



# eHealth Network

## **EHEALTH DIGITAL SERVICE INFRASTRUCTURE**

### **PROCEDURE 1:**

### **THE PROCEDURE TO OBTAIN THE EHN DECISION REGARDING GO-LIVE FOR THE NCPEH**

**Adopted by the eHealth Network on 03.06.2020**

## PROCEDURE 1

### THE PROCEDURE TO OBTAIN THE EHN DECISION REGARDING GO-LIVE FOR THE NCPeH

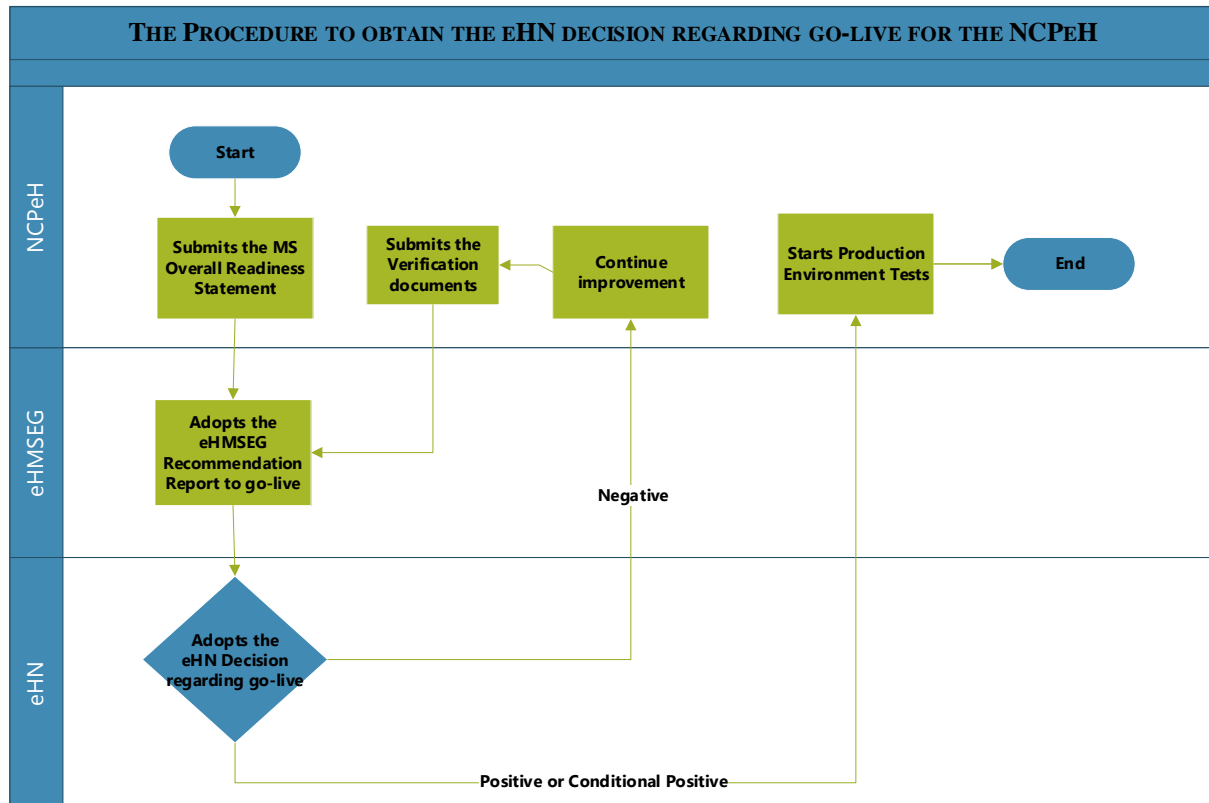
Applicable to MS, which applied to go-live by the end of 2019.

#### GENERAL REMARKS

- (1) The 'go-live' means to start the cross-border data exchange within the eHealth Digital Service Infrastructure.
- (2) The eHealth Digital Service Infrastructure Governance bodies work through their Secretariats provided by the Commission, as follows:
  - eHealth Operational Management Board – via eHOMB Secretariat (SANTE-EHEALTH-DSI@ec.europa.eu)
  - eHealth DSI Member States Expert Group – via eHMSEG Secretariat (SANTE-EHDSI-SECRETARIAT@ec.europa.eu)
  - eHealth Network – via eHN Secretariat ([eHEALTH-NETWORK@ec.europa.eu](mailto:eHEALTH-NETWORK@ec.europa.eu))
- (3) To request the eHN decision regarding go-live an NCPeH needs to go through the testing and auditing procedures (according to Test and Audit Frameworks). An NCPeH has to summarise its testing and audit results in the MS Overall Readiness Statement, which contains below annexes:
  - Outcome Summary Test Report after the eHDSI Formal Pre-Production Test event (depending on the NCPeH situation, one of the following documents could be applicable: Initial Outcome Summary Test Report or Updated Summary Test Report – after the Solution Provider verification process).
  - Audit Reports (depending on the NCPeH situation, one or several following documents could be applicable: the Initial Audit Report or Auditors assessment of Action Plan + Initial Audit Report or Follow-up Audit Report + proposed actions for addressing recommendations of the Follow-up Audit Report or Verification letter).
  - Signed Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services (the signed Agreement could be provided in the later stage, in due time for the eHealth Network decision).
- (4) As support materials for the impact assessment, the following verification documents have to be provided by the NCPeH:
  - Updated Outcome Summary Test Report (issued by the eHDSI Solution Provider, DG SANTE A4) – this report describes the status of the conformance and functional findings.
  - Follow up Audit Report or Verification of implementation of corrective actions (issued by the eHDSI Audit team, DG SANTE F5) – this report describes the status of the audit findings.

## I. PROCEDURE SCOPE

An NCPeH needs the eHN positive decision regarding go-live to be authorised to start the Production Environment Testing. The successful Production Environment Testing will allow the NCPeH to start the new service routine operations.



## II. ASSESSMENT PROCESS

1. An NCPeH submits the MS Overall Readiness Statement to the eHN via the eHMSEG Secretariat.
2. The eHMSEG Secretariat submits the MS Overall Readiness Statement to the eHMSEG.
3. The eHMSEG, after having assessed the submitted documentation, proposes and adopts the eHMSEG Recommendation Report to go-live for the NCPeH. The adoption takes place during the meeting or in a written procedure, according to the eHMSEG Rules of Procedure.
4. The eHMSEG submits the eHMSEG Recommendation Report to go-live for the NCPeH to the eHN.

## III. DECISION MAKING PROCESS

5. The eHN, after having examined the eHMSEG Recommendation Report to go-live for the NCPeH and any supporting documentation, adopts the eHN Decision regarding

go-live for the NCPeH. The adoption takes place during the eHN meeting or in a written procedure, according to the eHN Rules of Procedure.

The eHN may decide one of the following:

- I. Go-live, without observations (the eHN Positive Decision regarding go-live for the NCPeH);
- II. Go-live, with observations (the eHN Conditional Positive Decision regarding go-live for the NCPeH);
- III. Not to go-live (the eHN Negative Decision regarding go-live for the NCPeH).

#### IV. FINAL STEPS

6. If the eHN took a positive decision regarding go-live (without or with observations), the NCPeH can start the Production Environment Testing, according to the eHDSI Test Framework.

If the eHN took a negative decision regarding go-live (not to go-live), the NCPeH will continue the test and audit verification processes, according to the eHDSI Audit and Test Frameworks. The NCPeH can apply again to go-live after they meet the remaining go-live requirements indicated by the eHN.