EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: QRD post-opinion review of product information for initial applications and Annex II applications		
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1. Purpose

The purpose of this document is to ensure a consistent and efficient approach to reviewing the quality of translations of product information for Initial Applications[1] and Annex II Applications (including Article 29 Paediatric procedures) in the post-opinion phase of the centralised procedure.

2. Scope

This SOP applies to Initial Applications and Annex II Applications, including Generic/Hybrid/Biosimilar Applications and Article 29 Paediatric procedures, if applicable, submitted in the centralised procedure. The SOP applies to the Human Medicines Development and Evaluation Unit, the Patient Health Protection Unit and the Veterinary Medicines Sector.

3. Responsibilities

It is the responsibility of each Head of Unit, Head of Sector and Section Head to ensure that this procedure is strictly adhered to by all Product Team Leaders/ Project Managers within their own unit, sector and section. The responsibility for execution of a particular part of this procedure is identified in the right-hand column of section 9. Procedure.

4. Changes since last revision

Updated to reflect the new organisational names in the Agency, the new corporate identity and change from EDMS to DREAM.

Section 5 and 6 – Updated to reflect new document paths

[1] For SME (small and medium-size enterprises) Initial Applications, refer to SOP/EMA/0100

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Section 6 – addition of the veterinary guidance document and addition of '(Human only') after the Action list for secretaries

Revision of the following steps:

- step 1 ('Annex IV' renamed to 'Annex 127a' and added clarification on the submission of the EN version of generics/hybrid/biosimilar applications)
- step 3.1 (deleted PTL secretary)
- step 3.2 ('QRD' replaced with 'QRD secretariat')
- step 4 (added text 'in one word document with tracked changes')
- step 6 (modified and reworded)
- step 7 (deleted section 'For veterinary products')
- step 8 (modified and reworded)
- step 8.1 (deleted 'for Human products only')
- step 9 (added 'Human only')
- step 10 (modified to reflect changes from LCF to QRD Form 2 and changed WIN number to WIN/EMA/0098)

5. Documents needed for this SOP

- QRD Form 1 (http://www.ema.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500004330.doc)
- QRD Form 2 (http://www.ema.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500004331.doc)

6. Related documents

- Linguistic Review Process of Product Information in the Centralised Procedure - Human (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf)
- Linguistic Review Process of Product Information in the Centralised Procedure - Veterinary (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005250.pdf)
- QRD Convention (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf)
- QRD Human Product Information Templates (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59)
- QRD Veterinary Product Information Templates (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000185.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002d9b0)

- QRD Human Product Information Template with explanatory notes (http://www.ema.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500004368.pdf)
- QRD Veterinary Product Information Template with explanatory notes (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005257.pdf)
- Annex A Human Template in all languages (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59&jsenabled=true)
- Annex A Veterinary Template in all languages (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000185.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002d9b0)
- QRD Reference Documents (on terminology and style) (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59&jsenabled=true)
- Relevant Human Guidelines (e.g. SPC Guideline) and Notes for Guidance (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000254.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058008c34c&jsenabled=true)
- Relevant Veterinary Guidelines (e.g. SPC Guidelines) and Notes for Guidance (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000253.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058008af8a)
- List of Member States Contact Points for Translations (with guidance on the sending of product information to Member States) (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004437.pdf)
- Action List for Secretaries (saved under Word/File New/H-Opinion Corr) (Human only)
- WIN/EMA/0098 “QRD forms 2 (former Linguistic check forms)”

7. Definitions

DREAM: Document Records Electronic Archive Management

EN: English version

LoQ: List of Questions

MAH: Marketing Autorisation Holder

MS: Member State

NCA: National Competent Authorities

PI: Product information (SPC, Labelling and Package Leaflet)

PIQ: Product Information Quality

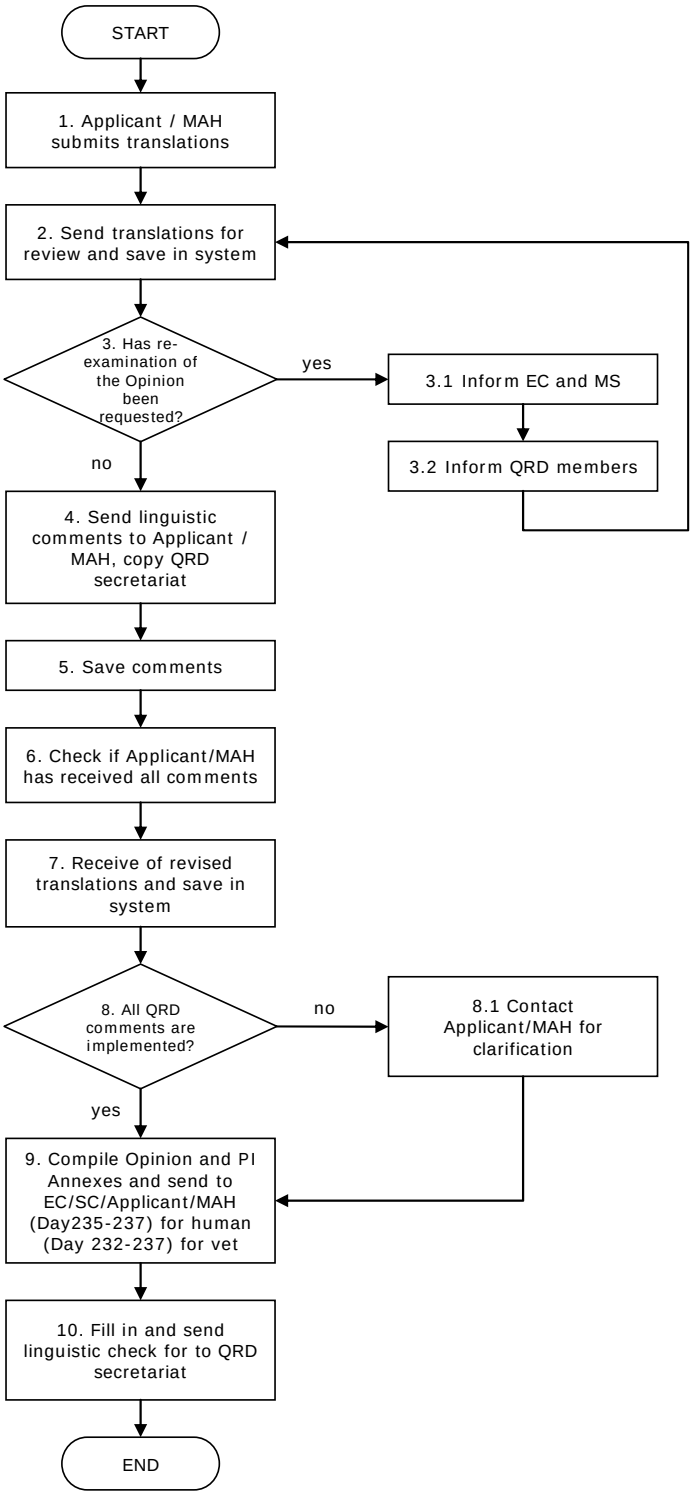
PTL: Project Team Leader (Human product only)

QRD: Quality Review of Documents

QRD Form 2 - submitted by the MAH with the final translations at Day 235/+25, checked and completed by secretaries and forwarded to the QRD Secretariat at Day 237/+27.

Vet PM: Project Manager (Veterinary products only)

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	By Day 215 Applicant/MAH submits translations of the adopted PI (including Annex 127a, where applicable) and Annex A in all EU languages (including EN, NO+IS) and QRD form 1 to the QRD secretariat (mailto:qrd@ema.europa.eu). All translations should be submitted in one Eudralink package. Translations of PI should be submitted in one Word document per language. Annex A is to be provided as a separate Word document per language. For generics/hybrid/biosimilar applications the EN product information should indicate those sections which differ from the reference product in track-changes.	Applicant / MAH
2	By Day 215 Send translations of adopted PI together with QRD form 1 to QRD members for review. Save translations and QRD form 1 in DREAM under <product name>/Translations/Day 215 Co Translations	QRD secretariat
3	Has re-examination of the Opinion been requested? If yes go to 3.1 If no go to 4.	Applicant / MAH
3.1	Inform EC and QRD secretariat that re-examination of the Opinion has been requested.	PTL /Vet PM
3.2	Inform QRD members that Linguistic checking procedure is suspended until adoption of the final Opinion (after re-examination). Upon adoption of the final Opinion go to step 2.	QRD secretariat
4	By Day 229[2] Send linguistic comments on the translation of PI (in one Word document with track changes) together with completed QRD form 1 electronically to the Applicant/MAH with a copy to the QRD secretariat.	QRD members
5	Save comments and forms from QRD members under <product name>/Translations/Day229-MS comments	QRD secretariat
6	Check with the Applicant/MAH whether all comments were received. Forward any missing comments to the Applicant/MAH, when available. Send reminder to those MSs who have not provided comments within the deadline	QRD secretariat
7	By Day 235[3] QRD secretariat (mailto:qrd@ema.europa.eu) receives from Applicant/MAH revised translations with track changes highlighted, incorporating the Member States' comments in Word format, as well as in PDF format (clean), and QRD form 2. Save revised translations and QRD form 2 under <product name>/Translations/Day 232 Co FINAL translations, inform PTL/VET PM and Secretary	QRD Secretariat

[2] Unacceptable translations should be returned to the Applicant/MAH within 3 days with a copy to QRD secretariat.

Step	Action	Responsibility
8	By Day 237 Check QRD form 2 for implementation of QRD comments. Have all comments been implemented? If yes go to step 9 If no go to step 8.1	Secretary
8.1	Contact the Applicant/MAH to clarify why certain comments have not been implemented and, where appropriate, request a revised QRD form 2, together with revised PI Annexes in Word (highlighted) and PDF format (clean), if necessary.	Secretary
9	By Day 237 Compile the EN Opinion and PI Annexes in all languages and send final copies to the Commission, Members of the Standing Committee and the Applicant/MAH. Save final translations under <product name>/Translations/Day 237-Commission For further details see "Action list for secretaries" (Human only)	Secretary
10	Fill in section 2 of the QRD form 2 and send it to the QRD secretariat For further details see WIN/EMA/0098 "QRD forms 2 (former Linguistic check forms)"	Secretary

10. Records

Translations and all relevant forms will be saved in the relevant folders as specified in the steps above.

[3] Any disagreements are to be discussed directly between the Applicant and the NCAs.