



# eHealth Network

## **Recommendation Report to Go Live for Luxembourg**

**Drafted and adopted by eHMSEG on 23.10.2018**

## **Purpose of this document:**

On 16/10/2018 the National Contact Point for eHealth (NCPeH) of Luxembourg, submitted to the secretariat of the eHDSI Member State Expert Group (eHMSEG) an application to 'go-live' for the service Patient Summary country-B. The application was accompanied by the following supporting documentation: a signed declaration; test reports; and a follow-up audit report.

In accordance with the 'go-live procedure', the eHMSEG has evaluated the application. This document contains a summary of the evaluation and recommendations to the eHealth Network.

## **Section 1 Executive summary**

The eHMSEG recommends that Luxembourg:

Goes-live, with observations, provided that all corrective actions identified have been taken and this has been verified by Auditors, before entering routine operations.

- The NCPeH needs to submit a statement of the Auditors to eHMSEG (via secretariat) that all corrective actions have been implemented.
- The NCPeH can then enter routine operations without need for further approval.

## **Section 2 Findings and evaluation**

### **Section 2.1 Main findings of the conformance and functional test reports**

The end-to-end functional testing aims to validate, from the user point of view, the process and the information provided by the eHDSI services to health professionals. It is expected to detect flaws or malfunctions in any step of the process, from the processing of the original document to its transfer and subsequent processing and display in the receiver country. The evaluation is carried out for all eHDSI services (Patient Summary and ePrescription/eDispensation) in an environment that intends to simulate normal operations as much as possible: e.g. a pharmacist dispensing a medicinal product or a physician in an emergency department providing care to a citizen from a different deploying country. The only difference with a real scenario is that only test data are used and no real patients are involved.

The reports submitted demonstrate that the NCPeH has passed the necessary conformance and functional tests.

### **Section 2.2 Main findings of the follow-up audit report**

The initial audit of the NCPeH, against the readiness criteria checklist (version 1.19), took place in May 2018. The scope of the audit covered the organisation of the NCPeH and its activities in relation to the service Patient Summary country-B, including sub-contracted parties. A follow-up audit was carried out in October 2018.

The follow-up audit report concluded that:

*"The NCPeH organisation is well advanced in complying with the readiness criteria pertinent to all domains. Nevertheless, actions remain to be completed in relation to identifying the data processor(s) for the cross-border exchange of patient summaries, management of access rights to information, and an extension to the change management procedure.*

*In particular, the lack of clarity in identifying the data processor(s) for Patient Summary country-B services and the missing elements of the service management plan relating to the management of access rights to information may pose a risk to the confidentiality of health data".*

### **Section 2.3 Evaluation**

No further actions are required in relation to conformance and functional testing.

The report of the follow-up audit identifies three non-compliances and contains recommendations to the NCPeH to address each of them. The following table 1 provides an overview of these non-compliances and recommendations, the proposed actions of the NCPeH for addressing them, and the opinion and rationale of the eHMSEG underpinning its recommendation to the eHealth Network, as shown in section 3 of this document.

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<sup>1</sup> The table has been produced based on the draft Follow-up audit report 2018-6755, on the assumption that the final report will essentially contain the same information.

	Non compliance	Audit conclusion	Recommendation	Corrective action proposed by the NPCeH
1	C.9 (critical): According to the Ministry of Health and Social Security and the NPCeH, Agence eSanté is the data controller for the cross-border exchange of patient summaries, in accordance with Regulation (EU) 2016/679. However, the data processor(s) have not been unambiguously identified for the purposes of Patient Summary country-B services.	In the absence of a clear identification of the data processor(s) for the cross-border exchange of patient summaries, the NPCeH organisation cannot unambiguously demonstrate its accountability towards its stakeholders at national and EU level.	To identify clearly the responsible data processor(s) for cross-border health data pertinent to the service Patient Summary country-B, in accordance with readiness criterion C.9.	The NPCeH expects that updated documentation will be provided (either by the Ministry of Health and Social Security or by Agence eSanté) by the end of October 2018, which will include a clear identification of the data processor(s) in accordance with the definitions contained in Regulation (EU) 2016/679.
2	OS.1 [critical]: The current service management plan is at an advanced stage and is considered satisfactory with the exception of the following: <ul style="list-style-type: none"> <li>• Management of access rights to information, which is not included in the plan;</li> <li>• The monitoring function for the key performance indicators (KPIs), which is not described.</li> </ul>	Although service operations are largely ready for routine operations, the incomplete service management plan and change management procedures could create risks, in particular for the confidentiality and availability of services during routine operations.	To elaborate the Service (Level) Management Plan in order to include all the required elements and processes for the operation of the National Contact Point for eHealth, in line with readiness criterion OS.1.	The NPCeH expects the service level management plan to be updated to include arrangements to address these shortcomings by mid-November 2018.
3	OS.12 [critical]: The current change management procedures do not cover changes other than infrastructure changes.		To extend the change management procedure, in order to include all the necessary elements for the operation of the National Contact Point for eHealth, in line with readiness criterion OS.12.	The NPCeH expects the existing change management procedures to be updated to include software changes and to be extended to include changes other than those related to infrastructure and software by the end of October 2018.

### **Section 3. Recommendations to go live for Luxembourg**

The eHMSEG recommends that Luxembourg:

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- The NCPeH can then enter routine operations without need for further approval.