



eHealth Network

EHEALTH DIGITAL SERVICE INFRASTRUCTURE

PROCEDURE 5:

THE PROCEDURE TO OBTAIN THE EHMSEG DECISION TO START THE NCPEH NEW EXCHANGE FOR THE SERVICE ALREADY IN ROUTINE OPERATIONS

Adopted by the eHealth Network on 03.06.2020

PROCEDURE 5
THE PROCEDURE TO OBTAIN THE eHMSEG DECISION TO START THE NCPeH NEW
EXCHANGE FOR THE SERVICE ALREADY IN ROUTINE OPERATIONS

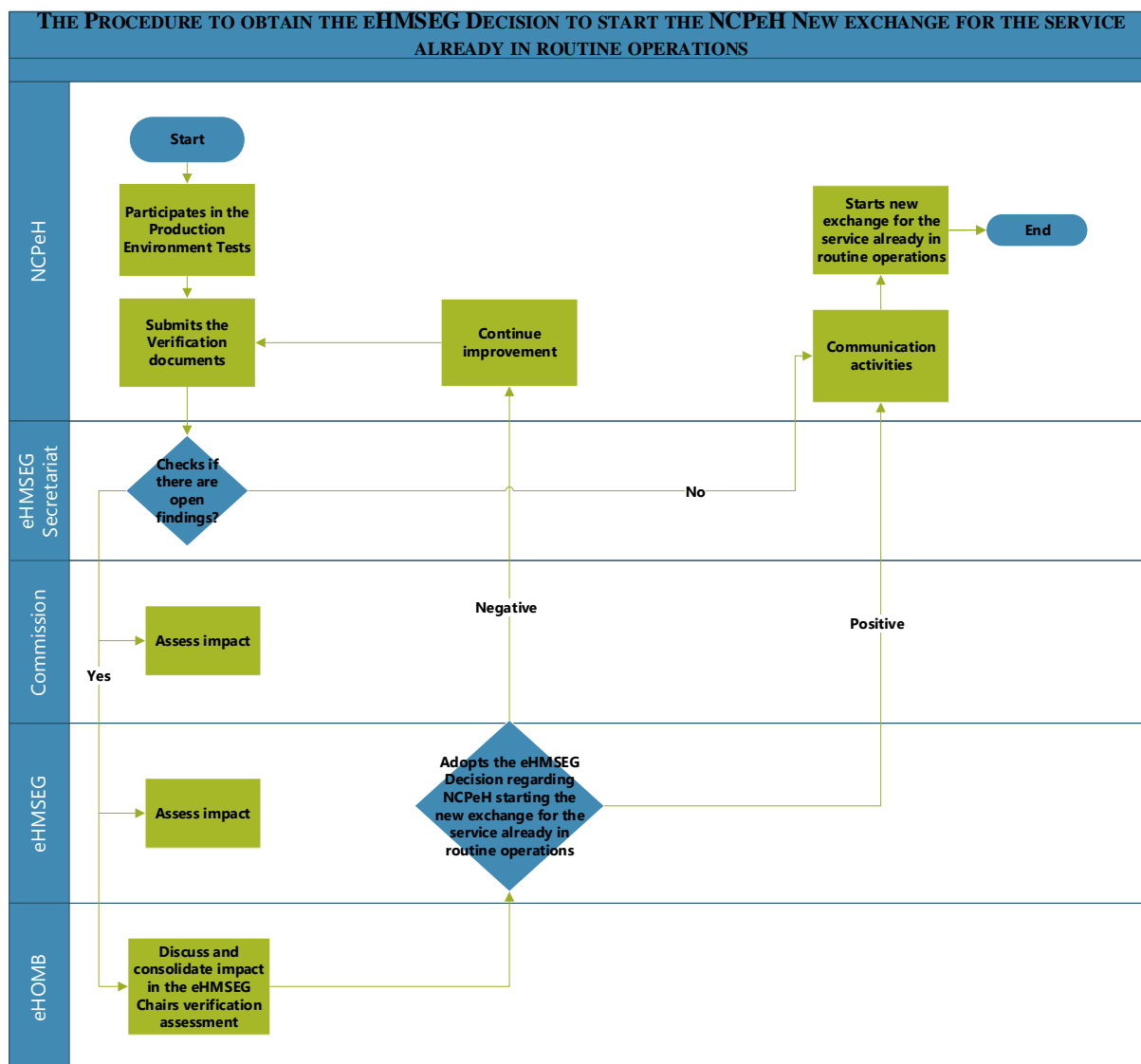
Applicable to Member States, which are applying (from 2020 onwards) to start the NCPeH new exchange for the service already in routine operations.

GENERAL REMARKS

- (1) 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)
- (2) The new exchange is an initiation of service provision with a new partner NCPeH for a service that is already in routine operations.
- (3) The NCPeH may apply to start the NCPeH new exchange for the service already in routine operations only after:
 - Completing the Production Environment Testing for this new exchange. This Production Environment Testing may result in (a) no findings (b) new open test findings. The status of the conformance and functional findings is recorded in the Updated Outcome Summary Test Report.
- (4) In the case of any open findings for this service, the eHDSI relevant governance bodies need to assess their impact on the eHDSI.
- (5) 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.
- (6) Separately from obtaining the eHMSEG decision to start the NCPeH new exchange for the service already in routine operations, the NCPeH can effectively start the new exchange for the service already in routine operations only with a partner who also fulfils all the above-mentioned criteria.

I. PROCEDURE SCOPE

The objective of this process is to obtain the eHMSEG Decision to start the NCPeH new exchange for the service already in routine operations.



II. ASSESSMENT PROCESS

1. The NCPeH submits the verification documents to the eHMSEG Secretariat.
2. The eHMSEG Secretariat checks if there are open findings for this new exchange.
3. In case of no open findings, step 9 should be directly entered.
4. In case of open findings:
 - a. The Commission¹ submits to the eHOMB the assessment of the open findings impact on the eHDSI.

¹ Commission is regarded as data processor for patients' personal data processed through the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services. In its capacity as processor, the Commission shall manage the core services of the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services (Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU).

- b. The Commission and the eHMSEG Chairs discuss the open findings impact during the eHOMB meeting.
5. The eHMSEG Chairs representing the eHMSEG propose the eHMSEG Decision regarding NCPeH starting the new exchange for the service already in routine operations and submit it to the eHMSEG Secretariat.

III. DECISION MAKING PROCESS

6. The eHMSEG, after having assessed the submitted documentation, adopts the eHMSEG Decision regarding NCPeH starting the new exchange for the service already in routine operations. The adoption takes place during the meeting or in a written procedure, according to the eHMSEG Rules of Procedure.
7. The eHMSEG informs the NCPeH, and the eHOMB about their decision.

I. FINAL STEPS

8. If the eHMSEG Decision regarding NCPeH starting the new exchange for the service already in routine operations is negative, the NCPeH continues the verification of the open Test and Audit findings.
9. In case of no open findings the eHMSEG Secretariat informs the NCPeH, the eHOMB, and the eHMSEG that the NCPeH can start the NCPeH new exchange for the service already in routine operations.
10. In case of no open findings or if the eHMSEG Decision regarding NCPeH starting the new exchange for the service already in routine operations is positive, the NCPeH has to inform the eHMSEG and the Commission's eHDSI Communication Unit (DG SANTE B3) about the exact date when they will start routine operations and prepare the communication related actions. Then the NCPeH can officially start new exchange for the service already in routine operations.
11. The eHMSEG Secretariat informs the NCPeH, the eHOMB, the eHMSEG, and the eHN about the date when the NCPeH started the NCPeH new exchange for the service already in routine operations and with which partner NCPeH.