EUnetHTA 21

Project Plan

D6.2 TEMPLATE BRIEFING BOOK

D6.3 TEMPLATE JSC REPORT

Version 1.0 03/12/2021
Template version 1.0, 30/09/2021

DOCUMENT HISTORY AND CONTRIBUTORS

Version	Date	Description
V1.0	**03/12/2021**	Final Project Plan

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 3.2.

Copyright

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LIST OF ABBREVIATIONS

AEMPS	Agencia Española de Medicamentos y Productos Sanitarios, Spain
AIFA	Agenzia Italiana del Farmaco, Italy
CEB	Consortium Executive Board
CSCQ	Committee for Scientific Consistency and Quality
EMA	European Medicines Agency
EUnetHTA	European Network of Health Technology Assessment
G-BA	Gemeinsamer Bundesausschuss (federal joint Committee), Germany
HAS	Haute Autorité de santé, France
HCP	Healthcare Professional
HTD	Health technology developer
HTA	Health Technology Assessment
INFARMED	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (National Authority of Medicines and Health Products, Portugal
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
KCE	Belgian Health Care Knowledge Centre
NIPN	National Institute of Pharmacy and Nutrition, Hungary
NOMA	Norwegian Medicines Agency
PICO	Population-Intervention-Comparator-Outcome
TLV	Dental and Pharmaceutical Benefits Agency, Sweden
ZIN	Zorginstituut Nederland

1 INTRODUCTION

In the technical offer, submitted on 04/05/2021, deliverables for the production of Joint Scientific Consultation (JSC) have been defined.

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

- D6.2: template for the briefing book for parallel advice with European Medicines Agency (EMA) and Health Technology Assessment (HTA)-only advice and further templates for JSC application (e.g. Letter of intent, short study synopsis) and interaction with Health technology developers (HTD) (e.g. Applicants written response).

- D6.3: template for the JSC report

2 BACKGROUND

The main objective of this project is to review and optimise existing templates for the Briefing Book, further templates for JSC application and interaction with HTD (e.g. Application form, applicant´s written response) and the template for the JSC report used in the framework of EUnetHTA Early Dialogues. Multiple templates were established, used and updated. This includes

– two templates for the letter of intent, two templates for the Briefing Book to be submitted by the HTD (for Parallel Consultation and Multi-HTA), one template for the final written recommendations that follows the Population-Intervention-Comparator-Outcome (PICO) scheme.

– various feedback questionnaires for patients and industry (last update June 2020 for HTD)

If necessary, further templates will be developed as part of this project (e.g. template for engaging Healthcare Professionals (HCPs) and corresponding feedback questionnaires).

Table 2-1. Existing EUnetHTA documents

Title	Scope
Template EUnetHTA ED Early Dialogue Request Form	EUnetHTA Early Dialogue Request Form
Template: EUnetHTA Short Study Information	Template with important key points of a clinical trial. to be completed by the HTD
Template EUnetHTA Multi-HTA ED Pharma Briefing Book (03-07-20)	This template is to be used by companies willing to submit an overview of relevant information necessary to support a EUnetHTA multi-HTA Early Dialogue discussion
Template EUnetHTA ED Parallel Consultation Briefing Document	Parallel Consultation Briefing Document
Template ED Applicant's Written Response	Template for written response by the HTD to the List of Issues
Template: EUnetHTA_Final Consolidated Written Recommendations Template	Template for Final Consolidated Written Recommendation

3 OBJECTIVE AND METHODS

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 objective of deliverable D6.2.is to:

- Update briefing book for parallel advice with EMA
- Review and update templates for Short study synopsis, letter of intent and others

The objective of deliverable D6.3 is to:

- Update JSC report for written recommendation

3.1 Methods to achieve the objectives

During the project, the following questions should be answered::

What changes are required due to outdated, replicated information, changes in the process flow, feedback from external sources?

The following steps will be taken in order to achieve the objective::

In deliverable D6.2.1 the briefing book for HTA-only advice and parallel advice with EMA will be updated. This includes amongst others the following tasks:

- Check Briefing Book Templates for repetitive information and adjust accordingly
- Check whether a chapter in lay language can be added to the Briefing book to help patient representatives understanding
- Check whether a section for a systematic overview of European evidence can be added to facilitate a systematically approach for the choice of the comparator
- Check whether a standardized section for a tabular study synopsis for clinical studies (Phase II/III) can be added to facilitate understanding
- For HCP involvement a system similar to patient involvement needs to be implemented. A form will be set up for clinicians to participate, asking specifically for comments on the clinical evaluation based on the briefing book. Exchange with the EMA to update the Briefing Book for parallel consultation
- Update the Briefing book after feedback of HTA – bodies (HTAb), patients, HCP and HTD

Final modifications of the Briefing Book will take place after methodological guidelines have been completed and feedback from external stakeholders were collected. Therefore, close cooperation between the hands-on teams of Methods and JCA is envisaged.

Furthermore, within deliverable D6.2.2 further templates needed for JSC application and interaction with HTD as the application form and the template for the applicant´s written response will be reviewed and updated according to methodological guidelines and feedback/experiences.

In deliverable D6.3.1 the JSC report for written recommendation will be updated. This will not include an initial update at the beginning of the tender as the current final report (final written recommendations) does not need any obvious adjustment. To ensure consistency in the final recommendations a collection of common recommendations will also be developed after the conduction of several JSC and advancement of methodological guideline.

For deliverable D6.2.2 and D6.3.1 strong cooperation with the hands-on teams of Methods and JCA is also intended. For all templates addressed to external parties such as clinicians and patients, there will be close cooperation with the hands-on group for the transversal activity to create a guidance for the interaction with patient representative, healthcare professional and other experts.

After initial update (if necessary) all templates will be reviewed at twice. The first review will be done after 3 - 4 JSCs. Feedback and experiences of the participants will be evaluated at the end of the tender and the templates will be revised accordingly. For collection of feedback and experiences of the participants structured questionnaires will be developed and provided.

3.2 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 public consultation in order to ensure the deliverables are applicable to all European HTAb.

Other members of the EUnetHTA 21 Stakeholder pool will 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 G-BA will be author of the guidance documents and templates. As detailed in Table 4-1 the author is responsible for definition of iterative process to continuously update the guidance documents and templates, revision of the guidance documents and templates based on endorsed outputs of EUnetHTA JA3 and EUnetHTA 21 as well as evaluation of the revised guidance documents and templates based on the production of JSC in EUnetHTA 21. The author and co-author (reviewers) will review each other's work prior to review by the CSCQ.

The hands-on group will have only meetings if needed. The reviewing and updating process should be possible in writing. In addition, the hands-on group will also have regular meetings with the relevant other hands-on groups, namely the teams of Methods and JCA.

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, the hands-on group will also have regular exchange with the relevant other HOGs, namely D7.4.1 interaction with regulators, EMA.

4.2 Timelines

Start of the project

For this project, a templates were already available and used in Joint Action 3 and endorsed by the Executive Board. Therefore, no concept paper is being drafted in the current project and thus no review of intermediate deliverables by the CSCQ is necessary before the first draft.

Table 4-1. Timetable

D6.2 Template Briefing Book

Milestones	Start date	End date
Project duration	28/08/2021	29/09/2023
1st Revision	28/08/2021	28/09/2021
Validate final version deliverable (CSCQ-JSC)	11/11/2021	
Endorsement final version deliverable (CEB)	01/12/2021	
Estimated finalisation date of the deliverable *	06/12/2021	

2nd Revision	02/07/2022	02/08/2022
Validate final version deliverable (CSCQ-JSC)	09/09/2022	
Endorsement final version deliverable (CEB)	28/09/2022	
Estimated finalisation date of the deliverable *	03/10/2022	

3rd Revision	20/05/2023	20/06/2023
Public consultation	01/08/2023	31/08/2023
Validate final version deliverable (CSCQ-JSC)	08/09/2023	
Endorsement final version deliverable (CEB)	27/09/2023	
Estimated finalisation date of the deliverable *	29/09/2023	

D6.3 Template JSC Report

Milestones	Start date	End date
Project duration	26/09/2021	29/09/2023
1st Revision	26/09/2021	26/10/2021
Validate final version deliverable (CSCQ-JSC)	18/11/2021	
Endorsement final version deliverable (CEB)	01/12/2021	

Estimated finalisation date of the deliverable *	06/12/2021

2nd Revision	02/07/2022	02/08/2022
Validate final version deliverable (CSCQ-JSC)	09/09/2022	
Endorsement final version deliverable (CEB)	28/09/2022	
Estimated finalisation date of the deliverable *	03/10/2022	

3rd Revision	01/07/2023	01/08/2023
Validate final version deliverable (CSCQ-JSC)	04/09/2023	
Endorsement final version deliverable (CEB)	27/09/2023	
Estimated finalisation date of the deliverable *	29/09/2023	

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