



eHealth Network

Recommendation Report to Go Live for Finland

Drafted and adopted by eHMSEG on 23.10.2018

Purpose of this document:

On 15/10/2018 the National Contact Point for eHealth (NCPeH) of Finland, submitted to the secretariat of the eHDSI Member State Expert Group (eHMSEG) an application to 'go-live' for the service ePrescription country A. 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 Finland:

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 March 2018. The scope of the audit covered the organisation of the NCPeH and its activities in relation to the service ePrescription country A, including sub-contracted parties. A follow-up audit was carried out at the end of September 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 the NCPeH's security clearance policy and access rights to information.

In particular, weaknesses in the access rights to information pose a risk to the confidentiality and the integrity of the data exchanged in cross-border health services."

Section 2.3 Evaluation

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

The report of the follow-up audit identifies two non-compliances and contains recommendations to the NCPeH to address each of them. The following table 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.

	Non compliance	Audit conclusion	Recommendation	Corrective action proposed by the NCPeH
1	O.13 [critical]: While security clearance has taken place for certain NCPeH staff, the NCPeH has not defined the security clearance policy for the organisation.	From the organisation perspective, the NCPeH is largely ready for routine operations. The absence of a security clearance policy, in particular linked to security-sensitive roles in the NCPeH, may pose a risk to the confidentiality and integrity of data.	To define the security clearance requirements for the NCPeH staff, in line with readiness criterion O.13.	The NCPeH is currently drafting its security clearance policy and expects to complete it by the end of October 2018.
2	IS 20 and 24 [critical]: The audit team found that NCPeH's approved documented procedure does not ensure that database administrators are assigned only the necessary rights for performing their specific duties.	The information security system is largely ready for routine operations. Nevertheless, weaknesses in the access rights to information pose a risk to the confidentiality and the integrity of the data exchanged in cross-border health services.	To put in place documented procedures which ensure that users are assigned only the necessary rights for performing their specific duties on the systems and services, in line with readiness criteria IS.20 and IS.24.	The NCPeH expects to take measures to address this shortcoming, including the approval of a new or amended procedure, by the end of October 2018.

Section 3. Recommendations to go live for Finland

The eHMSEG recommends that Finland:

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