eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

Project Plan

D6.4 PROCEDURAL GUIDANCE JSC

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

Participants

Hands-on-Group	Gemeinsamer Bundesausschuss, [G-BA], Germany National Institute of Pharmacy and Nutrition, [NIPN], Hungary
Project management	JSC Secretariat: Gemeinsamer Bundesausschuss, [G-BA], Germany
CSCQ-JSC/ CEB	Agencia Española de Medicamentos y Productos Sanitarios [AEMPS], Spain Austrian Institute for Health Technology Assessment [AIHTA], Austria Belgian Health Care Knowledge Centre, [KCE], Belgium Gemeinsamer Bundesausschuss, [G-BA], Germany Haute Autorité de Santé, [HAS], France Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, [IGWIG], Germany Italian Medicines Agency, [AIFA], Italy National Authority of Medicines and Health Products, I.P., [INFARMED], Portugal National Centre for Pharmacoeconomics, St. James Hospital, [NCPE], Ireland National Institute of Pharmacy and Nutrition, [NIPN], Hungary Norwegian Medicines Agency, [NOMA], Norway The Dental and Pharmaceutical Benefits Agency, [TLV], Sweden Zorginstituut Nederland, [ZIN], The Netherlands

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

TABLE OF CONTENTS

LIST OF TABLES

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
F2F	Face-to-Face
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
HTAb	Health Technology Assessment body
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
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 JSC have been defined.

This Project Plan describes the objectives, approach and timelines for the deliverable D6.4 Update procedural guidance for JSC.

2 BACKGROUND

Multiple guidance documents and templates to support the procedure have been produced for Early Dialogues in Joint Action 3 (JA3) which have to be updated and further developed for use in EUnetHTA 21.

Table 2-1. Existing EUnetHTA documents

Title	Scope
Early Dialogues procedures and guidelines	
Procedure and roles EUnetHTA EDs centralised (2020082) [internal guidance]	This guidance defines the roles of procedure and the individual tasks of all participating HTA bodies (HTAb) (for scientific coordinator, rapporteur as well as all other participant HTAb)
Guidance for industry [external guidance] published within Joint Action 3 as: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-parallel-consultation_en.pdf	This guidance for industry (common document EunetHTA and EMA) defines the roles of procedure including EMA for HTDs (published online)
Templates to support the procedure	
Template EUnetHTA Written Request For Clarifications	Template to request clarification from the Applicant on the briefing book submitted
Template EUnetHTA Draft Consolidated List Of Issues	Template in preparation of the issues to be discussed during the internal HTA eMeeting for each consultation; updated after the eMeeting; to be shared with EMA as well as the final Consolidated List of Issues to be shared with the applicant
Template EUnetHTA_E-meeting Draft Positions	This PowerPoint Template is to be used in preparation of the issues and draft positions to be discussed during the internal HTA eMeeting
Template EUnetHTA Presentation Closed HTAB Pre-F2FMeeting	This PowerPoint Template is to be used in preparation of the Face-to-Face (F2F) meeting to align common positions and to identify relevant divergent positions between all HTAb involved.
Template ED_Patient Questionnaire	This template is to be used when patients are interviewed during a consultation
Template for used qualitative analysis evaluation	Template used for evaluation once a consultation procedure is finished.

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 main objective of this project is to review and optimise existing procedural guidance for JSC for all participants, HTABs, HTD, patients and HCP (including both internal procedural guidance as well as

guidance for industry, both on parallel JSC with EMA as well as on HTA-only JSC). Furthermore, an update of templates related to the procedure of JSC will be carried out.

If necessary, further templates will be developed as part of this project.

In addition, a checklist for quality assurance in accordance with the Quality Management System will be established. For the development of this deliverable (6.4.2), please refer to project plan 6.1 production.

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 D6.4 the procedural guidance for JSC for HTA-only advice and parallel advice with EMA will be updated. This includes amongst others the following tasks:

Updates and further developments have to be done on:

o Guidance documents

- Parallel consultations: close cooperation with EMA is envisaged.
- HTA-only JSCs (pharma)
- EUnetHTA21-Internal procedural guidance on Roles of the Scientific Coordinator (SC) and Rapporteur (R) in a pharmaceutical JSC [internal procedural guidance]
- Guidance for industry [common external guidance in cooperation with EMA]

o Templates to support the procedure

Internal templates to support the procedure will be updated and will be used by the SC and R throughout the procedure.

- e.g. slides, timelines, template for Draft Positions and Issues (for all pharmaceutical JSCs) for the e-meeting to discuss the List of Issues
- Standardized template for the SC/R to use in preparing the pre-F2F HTAb meeting:
  - a template for requesting clarifications on the Draft Briefing Book (for all pharmaceutical JSCs),
  - a template for the List of Issues to be sent to the company (one each for Parallel Consultation and HTA-only JSC),
  - template for Draft Positions and Issues (for all pharmaceutical JSCs) for the e-meeting to discuss the List of Issues (if F2F Format) or the Draft Positions (if written-only)
  - a template for a short study summary
  - standardized template for the SC/R to use in preparing the pre-F2F HTAb meeting and
  - a template patient interview guide based on the HTAi questionnaire.

Modifications of the procedural guidance might have an impact on the internal templates and vice versa, hence a parallel update of guidance documents and internal templates will be ensured.

The guidance documents will provide detailed information about the roles of each actor and the steps of the JSC process. For the guidance for industry close collaboration with EMA will be conducted. For the guidance for internal use within EUnetHTA21 an exchange with EMA will be performed if needed. Furthermore, a close cooperation between the hands-on teams of Methods and JCA is envisaged.

Further documents could be produced (and reviewed later on by the Committee for Scientific Consistency and Quality (CSCQ)) as mentioned earlier in this document, including but not limited to guidance for patients/patient representatives participating in JSC and guidance for HTAb newcomers to the JSC process.

Much like the templates, guidance documents as well as potential further documents must be reviewed and updated on a regular basis in order to reflect any modifications in the procedure or makeup of participating HTAb.

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 be invited to contribute to the work through public consultation

In addition, the Hands-on Group (HOG) will consult specifically (HTD/HCP/Patients/Regulators) to collect their point of view prior to developing the deliverable/during development of the deliverable.

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, previous procedures were developed 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

Milestones	Start date	End date
Project duration	26/09/2021	29/09/2023
1st Revision	26/09/2021	23/11/2021
Validate final version deliverable (CSCQ-JSC)	31/12/2021	
Endorsement final version deliverable (CEB)	12/01/2021	
2nd Revision	27/08/2022	27/09/2022
Validate final version deliverable (CSCQ-JSC)	05/11/2022	
Endorsement final version deliverable (CEB)	30/11/2022	
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	