5 May 2014
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Redaction principles

Draft

The Clinical Study Reports (Module 5, "CSRs"), Clinical Overviews (Module 2.5) and Clinical Summaries (Module 2.7), together with Appendixes to the CSRs no. 16.1.1, 16.1.2 and 16.1.9 (collectively "CT Data") that will be made available on the EMA web portal in compliance with the EMA proactive publication policy shall be subject to redactions needed to protect those specific elements which qualify as commercially confidential information that should not be released. This complements the use controls that will need to be accepted by recipients of the documents in order to protect the originator against misuse of the data as a whole. This covers information that is not in the public domain or publicly available and where disclosure may undermine the economic or competitive position of the owner of the information. In this regard, the assessment of the relevant information will also take into account the evidence shown by the information owner with regard to various factors, including the nature of the product concerned, the competitive situation of the therapeutic market in question, the approval status in other jurisdictions, the novelty of the clinical development, and new developments by the same company.

In general, much of the information in CSRs pertaining to study designs, statistical analyses, and study results would not be considered CCI. There, are, however, limited circumstances where such information could constitute CCI such as in the case of novel statistical or other analytical methods and exploratory endpoint results about potential new uses of a medicine that are not the subject of the marketing authorisation application.

Exceptions to the general principle above are included in the table below. This information may have to be redacted. If justification for additional redaction is provided by industry in the future, the EMA and industry associations will discuss in good faith whether to integrate the table below with the new proposed redaction, based on real life experience (including applicants' comments) in the implementation of the EMA proactive publication policy.

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Annex I

Detailed list of the elements relating to clinical trials and contained in 'The common technical document for the registration of pharmaceuticals for human use' (from ICH harmonised tripartite guideline, Modules 2 and 5); Official guidance which is noted in column three advises what should be discussed in the following components.

Section	Title	Information that may be CCI	Justification for redaction
2.5 CLINICAL OVERVIEW			
2.5.1	Product Development Rationale	• "Describe the clinical development programme of the medicinal product, including ongoing and planned clinical studies and the basis for the decision to submit the application at this point in the programme…"	• Information for planned clinical studies may include "exploratory endpoints" that are not intended to yield data in support of the then-current approval of a use or indication, but could provide clues to potential uses and indications for competitors.
		• "Regulatory guidance and advice (at least from the region(s) where the Clinical Overview is being submitted) should be identified, with discussion of how that advice was implemented."	• Regulatory advice from outside the EU is typically non-public and includes agreements with regulators on study design, strategies for organization and presentation of findings, and other aspects of the regulatory process that competitors could copy.
		• "Formal advice documents (e.g., official meeting minutes, official guidance, letters from regulatory authorities) should be referenced…."	• Same justification as above.
2.5.2	Overview of Biopharmaceutics	• Detailed assay information	• As the Biopharmaceutical Summary Documents (2.7.1) are considered CCI, this section may contain some overlapping information.

Section	Title	Information that may be CCI	Justification for redaction
2.5.3	Overview of Clinical Pharmacology	• Stereochemistry issues	• Competitors could gain a detailed understanding of the stereoisomers and three-dimensionality of the molecule.
2.5.6	Benefits and Risks Conclusions	• Implications of any deviations from regulatory advice or guidelines	• The company may include justifications for any deviation from regulatory advice or guidance outside of the EU jurisdiction, a competitor may have an unwarranted new perception of the regulatory risk associated with a certain regulatory strategy.
2.7 CLINICAL SUMMARY			
2.7.1	Summary of Biopharmaceutic Studies and Associated Analytical Methods	• Information about specifications on company assays	• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.
2.7.2	Summary of Clinical Pharmacology Studies	• Information about specifications on company assays and immunogenicity	• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.
MODULE 5 CLINICAL STUDY REPORTS			
5.3.1	Reports of Biopharmaceutic Studies	• Information about specifications on company assays (e.g. Bioavailability, In Vitro – In Vivo Correlation)	• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.

34 # Annex II

35 Structure and content of clinical study reports (CSRs) (From ICH harmonised tripartite guideline, E3).

Section	Title	Information that may be CCI	Justification for redaction
7	Introduction	• Development of the protocol or any other agreements/meetings between the sponsor/company and regulatory authorities that are relevant to the particular study, should be identified or described.	• May contain non-public information that the sponsor agreed in another jurisdiction outside of the EU.
8	Study Objectives (including Exploratory Endpoints and Efficacy and Safety Variables; 9.5, 11.4)	• Statements/descriptions relating to objectives that are not supportive of a label claim and do not contribute to the overall benefit/risk evaluation. This includes the definition of efficacy and safety variables collected and analysed in support of exploratory objectives.	• The exploratory study objectives could be used by a competitor to gain insights into additional future study plans and/or indications for the product. For example, in some trials for a new anti-inflammatory medicinal product, an exploratory lipid profile was included, investigating the lipid metabolism in patients treated with the product, to inform future studies rather than to support the MAA. The results of these analyses were included in the CSRs submitted to the EMA in the course of the MAA procedure. • Alternatively the exploratory objectives may include biomarkers that could be used as 'hypothesis generating' for future studies. At that stage there would not be enough information to file patent applications on these objectives until some data are available from clinical and non-clinical studies. Disclosing these exploratory objectives may

Section	Title	Information that may be CCI	Justification for redaction
			preclude obtaining patents that would cover biomarkers/diagnostics themselves, as well as method of use patents directed to patient subpopulations.
9.7.2	Determination of Sample Size	• CCI concern is also applicable to Documentation of statistical methods in 16.1.9.	• The sample size per se is not considered CCI. However there may be occasions when the intellectual consideration that goes into the analysis of the information that drives the sample size calculation (e.g. estimates of endpoint variability, measurement precision, screening and retention rates) is considered CCI.
14.4	Method of PK/PD determination		• This section may have proprietary information on how analyses are performed.

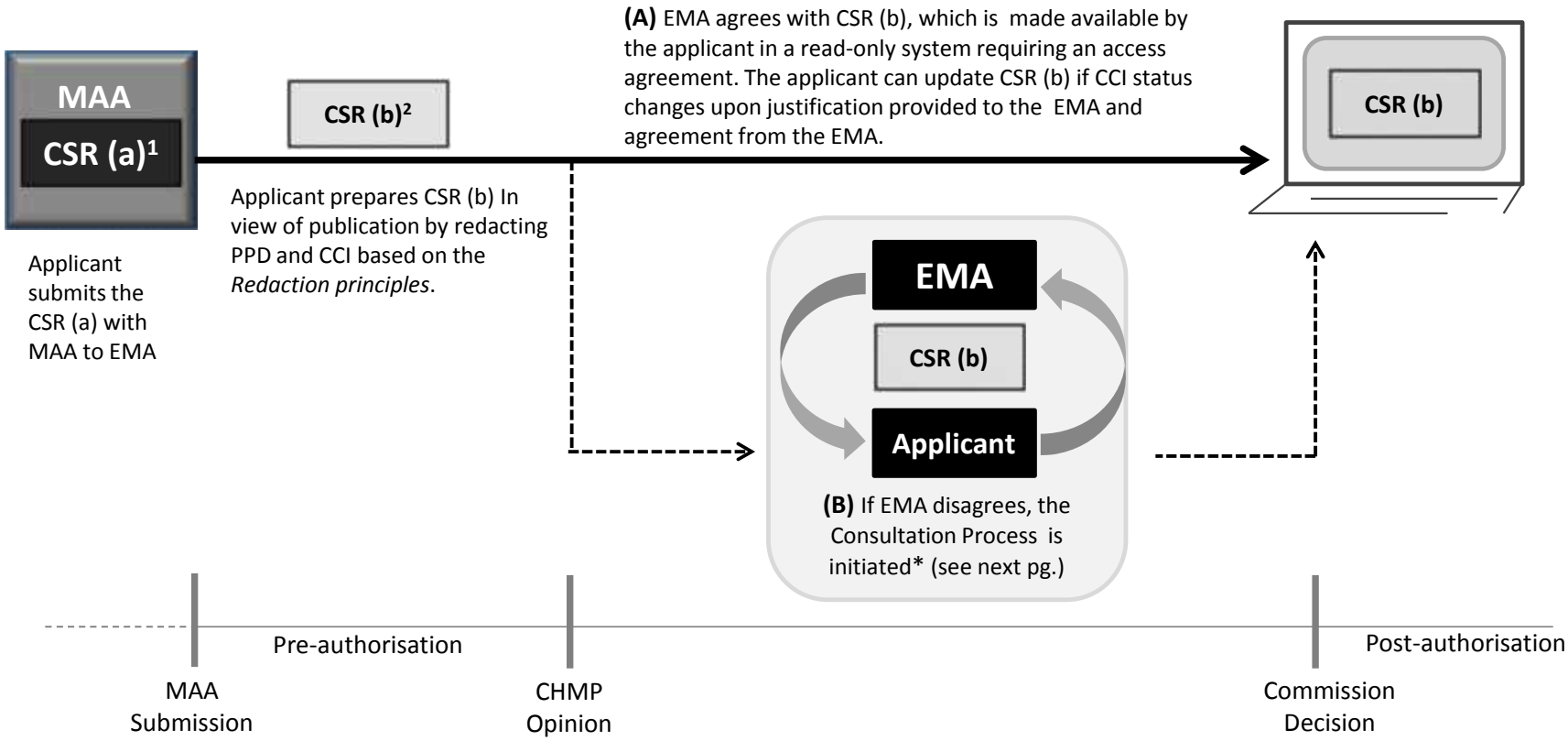
36

37 Procedural mechanism to conduct redactions of Full CSRs

38 See Figures in Appendix 1

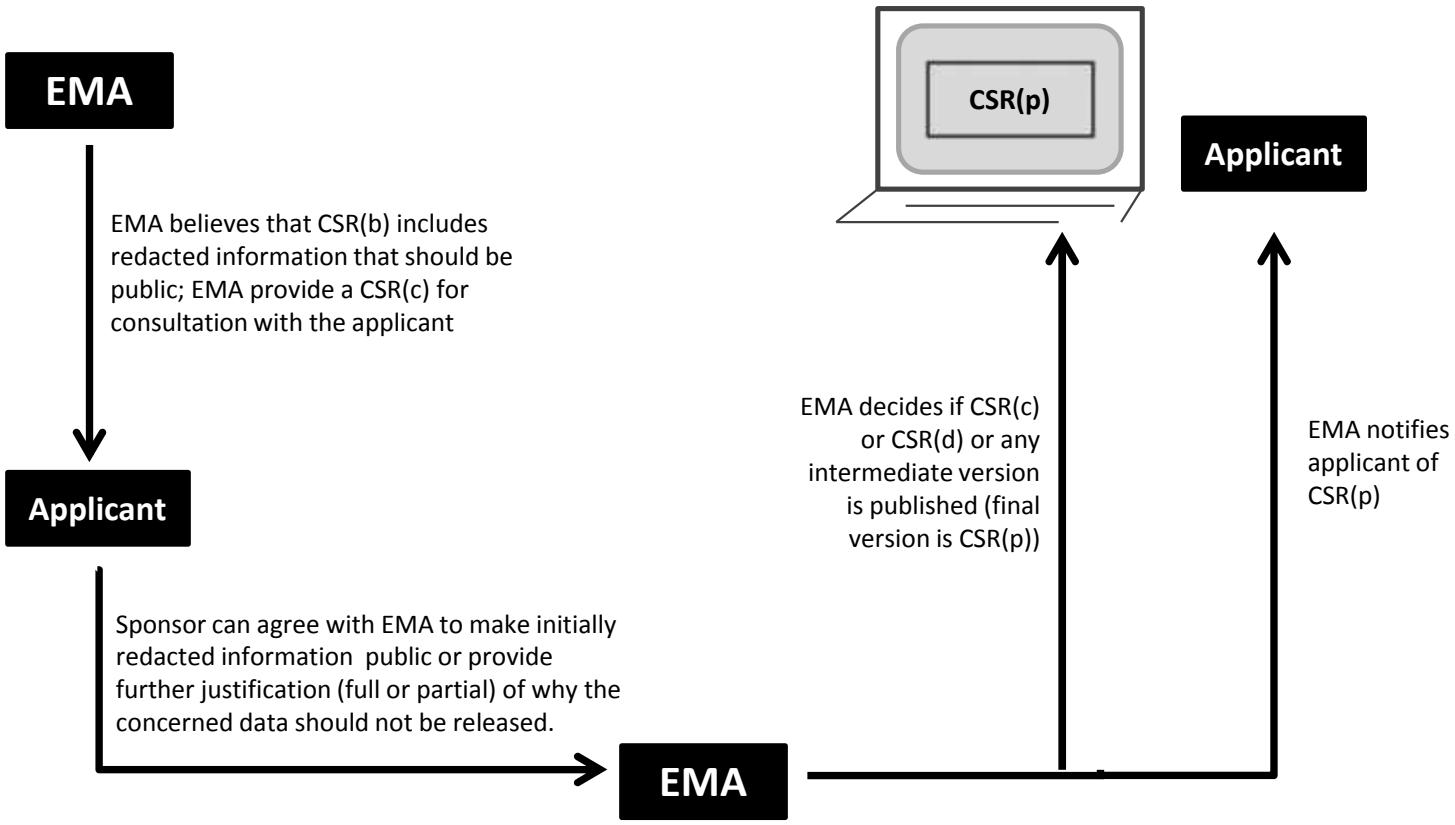
39

Appendix 1: Mechanism for making the CSR available on the EMA web portal under the EMA proactive publication policy



1. CSR (a) = CSR in accordance with EMA guidance (1995 and 2004)
2. CSR (b) = CSR available under the EMA proactive publication policy

*Consultation Process



* Consultation Process to be concluded within Decision making process timelines – exact timing to be agreed