



Work instructions

Title: QRD co-ordination of post-opinion linguistic reviews of Initial Applications and Annex II applications		
Applies to: QRD Secretariat and product secretaries in the H, P and V Units		
Status: PUBLIC		Document no.: WIN/EMA/0106
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Signature: ON FILE	Signature: ON FILE	Supersedes: N/A
Date: 16-FEB-10	Date: 16-FEB-10	TrackWise record no.: 2478

1. Changes since last revision

New WIN.

2. Records

See step 7 and 8 of the Instructions.

All email templates are saved in: EDMS\Meetings\Scientific Meetings\Q R D - P I Q\02 E-mail templates - forms - table

3. Instructions

CxMP:	Committee for Medicinal Products for Human Use or Committee for Medicinal Products for Veterinary Use
EDMS:	Electronic Document Management System
MAH:	Marketing Authorisation Holder
MS:	Member State
NA:	New Application
PI:	Product Information
PM:	Project Manager (Veterinary products only)



PTL: Product Team Leader (Human products only)

QRD: Quality Review of Documents

QRD Form1: submitted by Applicant/MAH at day 215

QRD Form2: submitted by Applicant/MAH at day 232/235

SME: Small and medium-sized enterprise

Step	Action	Responsibility
1	<u>Day 215</u> Identify New Applications and Annex II Applications with a positive CxMP Opinion which will follow a post-opinion linguistic review (see <i>CxMP overview</i> ¹)	QRD secretary
2	Is the product an SME? If yes, consult SOP/EMEA/0100, step 24-32 If no, go to step 3.	QRD secretary
3	Have the translations of the adopted PI been received from the Applicant/MAH? If yes, go to step 4. If no, go to step 3.1	QRD secretary
3.1	Contact PTL/PTL secretary (VET PM/PM secretary) to check if translations have been received.	QRD secretary
3.2	If translations received, forward email from Applicant/MAH to the QRD Secretariat (P-MI-PIQ). If translations not received, contact Applicant/MAH to request translations	PTL/PTL secretary/ VET PM/secretary
4	Check if correct files submitted <u>For NA (excl. Generic NA)</u> 1. All PI Annex ² translations in Word clean format (24 languages) 2. All Annex IV translations in Word clean format – where applicable (24 languages) 3. All Annex A translations in Word clean format (24 languages) <u>For Annex II Applications and Generic NA</u> 1. All PI Annex translations in Word track changed format (24 languages) 2. All Annex IV translations in Word track changed format – where appl. (24 languages)	QRD secretary

¹ EDMS path: *Meetings\Scientific Meetings\Q R D - P I Q\10 QRD Post LinguisticTracking\01. Tracking of linguistic comments\200x\H(V)-products\<month>*. See also WIN/EMA/0105 on Preparation of CxMP overviews of procedures requiring Member States linguistic review.

² PI Annex include: Annex I Summary of Product Characteristics, Annex II, Annex III Labelling and Package Leaflet

	3. All Annex A translations in Word clean format (24 languages)	
5	Check if the QRD Form1 is submitted and completed in full in Section 1 and that it includes all details of contact person(s) for translations (name, email address and telephone number)	QRD secretary
6	Have all the correct files been received? If yes, go to step 7 If no, go to step 6.1	QRD secretary
6.1	Inform MAH of the missing/incorrect files and request additional/correct files to be submitted (email template <i>QRD Day 215 to applicant - missing files</i>)	QRD secretary
7	Create new QRD post-opinion translation folder Go to <i>EDMS\Meetings\Scientific Meetings\Q R D – P I Q\07 QRD P Info Rev POST-OPIN</i> Create new product folder : <i><number in sequence> <product name> <comments due date: dd-mm-yyyy></i> For NA and Generic NA, go to step 8 For Annex II Application, go to step 9	QRD secretary
8	Link to product folder (NA and Generic NA only) Go to <i>EDMS\Products\<Product name>\10 Translations</i> Cross-reference (copy link) translation sub-folders to the newly created QRD post-opinion translation folder: <i>Day 215 – Co Translations</i> <i>Day 229 – MS Comments</i> <i>Day 232(235) ³– Co FINAL Translations</i>	QRD secretary
9	Create translation sub-folders (Annex II Applications only) <i>Day 215 – Co Translations</i> <i>Day 229 – MS Comments</i> <i>Day 232(235) – Co FINAL Translations</i>	QRD secretary
10	Save day 215 translations to the <i>Day 215 - Co Translations</i> folder (all PI translations, all Annex IV translations – where applicable, all Annex A translations + QRD Form 1 and email received from Applicant/MAH)(see Naming of files ⁴)	QRD secretary
11	Link Annex A translations to <i>Day 232(235) – Co FINAL Translations</i> folder	QRD secretary

³ Day 235 relates to human medicinal products (except for referral procedures) and day 232 relates to veterinary medicinal products and human referral procedures

⁴ All PI Annexes translations should be **saved** as one ZIP file per set of files (i.e. 1 ZIP file with all PI Word clean format, 1 ZIP file with all Annex A etc.) and **renamed** as *<Abbreviated name-first 5 letters> <Day XXX> <Annex X>*, e.g. **'Insum Day 215 Annex A'**. MSs comments should be named as *<country code> <Abbreviated name-first 5 letters> Day 229*, e.g. **'DE Insum Day 229'**

12	Sending of translations to Member States Prepare a new Eudralink package (email template <i>QRD Post-Opinion Day 215 send to QRD</i>) and attach one ZIP file of PI translations (24 languages) + one ZIP file of Annex IV translations – where applicable (24 languages) + QRD Form 1	QRD secretary
13	Send Eudralink package to QRD Eudranet inboxes: H-QRD (human), V-QRD (veterinary) & Chrono H-QRD	QRD secretary
14	Inform Applicant/MAH that the translations have been sent to the Member States (email template <i>Day 215 email to MAH</i>) with a copy to PTL/PTL secretary (VET PM/PM secretary) & BCC to Chrono H-QRD	QRD secretary
15	Fill in the <i>QRD Comments Monitoring Form</i> template and file paper copy in the Workload folder	QRD secretary
16	<u>Day 215-229</u> Monitoring of incoming MS comments Upon receipt of MSs comments, check the files received. Is the translation rejected by MS? If yes, go to step 16.1 If no, go to step 17	QRD secretary
16.1	Create sub-folder <i>Unacceptable Translations</i> under <i>Day 215 – Co Translations</i> and cross-reference (copy link) to folder <i>Day 229 – MS Comments</i> . Save MS email and attachments in the folder <i>Unacceptable Translations</i>	QRD secretary
16.2	Check if Applicant/MAH submitted revised day 215 translation to the MS and the Agency. Contact Applicant/MAH if revised translation not received within 5 calendar days.	QRD secretary
16.3	Save revised day 215 translations in the folder <i>Unacceptable Translations</i>	QRD secretary
17	Check if MS sent revised PI translation (Word document with track changes) or confirmation that the MS has 'No Comments' on the translation. Check if QRD Form 1 is attached and Section 2 completed in full. Request revised QRD Form 1, if necessary.	QRD secretary
18	Save revised translation, QRD Form 1 and MS email to folder <i>Day 229 - MS Comments folder</i> (see Naming of files) and tick relevant box of the <i>QRD Comments Monitoring Form</i>	QRD secretary
19	<u>Day 229/230</u> Check with Applicant/MAH whether all comments were received.	QRD secretary

Forward/request any missing comments to/from Applicant/MAH, where applicable.

20	Send reminder to those MSs who have not provided comments within the deadline (email template <i>REMINDER – Day 229 comments missing</i>)	QRD secretary
21	Update Applicant/MAH on the status of missing MSs comments, indicate delays reported by MSs	QRD secretary
22	Have all MSs comments been received? If yes, go to step 23 If no, repeat step 20	QRD secretary
23	<u>Day 232 (235)</u> Receive final PI translations from Applicant/MAH	QRD secretary
24	Check if correct files submitted <u>For Human medicinal products excluding referrals</u> <ol style="list-style-type: none">1. All PI Annex translations in Word track changed format (24 languages)2. All PI Annex translations in PDF clean format (24 languages)3. All Annex IV translations in Word track changed format – where applicable (24 languages)4. All Annex IV translations in PDF clean format – where applicable (24 languages)5. Annex A in Word clean format - only if revised after day 2156. QRD Form 2 (with supporting documents, where applicable)7. Formatting Check List <u>For Veterinary medicinal products including human referrals</u> <ol style="list-style-type: none">1. All PI Annex translations in Word track changed format (24 languages)2. All PI Annex translations in Word clean format (24 languages)3. All Annex IV translations in Word track changed format – where applicable (24 languages)4. All Annex IV translations in Word clean format – where applicable (24 languages)5. Annex A in Word clean format - only if revised after day 2156. QRD Form 2 (with supporting documents, where applicable)	QRD secretary
25	Check that the QRD Form 2 is filled in correctly and the MSs boxes contain the correct symbols. The following symbols are allowed:	QRD secretary

✓ - comments received and implemented;

X - comments received, not all implemented;

NC- confirmation received that there are no comments

26	Have all the correct files been received? If yes, go to step 27 If no, go to step 26.1	QRD secretary
26.1	Contact Applicant/MAH and request additional/missing files	QRD secretary
27	Save received files to folder <i>Day 232(235) – Co FINAL Translations</i> (See Naming of files)	QRD secretary
28	Have all outstanding issues with Applicant/MAH been resolved? If yes, go to step 29 If no, repeat step 26.1	QRD secretary
29	Inform PTL/PTL secretary (VET PM/PM secretary) that the translations have been received and saved in the product folder (email template <i>Day 232(235) – email to PTL</i>)	QRD secretary
30	Fill in <i>QRD Comments Monitoring Form</i>	QRD secretary
31	<u>Day 237</u> Finalise procedure in accordance with SOP/EMEA/0047 (step 8-10), Action List for Secretaries & WIN/EMEA/0098	PTL secretary/ VET PM secretary

END OF PROCEDURE
