EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: QRD post-opinion review of product information for post-authorisation procedures affecting the annexes, excluding Annex II applications		
Status: **PUBLIC**		Document no.: SOP/EMA/0048
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Signature: On file	Signature: On file	Supersedes: SOP/EMEA/0048 (08-APR-09)
Date: 10-DEC-10	Date: 13-DEC-10	TrackWise record no.: 2635

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 Renewal Applications, Annual Reassessments, Type II Variations (60/90 Days), urgent 30-day Type II Variations, Type IB Variations (30 Days), Grouping Applications and Worksharing applications in the centralised procedure and Referral Procedures, including Article 29 Paediatric procedures, if applicable, in the post-opinion phase.

2. Scope

This SOP applies to the Product Information submitted for Renewal Applications, Annual Reassessments, Type II Variations (60/90 Days), urgent 30-day Type II Variations[1], Type IB Variations (30 Days)[1], Grouping Applications and Worksharing Applications in the centralised procedure and Referral Procedures, including Article 29 Paediatric procedures, if applicable, in the post-opinion phase. The same procedure applies to Article 29 Paediatric procedures in case of an extension of indication. The SOP applies to the Human Medicines Development and Evaluation Unit, Patient Health Protection Unit and 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.

[1] The linguistic review takes place in parallel to the scientific assessment.

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4. Changes since last revision

- Updated to reflect the new organisation names in the Agency and change from EDMS to DREAM; paths to documents in DREAM updated.
- Change/shortening of the title of the SOP to: '*QRD Post-opinion review of product information for post-authorisation procedures affecting the annexes, excluding Annex II applications*'
- Section 2: deleted 'Word'
- Update to replace "PTL Secretary" with "Secretary"
- Update to replaced "Linguistic Check Form' with "section 2 of the QRD form 2"
- Step 1: "if yes" was deleted.
- Step 2 and Step 8: Update to reflect the new requirements from Regulation (EC) N. 1234/2008 concerning the examination of variations for human and veterinary medicinal products.
- Step 3, 6, 7 and 13: Update to reflect that the task is performed by the Secretary and not the Vet PM.
- Step 2 and 5 : Delete "VMAP-translations@ema.europa.eu" and replace by "vet.translations@ema.europa.eu"
- Section 5 and 6 – all links to reference documents have been updated.
- Step 8: Deletion of the Veterinary requirement: Veterinary products will now follow the same timelines as human products (i.e. MAH to submit PI by day 25), the need to separate the handling of veterinary and human products is no longer applicable.
- Step 9: Deletion of "Day +22): Veterinary products will now follow the same timelines as human products (i.e. Secretary to check whether all MS comments have been implemented by day +25 to +27).
- Step 11: Added in bracket (human only)

5. Documents needed for this SOP

- 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 (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.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

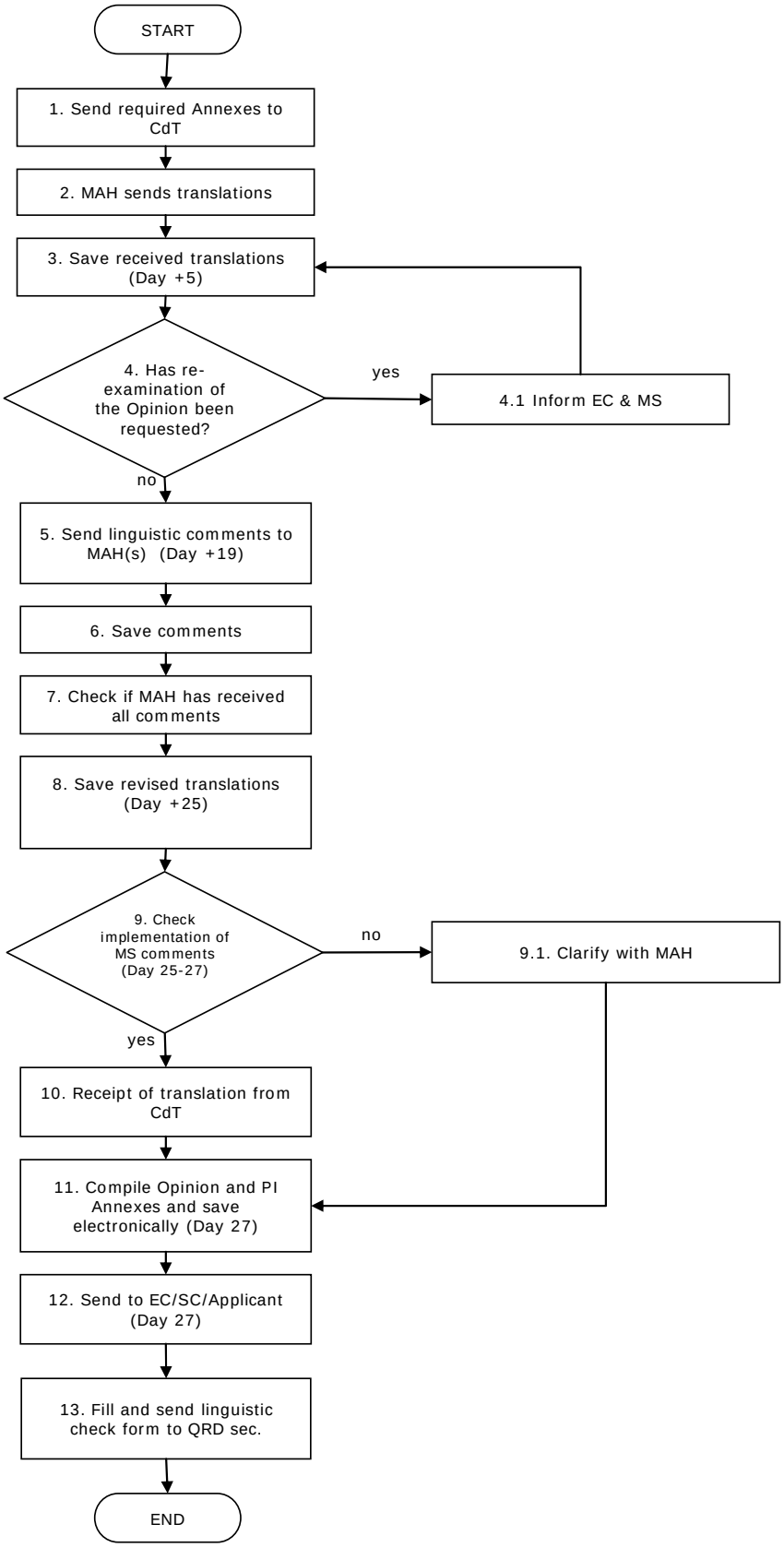
- QRD Veterinary Product Information Templates
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000185.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002d9b0
- QRD Human Product Information Template with explanatory notes
  http://www.ema.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500004368.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 Human Referral 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&jsenabled=true
- QRD Human Referral Template with explanatory notes
  http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Templates/QRD/CMDh_Annotated_QRD_template_2009_06_Rev5-Track.pdf
- Annex I Human referral 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
- 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
- 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

CdT:	Translation Centre, Luxembourg
EN:	English version
CAP:	Centrally authorised product
Coordinating Secretary:	For Worksharing procedures
DREAM:	Document Records Electronic Archive Management
LoQ:	List of Questions
MAH:	Marketing Authorisation Holder[2]
MS:	Member State
NCA:	National Competent Authority
PIQ:	Product Information Quality
PI:	Product information (SPC, Labelling and Package Leaflet/Insert)
PTL:	Project Team Leader (Human product only)
QRD:	Quality Review of Documents
Vet PM:	Project Manager (Veterinary products only)
V-PD-BUS:	Product and application business support

[2] For Referrals PI may also be submitted by Applicants.

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



9. Procedure

Step	Action	Responsibility
1	For Referrals, immediately after adoption of a positive CxMP opinion send to CdT for translation Annex II (Scientific conclusions) and Annex IV, if applicable, go to step 2. For Referrals, immediately after adoption of a negative CxMP opinion and if no re-examination has been requested, send to CdT for translation Annex I, II (Scientific conclusions) and Annex III, if applicable, end of procedure. For Referrals, in case of adoption of a negative CxMP and if a re-examination has been requested, go to step 4.1.	Secretary/ Vet PM
2	By Day +5[3] For Renewals, Annual Reassessments, Type II Variations, Type IB Variations[4], urgent 30-day Type II Variations and Grouping Applications including a Type II Variation, MAH submits PI translations and Annex A, where applicable, (plus Annex IV for Renewals, if applicable) in all EU languages (including EN, NO+IS) to the MS contact points for translations with a copy to the Procedure secretary or to vet.translations@ema.europa.eu for veterinary products. For Grouping Applications including an Extension (Annex II application), refer to SOP/EMA/0047. For Worksharing Applications[5] MAH submits **one set** of PI translations for **one CAP** and Annex A, where applicable, in all EU languages (including EN, NO+IS) to the MS contact points for translations with a copy to the Secretary or vet.translations@ema.europa.eu for veterinary products. For Referrals MAH submits translations of the adopted PI (Annex III together with the EN version) and Annex I in all EU languages to the MS contact points for translations with a copy to the CP Secretariat or to vet.translations@ema.europa.eu for veterinary products. In case of Article 31 referrals involving several MAHs refer to SOP/H/3144. All translations are to be submitted in one Eudralink package. PI Translations should be submitted in one Word document per language. Annex A and Annex I are to be provided as separate Word documents per language. For Referrals upon receipt of the Eudralink package conduct random checks regarding compliance with QRD template layout and whether major parts are missing in the translations. If not compliant inform MAH accordingly and request resubmission of revised texts.	MAH Secretary
3	Save received translations in DREAM under relevant product/	Secretary

[3] Day +5 after validation for Type IB variations and urgent 30-day Type II variations.
[4] For grouping applications including **only** Type IB variations, the linguistic review takes place in parallel to the scientific assessment.
[5] Extensions (Annex II applications) are excluded from worksharing.
For worksharing applications including **only** Type IB variations, the linguistic review takes place in parallel to the scientific assessment.

Step	Action	Responsibility
	procedure folder.	
4	Has re-examination of the Opinion been requested? If yes go to 4.1 If no go to 5	PTL / Vet PM
4.1	Inform EC and MS contact points for translations that re-examination of the Opinion has been requested. Linguistic checking procedure is suspended until adoption of the final Opinion (after re-examination). Upon adoption of the final Opinion go to Step 3.	Secretary / Vet PM
5	By Day +19[6] Send linguistic comments on the translation[7] of PI electronically to the MAH(s) with a copy to the Secretary or to vet.translations@ema.europa.eu for veterinary products.	MS reviewers
6	Save comments from MS reviewers in DREAM under relevant product/ procedure folder.	Secretary
7	Check with the MAH whether all comments were received. Forward any missing comments to the MAH when available.	Secretary
8	By Day +25[8][9] Secretary receives 2 ZIP files from MAH. One with revised translations[10] with track changes highlighted (the text for Article 31 referrals will not be highlighted), incorporating MS reviewers' comments, and one with clean versions in PDF format[11] with all changes accepted together with QRD form 2. For Worksharing applications, the Secretary receives (in zip files) from MAH revised translations of **all products** involved in the worksharing application together with **only one** QRD form 2. Revised translations should be received with track changes highlighted, incorporating MS reviewer's comments and clean versions in PDF format with all changes accepted. Save revised translations and QRD form 2 in DREAM under relevant product/ procedure folder.	Secretary / Vet PM/ Secretary
9	By Day +25 to +27 Check whether all MS comments have been implemented. If yes go to step 11 If no go to step 9.1	Secretary / Vet PM
9.1	Contact the MAH to clarify why comments have not been implemented and where appropriate request a revised QRD Form 2.	Secretary / Vet PM
10	For Referrals, receipt of translation of Annex II & Annex IV from CdT, if applicable.	Secretary / Vet PM

[6] Day +19 after validation for Type IB variations and urgent 30-day Type II variations
[7] Translations of unacceptable quality should be returned to the MAH within 3 days with a copy to Procedure secretary or to vet.translations@ema.europa.eu for veterinary products.
[8] Day +25 after validation for Type IB variations and urgent 30-day Type II variations.
[9] Day +22 for Referral procedures.
[10] Any disagreements are to be discussed directly between the MAH and the NCAs.
[11] Submission of clean translations in PDF is NOT applicable for Referral procedures.

Step	Action	Responsibility
11	By Day +27 Compile the EN Opinion and PI Annexes in all languages and provide V-PD-BUS with final texts (except for Article 29(4), 30 and 31 referrals). Save final translations in DREAM under relevant product/ procedure folder. For further details see “Action list for secretaries”(human only)	Secretary / Vet PM
12	Send final texts to the Commission, Members of the Standing Committee and the MAH.	V-PD-BUS
13	Fill in section 2 of the QRD form 2 and send it to the QRD secretariat. For further details see WIN/EMA/0098 “QRD form 2 (former Linguistic check forms)”	Secretary

10. Records

Translations and all relevant Forms will be saved in the relevant product/procedure folder.