EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: PIQ/QRD pre-opinion review of product information for renewal procedures		
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1. Purpose

The purpose of this document is to ensure a consistent and efficient approach to review the quality of English product information for Renewal Applications in the pre-opinion phase of the centralised procedure.

2. Scope

This SOP applies to Renewal Applications, including Generic/Hybrid/Biosimilar/Informed Consent Applications, in the centralised procedure. The SOP applies to the Human Medicines Development and Evaluation Unit and to the Veterinary Medicines Sector.

3. Responsibilities

It is the responsibility of each Head of Unit, Sector and Section to ensure that this procedure is strictly adhered to by all Product Team Leaders/Project managers within their own unit/sector/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 organisation names in the Agency and the new corporate identity; new links to documents; a few minor amendments in section 7 Definitions; inclusion of the final QRD check before Opinion in the flow chart and in section 9 Procedure (i.e. steps 8 and 8.1); addition of Vet PM and '*and other interested parties*' in step 5 of the Procedure section; minor clarification in step 7 of the Procedure section (deletion of '*incorporating PIQ/QRD comments*'); and change of EDMS to DREAM throughout.

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5. Documents needed for this SOP

No documents are needed for this SOP.

6. Related documents

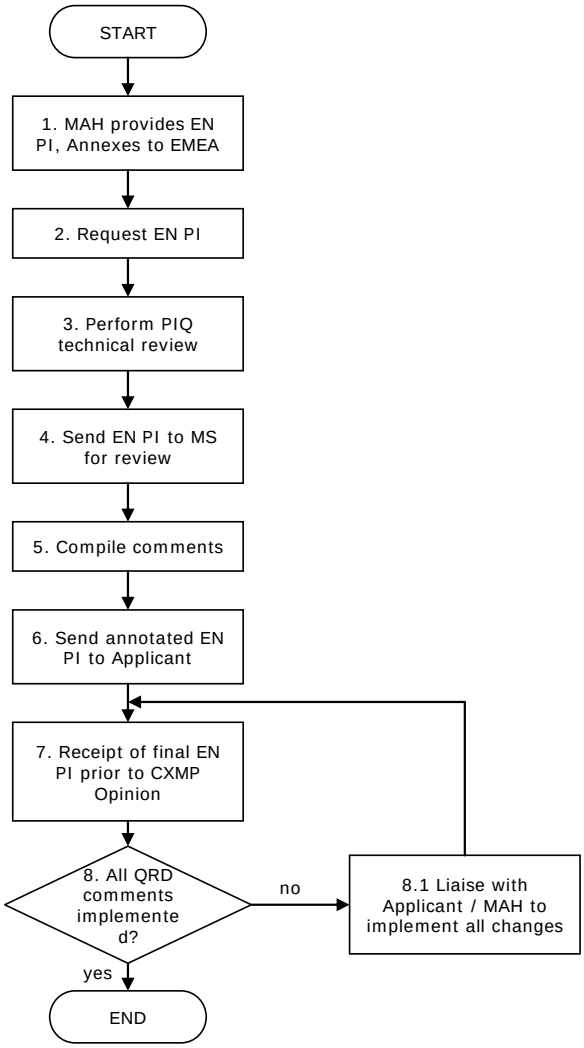
- Linguistic Review Process of Product Information in the Centralised Procedure (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf)
- QRD Convention (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf)
- 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)
- QRD Reference Documents (on terminology and style) (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000267.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800b378b)
- 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)

7. Definitions

ARs:	Assessment Reports
EN:	English version
Full set of Annexes:	Annex I, II, IIIA, IIIB and Annex 127a (when applicable)
LoQ:	List of Questions
MAH:	Marketing Authorisation Holder
MS:	Member State
PI:	Product information (SPC, Annex II, Labelling and Package Leaflet)

PIQ:	Product Information Quality
PTL:	Product Team Leader (Human products only)
QRD:	Quality Review of Documents
Vet PM:	Project Manager (Veterinary products only)
DREAM:	Document Records Electronic Archive Management

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



9. Procedure

Step	Action	Responsibility
1	At submission MAH provides a full set of EN PI Annexes electronically to the EMA. PTL/Vet PM to ensure that Annexes are in Word format, as one document. The pre-opinion linguistic review takes place between Day 1 and 75. Annexes should be submitted highlighted, reflecting changes introduced by the renewal application.	MAH/PTL/Vet PM
2	Request EN PI from PTL / secretary / Vet PM for PIQ/QRD review. Save in DREAM under PIQ/QRD pre-opinion review folder.	QRD secretariat
3	Perform PIQ-technical review on EN PI using appropriate guidance documents.	QRD secretariat
4	Send EN PI to QRD members and other interested parties for review. Reviewers should have at least 10 calendar days to comment. (Does not apply to Generic Applications. Generics are only reviewed by QRD secretariat)	QRD secretariat
5	Compile comments from QRD members and PIQ comments in one single Word document. Send to PTL-PTL secretary / Vet PM and other interested parties.	QRD secretariat
6	Ensure that comments in ARs/draft opinions (Vet only) are compatible with the PIQ comments. PTL / Vet PM to liaise with QRD secretariat/Rapporteurs in case of contradictions. Send annotated EN PI to MAH by Day 75. Save in DREAM under relevant product/procedure folder	PTL / Vet PM
7	PTL / Vet PM receives final EN PI from MAH before CxMP opinion and forwards document to QRD Secretariat.	PTL / Vet PM
8	QRD Secretariat receives final EN PI to perform a final check of the implementation of QRD comments prior to adoption of CxMP Opinion. If yes: end of procedure If no: send comments to PTL / Vet PM and continue with Step 8.1	QRD Secretariat
8.1	PTL / Vet PM to liaise with Applicant/MAH to implement proposed changes and ensure that comments in ARs are compatible with the QRD comments; liaise with QRD secretariat/Rapporteurs in case of contradictions. Back to Step 7.	PTL / Vet PM

10. Records

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