EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Article 30 referrals triggered by the European Commission or a Member State		
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1. Purpose

To describe the procedure for handling of referral procedures according to Article 30 of Directive 2001/83/EC as amended triggered by the European Commission or a Member State for non-centrally authorised medicinal products for human use.

2. Scope

This SOP applies to the Patient Health Protection Unit, the Human Medicines Development and Evaluation Unit, the Veterinary Medicines and Product Data Management Unit, the Information and Communications Technology Unit and Directorate.

The staff involved in this procedure is member of:

- Regulatory, Procedural and Committee Support Sector: Community Procedures Section, Regulatory Affairs Section and Scientific Committee Support Section
- Medical Information Sector: Product Information Quality Section, Public Information and Stakeholder Networking Section
- Quality of Medicines Sector
- Product and Data Management Sector: Product and Application Business Support Section, Product Database Management Section and Document and Information Services
- Communications Sector
- Legal Service Sector

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3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their own Sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section **9. Procedure.**

4. Changes since last revision

Extensive revisions to rewrite SOP.

5. Documents needed for this SOP

A list of all relevant templates (such as letters, time table, and sign-off slips) can be found in Word/File/New/Referrals and the templates themselves on the X:\ drive (X:\Templates\Others\H – Referral\Article 30).

Templates for CHMP opinion, CHMP assessment report, timetable for translations and for opinion related letters and the action list for product secretaries (covering opinion, day 27 after adoption of opinion and at the end of the Standing Committee phase) can be found in Word/File/New/H-Opin QRD Templates and on the X:\ drive (X:\Templates\Filenew\H-Opin QRD).

Other templates:

- Templates for translations (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59#section2 path: Home \ Regulatory \ Human medicines \ Product information \ Product information templates \ MR/DC/Referral procedures - product information templates)
- QRD form 2 (http://www.ema.europa.eu/htms/human/qrd/docs/qrdform2.doc path: Home \ Regulatory \ Human medicines \ Product information \ Linguistic review \ Linguistic review process)
- Template for Q-and-A for an Article 30 referral (Located at: X:\Templates\Others\H - Q-and-A documents)
- Template for transmission slip for referral publications (Located at: WORD/File/New/Transmissions Slips/TS – Referrals)

6. Related documents

Legislation

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended (http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf)
- Commission Regulation (EC) No 1662/95, of 7 July 1995, laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorisations for products for human or veterinary use (http://ec.europa.eu/health/files/eudralex/vol-1/reg_1995_1662/reg_1995_1662_en.pdf)

Guidance documents

- Notice to Applicants Volume 2A – Procedures for marketing authorisations, Chapter 3 – Community referral procedures (http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap3_rev09-2007_en.pdf)
- EC Guideline on summary of product characteristics (SmPC), Chapter 2C in the Notice to Applicants (http://ec.europa.eu/health/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf)
- Commission Communication on the Community marketing authorisation procedures for medicinal products (http://ec.europa.eu/health/files/eudralex/vol-1/com_1998/com_1998_en.pdf)
- EMA Questions and Answers on Referrals (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000018.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580024e97 path: Home \ Regulatory \ Human medicines \ Referral procedures \ Q&A)
- Guidance to applicants on CPMP oral explanations in relation to centralised procedures (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000168.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580027256# path: Home \ Regulatory \ Human medicines \ Pre-authorisation \ Guidance \ Application and Evaluation \ Evaluation)
- Convention to be followed for the EMA-QRD templates (EMEA/QRD/10/01) (http://www.ema.europa.eu/htms/human/qrd/docs/convention.pdf path: Home \ Regulatory \ Human medicines \ Product information \ Guidance \ QRD Templates)
- Procedural advice on the re-examination of CHMP opinions (EMEA/CHMP/50745/2005) (http://www.ema.europa.eu/pdfs/human/euleg/5074505en.pdf path: Home \ Regulatory \ Human medicines \ Post-opinion \ Opinion/Decision making)

SOPs and WINs

- SOP/EMA/0101 Conducting checks for conflicts of interest of Agency employees assigned duties relating to medicinal products for human or veterinary use
- SOP/H/3193 Master files for referrals
- SOP/EMA/0073 PIQ/QRD pre-opinion review of product information for referral procedures and Article 29 Paediatric procedures
- WIN/EMA/0070 Redaction of documents in relation to access to documents
- WIN/H/3145 Sending out documents in the context of referrals (Article 5(3), 5(11), 13, 20, 29(4), 29 (paediatric), 30, 31, 36 and 107 for medicinal products for human use)
- SOP/EMA/0048 QRD Post-opinion review of product information for post-authorisation procedures affecting the annexes, excluding Annex II applications.
- WIN/H/3205 Preparation of referral opinions for publication on the EMA website (Referrals according to Article 5(3), 5(11), 6(12), 6(13), 13, 20, 29(4), 29 (paediatric), 30, 31, 36 and 107 for medicinal products for human use)
- SOP/H/3176 CHMP rapporteur/co-rapporteur appointment for referrals
- SOP/H/3129 Organisation of Scientific Advisory Group (SAG) meetings and reporting of SAG position to the CHMP

- SOP/EMA/0111 on Preparation, dissemination and publication of safety-related EMA press releases and question-and-answer documents
- WIN/H/3234 on Preparation for publication of annexes to the CHMP meeting highlights by the CHMP Secretariat and CP Section.

7. Definitions

Article 30 Directive 2001/83/EC, as amended

1. If two or more applications submitted in accordance with Articles 8, 10, 10a, 10b, 10c and 11 have been made for marketing authorisation for a particular medicinal product, and if Member States have adopted divergent decisions concerning the authorisation of the medicinal product or its suspension or revocation, **a Member State, the Commission or the applicant or the marketing authorisation holder may refer the matter to the Committee for Medicinal Products for Human Use**, hereinafter referred to as 'the Committee', for the application of the procedure laid down in Articles 32, 33 and 34.

2. In order to promote harmonisation of authorisations for medicinal products authorised in the Community, Member States shall, each year, forward to the coordination group a list of medicinal products for which a harmonised summary of product characteristics should be drawn up.

The coordination group shall lay down a list taking into account the proposals from all Member States and shall forward this list to the Commission.

The Commission or a Member State, in agreement with the Agency and taking into account the views of interested parties, may refer these products to the Committee in accordance with paragraph 1.

Referral team:

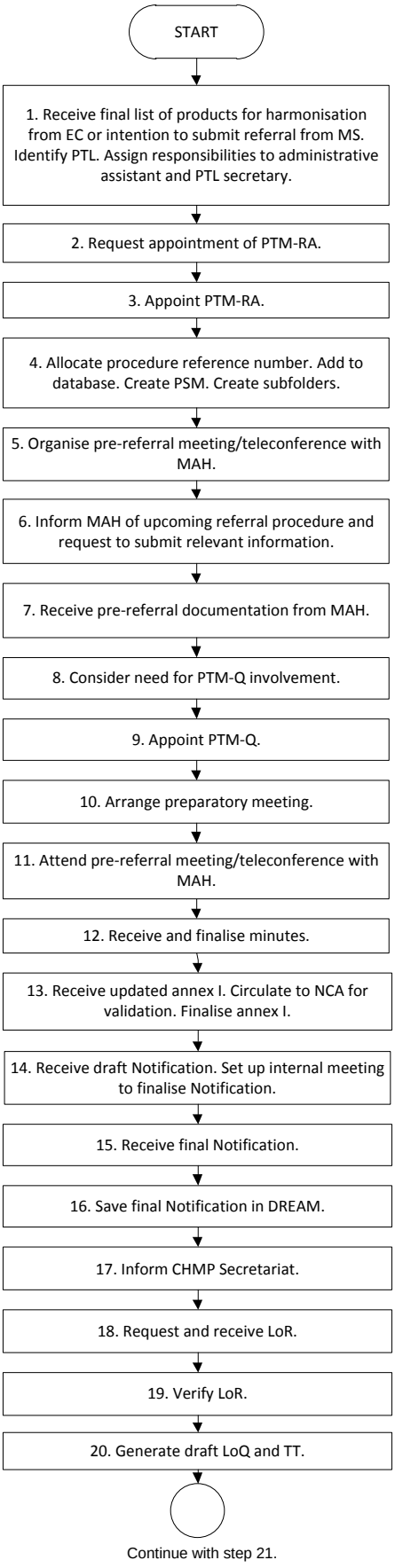
The PTL referral team includes the appointed Product Team Leader for the referral procedure from the Community Procedures section and the Product team members from the Regulatory Affairs section, the Legal Service Sector and the Quality of Medicines sector in cases where harmonisation of the quality sections of the Summary of Product Characteristics has been requested by the marketing authorisation holder.

Abbreviations:

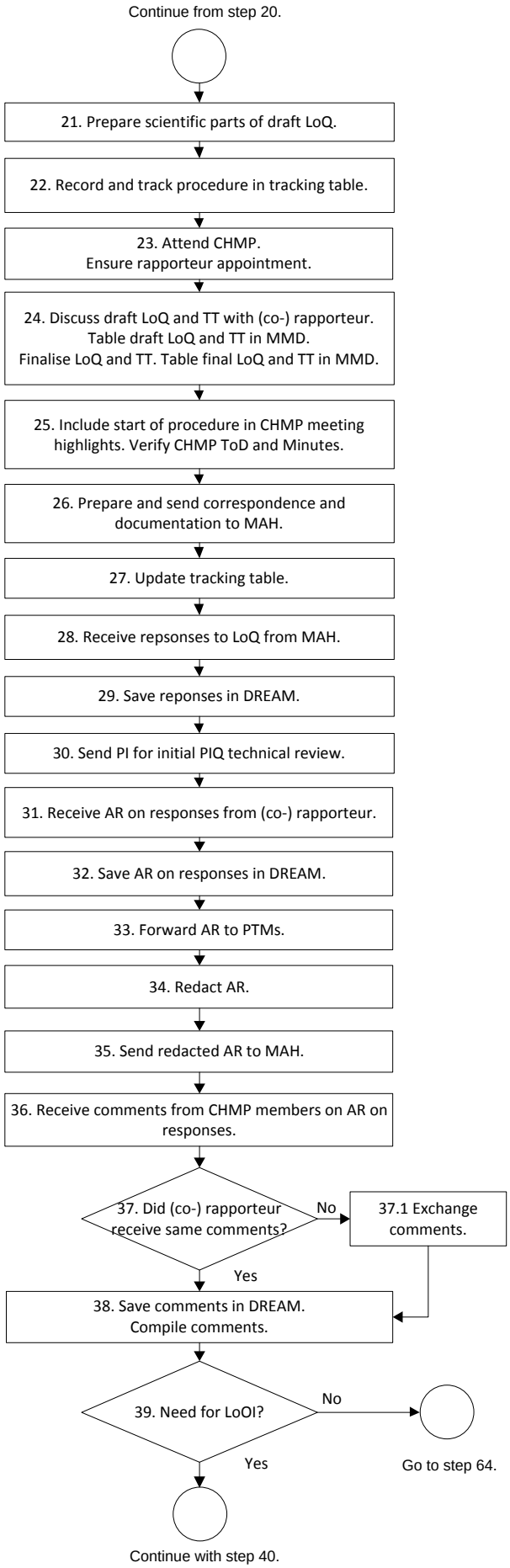
AR:	Assessment report
CHMP:	Committee for Medicinal Products for Human Use
CMDh:	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
D-CM:	Communications Sector
D-LS:	Legal Service Sector
DREAM:	Document Records and Electronic Archive Management system
EC:	European Commission
EMA:	European Medicines Agency
H-QM:	Quality of Medicines Sector
JAR:	Joint assessment report
LoOI:	List of outstanding issues

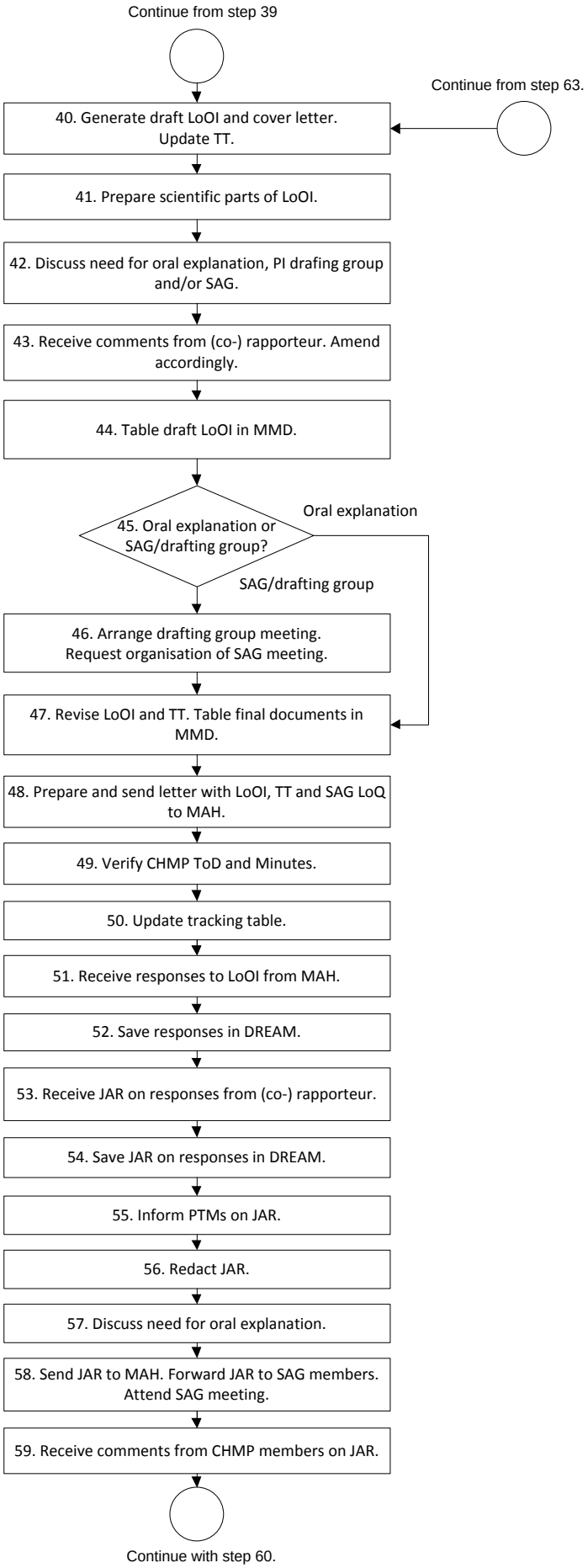
LoQ:	List of questions
LoR:	Letter of representation
MAH:	Marketing authorisation holder
MMD:	Management of Meeting Documents system
MS:	Member State
NCA:	National competent authority
NtA:	Notice to Applicants
PI:	Product information
PIQ:	Product Information Quality review
PSM	Product shared mailbox
PTL:	Product team leader for the referral procedure
PTM:	Product team member
PTM-Q:	Product team member from H-QM
PTM-RA:	Product team member from P-R-RA
P-MI-PIN:	Public Information and Stakeholder Networking Section
P-MI-PIQ:	Product Information Quality Section
P-R:	Regulatory, Procedural and Committee Support Sector
P-R-CP:	Community Procedures Section
P-R-RA:	Regulatory Affairs Section
Q&A	Question and Answers document
QRD:	Quality Review of Documents
r-MF:	Referral master file
SAG:	Scientific Advisory Group
SC:	Standing Committee
SH:	Section Head
SOP:	Standard operating procedure
ToD:	Table of decisions
TT:	Timetable
V-PD-BUS:	Product and Application Business Support Section
V-PD-DBM:	Product Database Management Section
V-PD-DIS:	Document and Information Services Section
WIN:	Work instructions

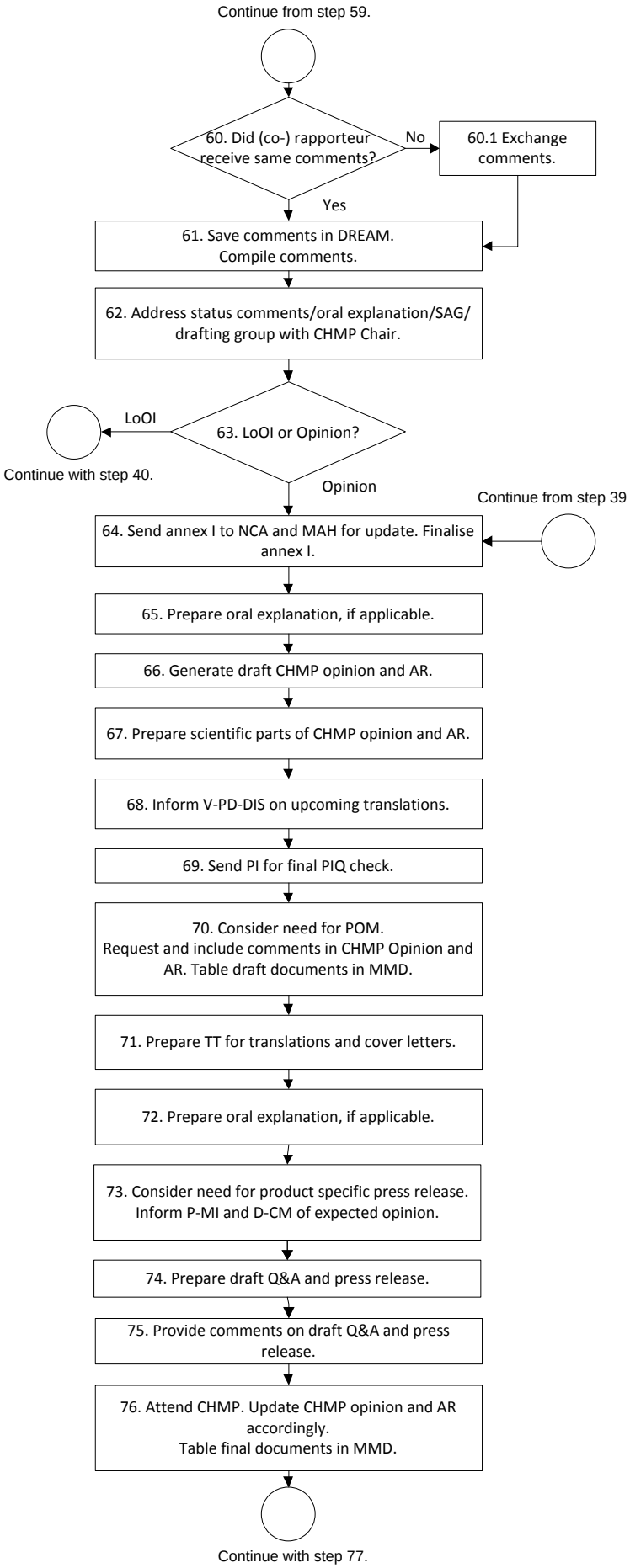
8. Process map(s)/ flow chart(s)

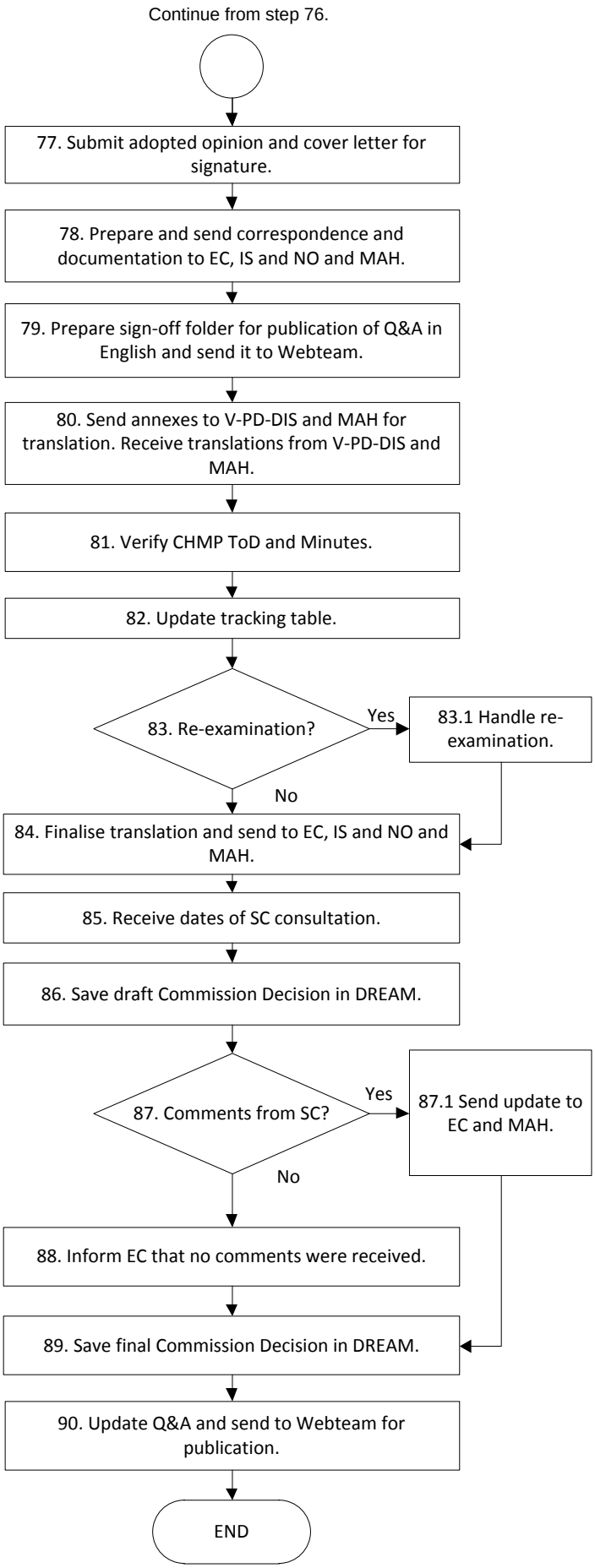


Continue with step 21.


Continue from step 20.
21. Prepare scientific parts of draft LoQ.
22. Record and track procedure in tracking table.
23. Attend CHMP.
Ensure rapporteur appointment.
24. Discuss draft LoQ and TT with (co-) rapporteur.
Table draft LoQ and TT in MMD.
Finalise LoQ and TT. Table final LoQ and TT in MMD.
25. Include start of procedure in CHMP meeting highlights. Verify CHMP ToD and Minutes.
26. Prepare and send correspondence and documentation to MAH.
27. Update tracking table.
28. Receive repsonses to LoQ from MAH.
29. Save reponses in DREAM.
30. Send PI for initial PIQ technical review.
31. Receive AR on responses from (co-) rapporteur.
32. Save AR on responses in DREAM.
33. Forward AR to PTMs.
34. Redact AR.
35. Send redacted AR to MAH.
36. Receive comments from CHMP members on AR on responses.
37. Did (co-) rapporteur receive same comments?
No
37.1 Exchange comments.
Yes
38. Save comments in DREAM.
Compile comments.
39. Need for LoOI?
No
Go to step 64.
Yes
Continue with step 40.


Continue from step 39
Continue from step 63.
40. Generate draft LoOI and cover letter. Update TT.
41. Prepare scientific parts of LoOI.
42. Discuss need for oral explanation, PI drafing group and/or SAG.
43. Receive comments from (co-) rapporteur. Amend accordingly.
44. Table draft LoOI in MMD.
45. Oral explanation or SAG/drafting group?
Oral explanation
SAG/drafting group
46. Arrange drafting group meeting. Request organisation of SAG meeting.
47. Revise LoOI and TT. Table final documents in MMD.
48. Prepare and send letter with LoOI, TT and SAG LoQ to MAH.
49. Verify CHMP ToD and Minutes.
50. Update tracking table.
51. Receive responses to LoOI from MAH.
52. Save responses in DREAM.
53. Receive JAR on responses from (co-) rapporteur.
54. Save JAR on responses in DREAM.
55. Inform PTMs on JAR.
56. Redact JAR.
57. Discuss need for oral explanation.
58. Send JAR to MAH. Forward JAR to SAG members. Attend SAG meeting.
59. Receive comments from CHMP members on JAR.
Continue with step 60.


Continue from step 59.
60. Did (co-) rapporteur receive same comments?
No
60.1 Exchange comments.
Yes
61. Save comments in DREAM. Compile comments.
62. Address status comments/oral explanation/SAG/ drafting group with CHMP Chair.
63. LoOI or Opinion?
LoOI
Continue with step 40.
Opinion
Continue from step 39
64. Send annex I to NCA and MAH for update. Finalise annex I.
65. Prepare oral explanation, if applicable.
66. Generate draft CHMP opinion and AR.
67. Prepare scientific parts of CHMP opinion and AR.
68. Inform V-PD-DIS on upcoming translations.
69. Send PI for final PIQ check.
70. Consider need for POM. Request and include comments in CHMP Opinion and AR. Table draft documents in MMD.
71. Prepare TT for translations and cover letters.
72. Prepare oral explanation, if applicable.
73. Consider need for product specific press release. Inform P-MI and D-CM of expected opinion.
74. Prepare draft Q&A and press release.
75. Provide comments on draft Q&A and press release.
76. Attend CHMP. Update CHMP opinion and AR accordingly. Table final documents in MMD.
Continue with step 77.


Continue from step 76.
77. Submit adopted opinion and cover letter for signature.
78. Prepare and send correspondence and documentation to EC, IS and NO and MAH.
79. Prepare sign-off folder for publication of Q&A in English and send it to Webteam.
80. Send annexes to V-PD-DIS and MAH for translation. Receive translations from V-PD-DIS and MAH.
81. Verify CHMP ToD and Minutes.
82. Update tracking table.
83. Re-examination?
Yes
83.1 Handle re-examination.
No
84. Finalise translation and send to EC, IS and NO and MAH.
85. Receive dates of SC consultation.
86. Save draft Commission Decision in DREAM.
87. Comments from SC?
Yes
87.1 Send update to EC and MAH.
No
88. Inform EC that no comments were received.
89. Save final Commission Decision in DREAM.
90. Update Q&A and send to Webteam for publication.
END

9. Procedure

Step	Action	Responsibility
Before the start of procedure		
1	Receive the final list of medicinal products for harmonisation from the European Commission or the intention to submit an Art 30 referral from (a) Member State(s). Identify a scientific administrator from P-R-CP to act as PTL for the upcoming Art 30 referral procedure and check possible conflicts of interest according to SOP/EMA/0101. Inform the appointed PTL about the referral procedure and the appointment as PTL for the referral procedure. Assign responsibilities to an administrative assistant and PTL secretary from P-R-CP and inform them accordingly.	SH P-R-CP
2	Request appointment of the PTM-RA for the procedure from the SH P-R-RA as per the latest 'RA Section Product and Project Portfolio's Allocation.'	PTL
3	Appoint the PTM-RA and inform the PTM-RA and PTL accordingly.	SH P-R-RA
4	Inform V-PD-DBM and V-PD-BUS about the upcoming referral procedure and request the following (see template): • Allocate a procedure reference number with 'A-30' as prefix and add the procedure to the referral database. • Create a PSM for the procedure. • Create subfolders in DREAM under 01. Evaluation of medicines \ Referrals \ H-Article 30 (see SOP/H/3193).	PTL secretary V-PD-DBM V-PD-DBM V-PD-BUS
5	Organise a pre-referral meeting/teleconference with the PTL, Administrative assistant, PTM-RA, D-LS and MAH. Send the invitation for the pre-referral meeting/teleconference to the MAH (see template) and EMA referral team.	PTL secretary
6	Inform the MAH of the upcoming referral procedure and request the MAH to submit to the Agency any relevant information.	PTL
7	Receive pre-referral documentation, including annex I, from the MAH and forward it to the EMA referral team members.	PTL
8	Consider the need for involvement of a PTM-Q. If involvement is needed, contact the relevant SH in H-QM and request the nomination of a PTM-Q.	SH P-R-CP
9	Appoint the PTM-Q and inform the PTM-Q and PTL accordingly.	SH H-QM
10	Arrange a brief preparatory meeting with the EMA referral team in advance of the pre-referral meeting/teleconference.	PTL

Step	Action	Responsibility
11	Attend the pre-referral meeting/teleconference. Clarify with the MAH whether or not the Quality module will be submitted for harmonisation.	PTL, administrative assistant, PTM-RA, D-LS and if necessary, PTM-Q
12	Receive the draft minutes of the meeting/teleconference prepared by the MAH and circulate to the EMA referral team for comments. Finalise the minutes integrating comments received and send the minutes to the MAH and the EMA referral team.	PTL
13	Following the discussion at the pre-referral meeting/teleconference, receive an updated annex I from the MAH and circulate it to the NCA contact points requesting validation of the list (see template). Receive comments from the NCAs and implement in track changes. Finalise annex I and send it to the MAH for checking and completion (if necessary).	Administrative assistant
14	Receive the draft Notification from the CMDh co-ordinator or the Member State for the referral procedure for the concerned product. Set up and hold an internal meeting/teleconference with the PTL, PTM-RA, D-LS and PTM-Q, to agree the draft Notification before sending the draft Notification to the Commission or Member State.	CMDh secretariat
15	Receive the final Notification from the European Commission or Member State. Forward it to the PTL and PSM.	V-PD-BUS
16	Save the final Notification in the procedure folder in DREAM.	PTL
17	Inform the CHMP secretariat to include the Art 30 Notification for the concerned product on the CHMP Agenda for discussion. Table the Notification for tabling in MMD for discussion at CHMP.	PTL PTL secretary
18	Request the LoR from the MAH (see template). Receive LoR and forward it to the Administrative assistant.	PTL secretary
19	Verify the LoRs and compliance with the draft annex I. Liaise with NCAs and/or MAH if necessary to solve any discrepancies.	Administrative assistant
20	Generate the draft LoQ and TT (see templates) and prepare the administrative parts of the draft LoQ and TT. Save the documents in the procedure folder in DREAM.	PTL secretary
21	Prepare the scientific parts of the draft LoQ.	PTL
22	Record and track the procedure in the tracking table.	Administrative assistant
Start of procedure		

Step	Action	Responsibility
23	Attend the CHMP discussion on the referral procedure. If the referral has been triggered by the European Commission and included in the list of medicinal products for harmonisation, ensure confirmation of (co-)rapporteur as appointed at the time of finalisation of the list. If the referral has been triggered by a Member State, assign (co-) rapporteur (see SOP/H/3176).	PTL
24	Discuss the draft LoQ and TT with the (co-)rapporteur prior to the CHMP discussion. Table the draft LoQ and TT in MMD for discussion at CHMP. Follow the CHMP discussion on the referral procedure. Amend the draft LoQ and TT taking into account the CHMP discusion. Inform the PTL secretary about the adoption of the LoQ and TT. Table the final documents in MMD for adoption by CHMP.	PTL PTL secretary PTL PTL PTL PTL secretary
25	Include the start of procedure in the annexes to the CHMP meeting highlights (see WIN/H/3234). Verify the CHMP ToD and minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL
26	Prepare the cover letter informing the MAH of the start of procedure and LoQ (see template). After signature by the SH P-R-CP, send the letter together with the LoQ and TT for the procedure adopted by the CHMP to the MAH (cc (co-) rapporteur) in accordance with WIN/H/3145 and verify receipt of the documents.	PTL secretary
27	Update the tracking table based on the CHMP ToD.	Administrative assistant
Receipt of responses to list of questions		
28	Receive responses to the LoQ from the MAH. Forward the responses to the PTL and PSM.	V-PD-BUS
29	Save the responses to the LoQ from the MAH in the procedure folder in DREAM.	PTL secretary
30	Send the EN PI to the PIQ/QRD secretariat for an initial PIQ technical review (see SOP/EMA/0073). Inform the QRD secretariat if the Quality Module has been submitted. Upon receipt of PIQ comments, send the PI to: • the MAH to implement the comments or provide justification for	PTL

Step	Action	Responsibility
	not doing so. • the (co-)rapporteur for their consideration when drafting the AR (see template e-mail).	
31	Receive (co-)rapporteur's assessment reports on the responses. Forward the reports to the PTL and PSM.	V-PD-BUS
32	Save the (co-)rapporteur's ARs in the procedure folder in DREAM.	PTL secretary
33	Forward the ARs to the PTMs as appropriate.	PTL
34	Redact any confidential information in the the (co-)rapporteur's ARs (see WIN/EMA/0070) and save the redacted version in the procedure folder in DREAM.	PTL
35	Send the redacted (co-)rapporteur's ARs by Eudralink to the MAH (see template and WIN/H/3145) and verify receipt of documents.	PTL secretary
36	Receive comments on the (co-)rapporteur's ARs from other CHMP members. Forward the comments to the PTL and PSM.	V-PD-BUS
37	Forward the comments to the PTMs as appropriate. Check with the (co-)rapporteur whether they have received comments and if the comments received are the same. If yes, go to step 38. If no, go to step 37.1.	PTL
37.1	Send the (co-)rapporteur any comments that they have not received and/or ask them to send any comments that have not yet been provided to the Agency.	PTL
38	Save the CHMP members' comments in the procedure folder in DREAM. Forward compiled CHMP members' comments to the PSM.	PTL secretary
39	Check with the (co-)rapporteur wether a LoOI is required and inform the CHMP secretariat accordingly. If yes, go to step 40. If no, go to opinion phase - step 64.	PTL
List of outstanding issues		
40	Generate the draft LoOI and cover letter (see templates) and prepare the administrative parts of the draft LoOI. Generate the TT (including recalculation of number of active days). Save the draft LoOI, TT and cover letter in the procedure folder in DREAM.	PTL secretary

Step	Action	Responsibility
41	Prepare the scientific parts of the draft LoOI. Liase with the relevant PTM(s) (e.g. PTM-Q for Quality related issues, PTM-RA).	PTL
42	Discuss with the (co-)rapporteur whether there is a need for: • an oral explanation and incorporate if necessary the specific issues to be discussed at the oral explanation in the LoOI and/or • a drafting group for the PI and/or • a SAG. Send the draft LoOI and TT to the (co-)rapporteur for comments.	PTL
43	Upon receipt of (co-)rapporteur's comments, amend the documents accordingly.	PTL
44	Table the draft LoOI and TT in MMD for discussion at CHMP.	PTL secretary
45	Attend the CHMP discussion. Check confirmation of the possible outcome of the CHMP discussion: If an oral explanation is needed, go to step 47. If a drafting group or/and SAG meeting is needed, go to step 46.	PTL
46	Arrange the drafting group meeting with the (co-)rapporteur and CHMP members who actively participated in the CHMP discussion to agree on a final proposal for the PI. If a SAG discussion is needed, inform the SAG secretariat about the need to organise a SAG meeting according to SOP/H/3129.	PTL
47	Revise the draft LoOI and TT taking into account the CHMP discussion and if necessary include the: • specific issues to be addressed at the oral explanation and/or • the final proposal for the PI agreed at the drafting group meeting and/or • the list of questions to the SAG. Inform the PTL secretary about the adoption of the LoOI, list of questions for the SAG, if applicable, and TT. Table the revised documents in MMD for adoption by CHMP.	PTL PTL secretary
48	Prepare the cover letter informing the MAH of the LoOI (see template). In case an oral explanation to the CHMP was deemed necessary, include information on the oral explanation (see template). Inform the MAH about the adoption of a list of questions	PTL secretary

Step	Action	Responsibility
	for a SAG, if applicable. After signature by the SH P-R-CP, send the cover letter together with the LoOI, TT an list of questions to the SAG adopted by the CHMP (cc (co-)rapporteur) in accordance with WIN 3145 and verify receipt of documents.	
49	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL
50	Update the tracking table based on the CHMP ToD.	Administrative assistant
Receipt of responses to list of outstanding issues		
51	Receive responses to the LoOI from the MAH. Forward the responses to the PTL and PSM.	V-PD-BUS
52	Save responses to the LoOI from the MAH in the procedure folder in DREAM.	PTL secretary
53	Receive (co-)rapporteur's JAR on the responses to the LoOI. Forward the (co-)rapporteur's JAR to the PTL and PSM.	V-PD-BUS
54	Save the (co-)rapporteur's JAR in the procedure folder in DREAM.	PTL secretary
55	Inform the relevant PTM(s) about the receipt of the (co-) rapporteur's JAR as appropriate.	PTL
56	Redact any confidential information in the the (co-)rapporteur's JAR (see WIN/EMA/0070) and save the redacted version in the procedure folder in DREAM.	PTL
57	Discuss with the (co-)rapporteur whether there is a need for an oral explanation to the CHMP. Inform the CHMP secretariat about the need for an oral explanation. Receive information whether or not the MAH/applicant will attend the oral explanation and who will be attending, if applicable. Inform the CHMP secretariat accordingly.	PTL
58	Send the redacted (co-)rapporteur's JAR by Eudralink to MAH (see WIN/H/3145) and verify receipt of documents. Forward the JAR to the SAG members in preparation of their meeting if applicable. Attend the SAG meeting.	PTL secretary
59	Receive comments on the (co-)rapporteur's JAR from other CHMP members. Forward the comments to the PTL and PSM.	V-PD-BUS

Step	Action	Responsibility
60	Forward the comments to the PTMs as appropriate. Check with the (co-)rapporteur whether they have received the same comments and if the comments received are the same. If yes, go to step 61. If no, go to step 60.1.	PTL
60.1	Send the (co-)rapporteur any comments that they have not received and/or ask them to send any comments that have not yet been provided to the Agency.	PTL
61	Save CHMP members' comments in the procedure folder in DREAM. Forward compiled CHMP members' comments to the PSM.	PTL secretary
62	Address the status of the comments and possible oral explanation/drafting group meeting/SAG with the CHMP Chairman and Vice-Chairman during the pre-CHMP teleconference.	PTL
63	Check with the (co-)rapporteur whether the procedure is going for an opinion or a further LoOI. If a further LoOI is necessary, go to step 40. If an opinion is foreseen, go to step 64.	PTL
Opinion		
64	1 week before the CHMP meeting, send annex I to the NCA contact points for final check of MAH's status. Follow up with a reminder if necessary. Forward all comments from the NCAs to the MAH for confirmation and implementation. Finalise annex I.	Administrative assistant
65	If an oral explanation is required, make preparations for the oral explanation as per the CPMP guidance to applicants on CPMP oral explanations CPMP/2390/01.	PTL
66	Generate the draft CHMP opinion and AR, including relevant annexes (see templates). Prepare the administrative parts of the draft CHMP opinion and AR, including relevant annexes. Save the draft CHMP opinion and AR, including relevant annexes, in the procedure folder in DREAM.	PTL secretary
67	Prepare the scientific parts of the draft CHMP opinion including annex II (scientific conclusions and grounds for amendment of the PI), and of the draft CHMP AR. Include a summary of the drafting group or/and SAG discussion if	PTL

Step	Action	Responsibility
	applicable.	
68	Inform V-PD-DIS (translations inbox – translationsrequests@ema.europa.eu) about up-coming translations (annex II and IV), if applicble.	PTL secretary
69	Send the EN PI received to the PIQ/QRD Secretariat for final PIQ check (see SOP/EMEA/0073). Upon receipt of QRD comments, send the PI to the MAH to implement the comments or provide justification for not doing so.	PTL
70	Consider whether the procedure needs to be added to the agenda of the Product Oversight Meeting and attend the meeting, if relevant. Circulate electronically the draft documents to the PTMs and the SH P-R-CP for review if possible at the latest by the Wednesday the week before the CHMP meeting. Receive comments from the PTMs and the SH P-R-CP (at the latest by Friday the week before the CHMP meeting). Update the draft CHMP opinion and AR as necessary. Table the draft CHMP opinion and AR in MMD for discussion at CHMP.	PTL PTL secretary
71	Prepare the draft TT for translations and draft letters for sending out the opinion, including the sign-off slip for checking and signing by the PTL, P-R-RA and D-LS (see templates and Action list for product secretaries). Save the documents in the procedure folder in DREAM.	PTL secretary
72	Inform the CHMP secretariat and arrange a time slot for the oral explanation, if necessary. Inform the MAH of the time and date of the oral explanation and request their presentation for the oral explanation and the list of attendees (see template). Receive information whether or not the MAH will attend the oral explanation and who will be attending, if applicable. Inform the CHMP secretariat accordingly.	PTL
73	Check with the SH P-R-CP whether there is a need for a product specific press release. A Q&A document is always required at the time of opinion. Inform P-MI-PIN and D-CM about the expected opinion.	PTL
74	Prepare a draft Q&A (according to SOP/EMA/0111). Prepare a draft press release (according to SOP/EMA/0111), if appropriate.	P-MI-PIN D-CM

Step	Action	Responsibility
75	Provide comments on the draft Q&A to P-MI-PIN and on the draft press release to D-CM.	PTL
76	Attend the CHMP meeting, including the oral explanation and/or the presentation of the outcomes of the drafting group/SAG, if applicable. Update the CHMP opinion and AR as needed to reflect the CHMP discussion, and if applicable the conclusions of the SAG, the oral explanation, the voting and any divergent positions. Table the revised documents in MMD for adoption by CHMP.	PTL PTL secretary
77	Submit the sign-off folder with the adopted opinion to the PTL, P-R-RA and D-LS for checking and sign-off and to the CHMP Chair for signature. Check and update cover letters to the MAH/applicant and EC if necessary.	PTL secretary
Post opinion phase		
78	Prepare the correspondence (see template) and documentation to be sent to the EC, IS and NO and MAH (cover letter, CHMP opinion and AR, together with all annexes and TT for translations, translations of INN/product name) in accordance with WIN/H/3145. After signature by the SH P-R-CP, send out the correspondence and documentation to the EC, IS and NO and MAH (cc (co-)rapporteur) in accordance with the Action list for product secretaries and verify receipt of documents.	PTL secretary
79	Prepare the folder and sign-off slip for the publication of the Q&A (English only). After signature by the SH P-R-CP, send it to the Webteam for publication.	PTL secretary
80	Send annexes I, II, III and IV (if applicable) of the CHMP opinion to V-PD-DIS (translations inbox – translationsrequests@ema.europa.eu) and the MAH for translation (see SOP/EMA/0048). Receive translations from V-PD-DIS and the MAH.	PTL secretary
81	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL
82	Update the tracking table based on the CHMP ToD.	Administrative assistant
83	Check whether a request for a re-examination of the opinion has been received within 15 days of the receipt of the paper copy of	PTL

Step	Action	Responsibility
	the opinion by the MAH. If yes, go to step 83.1. If no, go to step 84.	
83.1	In case the MAH requests a re-examination of the opinion within 15 days of the receipt of the paper copy of the opinion, the remaining steps of this SOP will be put on hold pending the finalisation of the re-examination procedure. • Upon receipt of the re-examination request, immediately inform the EC. • Handle the re-examination procedure according to the 'Procedural Advice on the re-examination of CHMP opinions' (EMEA/CHMP/50745/2005) document. Once the re-examination procedure is finalised, continue with step 84.	PTL
84	Prepare the correspondence (see template) and documentation (final translations) to be sent to the EC, IS and NO and MAH. After signature by the SH P-R-CP, send the documents to the EC, IS and NO and MAH in accordance with WIN/H/3145 and verify receipt of documents.	PTL secretary
Standing Committee and Commission decision phase		
85	Receive an e-mail from the EC with the start and end dates for the SC consultation phase and the draft Commission Decision. Check the documents and provide comments to the EC, if applicable.	PTL
86	Save the draft Commission Decision in the procedure folder in DREAM and forward the e-mail from the EC to the PSM.	PTL secretary
87	At the end of the SC phase, verify with the PTL if comments have been received. If yes, go to step 87.1. If no, go to step 88.	PTL secretary
87.1	Send the updated translations (if any) to the EC and MAH the day after SC consultation has ended (see templates, Action list for secretaries and WIN/H/3145 and verify receipt of documents. Go to step 89.	PTL secretary
88	Inform the EC whether or not comments were received.	PTL secretary
89	Receive information from the EC on the adoption of the final Commission Decision.	PTL secretary

Step	Action	Responsibility
	Retrieve the final Commission Decision documents from the EC website and save them in the procedure folder in DREAM.	
Post Commission decision phase		
90	Update the Q&A by adding the date of the Commission Decision and send it to V-PD-DIS (translation inbox – translationsrequests@ema.europa.eu) for translation. Upon receipt of the Q&A translations from V-PD-DIS, prepare all documents for publication (see WIN/H/3205). Prepare the folder and sign-off slip for publication. Send it to the Webteam for publication.	PTL secretary

10. Records

All required paper and electronic documents and records received and/or generated during this procedure are filed, saved and archived in the paper and/or electronic referral master file and/or in DREAM in accordance with SOP/H/3193.