FACT CHECK GUIDANCE
MANUFACTURER

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VERSION HISTORY

Version	Date	Description
V1.0	December 2018	Fact Check Guidance Document Publically available since March 2020

LIST OF ABBREVIATIONS

AT	Authoring Team
CoLP	Co - Lead Partner
HTA	Health Technology Assessment
INN	International non-proprietary name
JA3	EUnetHTA Joint Action 3
(p)MAH	(prospective) Marketing authorization holder
PM	Project manager EUnetHTA WP4 CoLP
PTJA	Pharmaceutical Joint Assessment
WP	Work Package

1 OBJECTIVE OF THIS FACTUAL ACCURACY CHECK GUIDANCE DOCUMENT

This factual accuracy check guidance document is targeted at (prospective) Marketing Authorisation Holders (pMAH) who have submitted a compound for a Pharmaceutical Joint Assessment (PTJA) within Joint Action 3 and for which the factual accuracy check will be included. This document includes the comments form, fact check checklist for the third draft assessment and e-mail templates. Although not obligatory, the pMAH is advised to follow new/updated procedures, tools and/or templates.

Each Authoring Team decides whether they want to include a factual accuracy check in their assessment. Such checks have been conducted in all Pharmaceutical Joint Assessments in JA3 so far.

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

The (p)MAH can only comment on fact-related typos/mistakes (e.g. numbers). 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 (AT). The comments made by the (p)MAH and the answers of the AT to the comments will be published on the EUnetTHA website at the same time EUnetHTA publishes the final JA report.

For further questions or comments you can reach out to the project management team of WP4 Pharmaceuticals (WP4_Pharmaceuticals@zinl.nl).

2 COMMENTS FORM

Please note that the Project Manager will share the correct comment form at the start of the factual accuracy check with the (p)MAH. The form presented here is an example for information purposes.

EUnetHTA JA3 WP4 - Pharmaceuticals, Identifyer, assessment title
Comments form for Market Authorisation Holders (MAH) – Fact Check
Comments should be submitted not later than *Weekday DD/MM/YYYY*

Please use see 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.
- 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 FACT CHECK CHECKLIST 3RD 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.

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 comparators). The MAH is asked to check whether the information presented for the technologies under assessment (including comparators) 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.

Questions	
Is the international non-proprietary name (INN)/ proprietary name of your product and comparator(s) mentioned correctly? Do the authors refer to the correct version of your product (i.e. the version that is available on the European market)?	☐
Are the features (including administration and dosing) of the technology and comparator(s) described correctly?	☐
Is the mode of action of your product described correctly?	☐
Is the information regarding the reimbursement status of your product correct?	☐
Are all estimates and statistics reported correctly?	☐
Is factual information from studies extracted/cited/referenced correctly?	☐
Is information regarding market authorisation status and approved indication described correctly?	☐