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European Medicines Agency

Clinical Data Publication (CDP)

Questions and Answers (Q&As) on the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy 0070) work-share initiative with Health Canada (HC)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Executive summary

The European Medicines Agency (EMA), in collaboration with Health Canada (HC), has established a voluntary work-share process to promote transparency and efficiency in the review and publication of clinical data. This initiative seeks to minimise duplication of effort and harmonise timelines for procedures common to both agencies. The following questions and answers provide guidance to applicants regarding the work-share process, eligibility criteria and applicants' responsibilities.

This document will be revised regularly as more information becomes available. New or revised questions will be marked with "New" or "Rev", together with the relevant date.

This document must be read in conjunction with Policy 0070 (Policy - Publication and access to clinical data (2019 revision) (europa.eu)) and the external guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy - Publication and access to clinical data (2019 revision) (europa.eu)), as well as the corresponding Questions and answers (Q&As) on the external guidance of Policy 0070 on clinical data publication (CDP). For information on the release of clinical information by Health Canada, please refer to Guidance document on Public Release of Clinical Information: profile page - Canada.ca.

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List of acronyms

AnR – Anonymisation report

CCI – Commercially confidential information

CDP – Clinical data publication

CHMP – Committee for Medicinal Products for Human Use

CSR – Clinical study report

eCTD – electronic Common Technical Document

EMA – European Medicines Agency

EU – European Union

FRDP – Final redacted document package

HC – Health Canada

LED – List of expected documents

MAA(s) – Marketing authorisation applicant(s)

MAH – Marketing authorisation holder

PPD – Protected personal data

RPDP – Redaction proposal document package

1. General information

1.1. What is the EMA–HC work-share process?

The work-share process is a voluntary collaborative review shared between European Medicines Agency (EMA) and Health Canada (HC) for procedures that are common to both agencies.
The objective is to reduce duplication for all parties by jointly assessing documentation.

2. Eligibility and criteria

2.1. How are regulatory procedures subject to work-share identified?

Currently only initial marketing authorisation applications submitted to both EMA and HC are currently eligible for work-share. Requests for a single review of common procedures are reviewed by the regulatory authorities upon request. At EMA, such requests may be submitted following receipt of the EMA invitation email.

2.2. What are the eligibility criteria for participation in the work-share?

A marketing authorisation application procedure may qualify for work-share if the following criteria are met:

- The marketing authorisation applicant wishes to participate in a joint review.
- The planned outcome date for both EMA and HC falls within a six-month period.
- There is approximately 70% overlap in the List of Documents (LED).
- Both agencies consent to the joint review.

Participation in the work-share is optional and does not change the standard review process if an applicant chooses not to participate.

2.3. What documentation must the applicant provide when participating in a work-share?

Applicants must submit the following:

- Expected dates for EMA/HC approval.
- Confirmation of agreement to participate.
- A List of expected documents (LED) identifying (1) common documents and (2) documents unique to EMA or HC.

2.4. How is the lead agency determined?

In the context of a work-share between EMA and HC, the lead agency is the authority responsible for conducting the primary assessment of the redaction package and coordinating the joint review process. The lead agency is assigned based primarily on regulatory timelines following discussion between both Agencies. Once agreed, the lead agency may change only in exceptional circumstances, e.g. change in timeline of the marketing authorisation evaluation process.

The Lead agency acts as the main procedural driver for the review and point of coordination with:

- The applicant

- The counterpart Agency (EMA or HC).

The applicant will be informed who has been appointed as the lead reviewer for their procedure and the relevant contact details for the review process.

2.5. Is it possible to request a pre-submission meeting?

Yes. Applicants may request a pre-submission meeting, which may include both agencies. This can be particularly useful for resolving issues related to:

- non-overlapping documents; and
- scoping or CCI questions

The decision rests with the applicant to request such a meeting if needed.

3. Package preparation and timelines

3.1. When out-of-scope (OOS) sections are agreed with the lead agency, do they also need to be checked and agreed with the other agency?

When OOS sections are agreed with the lead agency, they do not need to be rechecked with the other agency for common documents. OOS sections that appear only in documents submitted to one agency must be checked by that agency.

3.2. Does the applicant need to update out-of-scope statements in packages prepared for HC that are later submitted to EMA?

For document packages prepared as part of the work-share, the following overlay text format should be used for pages removed as out of scope:

"Pages from X to Y removed - Out of Scope in accordance with both Health Canada PRCI and EMA Policy 0070 guidance documents - <type of information removed>"

If documents have already been prepared for review by Health Canada using the HC PRCI statement, the EMA will accept the HC wording. However, where a joint package is prepared, the EMA prefers the use of the joint wording as specified above.

3.3. What are the LED requirements when EMA is in the lead?

The Agency sends a preliminary list of expected documents (LED) to the applicant/MAH with the invitation email. The applicant/MAH is expected to review the list of expected documents (LED) and clearly identify 1) the EMA-specific documents 2) shared or common documents.

The LED will be updated if documents submitted in response to Day 120 (D120 LoQ) or Day 180 (D180 LoOI) fall within the scope of Policy 0070.

3.4. When must the Redaction Proposal Package be submitted to EMA, when EMA is the lead agency?

The Redaction proposal package must be submitted to EMA within the standard procedural timelines. The same principle applies to the submission of the Final redacted package.

The clinical data publication procedures that have been selected as work-share are not in principle subject to any deviation from standard operating timelines. For more information on timelines please refer to and the external guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data).

3.5. What must be included in the Final Redacted Package submitted to EMA, when EMA is the lead agency?

The EMA final redacted document package must include:

- all LED documents (shared common documents and any EMA-specific ones);
- the common anonymisation report;
- any CCI redactions applied as agreed.

3.6. What must be included in the Final Redacted Package submitted to HC when EMA is in the lead?

The HC final package must include:

All LED documents (shared common documents and any HC- specific ones).

The common anonymisation report

Any CCI redactions agreed for the common documents and for HC-specific documents CCI submitted to HC and approved prior to final publication.

3.7. Is a redaction proposal package submitted to EMA when HC is the lead agency?

In cases where the is no CCI proposed for EMA specific documents the redaction proposal package is submitted only to the lead agency.

The redaction proposal document package submission is required by the EMA (when HC is the lead agency) **only** in cases where CCI will be proposed in EMA unique documents. In those cases the applicant should contact EMA to indicate they will propose CCI in EMA unique documents.

3.8. Do I need to re-apply redaction labels as per EMA requirements to the documents published already by Health Canada?

No, it is not necessary to re-format documents as per EMA requirements. The documents that are shared for both agencies should be submitted in the same form as published by Health Canada. The exception is for handwritten text where EMA requires all handwritten text to be redacted.

3.9. When does the publication of the clinical data package take place in case of a work-share?

EMA as a lead agency will inform the applicant about specific procedural timelines in advance of each step of the process. The publication timelines for all work-share procedures are in line with standard procedural timelines for CDP. The following specific steps apply:

- at the time of submission of the RPDP package to the lead agency, the MAA is requested to approach the other agency to provide them with specific CCI proposal (if any).

- upon completion of the assessment step, the applicant is informed of the outcome and requested to prepare the final package, implementing the AnR, PPD and CCI feedback received. The final redacted package is published by the lead agency, who notifies the other agency of the publication. The other agency subsequently publishes their clinical data package. Publication is dependent on the applicants ability to submit packages to both agencies within a similar timeframe and usually the lead agency will publish first.

For further information, please consult the EMA website or contact the designated EMA and HC points of contact as indicated in your invitation letter.

4. Assessment and publication

4.1. How is the review of commercially confidential information (CCI) managed?

The lead agency will review any proposed commercially confidential information as per its standard process and timelines. The lead agency will review the CCI proposal for shared documents and documents submitted only to the lead agency, eg (if HC is in the lead they will review CCI for all documents included in the package except those EMA specific). CCI proposals in documents specific to only one agency must be reviewed in advance of the publication by that Agency. For information on CCI in EMA specific documents please refer to question 4.2 of this document.

4.2. How are EMA-specific CCI proposals handled?

Where EMA is the lead agency, documents containing proposed CCI will be assessed together with the reminder of the package as part of the RPDP assessment stage.

Where HC is the lead agency, CCI proposed for EMA-specific documents must be submitted directly to EMA for review via eCTD. A corresponding justification table should be sent via Eudralink for an agreement before submission of the final redaction package. This partial submission should be made at the same time as making the proposals to Health Canada. The submission must consist only of the EMA-specific documents for which CCI is proposed. Once reviewed and final position agreed, the MAA

is expected to submit a complete final package (common documents and documents agency specific) via eCTD as a Final redacted document package.

4.3. Are CCI redaction proposals already reviewed by the lead agency to be resubmitted for review to the other agency?

CCI proposals for common documents reviewed by the lead agency do not need to be reassessed by the other agency. Only final redacted documents are submitted in the Final redacted package.

4.4. How is the anonymisation review managed?

The applicant is expected to submit an anonymisation report form (AnR) covering the full package, namely the documents common to both agencies and single Agency-specific to the lead reviewer. Any references to unique identifiers anonymised in single Agency specific documents should be removed from the form where not present in final package submitted to the other Agency.

The lead agency will review the anonymisation report to check whether the applicant followed the principles laid down in the anonymisation guidance and whether the anonymisation approach was applied consistently throughout the clinical reports submitted. The lead agency will adhere to its standard process and timelines. The lead agency will share its comments (which might include some points for clarification), if any, with the applicant. The applicant is expected to revise/update the anonymisation report taking into account the lead agency's comments. The same revised version of the anonymisation report must then be submitted as part of the Final Redacted Document Package along with the anonymised clinical reports to both agencies. The anonymisation report and the clinical reports will subsequently be published.

4.5. Are there any EMA specific considerations for the anonymisation report that is part of work-share?

When submitting an anonymisation report form to EMA where HC has been the lead reviewer, please make sure it includes the approved EU product name and related procedure number. Any references to identifiers anonymised in HC specific documents only, should be removed from the form.

4.6. PPD-related considerations for work-share procedures submitted to EMA:

All hand-written information must be redacted (also for packages where HC is in the lead). According to the EU data protection legislation handwritten information is considered personal data which could reveal personal details beyond the identity of the individual.

The name of Principal Investigator should be retained in all documents published by EMA.

Please note that HC is willing to accept information, as specified above, for all procedures part of the work-share initiative.

More information can be found under point 3.6 of external guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data).

4.7. Certification – what does it mean in the context of the work-share initiative?

Certification by HC of a package or part of the package previously published by EMA is a process where HC will acknowledge the documents published previously by EMA and will not conduct re-assessment of the anonymisation strategy or of applied CCI (if any). HC will re-publish the documents in the exact form as published by EMA.

4.8. Can I re-use previously published documents, if my procedure is a work-share?

Upon receipt of the invitation email from EMA, please inform your EMA contact point that there are documents within the agreed clinical data publication package that have already been published (either by EMA or Health Canada) as part of the same or another product or procedure. In principle, such documents can be re-used for publication.

4.9. Can I re-use documents previously published by another agency if it is for a post-authorisation procedure with EMA?

If the post-authorisation procedure has already been published by HC and is now subject to clinical data publication at EMA, please inform your EMA contact point when you receive an invitation email from EMA. While the post-authorisation procedures are not currently part of the work-share initiative (and the EMA invitation email will bear no references to this), it is recognised that in some cases it is possible to re-use already published documents upon further discussion with EMA.

4.10. Will it be reflected that the product was part of the work-share scheme on the clinical data publication portal?

Currently the EMA's Clinical Data Publication portal does not distinguish between procedures published as part of the work-share and those assessed outside the work-share agreement.