EUnetHTA 21

Guidance Document

D7.1.2 - PROCEDURE AND FRAMEWORK FOR THE FACTUAL ACCURACY CHECK

Part of D7.1 – Guidance for the interaction between HTA and HTD

Version 1.1, 07.02.2023

Template version 1.0, October 2021

Document history and contributors

Version	Date	Description
V0.1	22/04/2022	First draft
V0.2	22/06/2022	Second draft
V0.3	20/07/2022	For Public consultation
V0.4	29/09/2022	For CSCQ validation
V0.5	21/10/2022	For CEB endorsement
V0.6	04/11/2022	Final version endorsed by CEB
V1.0	31/01/2022	For publication after incorporation of EC comments
V1.1	07/02/2023	Date of publication

Disclaimer

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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group actively wrote the deliverable, the entire EUnetHTA 21 consortium was involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) reviewed and discussed several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) endorsed the final deliverable prior to publication.

Associated HTAb & Stakeholders participating in public consultation

The draft deliverables of D7.1 were reviewed by associated HTAb and was open for public consultation between 20.07.2022 and 19.08.2022.

Associated HTA bodies who reviewed	Dachverband der Österreichischen Sozialversicherung, [DVSV], Austria Norwegian Institute of Public Health, [NIPH], Norway Evaluation and Planning Unit – Directorate of the Canary Islands Health Service, [SESCS], Spain Regione Emilia-Romagna, [RER], Italy Health Information and Quality Authority [HIQA], Ireland Finnish Medicines Agency [FIMEA], Finland
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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
HaDEA	European Health and Digital Executive Agency
HTA	Health Technology Assessment
HTAR	Health Technology Assessment Regulation
HTD	Health Technology Developer
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultations
SOP	Standard Operating Procedure

1 GENERAL PRINCIPLES AND PURPOSE

1.1 General principles

On 17 September 2021, the European Health and Digital Executive Agency (HaDEA) signed the Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA with the aim to support EU cooperation on HTA beyond May 2021 when the EU co-funded EUnetHTA Joint Action 3 ended.

EUnetHTA 21 consortium consists of 13 European national HTA agencies and its work will build on the achievements and lessons learned from the EUnetHTA Joint Actions and focus on supporting a future EU HTA system under the Regulation (EU) 2021/2282 on health technology assessment (HTAR). The main objectives of this Service Contract are advancing the development of HTA methodology further and continuing the European Collaboration in HTA and EUnetHTA network producing a specified number of Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC).

1.2 General principles

A procedure and framework for a factual accuracy check of draft reports is outlined in the present guidance document, which is based on the process that was developed in EUnetHTA Joint Action 3 (JA3) and was evaluated accordingly. Furthermore, it takes into account the anticipated process under the HTAR. During the CSCQ review, the CSCQ made sure that the guidance is in line with/not contradictory to their processes.

Any other documentation will not undergo a factual accuracy check.

1.3 Purpose and Scope

The present guidance document aims to define the procedure and framework for a factual accuracy check of draft JCA reports, by the health technology developer (HTD), after validation by the CSCQ in EUnetHTA 21 or by the JCA subgroup in HTAR, which is applicable to both EUnetHTA 21 and HTAR. The document might need to be revised at a later date to ensure full compatibility with the HTAR and relevant implementing acts. It does not provide details on the duration of the steps mentioned for the JCA procedure, as the development of a timeline for JCA production are still ongoing.

The purpose of a factual accuracy check is to highlight any errors or inaccuracies with the factual content of the JCA report that are related to the technology under assessment. The HTD is asked to check whether the information presented for the technology under assessment is correct. Any comments affecting the interpretation of data (data presentation, description and summary of the report) are considered outside the scope of a factual accuracy check. Furthermore, the HTD shall highlight any information it considers confidential due to its commercially sensitive nature by following the D7.1.3 Guidance for handling commercially confidential data.

1.4 Relevant articles in Regulation (EU) 2021/2282

The HTAR specifies in Art 11 (5): "*The draft reports shall be provided to the health technology developer. The health technology developer shall signal any purely technical or factual inaccuracies in accordance with the timeframes established pursuant to Article 15. The health technology developer shall also signal any information it considers to be confidential and justify its commercially sensitive nature. The health technology developer shall not provide any comments on the results of the draft assessment*."

2 ACTORS AND THEIR SCOPE

2.1 Assessor and co-assessor

The assessor/co-assessor´s responsibilities include answering the factual accuracy check related comments, and updating the draft JCA report if necessary, in line with the present guidance. Assessor/co-assessor are not in direct contact with HTD, any communication with the HTD runs via the Secretariat. This is important to guarantee the independence of the (co-)assessor team. The names of individual assessors/co-assessors are not mentioned; only the names of the organisations acting as the assessor and co-assessor are included.

2.2 Secretariat

The Secretariat is responsible for the communication with the HTD and is their main contact person. The Secretariat forwards any comments received from the HTD to the assessor/co-assessor and is not responsible for judging if the comment is within the scope of a factual accuracy check.

2.3 Health technology developer

The HTD receives the draft JCA report after validation by the CSCQ JCA (or JCA subgroup in HTAR) from the Secretariat and is requested to conduct a factual accuracy check. During the factual accuracy check the HTD needs to follow the guidance and respective checklist (see Appendix). No comments on interpretation of data are accepted. Comments shall focus on the technical facts, what has been cited from the submission dossier and possible confidentiality issues with regard to commercially sensitive information. Further information on the latter can be found in the D7.1.3. Guidance for handling commercially confidential data.

Please see section 4.2. for details on the process, if no comments are received from the HTD.

2.4 CSCQ JCA

The CSCQ JCA (or JCA subgroup in the HTAR) can be involved by the assessor/co-assessor in case it is unclear if the comments received are factual accuracy check related or not. If comments are outside the scope of a factual accuracy check, paragraph 4.4 point 2 is applied.

3 RULES OF THE COLLABORATION

3.1 Confidentiality

Detailed rules on confidentiality of submitted information by the HTD, are described in the guidance for handling commercially confidential data (part of D7.1 documents – D7.1.3: process for handling commercially confidential data)

3.2 Status of Outputs

According to Art 30 3 (i) of the HTAR, the JCA reports considered procedurally compliant in accordance with Art 12, together with all comments received during their preparation will be published on a publicly accessible webpage. This means that the comment forms from the factual accuracy check by HTD including the answers from assessor/co-assessor and the completed checklist, will be published together with the final JCA on the EUnetHTA website (as it has already been done in EUnetHTA JA3), after possible redaction following the D7.1.3 Guidance for handling commercially confidential data).

4 PROCESS

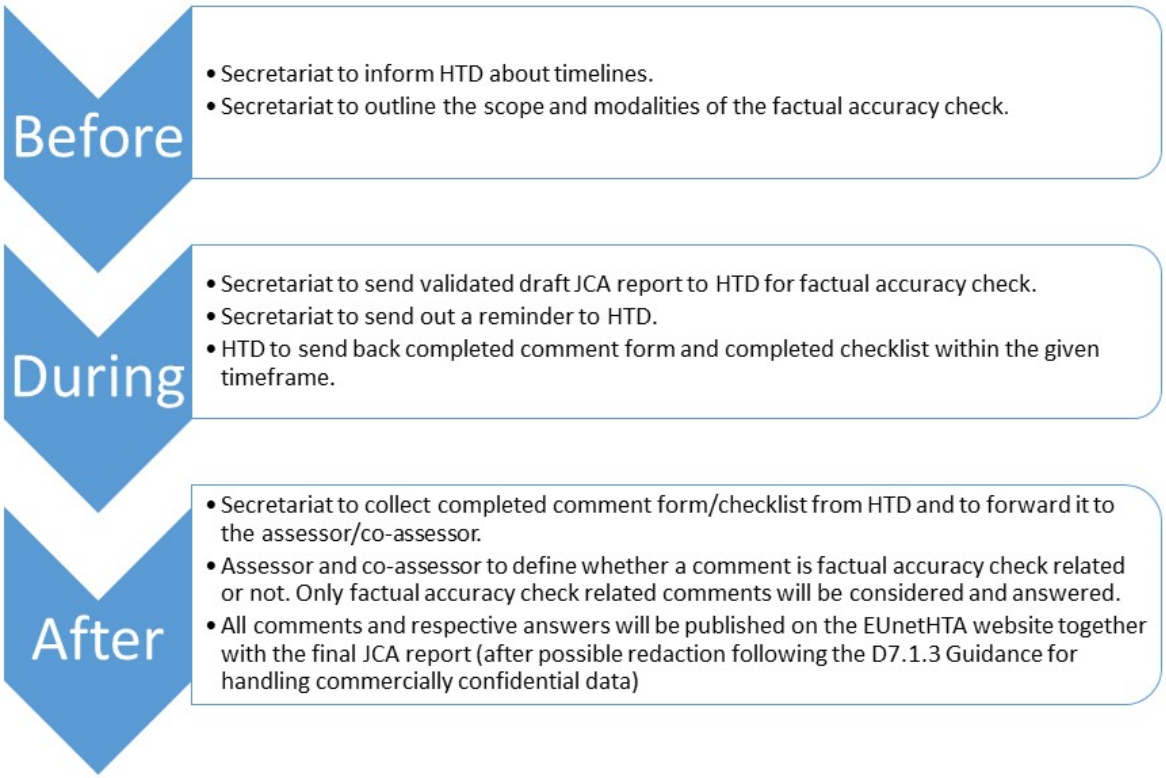

***Figure 1**:* Process flow outlining the steps before, during and after the factual accuracy check by the HTD

4.1 Notification of HTD about the factual accuracy check

The factual accuracy check will be done on the draft JCA report that was validated by the CSCQ JCA (or JCA subgroup in HTAR). Prior to the start of the factual accuracy check period, the Secretariat gives notice of the upcoming factual accuracy check to the HTD via e-mail:

- Inform them about the timelines set.
- Inform them that if the assessor/co-assessor need any clarification on comments, they only have a short timeframe (i.e. specific deadline is indicated) to respond to the query.
- Tell them what the scope of a factual accuracy check is (see 1.2. Purpose and Scope) and what will happen to their comments including the checklist, i.e. they will be made publicly available together with the final report (after possible redaction following the D7.1.3 Guidance for handling commercially confidential data); in the published comments form and in the final assessment only company names will be disclosed.
- Make clear that comments outside the scope of a factual accuracy check will not be considered nor answered. However, these comments will be published as well together with a standard sentence (see 4.4.).

4.2 Sending of the validated draft JCA report to HTD who performs the factual accuracy check

The factual accuracy check period starts according to the timelines indicated in the final project plan.

- The Secretariat will share, via a secure platform (i.e. the EUnetHTA 21 SharePoint), the draft JCA report (that was validated by the CSCQ JCA or JCA subgroup in HTAR) with the HTD (as

a PDF file, including line numbers and 'confidential' watermark), together with the guidance including checklist and comment form for the factual accuracy check.
- The HTD is requested by the Secretariat to perform the factual accuracy check in accordance with the factual accuracy check guidance including the completed checklist, and to provide its input in the corresponding comment form and to share it via a secure platform by the set deadline.
- All comments must be validated by published sources (full reference) and/or by indication of the documents/page numbers from the submission dossier.
- During the given timeframe, the Secretariat sends out a reminder to the HTD, reminding them of the deadline.
- The Secretariat is responsible for internally coordinating the process of reviewing the comments received.

No deadline extension for the factual accuracy check can be granted. In case the HTD does not submit any comments, the Secretariat will notify the assessor/co-assessor accordingly. The process will proceed as foreseen and the publication of the JCA report will not be delayed. The assessor/co-assessor will then transparently state in the final JCA report that the HTD was offered to do a factual accuracy check, but that no comments were received within the specified timeframe.

4.3 Collecting comments from HTD

The Secretariat collects the comment form and the completed checklist sent by HTD, confirms its receipt to the HTD and forwards them to the assessor/co-assessor.

4.4 Providing written answers to the comments received

After the factual accuracy check period, while revising the draft report, the assessor and co-assessor provide written answers to all factual accuracy check related comments received from HTD directly in the comments form (i.e. in the column "assessor/co-assessor reply").

- Assessor and co-assessor are responsible for defining whether a comment is factual accuracy check related or not (based on the definition of the purpose and scope of a factual accuracy check). In case of doubt, the CSCQ JCA (or JCA subgroup in the HTAR) can be involved. The assessor and co-assessor inform the Secretariat accordingly, who will forward any questions to the CSCQ JCA (or JCA subgroup in the HTAR).
- Comments that are outside the scope of a factual accuracy check, i.e. any comments affecting the interpretation of data (data presentation, description and summary of the report), are neither considered nor answered by the assessor/co-assessor. In the "assessor/co-assessor reply" column, the author states: "*The health technology developer was asked to check for factual accuracy of the document. This comment is not related to a factual inaccuracy and is, therefore, outside the scope of a factual accuracy check*".
- The period for providing answers to factual accuracy check related comments is prior to the CEB (coordination group in HTAR) endorsement.
- In case assessor/co-assessor need clarification regarding a comment, the Secretariat sends a request to the HTD. The HTD is requested to answer the comment until the deadline indicated by the Secretariat at the start of the process[1], otherwise their comment is disregarded. Clarification provided is noted down in the "comments" column in the comments form. If no clarification is provided by the HTD, then it will be mentioned in the column "assessor/co-

[1] the time window available is dependent on the situation and overall timelines of the JCA, therefore no specifics can be given in this guidance

assessor reply" that the comment was unclear and no further clarification was provided by the HTD.

- All comments received and answers provided are shared with the entire CSCQ (JCA subgroup in HTAR) and CEB (coordination group in HTAR), prior to final endorsement of the JCA report.
- All comments from factual accuracy check and respective answers are published on the EUnetHTA website (or IT platform under the HTAR) together with the final JCA report.
- The Secretariat sends the link to the published document to the HTD who was involved in the factual accuracy check.
- In case there are objections regarding the published document, the process defined in the "Error Reporting and Correction Procedure" needs to be followed. Further information can be found on the EUnetHTA website (see question "What should I do if I see a potential error in a EUnetHTA report?"). Under the HTAR, the Coordination Group will have to decide and investigate if such process also will be applied under the HTAR.

5 FUTURE CONSIDERATIONS UNDER HTAR

A body or committee at the level of the JCA subgroup could be responsible for performing the distinction if a comment is factual accuracy check related or not and they could be involved in any issues related to confidentiality that are highlighted by the HTD during the factual accuracy check. This will ensure consistency and takes away the burden of the assessor/co-assessor. Answers should be provided by the assessor/co-assessor on the relevant comments.

6 PRACTICAL ISSUES

6.1 Contact Points

Under EUnetHTA21, the JCA Secretariat (JCA_Secretariat@zinl.nl) is the primary point of contact for HTD for JCA on medicinal products and medical devices.

6.2 Other

A secure system will be used for data sharing between HTD and EUnetHTA 21, in the form of a secure e-mail system and through SharePoint.

7 APPENDIX – FACTUAL ACCURACY CHECK *CHECKLIST*

The HTD shall use the **checklist** to make sure that only factual accuracy check related aspects are considered and shall add a cross to the applicable column if the respective topic was checked. The **comment form** needs to be used to state which errors or inaccuracies were identified. All comments must be validated by published sources (full reference) and/or by indication of the documents/page numbers from the submission dossier. The purpose of a factual accuracy check is to highlight any errors or inaccuracies with the factual content of the document that are related to the technology under assessment. The HTD is asked to check whether the information presented for the technology under assessment is correct. Any comments affecting the interpretation of data (data presentation, description and summary of the report) are considered outside the scope of a factual accuracy check and will not be answered by the assessor/co-assessor.

Question	Checked and correct	Checked and not correct *
Is the international non-proprietary name (INN)/ proprietary name/product name/ trademark of your product and comparator(s) mentioned correctly?		
Do the assessor/co-assessor refer to the correct version of your product (i.e. the version that is available on the European market)?		
Is information regarding approved indication (as stated in the CE marking for medical devices; or as stated in the EC decision for medicinal products) described correctly?		
Is the mode of action of your product described correctly?		
For medical devices: Are the technical characteristics of your product described correctly?		
For medicinal products: Are the features (including administration and dosing) of the technology described correctly?		
Is the information regarding market authorisation status / CE marking of your product correct?		
Are all estimates and statistics as indicated in the submission dossier reported correctly in the assessment report?		
Is factual information from studies extracted/cited/referenced correctly?		
Is there any information that you consider confidential due to its commercially sensitive nature? Please state page and line number of the confidential information that should be redacted. Please refer to the D7.1.3 Guidance for handling commercially confidential data.		

*** Please use the comment form to provide the correction**