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

6 July 2015, London

Presented by Anne-Sophie Henry-Eude
Head of Access to Documents Service
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

• Approach to redaction of CCI
• Information that is not considered CCI
• The 5 rejection codes
• The Justification table
• Redaction Consultation Process
Approach to redaction of CCI

- Has to fall under the types of information that may *potentially* be considered CCI according to Policy 0070 Annex 3
- Has to be adequately justified
- Justifications solely based on Annex 3 justification text or referring to Annex 3 information types will not be considered relevant, therefore will be rejected
Information that is not considered CCI (1/5)

Rejection code: CCI - Rejection 01 – Public Information

- 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.
Information that is not considered CCI (2/5)

**Rejection code: CCI - Rejection 02 – Public knowledge**

- 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
Information that is not considered CCI (3/5)

Rejection code: CCI - Rejection 03 – Disclosure due to public interest

- 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
Information that is not considered CCI (5/5)

Examples of what will be considered by the Agency of Public Interest:

- Names of all CROs and vendors involved in trial-related duties and functions
- Lot/batch numbers of the investigational products understood as either test product, active comparator or placebo (excluding manufacturing site(s) IDs);
- The justification of planned sample size
- The section on drug concentration measurements including results
- Primary and secondary endpoints
- Drug concentration in humans and pharmacokinetic parameters
- Excipient batch numbers
Information that is not considered CCI (4/5)

CCI – Rejection 04 – Insufficient justification
CCI - Rejection 05 – Irrelevant justification

• If Agency considers the justification insufficient or irrelevant 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:
Information that is not considered CCI (5/5)

Examples of justifications that will be considered by the Agency either insufficient or irrelevant:

- “This information can be interpreted out of context. Such interpretation could lead to a misleading image of the safety profile of the product.”
- “The analytical methods are [the company]’s intellectual property, which [the company] developed by expending a significant amount of time, and human, financial and commercial resources.”
- “Unpublished data - These study results have not been published in any peer-reviewed [sic] publication”
- “Information on the safety profile of the product not reflected in the SmPC.”
- “Detailed Statistical/Analytical Method : See Article 4.2 1st indent of Regulation (EC) The institutions shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.”
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
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.

---

<table>
<thead>
<tr>
<th>Page number(s)</th>
<th>Title of section(s)</th>
<th>Text proposed for redaction by the Applicant/MAH</th>
<th>Reference to the section(s) of the Annex 3 of Policy 0070 based on which the redaction is requested</th>
<th>Explanation why this/these particular section(s) of Policy 0070 and is/are relevant for the text that is proposed to be redacted</th>
<th>Justification of CCI (Please explain how the release of this information will damage your company’s commercial interest or competitive position)</th>
<th>Agency Assessment of the proposed redaction:</th>
<th>Agency’s rationale/redaction code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Guidance to pharmaceutical industry on redacting commercially confidential information (CCI) in clinical reports & Process**
Justification table (3/3)

• 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.
Internal receipt/distribution stage – 5 calendar days

**Receiving documents**
Dedicated team receives documents and justification tables

**Assignment**
Assessment task is assigned to a dedicated team member
Validation stage – 11 calendar days

**Validation**
Validation of the justification table

**Clarification**
EMA contact person to request from MAH/Applicant a revised justification table if needed
Assessment of CCI stage – 31 calendar days

**Assessment of proposals for redaction of CCI**
Justifications will be assessed by the EMA taking into account the principles described in the Guidance on CCI redaction

**Request for additional information**
Will be sent to the MAH/Applicant via Eudralink if needed

**Agency final conclusion**
Agency sends final justification table to MAH/Applicant with accepted and/or rejected proposals for redaction of CCI
Outcome of the assessment

Based on the outcome of the assessment in the justification table, the company is expected to **update the proposed redacted** documents to reflect the proposals for redaction of CCI agreed by the EMA.

**Implementation of conclusion**

**Final redacted document**

The MAH/Applicant will provide final redacted documents for publication
Thank you for your attention

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on @EMA_News