EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

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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

- 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, **<u>does not constitute CCI</u>**
  - **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

Primary and secondary endpoints

Lot/batch numbers of the investigational products understood as either test product, active comparator or placebo (excluding manufacturing site(s) IDs);

Drug concentration in humans and pharmacokinetic parameters

The justification of planned sample size

Excipient batch numbers

The section on drug concentration measurements including results

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."

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

"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."

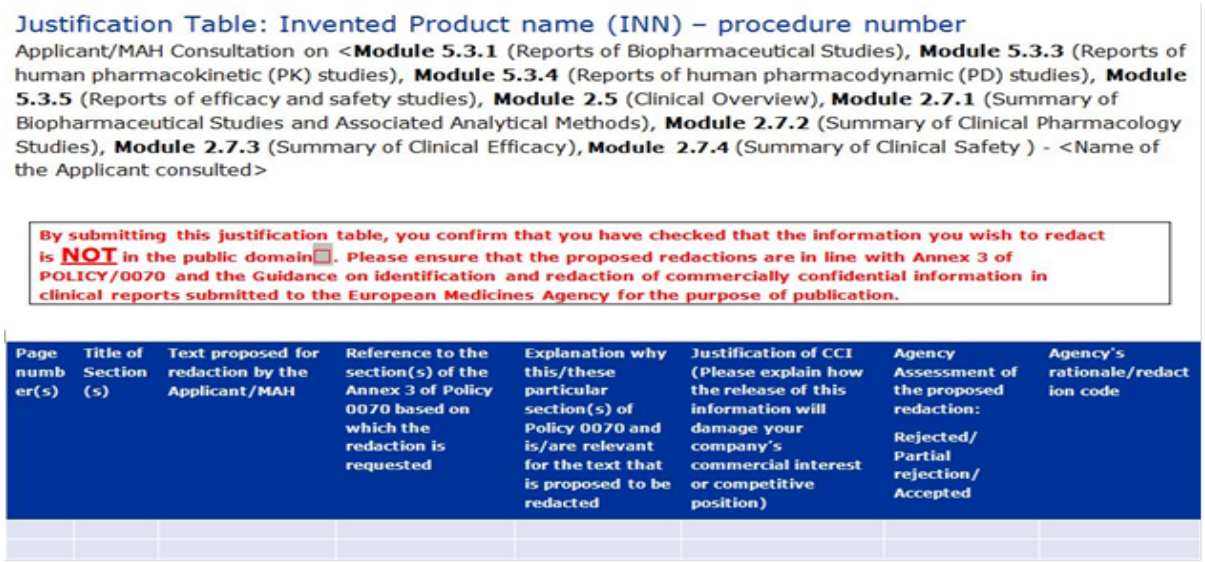
"Unpublished data - These study results have not been published in any peered-reviewed [sic] publication"

"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

Justification table (2/2)



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

Applicant/MAH Consultation on <**Module 5.3.1** (Reports of Biopharmaceutical Studies), **Module 5.3.3** (Reports of human pharmacokinetic (PK) studies), **Module 5.3.4** (Reports of human pharmacodynamic (PD) studies), **Module 5.3.5** (Reports of efficacy and safety studies), **Module 2.5** (Clinical Overview), **Module 2.7.1** (Summary of Biopharmaceutical Studies and Associated Analytical Methods), **Module 2.7.2** (Summary of Clinical Pharmacology Studies), **Module 2.7.3** (Summary of Clinical Efficacy), **Module 2.7.4** (Summary of Clinical Safety) - <Name of the Applicant consulted>

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 ensure that the proposed redactions are in line with Annex 3 of POLICY/0070 and the Guidance on identification and redaction of commercially confidential information in clinical reports submitted to the European Medicines Agency for the purpose of publication.

Page number(s)	Title of Section (s)	Text proposed for redaction by the Applicant/MAH	Reference to the section(s) of the Annex 3 of Policy 0070 based on which the redaction is requested	Explanation why this/these particular section(s) of Policy 0070 and is/are relevant for the text that is proposed to be redacted	Justification of CCI (Please explain how the release of this information will damage your company's commercial interest or competitive position)	Agency Assessment of the proposed redaction: Rejected/ Partial rejection/ Accepted	Agency's rationale/redaction 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

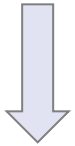
Justification table (3/3)

- 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

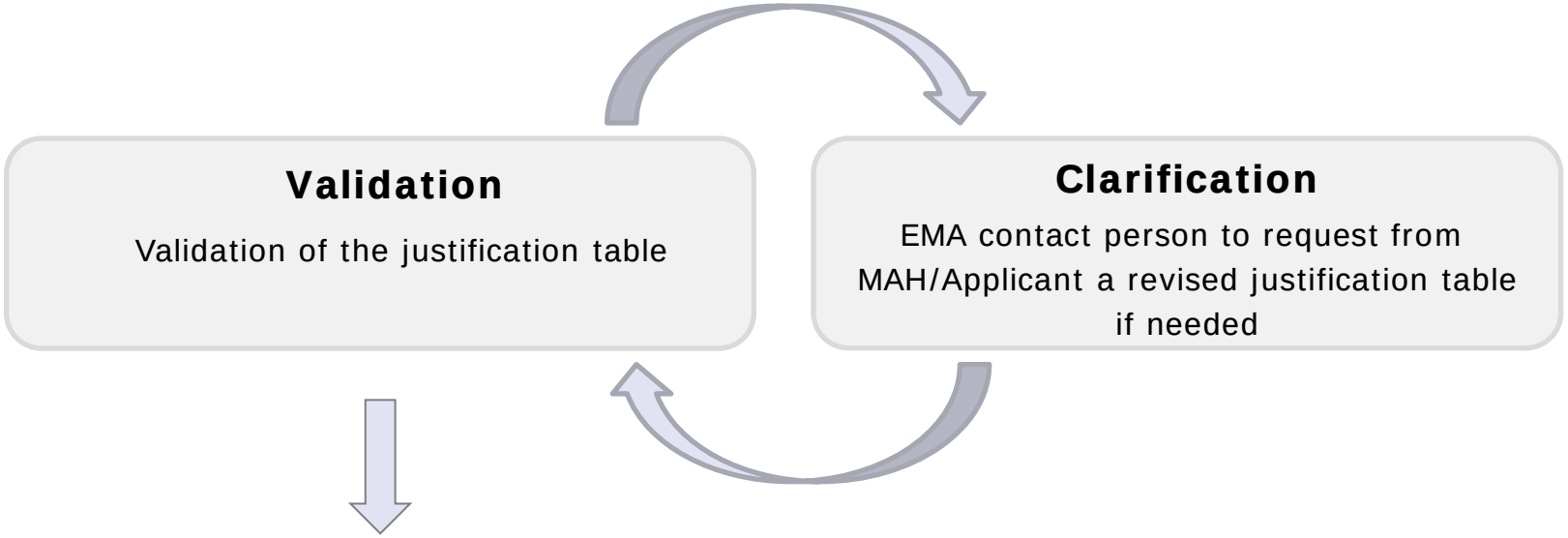
Dedicated team receives documents and justification tables



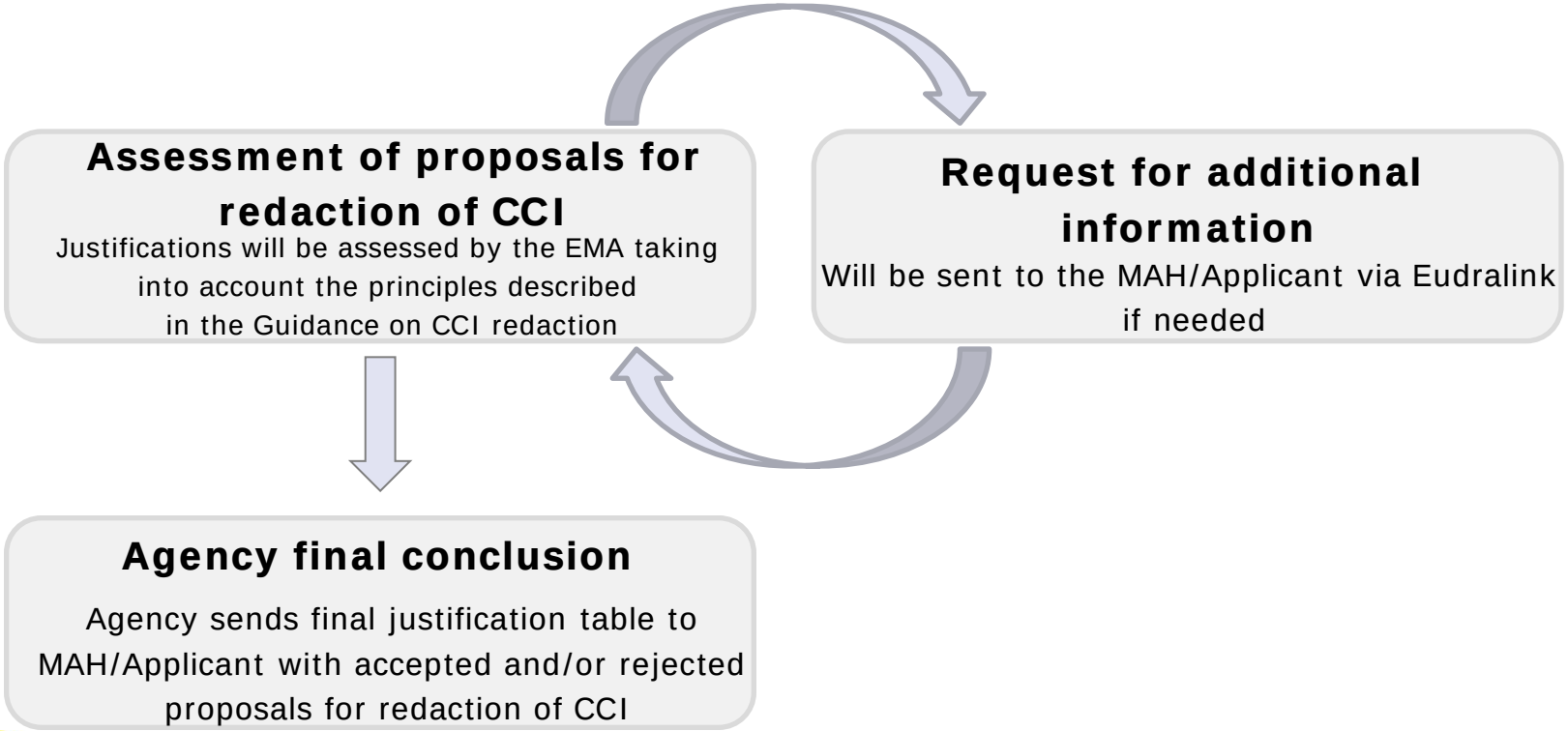
Assignment

Assessment task is assigned to a dedicated team member

Validation stage –11 calendar days



Assessment of CCI stage – 31 calendar days



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

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