EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: PIQ/QRD pre-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 review the quality of English product information for Initial Applications and Annex II Applications in the pre-opinion phase of the centralised procedure.

2. Scope

This SOP applies to Initial Applications and Annex II Applications, including Generic/Hybrid/Biosimilar/Informed Consents Applications, submitted 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; addition of new step 2 to clarify that QRD secretariat should request the EN PI from PTLs; renumbering of all subsequent steps; reference to hybrid, biosimilar and Informed Consent applications in the scope and in step 3 of the Procedure section; under step 4, addition of day 60 for informed consent applications

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and day 70-110 for vet products as well as clarification that QRD secretariat is to perform the PIQ tec check and then discuss comments with PTL/Vet PM; new links to documents; minor clarifications in steps 6 (addition of '*By day 120*', ''*LoQs*', 'QRD secretariat', '*as an annex*' instead of '*as a separate set of comments*'), 7 (addition of '*and inform QRD secretariat*'), 9 (addition of '*Informed Consent applications*'), 11 (addition of '*and other interested parties*')15 (addition of '*The meeting will be chaired by the PTL*'), 18 (addition of '*and informs PTL/Vet PM*') and 19.1 (addition of '*and ensure that comments in AR are compatible with the QRD/medical writers' comments; liaise with Rapporteurs in case of contradictions*') of the Procedure section; inclusion of Vet PM in steps 5, 17 and 19.1 of the Procedure section; and change of EDMS to DREAM throughout; inclusion of new step 19 to reflect the involvement of medical writers in the review of the final EN PI.

5. Documents needed for this SOP

- PIQ Form
  http://www.ema.europa.eu/docs/en_GB/document_library/Templates_and_Form/2009/10/WC500004328.doc

6. Related documents

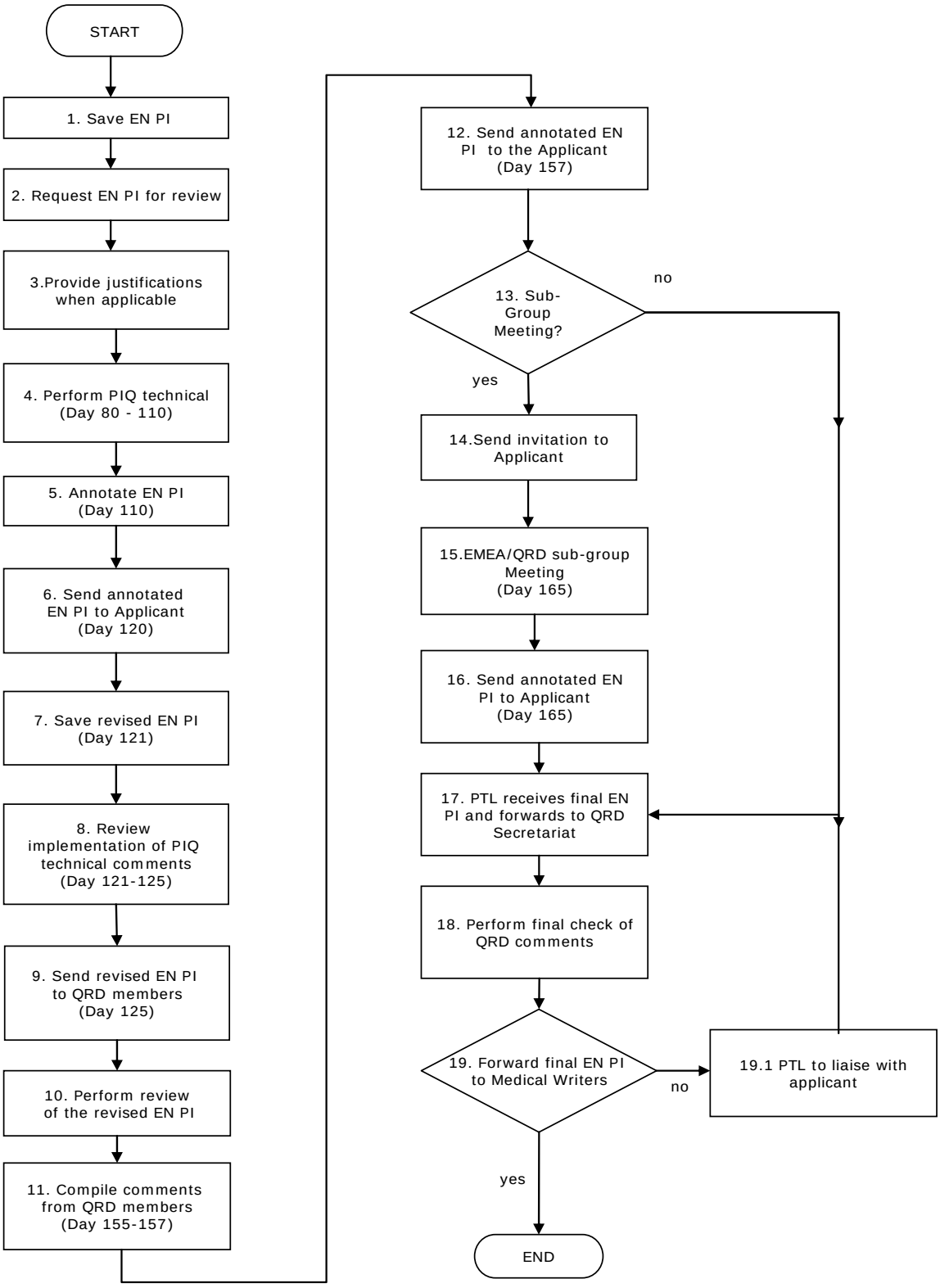
- Linguistic Review Process of Product Information in the Centralised Procedure
  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf
- QRD Convention
  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf
- 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
- 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 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:	Project Team Leader (Human product only)
QRD:	Quality Review of Documents
Vet PM:	Project Manager (Veterinary products only)
DREAM:	Document Records Electronic Archive Management

* For initial applications, ANNEX II is completed in English by the EMA at the time of the opinion.

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



9. Procedure

Step	Action	Responsibility
1	At submission Applicant/MAH provides a full set of EN PI Annexes electronically to the EMA. The Annexes must be in Word format, one document and saved in DREAM under <product name>/Translation/Day 1-CO submission Prod Info.	Secretary / 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	When Applicant/MAH provides justifications for combined package leaflet, Braille or User testing, forward these justifications to the QRD secretariat for information/discussion at QRD plenary meeting. In case of Generic/Hybrid/Biosimilar/Informed Consent Applications, inform the QRD secretariat and provide the name of the reference product.	PTL
4	Day 80-110 (Day 60 for Informed Consent applications) (Day 70-110 for veterinary applications) QRD secretariat to perform PIQ-technical review on EN PI, using appropriate guidance documents, the Assessment Reports, or relevant core SPCs, if available, and discuss comments with PTL / Vet PM.	QRD secretariat + PTL / Vet PM
5	Day 110 Annotate the EN PI with PIQ technical comments and save in DREAM under <product name>/Translations/Day 110-PIQ Tech, inform PTL-PTL secretary / Vet PM.	QRD secretariat
6	By Day 120 Ensure that comments in ARs/LoQs are compatible with the PIQ comments, liaise with QRD secretariat/Rapporteur in case of contradictions. Send annotated EN PI to Applicant/MAH (as an annex to the Day 120 list of questions) at the same time as the adopted list of questions.	PTL / Vet PM
7	Day 121 - restart of the clock, Applicant/MAH submits revised EN PI in Word format together with PIQ form. Save revised EN PI and PIQ form in DREAM under <product name>/translations/Day 121 Co Post LoQ Prod Info and inform QRD Secretariat If User testing was provided at Day 121 forward it to the QRD secretariat.	Secretary
8	Day 121-125 Review implementation of PIQ technical comments, liaise with Applicant/MAH if certain comments have not been implemented.	QRD secretariat
9	Day 125 Send revised EN PI to QRD members and other interested parties for review. (Does not apply to Generic and Informed Consent applications.	QRD secretariat

Step	Action	Responsibility
	Generics and Informed Consent applications are only reviewed by QRD secretariat).	
10	Perform review of the EN PI by Day 155.	QRD Members
11	Day 155 – 157 Review comments from QRD MSs and other interested parties using appropriate guidance documents, the ARs, or relevant core SPCs, if available, and compile relevant comments in one single Word document in the form of track-changes. Send to PTL-PTL secretary / Vet PM and other interested parties. Save EN PI in DREAM under <product name>/Translations/Day 155-QRD.	QRD secretariat
12	Day 157 Send annotated EN PI to Applicant/MAH. Inform the Applicant/MAH about the possibility to hold a "QRD sub-group" meeting where comments can be further discussed, if necessary (sub-group is not applicable to veterinary applications).	PTL / Vet PM
13	Does the Applicant/MAH require a sub-group meeting? If yes go to step 14. If no, go to step 17.	Applicant/MAH
14	Send an invitation for a sub-group meeting to the Applicant/MAH.	Procedure secretary
15	Day 165 EMA/QRD sub- group meeting. Review of the compiled QRD comments by 2-3 EMA representatives and 2 QRD representatives with the (optional) participation of 1-2 Applicant/MAH representative(s) and 1 representative from interested parties. The meeting will be chaired by the PTL.	PTL
16	Day 165 Send annotated EN PI to the Applicant/MAH.	PTL
17	PTL / Vet PM receives final EN PI from Applicant/MAH before CxMP Opinion and forwards document to QRD Secretariat.	PTL / Vet PM
18	QRD Secretariat receives final EN PI to perform a final check of the implementation of QRD comments prior to adoption of CxMP Opinion and informs PTL/Vet PM.	QRD secretariat
19	QRD Secretariat forwards in parallel the final EN PI to medical writers for review. If all comments implemented: end of procedure. If not implemented or comments from medical writers received: continue with Step 19.1	QRD secretariat
19.1	PTL / Vet PM to liaise with Applicant/MAH to implement proposed changes and ensure that comments in AR are compatible with the QRD/medical writers' comments; liaise with Rapporteurs in case of contradictions. Back to Step 17.	PTL / Vet PM

10. Records

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