20 September 2017
EMA/456715/2017
European Medicines Agency

Summary of changes to the 'External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use'

Published 22 September 2017

On 3 March 2016, the European Medicines Agency published the 'External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use' (Policy 0070). Additional information that has been included in the guidance published on 22 September 2017 is outlined in the table below, including the location within the document with a summary of the additional information provided.

1. Major changes

Chapter and Section reference	Summary of the change
Chapter 1: • section 2, page 7	Clarification has been provided on which clinical reports should be submitted for publication with regards to extension or modification of indications in the paediatric population: *"Where clinical study reports are cross-referred to within paediatric extension or modification of indication applications, the MAH is required to submit for publication pivotal clinical study reports as well as all supportive studies conducted in the paediatric population that were submitted in the context of regulatory procedures not falling within the scope of Policy 0070 and considered the basis for that application."*
Chapter 1: • section 2, page 8	Inclusion of revised wording regarding the submission of duplicate marketing authorisations and inclusion of a cover letter template to be used upon the submission of the final redacted document package of duplicate applications: *"When submitting duplicate marketing authorisation*

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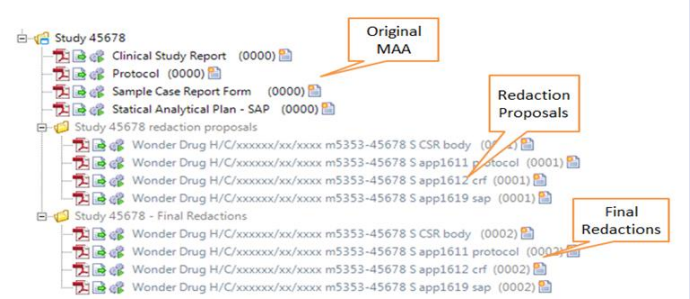
Chapter and Section reference	Summary of the change
Chapter 5: • annex 1.16, page 102	*applications, the Agency understands that the clinical reports included in such submissions are identical to the ones submitted in the application of the original medicinal product.* *However, duplicate submissions might contain **differences** in certain data, such as different salt, excipient or manufacturing sites[1]. In case these changes affect the content of the clinical reports submitted for publication, the applicant/MAH is required to flag such differences at the beginning of the procedure which will then be assessed by the Agency on a case-by-case basis.* *Where the clinical reports submitted for the original and duplicate medicinal products are **identical**, the Agency will only initiate one consultation process based on one redaction proposal document package, submitted for the original product. At the end of this consultation the Agency will send out the conclusion which will be equally valid for the duplicate medicinal product. A statement should be included in the cover letter of the duplicate final redacted document package confirming that the final redacted document package submitted for the duplicate is identical to the final redacted document package of the original medicinal product.* *Therefore, for identical duplicate medicinal products the Agency accepts that the redaction proposal package is only submitted for the original product, but still requires the submission of two stand-alone final redacted document packages, one for the original and the other for the duplicate medicinal product, as separate publications are needed.*"
Chapter 2: • section 2.2, page 14	Inclusion of an additional bullet point to provide guidance on the consideration of information presented in a language other than English: • ***"Documents** that are presented in a language other than English will not be published in the context of Policy 0070.* *If a **section within a document** considered in scope of Policy 0070 is presented in a language other than English, it is acceptable to have it removed from the clinical reports prepared for publication. In this case, the MAH should follow the below labelling requirements as per section 3.3.1.8. Technical requirements for the preparation of the Redaction Proposal version of the clinical reports:* *"Page(s) removed **– non-English text removed"***

[1] https://ec.europa.eu/health/sites/health/files/files/latest_news/2011_09_duplicates_note_upd_01.pdf

Chapter and Section reference	Summary of the change
Chapter 2: • section 2.2, page 14 and section 3.3.1.8., page 25	Clarification added on the definition of listings out of scope of Phase 1 of Policy 0070: *"Nevertheless, individual patient data listings (other than abnormal laboratory value listings) presented in other sections of the body of the clinical study report (e.g. concerning PK and immunogenicity results, laboratory values, case narratives or protocol deviations) cannot be considered out of scope and should not be removed. They should instead be anonymised."* *"For documents containing information throughout all sections (e.g. CSR body, appendices) which is agreed to be removed as out of scope of phase 1 of Policy 0070 (see section 2.2)…"*
Chapter 2: • section 3.3.1.8., page 25	Clarification on the instructions on how to process information considered to be out of scope of phase 1 of Policy 0070: *"…the removed pages should be replaced by an overlay text in black on a single blank page which must clearly indicate that pages have been removed and* ***the nature of the information*** *that has been removed, as follows:* *1. Title of section removed;* *2. Statement to reflect the above ("Page(s) removed- Out of Scope of phase 1 of Policy 0070 – <type of information/heading removed>").* *The page numbers of the removed information are not required to be included in the overlay text when the overall pagination remains intact in the document (i.e. the pages preceding and following the removed pages should retain their original page numbers) and it would be therefore obvious which pages were removed.* *For example in case there are individual patient abnormal laboratory value listings removed as out of scope of Policy 0070, it should read:* *"Page(s) removed-* ***Out of Scope of phase 1 of Policy 0070 - Individual Patient Abnormal Laboratory Value Listings****"*
Chapter 2: • section 3.3.1.11., page 28	Addition of guidance on the use of node extensions in the eCTD sequence: *"The EMA understands that in some cases the number of submitted documents in Module 5 can make it difficult to differentiate between the redaction proposal and final redacted document files as labelling them differently is not a requirement as per the naming convention. Therefore, to distinguish between*

Chapter and Section reference	Summary of the change
	the redaction proposal and final redacted files, and for a clearer structure of the submitted documents, the EMA recommends the use of two additional node extensions, as per the eCTD guidance[2], for submissions, for example:" 
Chapter 5: • annex 1.4 and 1.5, pages 72 and 74 respectively and annex 1.15, page 101	Inclusion of two template paragraphs and their use instructions within the Cover Letter regarding the identification of out of scope information and addition of a template to be used for listing out of scope sections (Annex 1.15).

2. Minor changes

Chapter and Section reference	Summary of the change
Chapter 2: section 3.3.1.5., page 18	Clarification added on the use of hyperlinks and bookmarks.
Chapter 2: section 3.3.1.11., page 27	Addition of guidance on the resubmission of a redaction proposal document package in the case of content invalidation.
Chapter 2: section 3.3.1.11., page 27 of guidance version 1.2	Deletion of paragraph referring to the submission of multiple applications. All relevant information regarding the submission of multiple applications is added in chapter 1, section 2.
Chapter 2: section 3.3.2.1.2., page 29	Amendment of first paragraph of corresponding section to reflect current process.
Chapter 2: • section 3.3.3.5., page 33	Clarification on the selection of relevant fields as per the Cover Letter table template – **field 7.3** should be selected as "clinical d/f publication Final Ver-Complete" or "clinical d/f publication Final Ver-Partial" as applicable for complete or partial packages

[2] http://esubmission.ema.europa.eu/eumodule1/docs/EU%20M1%20eCTD%20Spec%20v3.0.1.pdf

Chapter and Section reference	Summary of the change
	submitted.
Chapter 3: • section 6., page 48	Clarification added on the release of identities of investigators: *"The sponsor and coordinating investigator signatories of the clinical study report and the identities of the **principal or coordinating** investigator(s) who conducted the trial and their sites."*
Chapter 4: • section 4.2., page 59	Update of link to the justification table templates and inclusion of one link for all the justification table templates.
Chapter 4: • section 4.2., page 61	Amendment on the guidance provided for the completion of column 4 of the justification table: *"If the reference to the section of the Annex 3 is not obvious, EMA expects the applicant/MAH to provide **a broader category to which the information proposed for redaction would fall into.**"*
Chapter 5 • annex 1.4, 1.5 and 1.6, pages 71 to 77	Editorial changes to comply with the above-mentioned amendments.
Chapter 5: • annex 1.13., page 97	Alignment of "Conclusion" template wording between annex 1.2 and annex 1.13: *"[Company name] declares that the anonymisation report has been prepared following the guidance made available by EMA for the preparation of the documents comprising the **Final Redacted Document package**."*
Chapter 5: • annex 1.14., page 98	Editorial amendment of the checklist to exclude reference to bold and non-bold fonts.