EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guidance to pharmaceutical industry on redacting commercially confidential information (CCI) in clinical reports

Stakeholder webinar
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An agency of the European Union

Introduction

The purpose of this guidance is to clarify:

- How to **identify** and **mark** in the documents the proposed CCI redactions
- What is the expected **justification level of detail** that would allow the Agency to perform an adequate and informed assessment of the proposed redactions
- How to apply the **redaction principles** laid out in Policy 0070

The ultimate goals of the guidance

- to ensure a **common understanding** of what can or cannot be considered CCI within clinical reports
- to increase **consistency** in the proposed and accepted redactions across the range of clinical reports

Contents

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Documents subject to publication

- **Clinical overviews** (generally submitted in module 2.5)
- **Clinical summaries** (generally submitted in module 2.7 – sections 2.7.1 to 2.7.4)
- **Clinical study reports** (CSRs) (generally submitted in module 5 - section 5.3*) together with the following appendices as defined in ICH E3:
  - 16.1.1 (**protocol and protocol amendments**)
  - 16.1.2 (**sample case report form**)
  - 16.1.9 (documentation of **statistical methods**)

**The Agency would like to emphasize that although other type of reports may be found in section 5.3, the subject of this policy is restricted to the publishing clinical study reports only (CSR), excluding for example PSURs submitted usually in 5.3.6 and Case report form and individual patient listing submitted usually under section 5.3.7.*

Justification table (1/2)

- A **living document** that will reflect the justifications put forward by the company and the Agency's conclusions
- A **separate** justification table for **each** of the clinical reports
- Will be used as a **communication tool** between the Agency and the company during the redaction consultation process
- Submitted as **word** document

Justification table (2/2)

Justification Table: Invented Product name (INN) – procedure number

MAH/Applicant Consultation on <Clinical Report Name> - <Name of the Applicant consulted>

Please ensure that by submitting this Justification Table, you confirm that you have checked that the information you wish to redact is not in the public domain. ☐ Please also ensure that the redactions that you propose are in line with Annex III of POLICY/0070 and the Guidance to pharmaceutical industry on redacting commercially confidential information (CCI) in clinical reports.

Page number(s)	Title of Section(s)	Text proposed for redaction by the MAH/applicant	Reference to the section(s) of the Annex III of Policy 0070, based on which the redaction is requested.	Explanation why this/these particular section(s) of Policy 0070 Annex III is/are relevant for the text that is proposed to be redacted.	MAH's/Applicant's justification	Agency Assessment: Rejected/ Partial rejection/ Accepted	Agency's rationale/rejection code
•	•	•	•	•	•	•	•
•	•	•	•	•	•	•	•

- Each table should list **all proposed CCI redactions**
- Each table should be **fully completed** by the Applicants/MAHs
- The justification table is not part of the documents to be published

Information that is not considered CCI (1/3)

- Information available in the **public domain** from various sources*
  - Company website
  - Scientific guidelines
  - Clinical trial registries
  - Websites of other regulatory authorities within and outside of the EU
  - Scientific literature and articles (such as Textbooks, PubMed, Medline)
  - Patent application

**The information sources listed above should be checked as the minimum number of sources and are not meant to constitute an exhaustive list*

Rejection code: CCI - Rejection 01 – Public Information

Information that is not considered CCI (2/3)

- Information that does not bear any **innovative features**
- Information reflecting **common knowledge** shared within the scientific community via:
  - Scientific literature and articles (Textbooks, PubMed, Medline)
  - Scientific and regulatory guidelines and guidance documents
  - Treatment guidelines

Rejection code: CCI - Rejection 02 – Public knowledge

Information that is not considered CCI (3/3)

- Information that, in the Agency's view, **does not constitute CCI**
  - **General or administrative information:** names of all CROs and vendors
  - **Some/Certain quality related information:** temperature, humidity parameters and storage duration as applied in stability tests
  - **Non-Clinical related information:** quantification range (lower and upper quantification limits) of pharmacokinetic and pharmacology tests/methods; information concerning a generally-used/well-known immunohistochemistry method (e.g. ELISA/LC-MS)
  - **Clinical related information:** statistical methods (including imputation methods used for missing data); protocol and protocol amendments

Rejection code: CCI - Rejection 03 – Public interest

Information that may be considered CCI

- Has to fall under the types of information that may **potentially** be considered CCI according to Policy 0070 Annex III
- Has to be adequately justified
- Justifications solely based on annex III justification text or referring to annex III information types will not be considered relevant, therefore will be rejected

Justification – expected level of detail (1/3)

- The applicants are expected to submit a **specific**, **pertinent**, **relevant**, **not overstated** and **appropriate** justification for each of the pieces of text proposed to be redacted
- The justification wording has to meet the following criteria:
  - Clearly **refer to/identify** the information proposed to be redacted
  - Highlight the **innovative features** of the information in the context of the public knowledge within the specific scientific area
  - Explicitly **indicate** to which **on-going development programme** the information relates to
  - Explain **how** the disclosure of the concerned information **would undermine** the applicant's/MAH's economic interest or competitive position

Justification – expected level of detail (2/3)

- If Agency considers the justification insufficient ⟹ additional clarifications are requested
- Whenever the Agency considers that the justification is not sufficiently specific or too vague, the following **rejection codes** will be included in the justification table:

CCI – Rejection 04 – Insufficient justification

CCI - Rejection 05 – Irrelevant justification

Justification – expected level of detail (3/3)

- Justifications that will be considered by the Agency either insufficient or irrelevant:

"Information is commercially confidential, competitively sensitive information and includes intellectual property including trade secret information."

"Company confidential information - Disclosure of these elements will harm <company>'s commercial interests because it may enable third party access to business-critical information."

"The text proposed to be redacted reveals purpose and timing of discussions with health authorities, this is considered sensitive information that is not consolidated in this way within the public domain, indeed we cannot find this information in public forum."

"Information on the safety profile of the product not reflected in the SmPC."

"This information can be interpreted out of context. Such interpretation could lead to a misleading image of the safety profile of the product."

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Thank you for your attention

Further information

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