EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guidance on the Submission of Clinical Reports intended for Publication in Accordance with Policy 0070

Principles

Stakeholder webinar
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Contents

The following will be detailed with respect to the submission requirements for clinical reports provided by Applicants for publication in line with Phase 1 of Policy 0070:

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Packages for Submission

Applicants must submit two packages, a Redaction Proposal package and Final Redaction package, to the Agency. The following are the required components of the Redaction Proposal package:

- All redaction proposal versions of the clinical reports
- A cover letter with a declaration confirming that the clinical reports submitted for scientific evaluation are the same as that submitted for publication, with the exception of redactions
- A completed justification table (detailing CCI redactions only) in Word format for each document. Where there are disagreements, concomitant outcomes must be addressed in all corresponding documents
- An anonymisation report

and that of the Final Redaction package:

- All final redacted versions of the clinical reports
- A cover letter

Submission & Publication Timelines: MAAs and Line Extension Applications

The timelines[1] for the provision of the Redaction Proposal and Final Redacted version of the clinical reports and their publication by the Agency are as follows for **MAAs and line extension applications**:

Submission by the Applicant

Redaction Proposal: Day 181 to Day 220 (≤ 30 days pre-opinion and ≤ 10 days post-opinion)

Publication by the Agency

Final Redacted Version: ≤ 60 days of the issuance of EC Decision

[1] ***(in calendar days)***

Submission & Publication Timelines: Extensions of Indications and Withdrawals

Submission by the Applicant

Redaction Proposal for Extensions of Indications: ≤ 30 days pre-opinion and ≤ 10 days post-opinion

Redaction Proposal for Withdrawn Applications: ≤ 30 days post-receipt of the withdrawal letter

Publication by the Agency

Final Redacted Version for Extension of Indication: ≤ 60 days of the issuance of EC Decision

Final Redacted Version for Withdrawn Applications: ≤ 150 days post-notification of the withdrawal to the Agency by the Applicant

Redaction Proposal

Applicants must prepare a Redaction Proposal version of their clinical reports for publication. The preparation of these documents must adhere to the following requirements:

- Documents must be submitted in PDF format
- The text proposed for redaction should be clearly identified as such (i.e. marked) and the text itself should be legible (read-through)
- It should be possible to easily (with minimal intervention) render the proposed redactions permanent or to remove the redaction
- It should be possible to select one or more marked proposed redactions for comment, redaction or deletion. Editing individual proposed redactions should be possible for all parties and clearly tracked.

To upload the Redaction Proposal via the Gateway, a separate sequence with submission type 'Supplemental Information' as a separate document set in the eCTD format must be created (using eCTD operator 'new').

Notifications to Applicants: MAAs and Line Extension Applications

Applicants will receive 3 advanced warnings of their requirement to submit a Redaction Proposal at the following time points for **MAAs and line extension applications**:

1. With the validation letter
2. With the day 180 list of outstanding issues
3. With the CHMP opinion letter

In each case, the notification will be issued within the letter sent to the Applicant for the relevant stage of the scientific review process

Notifications to Applicants: Extensions of Indications and Withdrawals

Applicants will also receive 3 advanced warnings of their requirement to submit a Redaction Proposal at the following time points for **extensions of indications**:

1. With the validation letter
2. With the Request for Supplementary Information
3. With the CHMP opinion letter

and 2 advanced warnings at the following time points for **withdrawn applications**:

1. With the validation letter
2. With the withdrawal letter to the Applicant

Final Redacted Version (1/2)

Applicants must produce, using a redaction tool, a Final Redacted Version of the clinical reports prior to publication. Documents submitted to the Agency for publication with the final redactions must adhere to the following requirements:

- Documents must be submitted in PDF format
- The unredacted text only must be text-searchable. Redacted text and the redaction box should neither be searchable nor subject to editing
- Redactions must be clearly visible (typically using a black rectangle)
- Should any redaction codes be agreed these should be visible and irremovable together with the redacted text
- The Final Redacted Version of documents in colour should also be in colour

Final Redacted Version (2/2)

- Applicants must create a separate sequence with submission type 'Supplemental Information' as a separate document set in the eCTD format (using eCTD operator 'new') for the Final Redacted Version
- This sequence must be separate from that created for the Redaction Proposal
- Applicants must also upload a cover letter with the Final Redacted Version
- In the cover letter Applicants must also confirm that what is submitted as the Final Redacted Version is the **full set** of documents for publication

Support for Applicants

The EMA will be offering the following support to Applicants to assist with the redaction of clinical reports for publication:

- A user license for a redaction tool for use by SMEs
- A helpdesk to support SMEs with redactions and the consultation process

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Thank you for your attention

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