EUnetHTA 21

Project Plan

D5.2.1 – JCA/CA ASSESSMENT REPORT TEMPLATE

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DOCUMENT HISTORY AND CONTRIBUTORS

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

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CEB	

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

CEB	Consortium Executive Board
CSCQ	Committee for Scientific Consistency and Quality
EUnetHTA	European Network of Health Technology Assessment
HTA	Health Technology Assessment
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation

1 INTRODUCTION

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

This Project Plan describes the objectives, approach and timelines for the deliverable D5.2.1 on JCA/CA Assessment Report Template, including a revised Summary Template.

With the reached political agreement on the proposed EU HTA regulation, the main objective of this template revision is to ensure a template is developed that fits with this HTA regulation.

2 BACKGROUND

According to the tender specifications, a template for the JCA/CA reports and summary reports on medicinal products and medical devices shall be developed.

In EUnetHTA JA3, different templates exist for the production of JCA/CA on medicinal products and medical devices and both templates have undergone updating based on collected feedback and recommendations and outputs from other tasks groups (such as the Instructions on Authorship and Copyright).

In EUnetHTA JA3 working groups have been established in order to revise the pharmaceutical and other technology JCA/CA reporting template. For pharmaceutical JCA a revised template was put in use in 2019 and in 2020 a survey was conducted among assessors and end-users of the pharmaceutical JCA to evaluate this template. This activity resulted in recommendations for further revisions of the JCA reporting template. For other technologies, the JCA/CAs reporting template underwent revisions in 2018 and this revised template was piloted in 2020.

Table 2.1 shows the revised Assessment Report Templates of JA3. There are templates available for both the medicinal products as the medical devices, and both templates include a section for the Executive Summary. In EUnetHTA JA3 the template has been fine-tuned to increase readability and user-friendliness, and provides recommendations for these two templates for pharmaceutical JCA. For the Assessment Report Template, also minor modifications were accepted based on the findings of this subgroup.

During the usage of the JCA report template and based on the findings of the survey conducted by this working group, the following challenges were identified that have to be solved by this template revision. It is important to state that the template revisions will be based on the outcomes of the Methodological Guidelines:

1 The workload associated with the current JCA report template is perceived as high and excessive compared to that of the national templates. The information requested in the template should be carefully balanced against its usability of the final output at the national level;

2 Low uniformity among assessments due to a lack of guidance on specific methodological aspects (i.e. indirect comparison, the use and role of PICO, identification and reporting of bias and uncertainties). This also resulted in a lack of transparency for some PICO-related aspects, namely reporting of deviations from the planned PICO and selection of (and agreement on) comparators. In addition, this led to discrepancy among pharmaceutical JCAs on how extensive the submission dossier was cited (see also challenge #6);

3 Authoring Teams indicated that the presentation of results and conclusions was challenging and more guidance is needed;

4 Guidance on partial use of GRADE processes & common phrases (as developed in EUnetHTA JA3) needs to be developed and included in the JCA report Template;

5 Identification of evidence gaps during assessment was difficult and required specific expertise;

6 Challenges on how to avoid duplication of information in the Submission Dossier and the JCA report. For pharmaceutical JCA the Core Submission Dossier (as received from the HTD) is published, as this increases transparency. The challenge is whether the JCA report should be an independent report, or whether it is acceptable to not copy the information from the Submission Dossier but refer to exact pages;

7 Guidance on how to incorporate patient input needs to be developed and included in the JCA report template;

8 A procedure needs to be developed on how to deal with missing data or incomplete submission dossiers and in the JCA template standard text needs to be provided to address this;

9 In the JCA report template an Executive Summary is included. More guidance should be provided on how detailed and extensive this Executive Summary should be. Also, it needs to be decided whether this Executive Summary is presented as a separate document, or kept in the JCA report;

10 The JCA report templates are not fully aligned between pharmaceutical and other technologies. It needs to be investigated whether and where more alignment is needed.

Table 2.1. Existing EUnetHTA documents

Title	Scope
Assessment Report Template for pharmaceutical compounds	Template including an Executive Summary section. This template includes guidance for the authoring team on how to fill the template.
Assessment Report Template for Other Technologies	Template including an Executive Summary section.
Mapping of how patient input has been used throughout JA3 assessments	This is an excel in which for all medicinal and medical device assessment produced in JA3 we mapped which patient involvement method was used and how the patient input was incorporated in the report.

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 this deliverable is to update the JCA/CA Assessment Report Template based on the recommendations of JA3 and create a template that fits with the proposed EU HTA regulation. This is also believed to be a ground for balance in the wishes of the different HTA agencies. Other objectives are:

- Update the JCA/CA Assessment Report Template based on the recommendations of JA3;
- Fine-tune the summary template, which currently is an Executive Summary in the full JCA/CA report template;
- Ensure the templates follow the outputs as developed in EUnetHTA 21, e.g. methodological updates.

3.1 Methods to achieve the objectives

Consecutive planning

It is important that the methodological guidelines groups provide input on elements that concern presentation of content in assessment reports which are developed by those groups. For example, tables on data presentation could be suggested by those groups. The final lay-out and ensuring consistency between different tables will be done by the template hands-on group.

The work is linked to, and depends on, the production of JCA/CA, development or revision of methodological guidelines used for JCA/CA regarding scoping procedure (development of PICO questions in particular the scoping phase, comparators & comparisons, endpoints, applicability of evidence for JCA, the validity clinical studies, assessment of high risk medical devices), the development or revision of the Submission Dossier template and on the update of procedural guidelines for the appointment of assessors and co-assessors for JCA/CA.

The template revisions need to be finalized by M12 of EUnetHTA 21. The planning will be done consecutively: it will start with work from JA3 that can be implemented, and will follow with finalized work from methods groups in EUnetHTA21. The template project will start with revision work as soon as a methodological topic is finalized.

This means:

- Start revision of the templates based on methodological recommendations endorsed by the EUnetHTA JA3 Executive Board, such as the PICO concept paper and the GRADE & Common Phrases recommendations; The GRADE & Common phrases recommendations are being piloted in JA3's PTJA17 and the learnings and experiences from this pilot will be used as a basis to draft the guidance in the template;
- Specific to medical devices: Ensure the JCA/CA reporting and summary template address the needs and requirements for medical devices; Since the CA template for medical technologies was recently updated (April 2021), it is proposed to inquire about experiences of working with this template before any further updates will be made. Experiences of assessment teams that used the OT HTA Core Model template have been previously mapped, and this will be used as a basis. Of course, this template also needs to reflect any outcomes of the Methodological Guideline development. It is important that these updates are reviewed by agencies experienced with Med Tech assessments;
- Information exchange with other hands-on teams is necessary. The mode of interaction and frequency needs to be balanced. The CSCQ should inform this group about the status of those groups and which decisions on methodological issues have been endorsed, so that they can be reflected in the template revision. Hands-on groups with relevant work includes the projects on submission dossier template, methodological guidelines and transversal teams on stakeholder input.

3.1.1 Objective 1 & 2 - Update the JCA/CA Assessment Report Template based on the recommendations of JA3 & Summary Template

To fine-tune the JCA report template, the recommendations developed by the responsible JA3 subgroup will be used as a starting point. Since the recommendations of this subgroup only focus on pharmaceuticals, it needs to be explored whether the same challenges persist for the other technologies. This will be done by investigating the results of the assessment team surveys after finalization of each JCA/CA in JA3 as well as feedback received via e-mail or during previous feedback workshops.

The JCA report template, as well as the Executive Summary template, has a great impact on the usability of the JCA report on a national level. Therefore, the JCA report needs to include all relevant information. On the other hand, a perceived challenge was the high workload for JCA's and this implies that a balance needs to be sought between the reported information and the additional work to be done on a national level. To ensure the JCA report template is fit for purpose, a broad consultation process needs to be pursued and members from the EUnetHTA network be invited to participate in a workshop (see section 3.2) to identify further pressing revision needs as well as reviewing the updated JCA report template.

3.1.2 Objective 2 - Ensure the templates follow the outputs as developed in EUnetHTA 21, e.g. methodological updates

Some hands-on groups will develop elements that concern content representation in the assessment report. In order to avoid that the template hands-on group needs to interpret guideline recommendations relevant for the templates (e.g. suggestion on table content and layout), the hands-on groups of the relevant methodological guidelines or guidance will be asked to provide input on which elements belong in, for example, a table or figure or other sections of the JCA/CA report. The final lay-out of such tables, figures or sections will be done by the JCA/CA template hands-on group in order to ensure consistency of the template.

It is important to include guidance throughout the JCA report template on how to document the input received from involved patients or patient organisations and how to make it visible. While during JA3 it was piloted how to incorporate patient input in the assessment, no guidance has been developed only practices have been mapped. This will need to be considered together with the output from the

deliverables on patient involvement. If the transversal hands-on groups also define other methods for involvement of Healthcare Professionals and guidance for how to incorporate that input, this may also need to be considered for the JCA/CA template revision.

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 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 be invited to review, at the same time as 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.

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 hands-on group (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 hands-on group will have bi-weekly meetings, to update each other on the progress. In addition, the hands-on group will also have regular meetings with the relevant other hands-on groups, namely the SubDos hands-on group (D5.1); methodological development (D4); JCA/CA production (D5.4); transversal activities on involvement of patient and HCP (D7.2/3); interaction between HTD and HTA (D7.1); and COI management (D7.5).

4.2 Timelines

Table 4.1. Timetable

Milestones	Start date	End date
Project duration	25/04/2022	04/11/2022
1st Draft deliverable	25/04/2022	25/05/2022
Public consultation	01/08/2022	30/08/2022
Validate final version deliverable (CSCQ)	18/10/2022	
Endorsement final version deliverable (CEB)	02/11/2022	
Estimated finalisation date of the deliverable *	04/11/2022	

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