eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

Project Plan

D7.2/3 GUIDANCE AND TEMPLATE FOR THE INTERACTION WITH PATIENT REPRESENTATIVE, HEALTHCARE PROFESSIONAL AND OTHER EXPERTS

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DOCUMENT HISTORY AND CONTRIBUTORS

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Disclaimer

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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group will be actively writing the deliverable, the entire EUnetHTA 21 consortium is involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) will review and discuss several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) will endorse the final deliverable prior to publication. For further information on stakeholder involvement in this deliverable, please see section 3.3.

Copyright

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LIST OF ABBREVIATIONS

AIHTA	Austrian Institute for Health Technology Assessment, Austria
CA	Collaborative Assessment
CEB	Consortium Executive Board
COI	Conflict of interest
CSCQ	Committee for Scientific Consistency and Quality
DOI	Declaration of interest
ECA	EUnetHTA Confidentiality Agreement
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
G-BA	Gemeinsamer Bundesausschuss, Germany
HTA	Health Technology Assessment
HCP	Health Care Professional
HOG	Hands-on Group
JA3	Joint Action 3
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
KCE	Belgian Health Care Knowledge Centre, Belgium
NCPE	National Centre for Pharmacoeconomics, Ireland
OT	Other Technologies
PC	Patient Citizen
PICO	Population, Intervention, Comparator, Outcome
PLS	Plain Language Summary
REA	Relative effectiveness assessment
SOP	Standard Operating Procedure
ZIN	Zorginstituut Nederland, Netherlands

1 INTRODUCTION

In the technical offer, submitted on 04/05/2021, deliverables for the production of transversal tasks have been defined.

This Project Plan describes the objectives, approach and timelines for the following deliverables:

- Deliverable 7.2.1 "Guidance for the interaction with patient representatives, health care professionals (HCP) and other experts";
- Deliverable 7.3.1 "Template for patient representative input into JSC and JCA/CA";
- Deliverable 7.3.2 "Template for HCP input into JSC and JCA/CA".

2 BACKGROUND

There needs to be a mutual understanding of Health Technology Assessment (HTA) activities between all participants to ensure that the input from external stakeholders is relevant for joint HTA activities and that their perspective is included. Involvement of external experts is foreseen in the model for future HTA cooperation, to be developed under the HTA regulation. Stakeholders in HTA include patients, their representatives and organisations, health care professionals and their professional representative bodies, HTA bodies, HTA networks and regulatory authorities, health technology developers, technical experts (statisticians, information specialists and others), and payers, amongst others. Involvement encompasses direct contribution to the production of HTA outputs, contributions and consultations on HTA procedures and methodologies, and joint working and cooperation on the development of HTA cooperation.

Involvement of patients, patient representatives and patient organisations in JSCs and JCA/CAs

During EUnetHTA JA3, significant work was carried out to create a framework for the involvement of patients**,** patient representatives and patient organisations in the conduct of JCA/CAs and JSCs.

For JSC, the EUnetHTA Early Dialogue Secretariat contacted European and national associations as well as EURORDIS to identify potential patient experts. A significant majority of the patients were identified via direct contact with national and European patient associations. The patients gave input via interview on the disease, symptoms and their treatment experience, depending on the expertise of the patients. They can also participate in different meetings during JSC process. Summary of their interviews are shared with HTD as an appendix of final recommendations. Challenges identified in this process included the need for a template for HCP input, and the need for a clear process on how the input is incorporated into HTA outputs.

For JCA/CA of pharma products and other technologies (OT), the preferred method of patient involvement was to collect input during the scoping phase. A patient submission template was completed by submitting organizations, or was taken as a starting point for one-on-one conversations, group discussions or participation in scoping e-meetings, to obtain patient perspectives. Open calls for patient input are issued at the start of each JCA of medicinal products, and may be complemented by other involvement methods. For JCA/CA of OTs, the involvement methods for patients were discussed and agreed upon within the assessment team, and varied depending on the topic under assessment. An important requirement identified was that input should occur as early in the process as possible to inform development of the PICO.

Involvement of Healthcare Professionals in JSCs and JCA/CAs

The input of clinical experts is hugely important in informing key uncertainties and assumptions which arise in JCA/CAs and JSC. Input from HCPs was also obtained during JA3, although in a less standardised manner than input from patients. Challenges identified in this process included the need for a template for HCP input, and the need for a clear process on how the input is incorporated into HTA outputs.

For JSC: While prior efforts have been made during EUnetHTA JA3 to include HCP in pharmaceutical JSC, the involvement was challenging. Most HTA bodies already included their own experts in an informal manner. This complicated the involvement of a common clinical expert.

For JCAs/CAs: EUnetHTA JA3 developed 'Recommendations for Healthcare Professional Involvement in Relative Effectiveness Assessments'.

The preferred method of HCP involvement in JCA/CAs in JA3 was through medical/clinical societies, and/or via direct individual expert input. HCPs could be involved at the scoping stage, and in reviewing drafts of the preliminary PICO, project plan and assessment report. HCPs are identified and recruited through direct contact with EU or national level organisations, the HTA Network Stakeholder Pool, or direct contact with the experts themselves.

The DOI and ECA forms must be completed by individuals participating in the process.

Table 2.1. Existing EUnetHTA documents

Title	Scope	Assessment specific
Identification of Stakeholders *SOP (OT-PT-01-IdentStake, version 1.0)*	The SOP describes the process steps and responsibilities associated with identification and selection of stakeholders e.g. patients/patient representatives, consumers, healthcare professionals (HCP), manufacturers and Marketing Authorisation Holders (MAH) at the start of the Joint Assessment (JA) or Collaborative Assessment (CA) and the process on deciding on the mode of involvement	JCA/CA
Compensation of External Parties in Joint Action 3 *SOP (ADMIN-00-CompExt)*	The SOP describes the processes and timelines in compensation of external parties. External parties in the assessment process may include, but are not limited to, patient organisations, experts (e.g. patients/patient representatives and clinicians), medical and graphical editors.	No
Open Call for Patient Input *Process-related Guidance (version 1.0, 12/08/2020)*	This process guidance is applicable to the project start of an assessment and outlines the procedural steps necessary to conduct the specific patient involvement approach: the open call for patient input	JCA/CA
Patient Input in Relative Effectiveness Assessments (REA) *Process-related Guidance (version 29.05.2019)*	This document reports the development of recommendations for direct patient input in EUnetHTA REA process within JA3.	JCA/CA
Healthcare Professional Involvement in Relative Effectiveness Assessments *Process-related Guidance (version 17/04/2020)*	This document reports the development of recommendations for Healthcare Professionals (HCP) involvement in EUnetHTA REA process within JA3.	JCA/CA
EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and Confidentiality Agreement forms *Process-related Guidance (version 1.2, May 2021)*	This document has been developed for transparent description of EUnetHTA JA3 processes in handling conflict of interest declared in the EUnetHTA Declaration of Interest (DOI) form. Its aim is to assist in decision-making on the involvement of individuals into EUnetHTA JA3 activities in terms of presence of conflicts based on the assessment of interests declared. This procedure equally applies for individuals representing HTA bodies participating in a EUnetHTA task (internal) and experts (external).	No
Plain Language Summary Template *Template (version 1.1, Nov. 2020)*	The aim of the HTA plain language summary (PLS) is to disseminate and share information to non-HTA experts and researchers such as patients, policy-makers, health care professionals, and the general public. The PLS	JCA/CA

	template provides some standard text, free text and related guidance on how to complete it.	
Early Dialogues Patient Questionnaire Template for semi-structured patient input interview for JSC *Template (version Dec. 2019)*	The template includes questions on the general feedback on the procedure, feedback on documents during the process, feedback on investment, and process improvement.	JSC
Declaration of Interest (DOI) *Form (version Nov. 2019)*	This form is designed to specifically address conflict of interest (COI) and assist in the decision-making process concerning the involvement of individuals in EUnetHTA JA3 activities, whether as internal (EUnetHTA task) representatives or as external experts, based on a transparent assessment of interests declared within the form.	No
EUnetHTA Confidentiality Agreement *Form (version Nov. 2019)*	The EUnetHTA Confidentiality Agreement (ECA) outlines issues related to confidentiality within EUnetHTA JA3.	No
EUnetHTA – Patient Input Template for REAs *Form (version May 2019), available in all EU official languages*	It is a modified version of the HTAi [Patient group Submission] Template. Patient organizations interested in participating can complete the online and self-administered EUnetHTA Patient Group Submission Template.	JCA/CA
EUnetHTA Assessment Evaluation Questionnaire for Patient Input *Form (version March 2020)*	It is based on the Early Dialogues Patient Questionnaire Template for semi-structured patient input interview for JSC and was modified for the purpose of EUnetHTA assessments.	JCA/CA
Getting involved in a EUnetHTA assessment: information for patients *Flyer (version Jan. 2020)*	The flyer includes general information on HTA, EUnetHTA, the benefit for patients, the involvement methods and feedback.	No

3 OBJECTIVE AND METHODS

3.1 Objectives

For all of the objectives below the future EU HTA regulation will serve as the basis and the past JA3 experiences will be taken into account.

The objectives of the Hands-on Group (HOG) are to:

- Develop guidance for the interaction with and involvement of patient representatives, healthcare professionals and other experts in JSC and JCA/CA (deliverable 7.2.1);
- Develop a template for patient input into JSC and JCA/CA (deliverable 7.3.1);
- Develop a template for HCP input into JSC and JCA/CA (deliverable 7.3.2).

Each deliverable has several sub-deliverables, as specified below.

3.1.1 Deliverable 7.2.1 (D7.2.1) "Guidance for the interaction with patient representatives, HCP and other experts"

a) PC, HCPs and other experts **recruitment** for JSC and JCA/CA (pharma and other technologies)

- D7.2.1.a.1 - Refine the process for identifying interested patient and HCP parties, including guidance on who can provide input;
- D7.2.1.a.2 - Update the Process Guidance-Open call for Patient Input, and the Patient Information leaflet to reflect changes introduced during this project;
- D7.2.1.a.3 - To explore ways of disseminating information to HCPs on JCA/CAs and JSC via disease-specific conference presentations to raise awareness of what HTA work involves as distinct from EMA;

- D7.2.1.a.4 - To establish a database of patient experts, to develop SOPs around the management of such a database and to collaborate with other stakeholders, including regulatory, in relation to development of such a database to reduce any duplication that may take place;
- D7.2.1.a.5 - To establish a database of HCPs, to develop appropriate practices around managing such a database and to make this database available for use across each of the core functions of a future HTA regulation including JCA/CAs and JSC;
- D7.2.1.a.6 - To develop guidance on different contexts where involvement of specialist networks and institutional collaborators is needed, in cooperation with HOG of D5.3, which involves developing an SOP for the recruitment of technical experts, and designing a proposal for sustaining and resourcing of technical expert networks;
- D7.2.1.a.7 - To ensure that the COI documentation can clearly identify any relevant COIs for both patients and HCPs and other experts, and to link in with the work on the COI group to ensure all relevant updates captured.

b) PC, HCPs and other experts **involvement** in JSC and JCA/CA

- D7.2.1.b.1 - To produce a clear guidance for assessors in how to communicate information from HTD submission, to use input from patients/citizens, HCPs and other experts, including how it should be incorporated in reports, and to update JCA/CA and JSC templates to identify how external expert input has been included, in collaboration with the hands-on groups of D5.2.1 (JCA template) and D6.3 (JSC report);
- D7.2.1.b.2 - Update guidance for patients, HCP and other experts on how to provide input to JCA/CA and JSC;
- D7.2.1.b.3 - To fine tune the proactive feedback mechanism to ensure patient and HCP involvement is appropriate, timely, and meaningful for all partners;
- D7.2.1.b.4 - To clearly outline the language around patients, patient representatives and patient organisations, to define clearly what is meant by each term, and to ensure consistency in use across HTA outputs.

3.1.2 D7.3.1 Deliverable 7.3.1 (D7.3.1) "Template for patient input into JSC and JCA/CA"

- D7.3.1.a - To refine the current template for patient input, so that it can be used more broadly throughout joint HTA work;
- D7.3.1.b - To translate the templates to all relevant EU languages.

3.1.3 D7.3.2 Deliverable 7.3.2 (D7.3.2) "Template for HCP input into JSC and JCA/CA"

- D7.3.2.a - To develop a template for HCP input into HTA outputs, using the template for patient input and learnings from its development as a starting point.

3.2 Methods to achieve the objectives

3.2.1 (D7.2.1) "Guidance for the interaction with patient representatives, HCP and other experts"

The following steps will be taken in order to achieve the objective and to create a "Guidance for the interaction with patient representatives, HCP and other experts".

- A guidance development team will be established within the HOG, DOI collected and a detailed planning for each activity (objectives) will be defined, including a communication plan with other hands-on-groups (JSC, COI, GDPR);
- Output of JA3, including the existing guidance and feedback surveys' results, will be collected and evaluated, and if necessary, supplemental information from JA3 assessors may be obtained. Existing outputs from the IMI-PARADIGM project will be reviewed for overlap and reused or act as a starting point for further development, where appropriate;
- New guidance documents that meet the described objective will be drafted;

- The new guidance will be piloted along with the new templates (D7.3.1, D7.3.2), feedback will be collected and an update of the guidance will be developed accordingly (following the PDCA method);
- After review by CSCQ and endorsement by the CEB, the new guidance (and related templates) will be published and disseminated; the related SOPs will be revised where necessary.

3.2.2 (D7.3.1) "Template for patient input into JSC and JCA/CA"

The following steps will be taken in order to achieve the objective and to create a "Template for patient input into JSC and JCA/CA".

- A template development team will be established within the HOG, DOI collected and a detailed planning for each activity (objectives) will be defined;
- Output of JA3, including the existing templates and feedback surveys' results, will be collected and evaluated, if necessary, supplemental feedback from JA3 assessors or patient representative will be collected (e.g., EUPATI), external advice on plain language writing will be sought. Existing outputs from the PARADIGM-IMI project will be reviewed for overlap and reused or act as a starting point for further development where appropriate;
- A new template that meets the described objective will be drafted;
- The new template will be piloted along with the new guidance (D7.2.1), feedback will be collected;
- After review by CSCQ and endorsement by the CEB, the new template (and related guidance) will be published and disseminated; the related SOPs will be revised where necessary, and the template translated into all relevant EU languages.

3.2.3 (D7.3.2) "Template for HCP input into JSC and JCA/CA"

The following steps will be taken in order to achieve the objective and to create a "Template for HCP input into JSC and JCA/CA".

- A template development team will be established within the HOG, DOI collected and a detailed planning for each activity (objectives) will be defined;
- Output of JA3 will be collected and evaluated, if necessary, supplemental feedback from JA3 assessors will be collected;
- A new template that meets the described objective will be drafted; this template will take benefit of the work on D7.3.1 "Template for patient representatives";
- The new template will be piloted along with the new guidance (D7.2.1) in the production of JCAs and JSCs, feedback will be collected from EUnetHTA partners and HCP representative groups; an update of the template will be developed accordingly (following the PDCA method);
- After review by CSCQ and endorsement by the CEB, the new template (and related guidance) will be published and disseminated; the related SOPs will be revised where necessary.

3.3 Stakeholder inclusion

EUnetHTA 21 Stakeholder Pool is composed of HTA bodies (HTAb) outside of EUnetHTA 21 consortium, as well as stakeholder groups on patients, health technology developers (HTD), healthcare professionals (HCP), payers, and regulatory agencies from the EU/EEA countries.

Non-consortium HTAb (i.e. those not part of the EUnetHTA 21 consortium) who will be involved in the future subgroups of the HTA Regulation, should participate in the development of this project in order to ensure the deliverables are applicable to all European HTAb. They should be consulted at the beginning of the project. Additionally, they will also be invited to review, in parallel to that of the Committee for Scientific Consistency and Quality (CSCQ), the 1st draft of the deliverable and the pre-final draft that will be submitted for public consultation.

Furthermore, the HOG will consult with patient representatives and HCP during development of the deliverables.

Other members of the EUnetHTA 21 Stakeholder pool will also be involved in this project. Their involvement will include, at minimum, participation in an informational kick-off meeting and regular stakeholder fora. They will also be invited to contribute to the work through public consultation.

4 ORGANISATION OF THE WORK

4.1 Mode of collaboration and frequency of meetings

The work will be distributed evenly between the agencies of the HOG. All HOG members will review each other's work prior to review by the CSCQ. The HOG will appoint one agency to interact with the three CSCQ configurations and the CEB.

The HOG will have meetings/email updates when needed, but at least monthly meetings, to update each other on the progress. In addition, when needed, the HOG will also have regular meetings with the other relevant HOGs.

4.2 Timelines

Table 4.1. Timetable

Deliverable	**D7.2 – PC/HCP/Experts Guidance**		**D7.3 – PC/HCP/Experts Template**	
Milestones	Start date	End date	Start date	End date
Project duration	14/03/2022	04/11/2022	25/04/2022	04/11/2022
1st Draft deliverable	14/03/2022	26/04/2022	25/04/2022	25/05/2022
Public consultation	01/08/2022	30/08/2022	01/08/2022	30/08/2022
Validate final version deliverable (CSCQ)	18/10/2022		18/10/2022	
Endorsement final version deliverable (CEB)	02/11/2022		02/11/2022	
Estimated finalisation date of the deliverable *	04/11/2022		04/11/2022	

*publication date may fluctuate depending on the outcome of the Consortium Executive Board endorsement