May 2020

FACT CHECK GUIDANCE

MANUFACTURERS

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VERSION HISTORY

Version	Date	History
V1.0	December 2018	Fact Check Guidance Document Publically available since May 2020

1 OBJECTIVE OF THIS FACTUAL ACCURACY CHECK GUIDANCE DOCUMENT

This factual accuracy check guidance document is targeted at manufacturers who are willing to be involved in an Other Technologies EUnetHTA Assessment (Joint or Collaborative Assessment) within Joint Action 3, in which the factual accuracy check is conducted. This document includes the comments form, fact check checklist for the second draft project plan and the second draft assessment. The document describes the processes and the timelines.

In Joint Action 3 the factual accuracy check is optional. Each Authoring Team decides whether they want to have a factual accuracy check. Such checks have been conducted in almost all Other Technologies EUnetHTA Assessments in JA3 so far (either for the draft project plan or for the draft assessment or both).

The factual accuracy check takes place in parallel with external review of the draft project plan and the draft assessment report and takes 5 calendar days. Comments submitted after the deadline or in a different format will not be considered.

The purpose of a fact check is to highlight any errors or inaccuracies with the factual content of the draft project plan or draft assessment that are related to the technologies under assessment (including technologies of competitors). The manufacturer is asked to check whether the information presented for the technologies under assessment (including technologies of competitors) is complete and correct. Any comments affecting the interpretation of data (data presentation, description and conclusions of the report) are considered outside the scope of a fact check. Please follow the guidance/checklist as presented in section 3.

Only comments within the scope of a factual accuracy check will be considered and answered by the Authoring Team. Comments that, according to EUnetHTA, do not belong to a factual accuracy check, will not be considered nor answered by the Authoring Team. The comments made by the manufacturer and the answers of the Authoring Team to the comments will be published on the EUnetHTA website at the same time EUnetHTA publishes the final project plan or final assessment report.

One person needs to sign a Confidentiality Agreement form on behalf of the company prior to the consulting period. The project manager of the respective assessment sends and collects the form. The manufacturers are given notice of the upcoming consulting period in advance. The project manager of the respective assessment informs the manufacturer about the timelines, sends the drafts and collects the comments form.

For further questions or comments you can reach out to the project management team of WP4 Other Technologies (eunethta@aihta.at).

2 COMMENTS FORM

EUnetHTA JA3 WP4 - Other technologies, Identifyer, assessment title
Comments form for manufacturers – Fact Check

Comments should be submitted not later than *Weekday DD/MM/YYYY*

Please use this form for submitting your comments to the project manager: e-mail address

1. Please use the checklist for fact check and follow the instruction provided via e-mail when checking the document.
2. Please put each new comment in a new row.
3. Please insert the page number and section number to which your comment applies.
4. Please provide a description of your comment as specific as possible and provide a suggestion for amendment.
5. All comments (either on your own product or on the product of a competitor) must be validated by published sources (full reference).
6. Please **do not** comment on typos or wording as long as they do not lead to inaccuracy.

All comments will be formally responded to in a combined document that will be published on the EUnetHTA website, company names disclosed. Comments that are outside the scope of a fact check are neither considered nor answered by the authors.

Comment from *Insert your company's name*	Page number	Line or section number	Description of factual inaccuracy and proposed amendment *Please insert each new comment in a new row.*	Character of comment • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3 *Please indicate your choice by writing the according number in this field, e.g. for major choose "1".*	Authors' reply

Please add extra rows as needed.

[1] a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)
b "minor": the comment does not necessarily have to be answered in a detailed manner
c"linguistic": grammar, wording, spelling or comprehensibility, only if they lead to inaccuracy.

3 CHECKLISTS

3.1 Fact check checklist 2nd draft project plan

Please use the checklist to make sure that only fact check related aspects are considered. Please comment *in the comments form* if you have identified any errors or inaccuracies.

All comments (either on your own product or on the product of a competitor) must be validated by published sources (full reference).

The purpose of a fact check is to highlight any errors or inaccuracies with the factual content of the document that are related to the technologies under assessment (including technologies of competitors). The manufacturer is asked to check whether the information presented for the technologies under assessment (including technologies of competitors) is complete and correct.

Any comments affecting the interpretation of data (data presentation, description and conclusions of the report) are considered outside the scope of a fact check and will not be answered by the author.

Question	Checked
Are relevant manufacturers missing in the list of project stakeholders (i.e. companies producing the technology under assessment)?	☐
Do the authors describe the intervention/ technology under assessment correctly?	☐
Are relevant CE marked products missing in the description of the intervention?	☐
Are products without CE mark/ with expired CE mark listed in the description of the intervention?	☐
Does your product have market authorization for the indication under assessment?	☐
Is the product name/ trademark of your product mentioned correctly? Do the authors refer to the correct version of your product (i.e. the version that is available on the European market)?	☐

3.2 Fact check checklists 2nd draft assessment

Please use the checklist to make sure that only fact check related aspects are considered. Please comment *in the comments form* if you have identified any errors or inaccuracies. When checking the document, please focus mainly on the domain "Description and technical characteristics of technology" and the Appendix ("Regulatory and reimbursement status").

All comments (either on your own product or on the product of a competitor) must be validated by published sources (full reference).

The purpose of a fact check is to highlight any errors or inaccuracies with the factual content of the document that are related to the technologies under assessment (including technologies of competitors). The manufacturer is asked to check whether the information presented for the technologies under assessment (including technologies of competitors) is complete and correct.

Any comments affecting the interpretation of data (data presentation, description and conclusions of the report) are considered outside the scope of a fact check and will not be answered by the author.

Question	Checked
Are relevant CE marked products missing in the assessment?	☐
Are products without CE mark/ with expired CE mark included?	☐
Is the product name/ trademark of your product mentioned correctly? Do the authors refer to the correct version of your product (i.e. the version that is available on the European market)?	☐
Does your product have market authorization for the indication under assessment?	☐
Are the technical characteristics of your product described correctly?	☐
Is the mode of action of your product described correctly?	☐
Is the information regarding market authorisation and CE marking of your product correct?	☐
Is the information regarding the reimbursement status of your product correct?	☐
Is relevant factual information regarding your product missing? If yes, please provide a full reference (published, non-confidential information only).	☐