



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Redaction Consultation Process

Assessment of justification for proposed redactions of commercially confidential information

Stakeholder webinar
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An agency of the European Union





Introduction

Following the submission of the clinical reports for the purpose of publication, the Agency will initiate a **redaction consultation process**.

- The purpose of the redaction consultation process is to:
 - Ensure a **consistent** level of redaction of the commercially confidential information (CCI) throughout the documents.
 - Ensure that only **duly justified redactions of CCI** are applied to the documents.

Therefore, the published study reports would provide the highest possible level of transparency while aiming at the protection of CCI.



Contents

Stages of the process

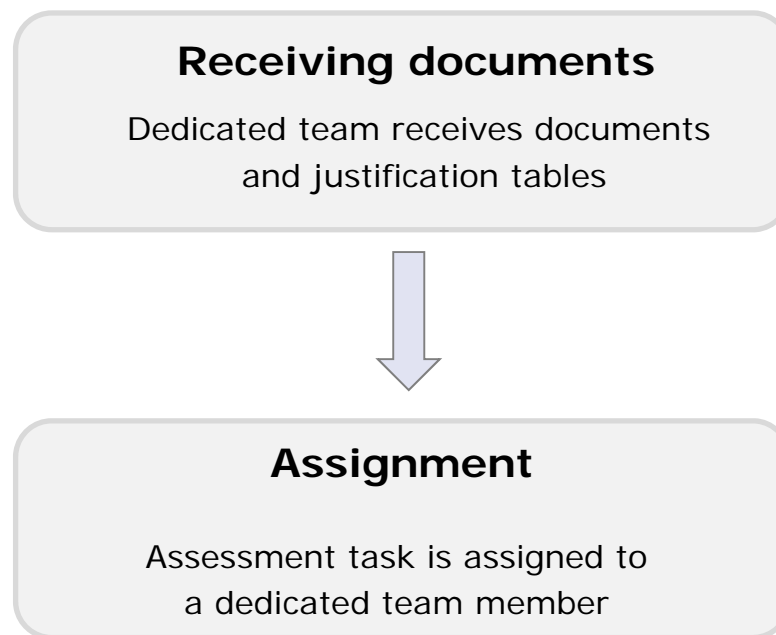
- Internal receipt/distribution stage
- Validation stage
- Assessment of CCI stage

Outcome of the redaction consultation process



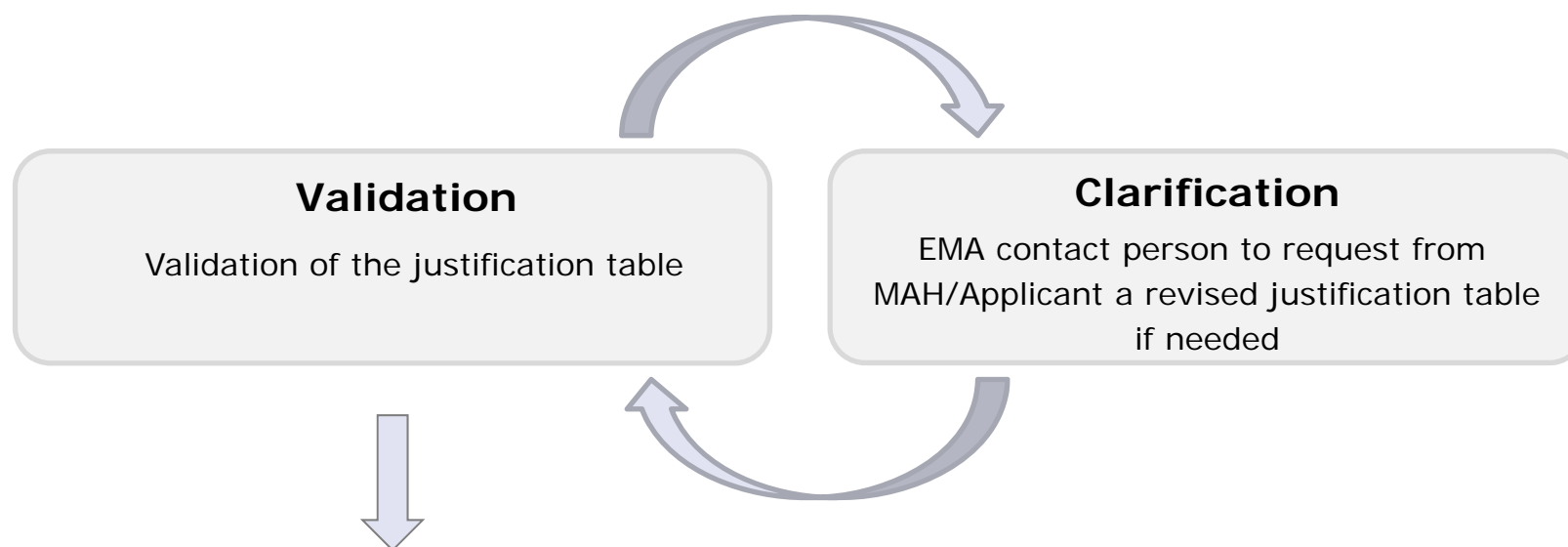


Internal receipt/distribution stage – 5 calendar days



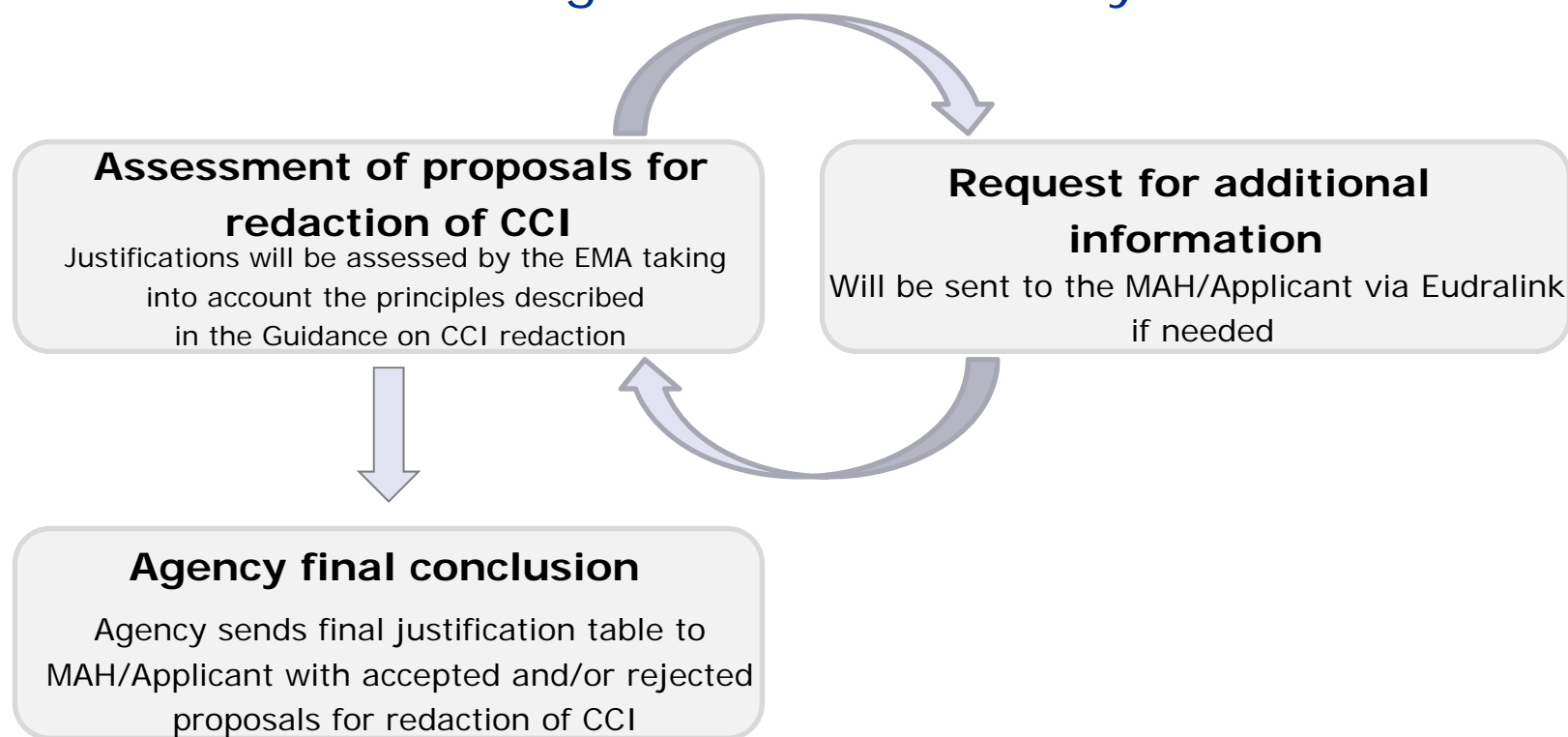


Validation stage –11 calendar days





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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