



Innovation and Networks Executive Agency

Department C - Connecting Europe Facility (CEF)

**AMENDMENT N° 1
TO AGREEMENT No INEA/CEF/ICT/A2015/1159295**

The **Innovation and Networks Executive Agency (INEA)** ("the Agency"), under the powers delegated by the European Commission ("the Commission"), represented for the purposes of signature of this amendment by the Head of Department C of the Agency, **Andreas Boschen**,

on the one part,

and

Állami Egészségügyi Ellátó Központ / National Healthcare Service Center (NHSC)

Public Law Body

Registration No 324689

Diós árok 3

1125 Budapest

Hungary

VAT No 15324683-2-43,

represented for the purposes of signature of this amendment by Director General, **Miklós Gondos**

hereinafter referred to collectively as "the beneficiaries", and individually as "beneficiary" for the purposes of this amendment

on the other part,

Having regard to the above-mentioned grant agreement concluded between the Agency and the beneficiary on 27/12/2016,

Whereas:

- (1) The beneficiary has requested the Agency on 25/10/2018 to amend the above-mentioned grant agreement for the following reasons:
 - Delay in the implementation of the action due to unforeseen management and personnel changes;
 - Change of the authorised representative and contact details of the Beneficiary due to organisational changes;
 - Change in the distribution of eligible costs between different cost categories due to more detailed analysis of the products and services needed.
- (2) The measures provided for in this amendment do not affect the award of the Union financial aid.

HAVE AGREED AS FOLLOWS:

Article 1

(1) Article 2.2 is replaced by the following article:

"2.2 The action shall run from 01/01/2017 ("the starting date") until 31/12/2020 ("the completion date")".

(2) Article 6.3 is replaced by the following article:

"6.3 Communication details of the beneficiaries

Any communication from the Agency to the beneficiaries shall be sent to the following addresses:

- for Állami Egészségügyi Ellátó Központ / National Healthcare Service Center:
Petra Pölöskei
Project coordinator
Alkotás u 17-19, 1123 Budapest, Hungary
E-mail address: poloskei.petra@aeek.hu "

(3) Annex I shall read as follows:

**"ANNEX I
DESCRIPTION OF THE ACTION**

ARTICLE I.1 – SCOPE AND OBJECTIVES OF THE ACTION

The main objective of the Action is to prepare, test and deploy the cross-border Patient Summary and ePrescription and operate a National Contact Point for eHealth (NCPeH) in Hungary, taking into account the already existing national infrastructure. The NCPeH, endorsed by the eHealth Network, will manage Hungary's eHealth services.

Specifically, Hungary intends to implement both the cross-border Patient Summary and ePrescription in the first quarter of 2020. The two services will be provided both as country of affiliation/prescription (Country A) and country of treatment/dispensation (Country B).

The beneficiary, ÁEEK (the national Healthcare Service Center), is mandated by the Ministry of Human Capacities (the Ministry responsible for health) to ensure the seamless provision of cross border service within the national eHealth system (EESZT).

This Action will allow Hungary to broaden the level of care provided to European citizens visiting the country, in line with the Directive 2011/24/EU, as well as to better support Hungarian citizens' health information needs while travelling to European countries.

ARTICLE I.2 – LOCATION OF THE ACTION

I.2.1 Member State(s): Hungary.

I.2.2 EEA country(ies): not applicable.

I.2.3 Third country(ies): not applicable.

ARTICLE I.3 – ACTIVITIES

I.3.1 Activities timetable

Activity number	Activity title	Indicative start date	Indicative end date	Milestone number
1	Preparation and Implementation	01/01/2017	31/01/2020	5, 1
2	Service Testing, Approval and Deployment	01/04/2019	31/12/2020	4
3	Dissemination, Training and Support, Governance and Management activity	01/01/2017	31/12/2020	6, 2, 3

I.3.2 Activities description

Activity 1: Preparation and Implementation

The main objective of this activity is to design a national deployment plan and perform national preparatory and implementing activities towards provision of cross-border eHealth services.

The National Contact Point for eHealth (NCPeH) will be implemented as a separate system running alongside the already available national infrastructure (the EESZT), within the premises of NISZ.

This activity will be broken down into the following tasks:

T1.1 Plan and monitor progress towards service operation

This task will comprise the following steps:

- Definition of the detailed preparation and implementation plan;
- Adoption and localisation of the monitoring tools, in line with the other Member States in the Cross-Border eHealth Information System (CBeHIS);
- Monitoring of the overall progress.

T1.2 - Design national architecture

The aim of this activity is to design the architecture of the Hungarian NCPeH. The activity will take into account the following specificities of the Hungarian eHealth environment:

- The EESZT is a nation-wide system, therefore Portal-B (and epSOS-Web) is not needed, as health care professionals will use their usual IT environment.
- The functionalities of several modules (e.g. TRC-STs, Audit Repository, TSAM) are already provided by the EESZT. Using (and possibly extending) EESZT's components for the NCPeH will reduce risks and costs during the development and maintenance of the system. However, some components of the OpenNCP (e.g. protocol terminators, TSL-Sync, TSL-Editor) could be used during the implementation of the Hungarian NCPeH.
- Analysis of openNCP requirements.
- Analysis/integration of Security requirements of EESZT.
- Analysis/integration of Security requirements of NISZ.

T1.3 - Establish organisational requirements and procedures

The organisational procedures, put in place during the previous epSOS project, will be revised and extended in line with the eHealth Network (eHN) Organisational Framework. Roles, procedures and tasks will be identified and assigned to the specific actors, including the involvement of relevant institutions.

This task will be partly carried out by the team responsible for EESZT at AEEK. The technical infrastructure support and partly the identification of procedures will be subcontracted.

T1.4 - Establish legal, security and privacy requirements and procedures

The EESZT has the necessary legal basis and the privacy procedures have already been established. Due to cross-border data access, the legal regulations, the privacy procedures and maybe even the security policies of EESZT have to be modified (lowered).

Since the EESZT system ensures maximum security (according to L./2013 Act on Electronic Information Security of Governmental and Municipal Bodies), only the creation of epSOS circle of trust is necessary. All the other security requirements are already met. A Temporary Legal Agreement (TLA) or bi-lateral agreements with the other Member State will be prepared in case the eHealth Network does not adopt the new Multilateral Legal Agreement in time for the operation of the services.

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T1.5 - Assure semantic interoperability of Patient Summary (PS) and ePrescription (eP)

This task will consist in the:

- Creation of transformation rules between epSOS Clinical Document Architecture (CDA) Level 3 documents and the corresponding EESZT documents;
- Review of the Master ValueSet Catalogue (MVC) translation performed in the phase 2 of the epSOS project;
- Creation of transcoding tables from the relevant national coding systems into the epSOS ones.

T1.6 - NCP implementation, integration and deployment

This task will comprise the following steps:

- Implementation of changes in EESZT to allow the connection of the NCHeH gateway;
- Implementation of the National Interface Component, purchased from an EESZT solution provider;
- Integration of the National Interface Component into the openNCP gateway, performed by the developer;
- Deployment of the test NCPeH gateway.

T1.7 - Perform unit and integration testing

Detailed test procedures and acceptance criteria for security, system availability and safety will be prepared. Acceptance criteria will be classified as critical, essential and marginal, determining the action taken to correct them.

The unit tests will be performed before interfacing the NCP gateway to the EESZT. The module will be connected to the User Acceptance Testing (UAT) environment of EESZT to perform the Pre-production Testing (PPT) according to the Testing Strategy agreed in the OpenNCP Community.

The integration and testing process will be repeated every time a new version is released.

Activity 2: Service Testing, Approval and Deployment

The purpose of this activity is to test (nationally and internationally), to audit and provide evidence of the Hungary's readiness level towards the provision of services.

This activity will be broken down into the following tasks:

T2.1 - Perform testing to assure quality of the service provision

Pre-production conformance tests will be performed and documented in order to be admitted to the Projectathon conformance and clinical testing (in compliance with the Conformance Gate defined in the epSOS project).

The User Acceptance Testing (UAT) environment of EESZT will be used to ensure compliance with the same security requirements as for the operational environment.

T2.2 - Undergo pre-production testing and Projectathon

The Hungarian NCPeH will register for the 2019 Projectathon, for both the Patient Summary (PS) and ePrescription (eP) services. End-to-end functional testing will be performed by clinical experts.

T2.3 - Perform security audit

According to the process indicated in the Joint Action supporting the eHealth Network (JAseHN) organisational Guidelines, the internal audit, focusing on legal, organisational and



security aspects, will be performed to provide evidence of fulfilment of the requirements set by the Multilateral Legal Agreement and the organisational guidelines. The audit results will be provided to the eHealth Network (or other designated body) to approve the Member State to enter operation with the cross-border eHealth services. Applying the security rules, the security audit will be repeated by external accredited auditors, six months after the start of the operational services.

T2.4 - Prepare country readiness approval processes

Objective evidence of the technical and semantic readiness (through the Projectathon test results), as well as the legal, organisational and security readiness (through the internal audit results) will be provided to the eHealth Network (or other designated body), in order to get the formal authorisation to start the cross-border eHealth services.

T2.5 - Service deployment

The task will allow for bringing into the operational environment all the technical, semantic and organisational components requested to provide the cross-border eHealth services.

The main steps to be performed are:

- Deployment of the production version of the NCP gateway;
- Connection to the LIVE environment of EESZT;
- Deployment of the security assets for the operational gateway;
- Connection and configuration of the gateway toward the Central Configuration Services and the synchronization of the Local Terminology Service.

T2.6 – Non-regression testing

When the services have been deployed, the tests for non-regression will be performed.

These tests will be repeated as last action after the installation of minor and major releases of the NCP gateway.

Activity 3: Dissemination, Training and Support, Governance and Management activity

The aim of dissemination, training and support is to raise awareness among citizens and health professionals in Hungary regarding the provision of cross-border eHealth services.

The activity will put in place and make use of different communication channels:

- Project content management system;
- Project web portal, co-ordinated with the portals of the other Member States;
- On-line training tools;
- Social media and web channels.

The overall communication strategy will be defined and as far as possible aligned with the other Member States' strategies.

Tasks of this activity:

T3.1 Stakeholder engagement including health professional dissemination, education and training

To ensure proper stakeholder engagement, overall strategies and action roadmap will be agreed with the other Member States and implemented according to national specificities. The goal of these actions is to stimulate the triggering of the specific initiatives toward health professionals and citizens.

The following Hungarian professional bodies will be targeted:

- Medical Chamber;

- Pharmacists Chamber;
- Hungarian Hospital Association
- Medicina2000 (Association of Polyclinics);
- Chamber of Allied Health Professionals.

Also, specific communication and educational sessions will be organized in order to inform and train the health professionals using cross-border services.

The training will not be limited to teach how to use the system but also to learn about the differences among the Member States' approaches, e.g. consent management, way of creating the Patient Summaries and clinical implications of these differences.

Dissemination of project achievements will be carried out through various channels, such as:

- Project website health professionals (and for the public as well);
- Conferences and meetings;
- Specially organised press conferences;
- eLearning material.

T3.3 Citizen and end-users dissemination and motivation

Citizens would be made aware of their rights about cross-border care and about the availability of eHealth cross-border services (both in the home and in the visited countries).

The communication strategy for the citizens will be elaborated in close cooperation with the National Center for Patients' Rights and Documentation (OBDK), appointed National Contact Point under Directive 2011/24 to ensure adequate exchange of information on cross-border health care. Specific mass communication and focused actions towards tourists, students and business travellers will be designed and put in place (information materials, internet campaign, etc.)

At the same time, dedicated workshops will be held for the end users of the system (physicians, pharmacists) in the framework of mandatory specialised training to upgrade skills for health professionals.

T3.4: Training of helpdesk personnel

Training to the helpdesk team of EESZT on cross-border services will be provided.

T3.5: Support to developers

A manual with the specifications of the NCP interface will be created and provided to all health information system developers as a confidential document.

With regard to the governance and management of the national activities, the aim is to establish the link and the binding channel between Hungary, the eHealth DSI and other Member States providing the services, as well as to establish the appropriate national management structure to assure the provision of cross-border eHealth services.

This will be achieved through the following tasks:

T3.6 Acting and reporting according to the governance model of the eHealth DSI
Hungary will participate and act according to the procedures defined by the eHealth DSI governance model. It will comply with the instructions and requests of the eHealth Operational Management Board (eHOMB) and eHealth Member State Expert Group (eHMSEG). It will also adopt the eHealth Network decisions regarding policies, guidelines and the approval to enter in operation with the eHealth cross-border services.

T3.7 Management of national activities

Hungary will establish a national governance and management structure that guarantees the

execution of the proposed plan (deployment, operation, dissemination and support), as well as to ensure the existence of the relevant skills and competences that lead to a successful deployment strategy adjusted to national specificities.

Hungary will identify the person responsible for at least the following roles of the NCPeH: Organisation; Contact person; Technical responsible; Security responsible; Help desk responsible.

ARTICLE I.4 – MILESTONES AND MEANS OF VERIFICATION

Milestone number	Milestone description	Indicative completion date	Means of verification
1	Definition of the Service Deployment Plan with activities, milestones and tasks.	31/03/2017	Approved service deployment plan with activities, milestones and tasks
2	Definition of service dissemination, education and training schedule	30/06/2017	Approved service dissemination, education and training plan
3	Definition of the service support plan with responsibilities, workflow and stakeholder definition	30/11/2019	Approved service provision support plan
4	Compliance with the service requirements and recommendations for ePrescription and Patient Summary achieved	30/11/2019	Service Readiness Statement for ePrescription and Patient Summary approved by the eHealth Network
5	Completion of the preparation and implementation activity.	31/01/2020	Submitted final progress report on the preparation and implementation activity, containing Hungarian requirements and recommendations
6	Completion of dissemination, training and support, governance and management activity	31/12/2020	Yearly reports on service dissemination, education, training, service support, helpdesk performance, governance participation and national governance activities

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(4) Table 2 of Annex III "Estimated budget of the Action" is replaced by the following table:

" Table 2: Indicative breakdown per activity of estimated eligible costs of the action (EUR)

	Direct eligible costs				Indirect eligible costs	Total eligible costs	Estimated CEF contribution
	Personnel costs	Subcontracting costs	Other costs	Total			
Activity 1 NHSC	126,000	339,200	0	465,200	8,820	474,020	355,515
	126,000	339,200	0	465,200	8,820	474,020	355,515
Activity 2 NHSC	66,000	0	10,000	76,000	5,320	81,320	60,990
	66,000	0	10,000	76,000	5,320	81,320	60,990
Activity 3 NHSC	87,335	0	3,550	90,885	6,361.95	97,246.95	72,935.21
	87,335	0	3,550	90,885	6,361.95	97,246.95	72,935.21
TOTAL NHSC	279,335	339,200	13,550	632,085	20,501.95	652,586.95	489,440.21
	279,335	339,200	13,550	632,085	20,501.95	652,586.95	489,440.21

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Article 2

All the other provisions of the grant agreement shall remain unchanged.

Article 3

The present amendment shall form an integral part of the grant agreement and it shall enter into force on the date on which it is signed by the last party. It shall take effect on the date of its entry into force.

SIGNATURES *Limbach Viktor*

For the beneficiary *Alláshí Egészségügyi*
Ellátó Központ *National Healthcare*
Service Center
Miklós Gondos



For the Agency

Andreas Boschen

Done at Budapest, on

23 JAN. 2019

In duplicate in English.

In 5 originals

Done at Brussels, on

07 FEB. 2019