



**eHealth Governance Initiative:  
Joint Action JA-EHGov & Thematic Network SEHGovIA**

**DELIVERABLE**

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on impact of foundation of the eHealth Network Art. 14**

**WP3 (JA) Evaluation**

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<b>ABSTRACT</b>
<p>This evaluation report describes activities undertaken by the eHealth Governance Initiative in maximising benefits in relation to work with eHealth across the European Member States. The focus is on the impact of the eHealth Governance Initiative with reference to the establishment and running of the eHealth Network established under the auspices of Directive 2011/24/EU.</p>

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## ABBREVIATIONS

eHealth	electronic Health
eHGI	eHealth Governance Initiative
eHN	eHealth Network Art. 14
eID	Electronic Identification
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
EU	European Union
EU	European Union
HLeHGG	High Level eHealth Governance Group

## LIST OF REFERENCES

Name of Author	Reverence / Source
eHGI	JA D1.1.1 Interim technical report_RP1 / Annex 1 Meeting Conclusions, Budapest 2011
European Parliament and the Council	Directive 2011/24/EU

## TABLE OF CONTENTS

<b>1. Background .....</b>	<b>6</b>
<b>2. Status .....</b>	<b>7</b>
2.1 Meeting of the HLeHGG in Budapest May 2011 .....	9
2.2 First meeting in Copenhagen May 2012 .....	10
2.3 Second meeting in Brussels November 2012.....	11
<b>3. Conclusion .....</b>	<b>13</b>

# 1. Background

Up until 2010 high-level ministerial meetings were held by the European presidency as separate events. At the meeting in Stockholm in the autumn of 2009 the network of European state secretaries responsible for electronic Health (eHealth) issues backed a proposal – made by the Swedish presidency at the high-level meeting in Stockholm on 22–23 October 2009 – to establish an initiative focusing on the governance of eHealth. The participants reached a broad consensus over how the Member States should continue their work to realise the Council conclusions on eHealth that were adopted on 1 December 2009.

The Council conclusions, among others, contained a paragraph dedicated to work on eHealth. In article 11 of the conclusions it is stated that:

“The Council of the European Union:

CALLS UPON Member States and the Commission to:

- 1) Build upon the political momentum created by the existing informal meetings of state secretaries and their equivalents, in order to develop, via the most efficient and suitable Member State led high-level mechanism, the governance, coordination and consolidation of ongoing activities in the field of eHealth, in liaison with the European Commission, to bring forward eHealth deployment and actual use of interoperable eHealth services within and between national healthcare systems;
- 2) Ensure that the main aims of this mechanism are to:
  - a. bring together and coordinate groups, projects and institutions at European Union (EU) level;
  - b. promote an alignment of eHealth with health strategies and needs at EU and national levels through the direct involvement of national health authorities;
  - c. disseminate scientific evidence of the cost-effectiveness and socio-economic benefits of eHealth services based on research at national and community levels;
  - d. report regularly on its activities to the relevant Council meetings;
- 3) Apply this mechanism in the following areas in particular
  - a. working together to address common issues and challenges related to bringing forward eHealth services for achieving health objectives;

- b. supporting Member States by the development of a roadmap including decision support and guidelines for the deployment, acceptance and use of eHealth services;
- c. working together with stakeholders, in particular patients and health professionals, to ensure that eHealth tools and services well reflect clinical needs and overall health system objectives."

With this background preparatory work was initiated by the Spanish presidency in the spring of 2010, and the eHGI was established as part of eHealth week in Barcelona in May 2010. In the spring of 2011 most administrative obstacles had been overcome and the first high-level meeting was held as part of eHealth week in May 2011 in Budapest.

## 2. Status

As stated, the first high-level meeting under the auspices of the eHGI was in Budapest on 11 May 2011. The meeting was held within the so-called High-Level eHealth Governance Group (HLeHGG). The HLeHGG was established as the successor to the informal state secretaries' group that had been meeting on a regular basis since 2002 at the high-level ministerial eHealth conferences. The HLeHGG was established as the top governing level of the eHGI.

Prior to the meeting in Budapest the Directive on the application of patients' rights in cross-border healthcare was adopted (on 9 March 2011) – DIRECTIVE 2011/24/EU. The Directive explicitly deals with eHealth in Article 14, which sets out a framework stating that: "The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States."

Article 14 further states that:

"1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2. The objectives of the eHealth network shall be to:

- (a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing

continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

- (i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and
- (ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

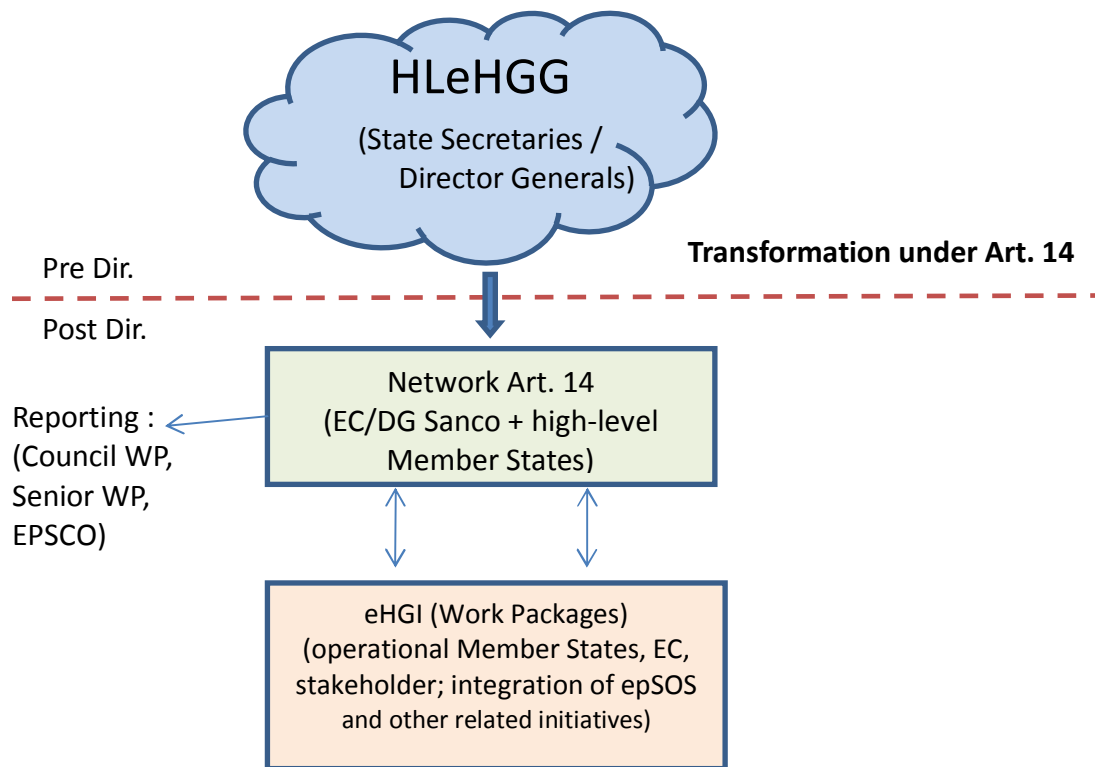
The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.”

It soon became obvious that the HLeHGG would be dealing with many of the same issues as the voluntary network set out in Article 14. Furthermore, the HLeHGG was of the view that it was crucial that the Article 14 network should be comprised of people with the same competences as the ones represented in the HLeHGG (i.e. states secretaries and/or director generals).

It was therefore proposed that the HLeHGG was merged with the voluntary network according to the figure below.





## 2.1 Meeting of the HLeHGG in Budapest May 2011

The HLeHGG met for the first time in Budapest on 11 May 2011 with the following agenda:

1. Welcome and Introduction by Hungarian EU-Presidency
2. European eHealth Governance Initiative (eHGI): Briefing on Status and Objectives
3. Latest developments in eHealth at the European level: The Digital Agenda, European Innovation Partnership on Active Healthy Ageing, Article 14 of Directive on patients' rights in cross border healthcare and other Initiatives - Goals and Interdependencies
4. European eHealth Governance Initiative (eHGI): "The Roadmap" – A Set of Priorities for Cross Border e-Health Policies
5. "eID in eHealth" – The Need for Coordinated Approach on Cross Border eID in the field of eHealth, to be completed by 2012
6. epSOS: Status and Interdependences
7. Meeting Conclusions
8. AoB

The output of the meeting was:

“The HLeHGG:

- Will provide – in cooperation with eHGI – a strong coordinated political leadership in developing cross-border eHealth services. This also implies a strong commitment to the national integration of such activities.
- Offers to cooperate closely with the EC to implement Patients’ Rights in Cross-Border Health Care Directive, especially regarding Art. 11 and 14, the initiation and creation of the voluntary network by Member States on eHealth, and also the revision process of the Data Protection Directive.
- Decided – on the basis of the Patients’ Rights Directive and the “Common European eHealth Interoperability Road Map” (CALLIOPE) – on a set of priorities for cross-border eHealth policies to give orientation regarding further activities and the development of policies in the Member States and the European Commission. To underline the importance of these recommendations on priorities, they should be presented to EPSCO as Council conclusions in December 2011.
- Takes the initiative to prepare a “Common European Framework for electronic Identification (eID) Management in eHealth”. Such a document with a clear set of recommendations and guidelines should be presented for further decisions at the meeting of the HLeHGG in Denmark, Q II, 2012”

### **Merging of HLeHGG with Article 14 eHealth Network of Directive 2011/24/EU**

During the autumn 2011 work was carried out aiming at ensuring a merging of the HLeHGG with the voluntary Article 14 network. The work was successful and resulted in a merging of the two, ensuring a solid platform for the continued joint European efforts with eHealth was established.

## **2.2 First meeting in Copenhagen May 2012**

The eHealth Network (eHN) met for the first time in Copenhagen at the tenth anniversary of the high-level ministerial eHealth conferences, and during the Danish EU presidency. The meeting was held on 8 May 2012.

The eHN’s members from 27 European Member States attended the meeting, including Norway and Switzerland as observers.

At the meeting the rules of procedure of the network were adopted and Dr. Clemens-Martin Auer from the Austrian Ministry of Health (and co-ordinator of

the eHGI) was elected co-chair of the network. A three year multi-annual work programme 2012-2014 was discussed at the meeting.

The eHN adopted the "Conclusions on identification EU Governance for eHealth Services" (which forms deliverable 5.1.1 of the eHGI joint action) after amendment.

At a subsequent meeting it was decided to put on the agenda the finalisation and adoption of the multi-annual work programme, discussion on the new proposal on data protection with the intention of achieving a common eHN position), interoperability of data bases for medicinal products and investments, and semantic interoperability.

Finally it was agreed that the discussions and decisions in the eHN's meetings shall be prepared and conducted at strategic political level with more limited technical presentations. Some of the Network's results could be presented to the EPSCO.

The eHGI was invited to undertake further work on:

- A follow up to the Network's "Conclusions on identification EU Governance for eHealth Services".
- A follow up to the Network's request to prepare a policy paper on semantic interoperability.
- Preparing a data protection discussion paper for the next Network's meeting.

## **2.3 Second meeting in Brussels November 2012**

At the meeting held on 7 November 2012 in Brussels all Member States except one were present. Croatia and Norway were observers. Switzerland was present on an ad-hoc basis.

Below is a summary of the conclusions reached at the meeting, illustrating the impact of the eHGI on decision-making in the eHN.

At the meeting the multi-annual work programme was put forward. At the meeting the eHN unanimously endorsed the multi-annual work programme 2012-2014.

At the meeting an eHGI paper on semantic interoperability was put forward, which the eHN's members endorsed unanimously as a first commitment at

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

Another item on the agenda was eID for health. At the meeting it was concluded that progress on eID for health is important. The work programme of the eHN anticipates the adoption of an eID position paper in May 2013 followed up by a roadmap giving a strategic approach to common measures on eID for health in November 2013. The Member States' Co-Chair proposed that the eHGI organised a workshop on eID for eHealth for the members to provide a clearer vision of the issues, and to prepare for the next meeting in Dublin in May 2013. This workshop was held in Brussels in February 2013, organised by the eHGI.

In preparation for the November 2012 meeting the eHGI prepared a "Discussion paper on implications of the proposed general regulation on data protection for health and eHealth". It was concluded that the future steps on the proposed Regulation will be discussed again by the eHGI and possibly re-discussed in the eHN's next meeting in Dublin in May 2013. The Commission Co-Chair stressed that it would be sensible to preserve the opportunity for a delegated act to implement Article 81 in case it would be needed in the future. This would avoid the need for specific secondary EU law. The eHN (with one objection) called on members to advocate this in the Council negotiations.

Finally during the meeting the topic of: "Interoperability of databases of medicinal products" was presented. Following the presentation of the topic the Co-Chair suggested that:

- a) The Network should be kept continuously informed of the further progress;
- b) 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;
- c) The Network should study the use of medicinal databases to promote other eHealth services, such as ePrescriptions.

This topic is of particular importance as it is closely linked to implementation of Article 11 of Directive 2011/24/EU and related Directive of execution 2012/52/EU.

At the meeting it was further concluded that additional draft agenda points for the subsequent meeting would include:

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

- **Interoperability:** adoption of a roadmap on semantic and technical interoperability
- **Sustainability:** adoption of a eHN recommendation on the governance of the Connecting Europe Facility
- An initial discussion on the dataset held within a patient summary

### 3. Conclusion

It can be seen that the eHGI has had a positive impact on the establishment and running of the eHN under Article 14 of Directive 2011/24/EU. The sustainability of the joint efforts in promoting cross-border healthcare by means of eHealth has been significantly improved by the establishment of the eHGI.

From the outset, a founding principle of the eHGI a founding principle was to reduce duplication of efforts. By ensuring that the original HLeHGG was merged with the Article 14 Network, this aim has been achieved. Previously, there was a tendency to have too many competing initiatives and activities. When resources are limited, they should be used wisely; this account of the activities to date of the eHGI is a good demonstration of this principle.

Reviewing the Council conclusions from autumn 2009, and adopted during the Swedish presidency, many of the goals set out have been accomplished. However, the Council conclusions state that the “mechanism” (i.e. the eHGI) shall “disseminate scientific evidence of the cost effectiveness and socio-economic benefits of eHealth services based on research at national and community levels.” It can be concluded that activities in this particular field have been limited during the project so far, and require more emphasis.

Revisiting the conclusions from the Budapest eHN meeting, it was stated that: “To underline the importance of these recommendations on priorities (on a set of priorities for cross-border eHealth policies), they should be presented to EPSCO as Council conclusions in December 2011.”

It should be noted that no Council conclusions regarding eHealth have been made since 2009.