussion on the set of data on patient's record summary

[Electronically signed]

Tapani Piha
Head of Unit