TOPIC 3A

DETAILED GO-LIVE PROCEDURE

To prepare to go-live, Member State first needs to successfully go through the testing and auditing procedures. Each MS then summarises its testing and audit results in the MS Overall Readiness Statement which is submitted to the eHealth DSI Member States Expert Group (eHMSEG) for review.

MS can submit their Overall Readiness Statement (Annex 2):

(1) after they have received their Initial Audit Report (only if there are no non compliances or if the non-compliances are considered as non-blocking by the applying MS); or

(2) after they have received the Assessment of their corrective Action Plan following the Initial Audit (only for Wave 1); or

(3) after they have undergone a Follow-up Audit to verify the implementation of their corrective action plan and received the Follow-up Audit Report (which replaces the Initial Audit Report).

To complement their overall readiness statement, countries need to submit to the eHMSEG the following documents: in Case (1), the initial audit report; in Case (2), the initial audit report, the action plan and its assessment; and in Case (3), the follow-up audit report and proposed actions for addressing recommendations of the Follow-up Audit Report (if applicable).

After having assessed the submitted documentation, the eHMSEG proposes one of the following recommendations:

1) Go-live, without observations;

2) Go-live, with observations;

3) Go-live only after auditors' recommendations have been implemented, without a follow-up audit; in this case, the Member State has to submit to the eHMSEG a revised overall readiness statement including evidence of implementation of the auditors' recommendations before the eHMSEG can issue a favourable recommendation to go-live;

4) Require a follow-up audit to verify that appropriate corrective actions have been implemented to address the critical issues identified by the initial audit;

5) Consider that there is not enough evidence to issue a recommendation and require additional information.

As outcome of the assessment, the eHMSEG (with the support of the eHMSEG Secretariat) drafts a go-live recommendation report which includes the main findings of the testing, a

statement on the degree of compliance with the readiness criteria (based on the outcome of the audit process), a risk assessment of the applicant country and the eHMSEG go-live recommendations. This report is then submitted to the eHealth Network which takes the final decision on whether an applicant country can go-live, in accordance with its Rules of Procedure.

FOR EHEALTH NETWORK ADOPTION:

PROCEDURE TO VERIFY FULFILMENT OF CONDITIONS IN CASE OF CONDITIONAL POSITIVE DECISION TO GO LIVE BY THE EHEALTH NETWORK (EHN)

The eHN may decide to allow a country to join the cross-border data exchange ("go-live") under the condition that certain corrective actions (still pending at the time of the eHN decision) are implemented satisfactorily. Should this be the case, it is necessary to clarify who verifies the pending corrective actions have been implemented since a procedure to this regard has not yet being endorsed / adopted by the eHMSEG and eHN (respectively). To this end, it is proposed to include, where necessary, one of the following scenarios in the Go-live Recommendations:

Option 1: <u>No formal verification.</u> When issuing its conditional decision, the eHN does not require a formal verification that the pending corrective actions have been implemented but requires the country concerned to inform the eHN (via the eHN Secretariat) that they have fulfilled the pending requirements and provide adequate supporting documents as proof before going live. The eHN Secretariat will circulate the country statement and supporting documents to the eHN and the eHMSEG. The country concerned can move to the production environment ("go-live") after the eHN is informed without seeking further approval.

Option 2: <u>Verification by the eHMSEG.</u> When issuing its conditional decision, the eHN asks the eHMSEG to verify that the pending corrective actions have been implemented. The eHN requires the country concerned to inform the eHMSEG (via the eHMSEG Secretariat) that they have fulfilled the pending requirements and provide adequate supporting documents as proof. The eHMSEG Secretariat will circulate the country statement and supporting documents to the eHMSEG, who can vote (by oral procedure if an eHN meeting is planned within 6 weeks, otherwise by written procedure) on whether they consider the pending requirements have been fulfilled.

If the opinion of the eHMSEG is positive, the country concerned can move to the production environment.

If the opinion of the eHMSEG is negative, the country will have to re-submit an application to go-live to the eHN.

Option 3: **Verification by the Commission.** The eHN requires the Commission to verify that the pending corrective actions have been implemented. In this case, the country concerned, once it has implemented all pending corrective actions, asks the Commission (Unit F5) to carry out a verification. The verification could be desk-based (remote) or on-the spot at the NCPeH premises, where necessary.

If the outcome of the verification is positive, the auditors will issue a statement ('clearing letter') that all necessary corrective actions have been taken. The country should send the clearing letter to the eHMSEG and the eHN (via the respective Secretariats) for information. The NCPeH can then move to the production environment ("go-live") without need for further approval.

If the country concerned is unable to obtain a favourable clearing letter from the auditors, the country will have to re-submit an application to go-live to the eHN.

For those countries that receive their eHSMEG recommendation concerning the "go live" process more than 2 months prior to eHealth Network meeting, a written procedure can be launched for the decision of the eHealth Network.