eHealth Network

Recommendation Report to Go Live

for Estonia

Drafted and adopted by eHMSEG on 23.10.2018

Purpose of this document:

On 12/10/2018 the National Contact Point for eHealth (NCPeH) of Estonia, submitted to the secretariat of the eHDSI Member State Expert Group (eHMSEG) an application to 'go-live' for the service ePrescription – 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 Estonia:
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 2.1 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 ePrescription Country B, 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 pertaining to the organisation, semantics and technical interoperability domains. Nevertheless, actions remain to be completed in the domains of contractual compliance, service operations and information security.

The absence of a legal basis to operate in the cross-border exchange of health data means that the NCPeH organisation cannot demonstrate its accountability towards its stakeholders at national and European Union level.

In the information security domain, the absence of a comprehensive log management system poses a risk to the confidentiality 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 nine 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 conclusions	Recommendation	Corrective action proposed by the NCPeH
1	C.1 [critical]: Current legislation does not designate the HWISC as the national organisation responsible for exchanging ePrescriptions with other Member States.	The absence of a legal basis for the HWISC to operate as an NCPeH in the cross-border exchange of ePrescriptions means that the organisation cannot demonstrate its accountability towards its stakeholders at national and EU level.	To ensure that the Health and Welfare Information Systems Centre is designated by the national competent authority as the organisation responsible for the cross-border exchange of health information pertinent to ePrescriptions, in line with readiness criterion C.1.	The HWISC as well as the Ministry of Social Affairs, informed the audit team that (changes to) two pieces of legislation are under preparation, both of which are needed to empower the HWISC to fulfil its role in exchanging ePrescription data with other EU Member States. The first of three readings of the legislation is due to take place in the Social Affairs Committee on 9 October. This legislation also identifies the responsible data controller and data processor referred to in the Data Protection Impact Assessment. The Ministry anticipates the legislation to become applicable on 13 November 2018.
2	C.4 [critical]: The HWISC is currently not empowered to make contracts with pharmacies for the cross-border exchange of ePrescriptions.		To ensure that there are contractual arrangements in place with the national health care organisations (pharmacies) for the cross-border exchange of health information pertinent to ePrescriptions, in line with readiness criterion C.4.	After the legislation referred to above will come into force, the HWISC intends to make contracts with all 131 pharmacy activity licence holders for the cross-border exchange of ePrescriptions. The signature of contracts may start after the third reading of the legislation referred to in Finding No 1 (i.e. in October), and HWISC expects to have signed all contracts by the end of **December 2018.**
3	OS.1 [critical]: The current service management plan is at an advanced stage but it does not address problem management.	Although service operations are largely ready for routine operations, shortcomings in problem management and in the recovery procedure in case of disruption, may pose a risk to the availability of the services.	To put in place the Service (Level) Management Plan, in line with readiness criterion OS.1.	The HWISC expects the problem management procedure to be completed by the end of October 2018.
4	OS.21 [major]: Even if real time capacity monitoring has been demonstrated and the technical capacity of the system has been identified as five simultaneous users (due to NCPeH technical limitations), the business requirement for capacity has not been described, and the monitoring tools have not been configured accordingly.		To put in place methods, procedures and/or techniques to monitor and provide adequate service capacity, in line with readiness criterion OS.21.	The HWISC expects to establish the business requirement for capacity by the end of September 2018 and to complete the configuration of the monitoring tools by the end of October 2018.

	Non compliance	Audit conclusions	Recommendation	Corrective action proposed by the NCPeH
5	OS.24 [major]: The HWISC does not have an approved procedure to recover back to normal operations in case of disruption.		To put in place a procedure to recover back to normal operations in case of disruption, in line with readiness criterion OS.24.	The HWISC expects that the procedure to recover back to normal operations in case of disruption will be completed and approved once the business impact plan, the risk assessment plan, the business continuity plan and the disaster recovery plan have been completed. They expect all these documents to be finalised by the end of November 2018. (See also Finding Nos 8 and 9.)
6	IS.6 [critical]: Even though the security controls relating to the trust models applicable to the cross-border exchange of health data have been identified, the safeguards being implemented are not documented.	The information security system is largely ready for routine operations. Nevertheless, there are gaps in the system for collecting, analysing, storing and retaining audit trails and logs, which pose a risk to the confidentiality and integrity of the data exchanged in cross-border health services. (The risks associated with the absence of the business continuity plan, are mentioned in the conclusions for the Operations and services domain).	To ensure that no cross-border data could be transmitted via their services to an entity that either does not belong to or is not allowed within the Cross Border eHealth Information System network, in line with readiness criterion IS.6.	HWISC expects to document these safeguards by the end October 2018.
7	IS.7 [critical]: The HWISC has not exhaustively identified: (a) the logs generated by the NCPeH technical gateway; (b) the security policies (access rights) applicable to each type of log.		To put in place an appropriate system of collecting, analysing, storing and retaining audit trails and logs, in line with readiness criterion IS.7.	The HWISC expects to complete work to address these shortcomings by the end of October 2018.
8	IS.11 [major]: The business continuity plan has not yet been approved.		To define service/business continuity requirements in a Business Continuity Plan, in line with readiness criterion IS.11.	The HWISC expects the business continuity plan to be approved and implemented by the end of November 2018.
9	IS.12 [critical]: The HWISC does not have a disaster recovery plan for the cross-border exchange of health data.		To establish a Disaster Recovery Plan for the National Contact Point for eHealth Technical Gateway and other critical services and resources, in line with readiness criterion IS.12.	The HWISC expects the current draft disaster recovery plan to be amended and approved by the end of November once the business impact and risk assessment plans are completed. (See also Finding Nos 5 and 8.)

Section 3. Recommendations to go live for Estonia

The eHMSEG recommends that Estonia:

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.