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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 19 December 2016

On 03 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 19 December 2016 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: Scope, page 6 and • "Clinical reports submitted as part of previous/other regulatory procedures", page 7	Clarification has been added regarding the terminology 'extension of indication procedures' falling within the scope of policy 0070. Additional information concerning EMA's position on clinical reports that are submitted as part of /or cross-referred to within a regulatory application in the context of policy 0070 has been added. These clinical reports will be subject to publication following the redaction of CCI and anonymisation of the clinic data. This includes CSRs previously submitted in the context of earlier regulatory procedures which form the basis of the regulatory decision for those applications falling in the scope of the policy. For example, the clinical data submitted in the context of Article 46 of Regulation (EC) No 1901/2006 to which reference is made in a regulatory procedure for the addition or

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Chapter and Section reference	Summary of the change
	modification of a paediatric indication is also subject to publication under policy 0070.
Chapter 2: • Section 3.3.1.8, page 24 • Chapter 5, Annex 1.12	Practical guidance for the individual patient data (IPD) out of scope sections has been included. For sections where per patient per visit IPD are identified in the clinical reports and the Agency agrees that they are out of the scope, these sections can be removed from the documents. However, the pages/sections considered out of scope and, therefore, removed the MAH must clearly indicate which pages and what information has been removed. The removed pages should be replaced by the following text in black contained on a white page: 1. removed page numbers (from-to) and the corresponding section title 2. statement to reflect the above ('Out of Scope of phase 1 of Policy 0070 - <type of information/heading removed>'). For example, where per patient per visit data has been removed as out of scope of policy 0070, it should read: "**Out of Scope of phase I of Policy 0070- Per patient/per visit line listings**". The Agency considers per patient per visit data as those listings including values of the measured parameters (e.g. lab values) listed for **all** patients recruited and covering **all** study visits. Therefore, for example, tables listing values of the measured parameters (e.g. HbA1C) or outcomes (protocol deviation, death, SAE, overall survival) at a certain **single** time point will not be considered as per patient per visit line listing. Also, the Agency does not consider as per patient per visit line listings those tables where parameter or outcome values for **selected** patients and **selected** visits are presented.
Chapter 2: • Section 3.3.1.3, page 16 • Section 3.3.3.3, page 30 • Section 3.3.1.9, page 25	EMA's position when applicants/MAHs submit an incomplete redaction proposal document package or a final redacted document package has been outlined. An incomplete Redaction Proposal document package or an incomplete Final Redacted document package submission will lead to the rejection of the package by EMA. Resubmission of the entire package within the original deadline is required to remain compliant with policy 0070. As additionally stated under Section 3.3.1.9 (page 25),

Chapter and Section reference	Summary of the change
	Redaction Proposal document package cover letters that do not contain the declaration text, also, will be rejected. The entire package containing the cover letter with the declaration text will need to be re-submitted within the original deadline in order to remain compliant with policy 0070.
Chapter 2: • Section 3.3.1.6, page 17 • Section 3.3.1.13, page 27 • Section 3.3.3.9, page 33	Applicants/MAHs that follow the file naming convention in the guidance when submitting either package should expect to receive 'best practice' warnings in the eCTD technical validation report. However, these warnings can be ignored and they will not lead to the rejection of either package on technical grounds.
Chapter 2: • Section 3.3.1.9, page 24 • Section 3.3.1.11, page 26 • Section 3.3.3.5, page 32	An update to the information required in the formatted table, (that applicants/MAHs should embed in the cover letter), has been made. The eCTD sequence for the procedure should be included under point 10. In the related sequence field, the same sequence number should be written as stated in the EU Module 1 v3.0.1 specification. In addition, when submitting the Final Redacted document package applicants/MAHs no longer have to select from the 'complete' or 'partial' submission option. Instead, 'Clinical data publication final version' should be selected.
Chapter 2: • Section 3.3.1.10, page 25 Chapter 5: • Annex 1.4, page 70	In cases where an applicant/MAH has identified CCI in some, but not all, clinical reports, applicants/MAHs should state this using the text provided in the Redaction Proposal Document package cover letter. It is important to include this statement to justify the corresponding number of justification tables submitted by the applicant/MAH. This section of the guidance also makes reference to the draft statement that is included in Annex 1.4.
Chapter 2: • Section 3.3.3.4 page 31 • Section 3.3.1.8 page 22-23	To distinguish between CCI and PPD redactions, when preparing only the Final Redacted document package applicants/MAHs are required to colour code the redactions. CCI redactions should have a black background with red overlay text, whilst PPD must have a blue (pantone 291 C - corresponding to RGB colours 115, 203 and 235) background with black overlay text.
Chapter 2: • Section 3.3.3.5, page 32	Applicants/MAHs must include, in the Final Redacted Document package cover letter (see Annex 1.6 of the guidance), a statement referring to the declaration in the Redaction Proposal document package. The declaration that is referred to states that the clinical reports submitted for publication are the same

Chapter and Section reference	Summary of the change
	as those submitted for scientific review, with the exception of redactions and anonymisations.
Chapter 2: • Section 4, page 34	In cases where an applicant/MAH (the Transferor) transfers a MA to another company (the Transferee), the Transferee becomes responsible for the transferred product and accepts all prior agreements under policy 0070 between the Transferor and the EMA. If the policy 0070 process has already started with the Transferor, the process will continue as normal with the Transferee taking over from the transfer date.
Annex 1.4, page 70	In cases where an applicant/MAH has identified CCI in some, but not all, clinical reports applicants/MAHs should state this using the text provided in the guidance. It is important to include this statement to justify the corresponding number of justification tables submitted.
Annex 1.6, page 74	Text has been included in the Final Redacted document package cover letter to reflect full and partial agreements with EMA's conclusion. Where an applicant/MAH agrees in full with EMA's conclusion, the applicable declaration text to reflect this full agreement must be included in the Final Redacted document package. Should an applicant/MAH partially agree with EMA's conclusion, the applicable declaration should also be included. In addition, in cases of partial agreement with EMA's conclusion, the applicant/MAH must state which redactions it has made in the Final Redacted document package that do not match the EMA's conclusion.

2. Minor changes

Chapter and Section reference	Summary of the change
Chapter 2: • Section 3.2, page 14	The time points for advance notifications to applicants have been streamlined. Advance notifications to applicants will only be received at validation and CHMP Opinion. Applicants/MAHs who have withdrawn applications will receive a notification either with the letter acknowledging withdrawal or with a CHMP opinion.
Chapter 2:	Existing links and the eCTD guidance reference have been

Chapter and Section reference	Summary of the change
• Section 3.3.1.3, page 15	updated in line with recent amendments.
Chapter 2: • Section 3.3.1.8, page 23	EMA has clarified that the license for a redaction tool will be made available to SMEs for a period of 12 months.
Annex 1.1, page 64	A product reference number field has been included in the application form.