EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division
Human Medicines Division

Anonymisation of personal data and assessment of commercially confidential information during the preparation and redaction of risk management plans (body and annexes 4 and 6)

General guidance

This document gives general guidance to applicants/marketing authorisation holders (MAHs) on the retention/transformation of personal data (PD)) and identification of commercially confidential information (CCI) when preparing risk management plans (RMPs) in the pre-approval process, and for the redaction of the RMPs for publication post-approval.

Recommendations in this guidance are of an editorial nature and should be implemented in the RMP during the scientific review of a medicinal product, prior to the opinion of the Committee for Medicinal Products for Human Use (CHMP) and adoption of the final RMP version. Changes not implemented before approval (at the time of CHMP opinion) should be considered for redaction post-approval, with a view of publishing the RMP on the European Medicines Agency (EMA) product page.

1. Procedural guidance

EMA publishes all RMPs for all centrally authorised products; RMPs are published for the initial marketing authorisation application and all post-authorisation updates.

1.1. Drafting the RMP

Before submitting an RMP to EMA for evaluation, applicants/MAHs are strongly encouraged to consider anonymising or transforming PD and removing CCI from the draft RMP. See the EU RMP Template recommendations.

Anonymising PD and removing CCI information from the RMP allows EMA to publish the RMP post-approval without further redaction.

The latest RMP submitted for evaluation at the time of CHMP opinion is considered the final RMP and will be published on the EMA product page. After CHMP's opinion, no further updates are allowed to the

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
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RMP, as there is no formal procedure to evaluate a new submission after the opinion and before the European Commission decision. Therefore, if there is an electronic common technical document (eCTD) closing sequence planned, the final RMP should also be the version submitted with the closing sequence.

The content requirements for the drafting of the RMP are described in section 2.1.

1.2. Publishing the approved RMP post-opinion

In the CHMP outcome documents, the applicant/MAH is requested to send three files to EMA via EudraLink:

1. The (redacted) RMP file. To avoid confusing the files, this should be named 'h-[product number]-RMPfull-redacted-en.PDF'. The applicant is strongly advised to apply only black redaction boxes without overlay text (i.e. no PPD/CCI labels) in the RMP. If no redactions are necessary, the extracted RMP body + annex 4 + annex 6, in one single PDF file, will be considered the "redacted RMP". Acceptable modifications in the redacted RMP are the redaction of PD/CCI, the removal of annexes not in the scope of the publication, and the redaction of the confidentiality statements and labels. No other changes included in the scientific content, headers, footers, numbering of pages, or table of contents will be accepted.

2. An RMP file showing the redaction proposals (see-through boxes). The applicant/MAH should use a redaction tool and save and send the file **before** applying the proposed redactions. To avoid confusion, this file should be named 'h-[product number]-RMPfull-redaction-proposals-en.PDF'. If no redactions are proposed, this file may be omitted.

3. The signed declaration for the RMP publication, see the template. To avoid confusion, this file should be named 'h-[product number]-RMPdeclaration-en.PDF'.

The purpose of any post-opinion redaction is to address any remaining PD and/or CCI in the RMP document that were not addressed during the drafting and evaluation of the RMP.

Please note that for RMPs submitted in the context of a type IB variation, the three files listed above are required to be submitted as working documents with the initial eCTD sequence.

The redaction requirements for the post-approval process are described in section 2.2., below.

2. RMP content guidance

2.1. Anonymisation or deletion of PD and CCI

This content guidance applies to drafting the RMP, before its submission for evaluation.

2.1.1. Personal Data (PD)

Identifiers related to study personnel/company employees	Anonymisation rules
Name of qualified person for pharmacovigilance (QPPV)	Always retain
QPPV contact details (i.e. email address, phone/fax number)	Delete

Identifiers related to study personnel/company employees	Anonymisation rules
Names of company employees (including contact person and/or authors of RMP) and their contact details (e.g. email, phone number)[1]	Delete
Handwritten signatures, names, dates or other handwritten text[2]	Delete

[1] Such information may be present, for instance, in the metadata fields of the RMP document.

[2] Handwritten and electronic signatures should be avoided since they will require redaction before publication. The MAH is encouraged to use the statement on the RMP template informing that the signature is kept on file.

Individual study participant/patient level information **is neither required nor expected in RMPs**. If such information was included as part of case narratives and/or individual patient entries, the decision on whether to retain or remove/reword PD depends on various factors (e.g. the type of medicinal product and its approved indication[s] [orphan product/rare indication], the cumulative post-marketing exposure and characteristics of the study [e.g. number of subjects enrolled, number of sites/countries, special or vulnerable populations]) and inclusion should be considered on a case-by-case basis.

Identifiers related to individual study participants or individual entries	Anonymisation rules
Study participant/subject ID or screening randomisation number	• Delete and transform (e.g. replace by 'one/a study participant')
Serious adverse event number/code	• Delete and transform if applicable (e.g. replace by 'one case')
Date of birth	• Delete OR • Transform as generalised age (age band[1])
Place of birth/nationality	• Delete
Date of death	• Generalise to relative study day (e.g. replace by 'Day 30' or '30 days after the first dose') OR • Delete if generalisation is not possible
Reporting country for adverse event/adverse drug reaction	• Delete OR • Transform (e.g. generalise to region)
Sensitive and/or newsworthy information at individual subject level (*e.g. drug abuse, genetics, elective abortion, means of attempting to commit suicide, sensitive means of death, specifics on accidents, country-specific concomitant medication, participant's profession)*	• Delete OR • Transform (e.g. generalisation)
Sex/gender and related pronouns	• Retain OR • Delete/transform if high risk of re-identification (e.g. patient in a small group for sex/gender)
Age	• Retain (if low risk of re-identification), • Transform (e.g. generalisation [age band[1]]) OR

Identifiers related to individual study participants or individual entries	Anonymisation rules
	• Delete (if high risk of re-identification, e.g. rare disease, small population)
Health data calendar dates	• Transform (e.g. generalisation to relative study day, month/year or year) OR • Delete if high risk of re-identification, (e.g. rare disease, small population)
Study relative days	• Retain
Racial group/ heritage	• Delete OR • Retain (if low risk of re-identification and/or relevant for data utility and interpretation)
Ethnicity	• Delete OR • Retain (if low risk of re-identification and/or relevant for data utility and interpretation)

[1] As an alternative to deletion, age can be generalised by using an age-range. Age ranges may start with 10-year age increments. Wider age ranges (e.g. <30, >60 or child) can be employed when considered clinically relevant for the context/pathology/medicine safety profile. Predefined age ranges (e.g. 0-2 year or infant, 2-12 year or child) can also be used and adapted to the clinical setting for the study. Terms defining broader age groups can also be employed: child, young adult, adult, elderly.

2.1.2. Editorial/administrative notes

- 'Confidential' labels/watermarks and confidentiality statements must be deleted from headers/footers of the document.
- All document properties (e.g. author's name) and metadata should be removed from the final RMP PDF document. To achieve this, the 'sanitise document' function from the redaction tool should be used.

2.1.3. Commercially Confidential Information

The MAH should propose CCI deletions where applicable. The MAH is strongly advised to only propose the redaction of those elements that, in their view, are considered CCI. The MAH should not propose the redaction of entire paragraphs or sub-sections of a document.

EMA can also request to remove certain elements that are not necessary.

No CCI is expected to be present in the RMPs. Nevertheless, the information detailed below (non-exhaustive list) **may** constitute CCI if properly justified, unless it can be found in the public domain or is publicly available:

- Exposure data (patient exposure and sales volume) presented by country[1];

[1] Including but not limited to individual EEA countries, USA, Japan, Canada, China.

- Detailed information on ongoing clinical studies, such as the evaluation of a *new* formulation or exploration of efficacy in a *new* indication or population, insofar that such information is not already available in the public domain (e.g. company webpage or clinical trial registers such as EudraCT, CTIS, Clinicaltrials.gov). This does not apply when such studies are required in the RMP (i.e. Part III: Pharmacovigilance Plan or Part IV: Plans for post-authorisation efficacy studies);
- Information on future development plans or regulatory strategy, such as a line extension/variation;
- Detailed information on studies which are part of an ongoing paediatric development plan (PIP), insofar that such information is not already in the public domain, including EMA's PIP decision published on the EMA website;
- Specifics on the manufacture and quality control of active substance(s) and final product (e.g. batch size, quantitative information on excipients, acceptance criteria not defined in European/national Pharmacopeia[s]);
- Names/contractual agreements of/with service providers/material suppliers (not applicable to clinical research organisations [CROs] for non-clinical and clinical studies).

The following information will **not be accepted** by EMA as CCI:

- Cumulative exposure data from clinical trials (e.g. RMP part II, module SIII), including cumulative data per indication, treatment duration, patient population and/or formulation, when presented in an aggregated form;
- Cumulative post-marketing exposure data (e.g. RMP part II, module SV) worldwide and per region, e.g. patient-years, number of doses;
- The standard method to calculate exposure based on the posology of the product and/or treatment cycles.

2.2. Redaction of the RMP

This content guidance applies to the anonymisation/redaction of the approved RMP, post-opinion: body and annexes 4 and 6.

2.2.1. Personal Data (PD)

Identifiers related to study personnel/company employees	Redaction rules
QPPV's name	• Always retain
QPPV's contact details (i.e. email address, phone number)	• Redact
Names of company's employees (including contact person and/or authors of RMP) and their direct contact details (e.g. email, phone number)[1]	• Redact
Handwritten signatures, names, dates or other handwritten text	• Redact

[1] Such information may be present, for instance, in the metadata fields of the RMP document.

Identifiers related to individual study participants in narratives or individual participant entries	Redaction rules
Study participant/subject ID or screening randomisation number	• Anonymise/Redact
Serious adverse event case number/code	• Anonymise/Redact
Date of birth	• Redact DD/MM only OR • Redact (if high risk of re-identification, e.g. rare disease, small population)
Place of birth/nationality	• Redact
Date of death	• Redact DD/MM only
Reporting country for adverse event/adverse drug reaction	• Redact
Sensitive and/or newsworthy information at participant's level, when not related to the product's indication (*e.g. drug abuse, genetics, elective abortion, means of attempting to commit suicide, sensitive means of death, specifics on accidents, country-specific concomitant medication, participant's profession*)	• Redact
Sex/gender and personal/possessive pronouns	• Retain OR • Redact (if high risk of re-identification, e.g. rare disease, small population)
Age	• Retain OR • Redact (if high risk of re-identification, e.g. rare disease, small population)
Health data/study calendar dates	• Retain OR • Redact DD/MM only (if high risk of re-identification, e.g. rare disease, small population)
Study relative days	• Retain
Racial group/heritage	• Retain OR • Redact (if high risk of re-identification, e.g. rare disease, small population)
Ethnicity	• Retain OR

Identifiers related to individual study participants in narratives or individual participant entries	Redaction rules
	• Redact (if high risk of re-identification, e.g. rare disease, small population)

2.2.2. Editorial/administrative notes

- 'Confidential' or confidentiality statements from headers/footers of document must be redacted.
- All document properties (e.g. author's name) and metadata should be removed from the final RMP PDF document. To achieve this, the 'sanitize document" function from the redaction tool should be used.

2.2.3. Commercially Confidential Information (CCI)

Redact the information below (non-exhaustive list), unless it can be found in the public domain:

- Exposure data (patient exposure and sales volume) by country[2];
- Detailed information on ongoing clinical studies, such as evaluation of *new* formulation or exploration of efficacy in a *new* indication or population, insofar that such information is not already available in the public domain (e.g. company webpage or clinical trial registries such as EudraCT, CTIS, Clinicaltrials.gov). This does not apply when such studies are required in the RMP (i.e. Part III: Pharmacovigilance Plan or Part IV: Plans for post-authorisation efficacy studies);
- Information on future development plans or regulatory strategy, such as line extension/variation;
- Detailed information on studies which are part of an ongoing paediatric development plan (PIP) insofar that information is not already in the public domain, including EMA's PIP decision published on the EMA website;
- Specifics on the manufacture and quality control of active substance(s) and final product (e.g. batch size, quantitative information on excipients, acceptance criteria not defined in European/national Pharmacopeia[s]);
- Names/contractual agreements of/with service providers/material suppliers (not applicable to clinical research organisations [CROs] for non-clinical and clinical studies).

Do **not** redact:

- Cumulative exposure data from clinical trials (e.g. RMP part II, module SIII), including cumulative data per indication, treatment duration, patient population, formulation, when presented in an aggregated form;
- Cumulative post-marketing exposure data (e.g. RMP Part II, Module SV) worldwide and per region e.g. patient-years, number of doses;

[2] Including but not limited to individual EEA countries, USA, Japan, Canada, China.

- The standard method to calculate exposure based on the posology of the product and/or treatment cycles.

3. Examples: most frequent issues regarding the redacted RMP that require interaction with applicants/MAHs

These examples are based on the EMA pilot for checking the RMP for publication (n=140, from 22 October 2023 to 4 April 2024). **RMPs version for publication with similar issues will not be accepted.**

Issue	EMA recommendation
The RMP version for publication has been modified beyond the application of redactions, removal of RMP annexes not in the scope of the publication, and redaction of the confidentiality statements and labels	• Such RMP version for publication will not be accepted. The applicants/MAHs should not change post-Opinion the scientific content, table of content, page numbering, nor headers and footers. The RMP for publication should remain as close as the one approved / submitted in the closing sequence, except the acceptable redactions and annexes deletions.
Confidentiality statements present in the footer/header of the document or in the body of the RMP	• Redact
QPPV name is redacted	• Un-redact; of note, if the deputy QPPV signed off the RMP, this name should be redacted
Author's name is present in the PDF file properties (proposed PD)	• Delete; consider use of the 'sanitise document' function
Cumulative clinical trial or post-marketing exposure data (worldwide or by region) is redacted (proposed CCI)	• Un-redact
Other annexes beyond 4 and 6 are included in the redacted RMP	• Remove pages corresponding to annexes 1, 2, 3, 5, 7 and 8 • If annex 7 contains only the references for the information included in the body of the RMP, retain annex 7
Pre-clinical safety results redacted (proposed CCI)	• Keep safety results and impact on clinical development program/safety in humans • Redact only the testing methodology/specifications that are commercially confidential
Proposed redacted information is only hidden, not redacted; sensitive text can still be selected and copied using the text selection tool	• Use redaction tool, not highlight tool