eHealth Network

eHEALTH DIGITAL SERVICE INFRASTRUCTURE

PROCEDURE 5:

THE PROCEDURE TO OBTAIN THE eHMSEG DECISION FOR 2 NCPeHs TO START A NEW EXCHANGE FOR A SERVICE ALREADY IN ROUTINE OPERATIONS (COUNTRY PAIR DECISION)

Adopted by the eHealth Network on 30.03.2023

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GENERAL REMARKS

(1) The eHealth Digital Service Infrastructure Governance (eHDSI) bodies work through their Secretariats provided by the Commission, as follows:

- eHealth Operational Management Board (eHOMB) – via eHOMB Secretariat (SANTE-EHEALTH-DSI@ec.europa.eu)
- eHealth DSI Member States Expert Group (eHMSEG) – via eHMSEG Secretariat (SANTE-EHDSI-SECRETARIAT@ec.europa.eu)eHealth Network (eHN) – via eHN Secretariat (eHEALTH-NETWORK@ec.europa.eu)

(2) The new exchange is an initiation of service provision with a new partner National Contact Point for eHealth (NCPeH) for a service that is already in routine operations.

(3) Two NCPeHs may apply to start a new exchange for a service already in routine operations only after:

- Completing the Production Environment Testing (PET) for this new exchange. This PET may result in (a) no findings or (b) new open test findings. The status of the conformance and functional findings is recorded in the Updated Outcome Summary Test Report.
- The PET must be finalised by both NCPeHs participating in the new exchange, which means both the NCPeH providing the A-service and the NCPeH providing the B-service need to finalise PET.
- Each NCPeH needs to provide its Updated Outcome Summary Test Report to support their joint request.

(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 Reports (issued by the eHDSI Solution Provider, DG SANTE R4) – these reports describe the status of the conformance and functional findings.

I. PROCEDURE SCOPE

The objective of this process is to obtain the eHMSEG Decision for 2 NCPeHs to start a new exchange for a service already in routine operations in both countries.

II. ASSESSMENT PROCESS

1. The 2 NCPeHs must submit the verification documents to the eHMSEG Secretariat. This request will be initiated by Country A. Country A is responsible for collecting and submitting the relevant documentation for Country A and Country B.
2. The eHMSEG Secretariat checks if there are open findings for this new exchange.
3. In the case of no open findings, step 9 should be directly entered.
4. In the case of open findings:
    a. The Commission[1] submits to the eHOMB the assessment of the open findings impact on the eHDSI.
    b. The Commission and the eHMSEG Chairs discuss the open findings impact during the eHOMB meeting.

[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).

5. The eHMSEG Chairs representing the eHMSEG propose the eHMSEG Decision for 2 NCPeHs to start a new exchange for a 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 for 2 NCPeHs to start a new exchange for a 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 Secretariat informs the 2 NCPeHs, and the eHOMB about their decision.

IV. FINAL STEPS

8. If the eHMSEG Decision for 2 NCPeHs to start a new exchange for a service already in routine operations is negative, the 2 NCPeHs continue the improvement in order to resolve any open findings.
9. In the case of no open findings, the eHMSEG Secretariat informs the eHOMB and the eHMSEG about the automatic decision. In the absence of any objection(s) within 5 days, the 2 NCPeHs can start a new exchange for a service already in routine operations. In the case there are objection(s) within the same timeline, the eHMSEG is asked to take a decision on the matter following the procedure defined under paragraph 6.
10. In the case of no open findings or if the eHMSEG Decision for 2 NCPeHs to start a new exchange for a service already in routine operations is positive, the 2 NCPeHs have to inform the eHMSEG and the eHDSI Secretariat about the exact date when they will start routine operations and prepare the communication related actions. Then the 2 NCPeHs can officially start the new exchange for the service already in routine operations.
11. The eHMSEG Secretariat informs the 2 NCPeHs, the eHOMB, the eHMSEG, and the eHN about the date when the NCPeHs started a new exchange for the service already in routine operations.