EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Article 107 procedures - Pharmacovigilance urgent measures		
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1. Purpose

To describe the procedure for handling of procedures according to Article 107(2) of Directive 2001/83/EC as amended for non-centrally authorised medicinal products for human use.

2. Scope

This SOP applies to the Patient Health Protection 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, Scientific Committee Support Section
- Pharmacovigilance and Risk Management Sector: Data Collection and Management Section, Risk Management Section
- Medical Information Sector: Product Information Quality Section, Public Information and Stakeholder Networking Section
- Product Data Management Sector: Product and Application Business Support Section, Product Database Management Section, Document and Information Services Section
- 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

New 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 107).

Templates for CHMP opinion, CHMP assessment report, timetable for translations and opinion related letters and action list for 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 107 procedure (Location: X:\Templates\Others\H - Q-and-A documents)
- Template for transmission slip for referral publications (Location: 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, as amended (http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf)
- Eudralex, Volume 9A of the rules governing medicinal products in the European Union Pharmacovigilance for Medicinal Products for Human Use (http://ec.europa.eu/health/documents/eudralex/vol-9/index_en.htm)

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)
- 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 WIN

- SOP/EMA/0073 on PIQ/QRD pre-opinion review of product information for referral procedures and Article 29 Paediatric procedures
- WIN/EMA/0070 on Redaction of Documents in relation to access to documents
- WIN/H/3145 on 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/H/3193 on Master file for referrals
- WIN/H/3205 on Preparation of referral opinions for publication 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/EMA/0101 on Conducting checks for conflicts of interest of Agency employees assigned duties relating to medicinal products for human or veterinary use
- SOP/EMA/0111 on Preparation, dissemination and publication of safety-related EMA press releases and question-and-answer documents
- SOP/H/3129 on Organisation of Scientific Advisory Group (SAG) meetings and reporting of SAG position to the CHMP
- SOP/H/3176 CHMP rapporteur/co-rapporteur appointment for referrals
- SOP/H/3346 on Early Notification System: procedure for advanced notification of emerging safety issues to EU regulatory network and international partners
- WIN/H/3234 on Preparation for publication of annexes to the CHMP meeting highlights by the CHMP Secretariat and CP Section.

7. Definitions

Article 107 procedures ("Pharmacovigilance Urgent Measures") of Directive 2001/83/EC, as amended

An article 107 procedure is the procedure by which CHMP adopts an opinion in case a suspension or revocation of the marketing authorisation for a non-centrally authorised product for human use is being considered by a member state based on pharmacovigilance data or an opinion is requested by a member state when a variation is being considered based on evaluation of pharmacovigilance data.

Referral team

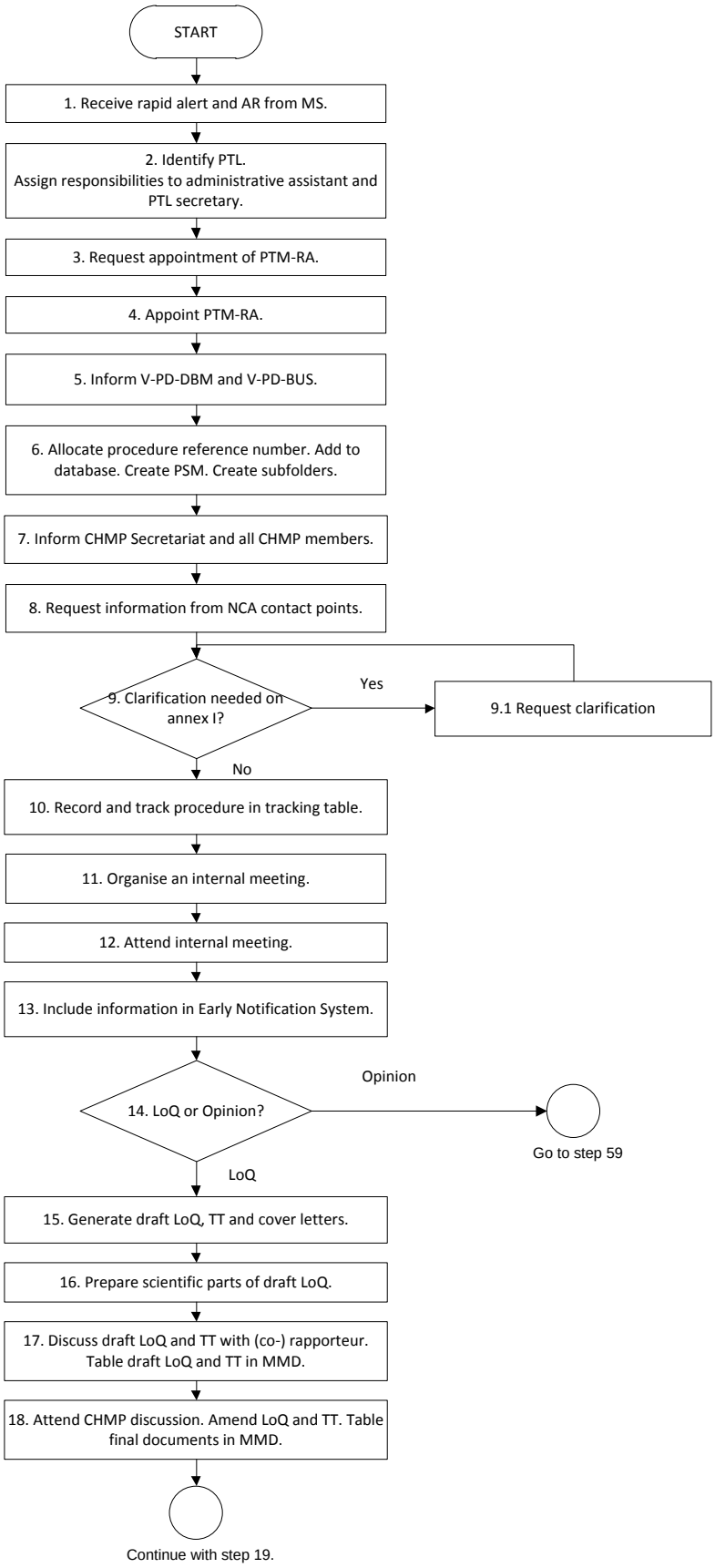
The referral team includes the appointed product team leader for the procedure from the Community Procedures Section and the product team members from the Regulatory Affairs Section, the Pharmacovigilance and Risk Management Sector and the Legal Service Sector, as appropriate.

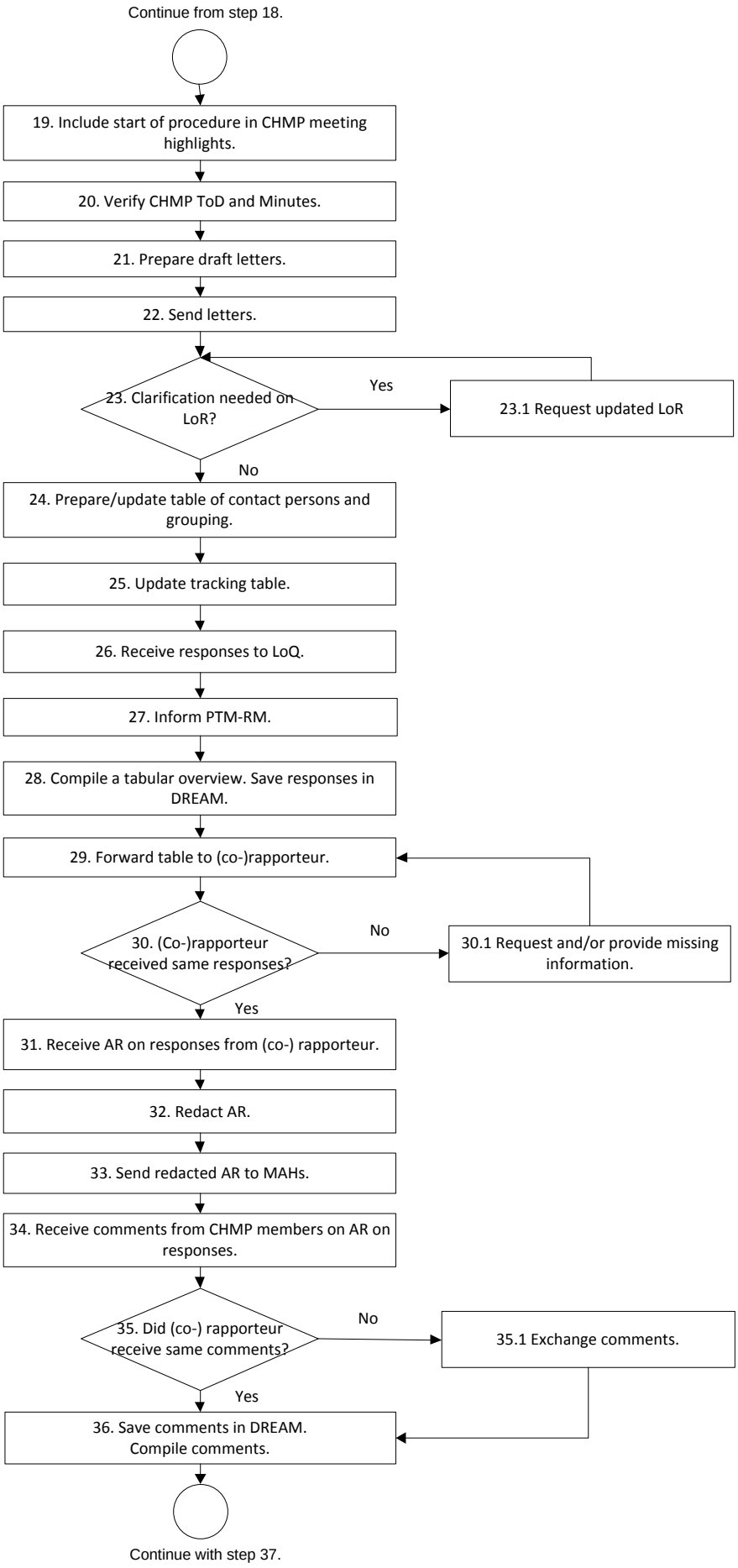
Abbreviations:

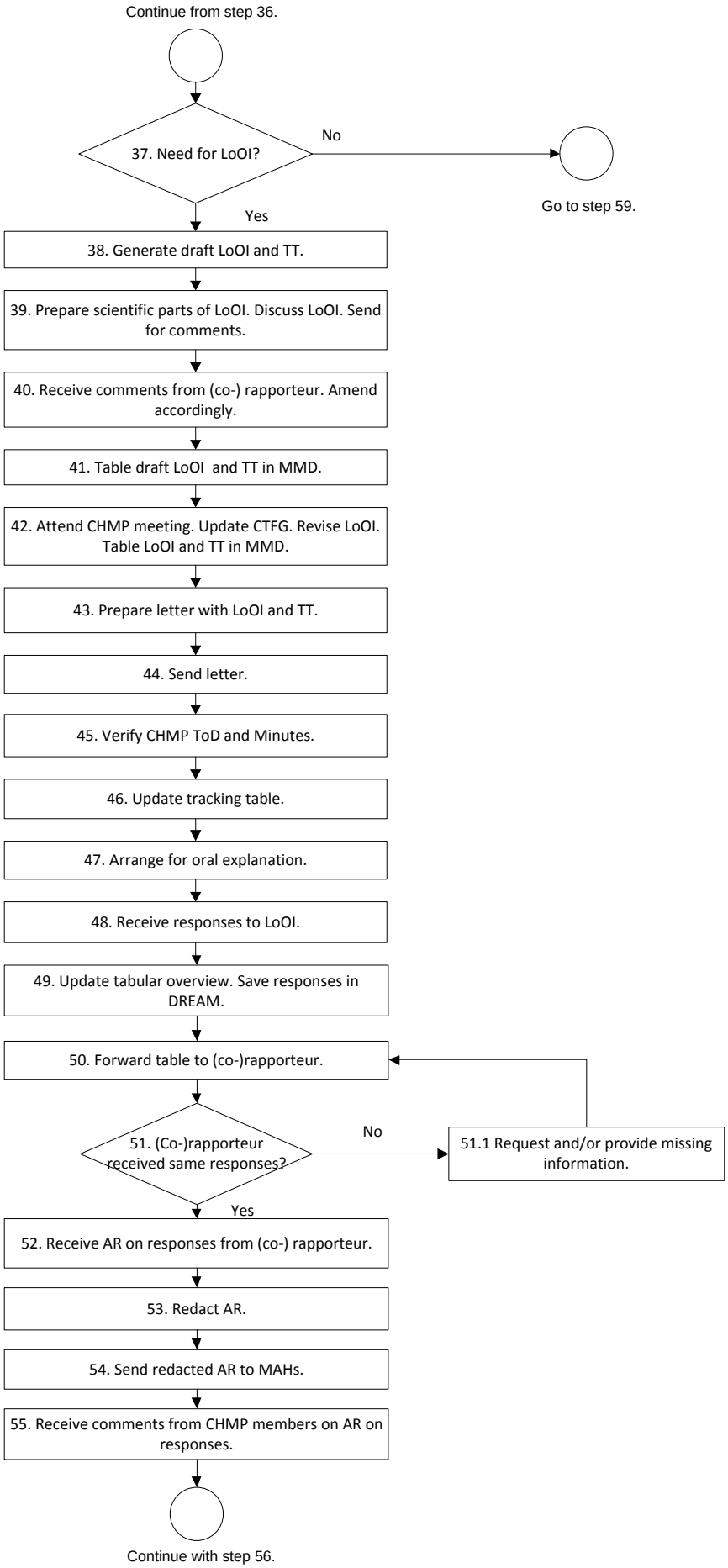
AR	Assessment report
CdT	Centre de Traduction
CHMP	Committee for Medicinal Products for Human Use
CTFG	Clinical Trials Falicitation Group
D-CM	Communications Sector
D-LS	Legal Service Sector
D-LS-LA	Legal Service Sector, Legal Advisers
DREAM	Document Records and Electronic Archive Management system
EC	European Commission
ECD	Eudra Common Directory
EMA	European Medicines Agency
EPAR	European public assessment report
HoS	Head of Sector
LoOIs	List of outstanding issues
LoQ	List of questions
LoR	List of representation
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MMD	Management of Meeting Documents system
MS	Member state
NCA	National competent authority
P-CI	Compliance and Inspections Sector

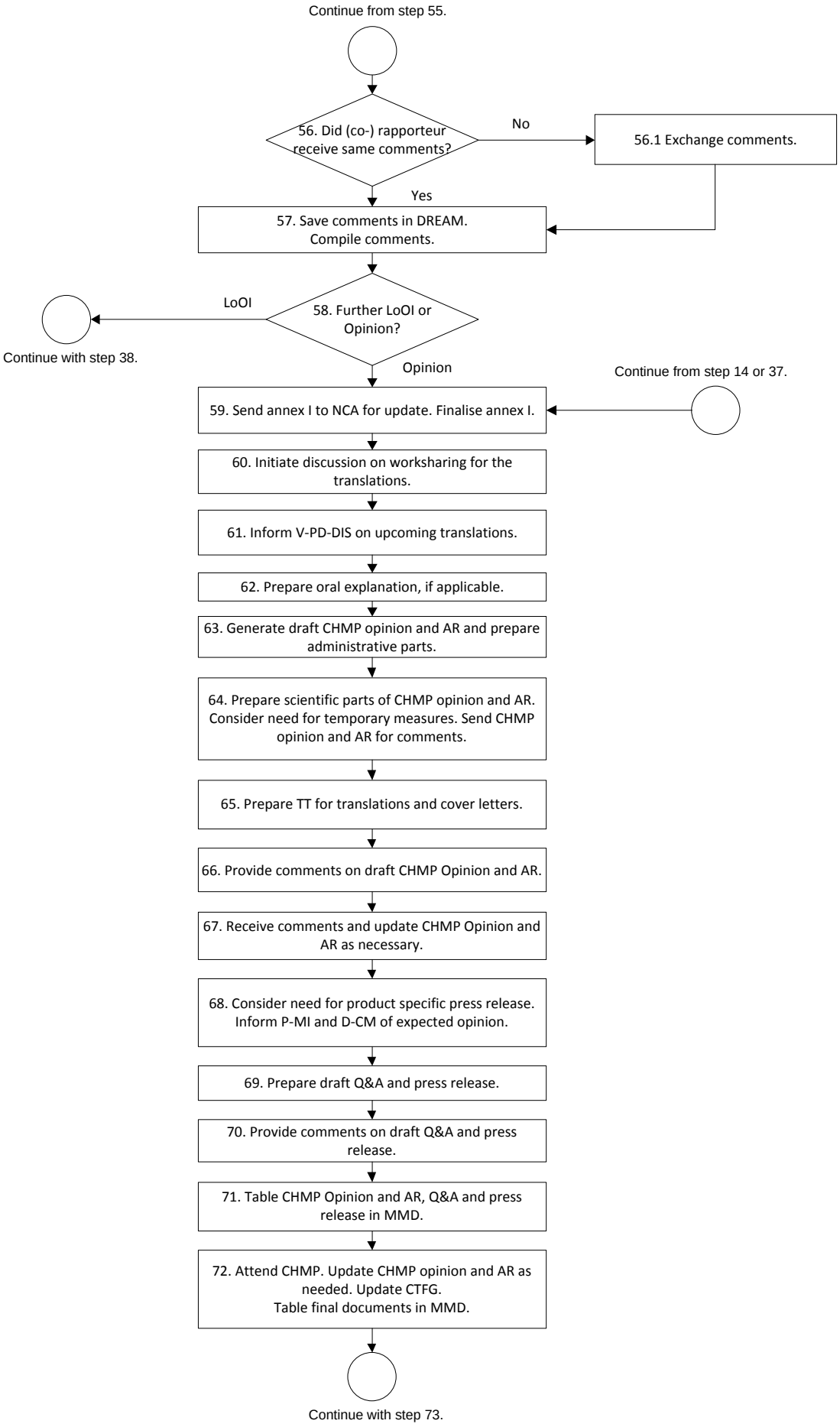
PhVWP	Pharmacovigilance Working Party of the CHMP
PIQ	Product Information Quality review
P-MI-PIN	Public Information and Stakeholder Networking Section
P-MI-PIQ	Product Information Quality Section
P-PV-DCM	Data Collection and Management Section
P-PV-RM	Risk Management Section
P-R-CP	Community Procedures Section
P-R-RA	Regulatory Affairs Section
PTL	Product Team Leader for the procedure
PTM	Product Team Member
PTM-RA	Product team member from P-R-RA
PTM-RM	Product team member from P-PV-RM
Q&A	Questions and Answers document
QRD	Quality Review of Documents
r-MF	Referral master file
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

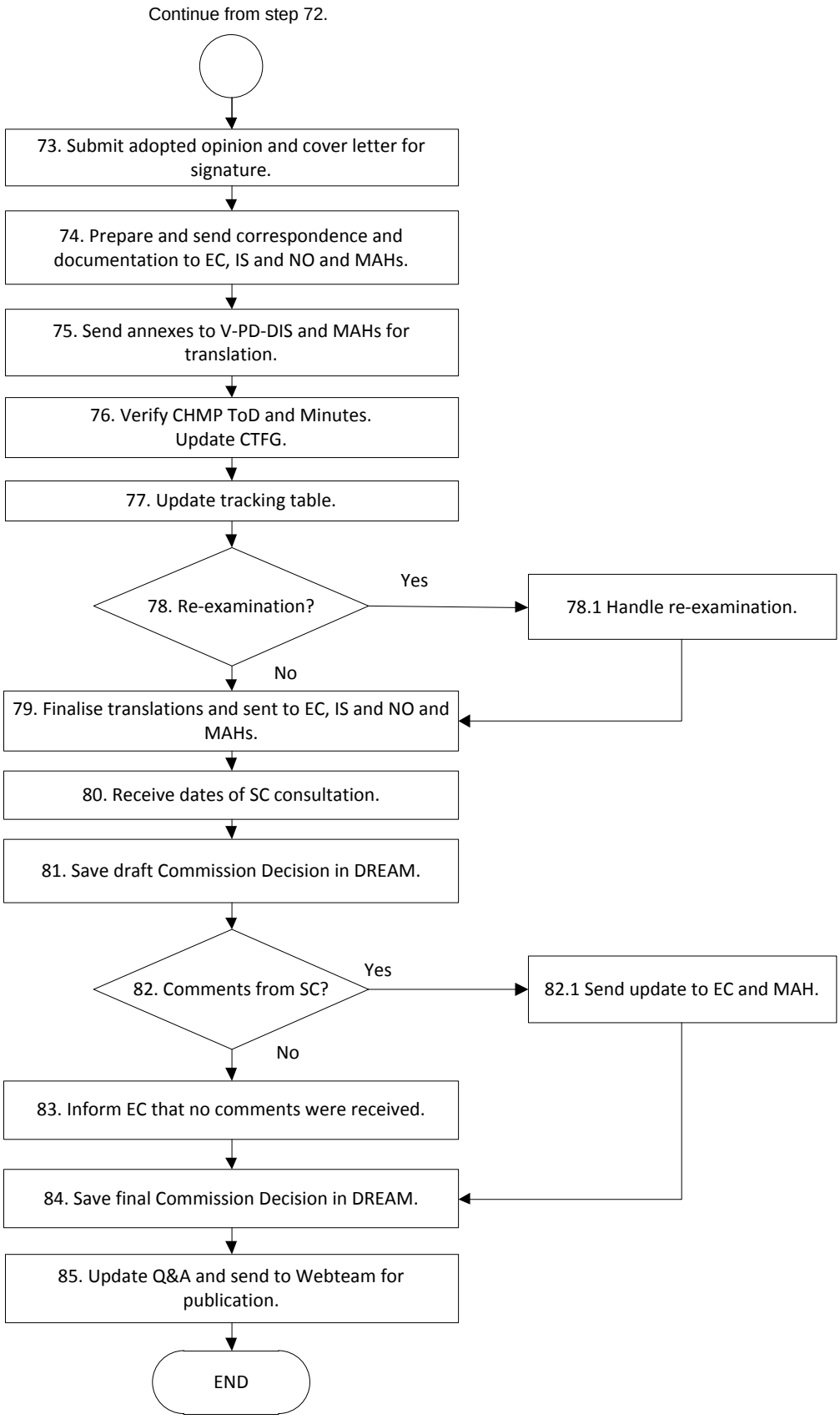
8. Process map(s)/ flow chart(s)




Continue from step 18.
19. Include start of procedure in CHMP meeting highlights.
20. Verify CHMP ToD and Minutes.
21. Prepare draft letters.
22. Send letters.
23. Clarification needed on LoR?
Yes
23.1 Request updated LoR
No
24. Prepare/update table of contact persons and grouping.
25. Update tracking table.
26. Receive responses to LoQ.
27. Inform PTM-RM.
28. Compile a tabular overview. Save responses in DREAM.
29. Forward table to (co-)rapporteur.
30. (Co-)rapporteur received same responses?
No
30.1 Request and/or provide missing information.
Yes
31. Receive AR on responses from (co-) rapporteur.
32. Redact AR.
33. Send redacted AR to MAHs.
34. Receive comments from CHMP members on AR on responses.
35. Did (co-) rapporteur receive same comments?
No
35.1 Exchange comments.
Yes
36. Save comments in DREAM. Compile comments.
Continue with step 37.


Continue from step 36.
37. Need for LoOI?
No
Go to step 59.
Yes
38. Generate draft LoOI and TT.
39. Prepare scientific parts of LoOI. Discuss LoOI. Send for comments.
40. Receive comments from (co-) rapporteur. Amend accordingly.
41. Table draft LoOI and TT in MMD.
42. Attend CHMP meeting. Update CTFG. Revise LoOI. Table LoOI and TT in MMD.
43. Prepare letter with LoOI and TT.
44. Send letter.
45. Verify CHMP ToD and Minutes.
46. Update tracking table.
47. Arrange for oral explanation.
48. Receive responses to LoOI.
49. Update tabular overview. Save responses in DREAM.
50. Forward table to (co-)rapporteur.
51. (Co-)rapporteur received same responses?
No
51.1 Request and/or provide missing information.
Yes
52. Receive AR on responses from (co-) rapporteur.
53. Redact AR.
54. Send redacted AR to MAHs.
55. Receive comments from CHMP members on AR on responses.
Continue with step 56.


Continue from step 55.
56. Did (co-) rapporteur receive same comments?
No
56.1 Exchange comments.
Yes
57. Save comments in DREAM. Compile comments.
58. Further LoOI or Opinion?
LoOI
Continue with step 38.
Opinion
Continue from step 14 or 37.
59. Send annex I to NCA for update. Finalise annex I.
60. Initiate discussion on worksharing for the translations.
61. Inform V-PD-DIS on upcoming translations.
62. Prepare oral explanation, if applicable.
63. Generate draft CHMP opinion and AR and prepare administrative parts.
64. Prepare scientific parts of CHMP opinion and AR. Consider need for temporary measures. Send CHMP opinion and AR for comments.
65. Prepare TT for translations and cover letters.
66. Provide comments on draft CHMP Opinion and AR.
67. Receive comments and update CHMP Opinion and AR as necessary.
68. Consider need for product specific press release. Inform P-MI and D-CM of expected opinion.
69. Prepare draft Q&A and press release.
70. Provide comments on draft Q&A and press release.
71. Table CHMP Opinion and AR, Q&A and press release in MMD.
72. Attend CHMP. Update CHMP opinion and AR as needed. Update CTFG. Table final documents in MMD.
Continue with step 73.


Continue from step 72.
73. Submit adopted opinion and cover letter for signature.
74. Prepare and send correspondence and documentation to EC, IS and NO and MAHs.
75. Send annexes to V-PD-DIS and MAHs for translation.
76. Verify CHMP ToD and Minutes. Update CTFG.
77. Update tracking table.
78. Re-examination?
Yes
78.1 Handle re-examination.
No
79. Finalise translations and sent to EC, IS and NO and MAHs.
80. Receive dates of SC consultation.
81. Save draft Commission Decision in DREAM.
82. Comments from SC?
Yes
82.1 Send update to EC and MAH.
No
83. Inform EC that no comments were received.
84. Save final Commission Decision in DREAM.
85. Update Q&A and send to Webteam for publication.
END

9. Procedure

Step	Action	Responsibility
Before the start of procedure		
1	Receive a Rapid Alert from a MS notifying a procedure under Article 107 and the accompanying AR. Forward the documents received electronically (Rapid Alert and AR) to the SH P-R-CP.	P-PV-DCM
2	Identify a Scientific Administrator from P-R-CP to act as PTL for the procedure and check possible conflicts of interest according to SOP/EMA/0101. Inform the appointed PTL about the procedure and the appointment as PTL for the procedure. Forward documents received to the PTL. Assign responsibilities to an administrative assistant and PTL secretary from P-R-CP and inform them accordingly.	SH P-R-CP
3	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
4	Appoint the PTM-RA and inform the PTM-RA and PTL accordingly.	SH P-R-RA
5	Inform V-PD-DBM and V-PD-BUS on the triggered procedure for appropriate actions (see template).	PTL secretary
6	Allocate a procedure number with 'A-107' 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 107 (see SOP/H/3193).	V-PD-DBM V-PD-DBM V-PD-BUS
7	Inform the CHMP secretariat that a procedure under Article 107 has been triggered and that the Rapid Alert needs to be added to the agenda of the next CHMP meeting. Circulate the Rapid Alert, the accompanying AR and any other background information, if relevant, to all CHMP members. Table the same documents in MMD for discussion at CHMP.	PTL PTL secretary
8	Request information from the NCA contact points on the name and contact details of MAHs, product name(s) and information about the product(s) included in the procedure (see template, see WIN/H/3145). *Note: Ongoing MAAs are not covered by an Article 107 procedure.*	Administrative assistant
9	Receive and verify the answers from the NCA contact points namely as regards pharmaceutical form(s), strength(s), address of	Administrative

Step	Action	Responsibility
	MAH(s). • If clarification is needed, go to step 9.1. • If no clarification is needed, go to step 10. Compile the information received in a draft Annex I table (see template).	assistant
9.1	Request clarification from the NCA contact points. Go to step 9.	Administrative assistant
10	Record and track the procedure in the tracking table.	Administrative assistant
11	Organise an internal meeting with the PTL, PTL secretary, Administrative assistant, PTMs and D-LS if applicable.	PTL secretary
12	Attend the internal meeting to check the Rapid Alert and to discuss the procedure.	PTL,PTMs, D-LS, Administrative assistant, PTL secretary
13	Include information about the start of the procedure in the Early Notification System (see SOP/H/3346).	PTL
Start of procedure		
14	Attend the discussion on the procedure at the PhVWP and CHMP meeting. Ensure assignment of a (co-)rapporteur (see SOP/H/3176). Discuss the urgency of the matter and if there is a need for an opinion to be adopted in the same month. • If yes, go to step 59. • If no, go to step 15.	PTL
15	Generate the draft LoQ(s), TT and cover letter (see templates) and prepare the administrative parts of the draft LoQ and TT. Save the documents in the procedure folder in DREAM.	PTL secretary
16	Prepare the scientific parts of the draft LoQ(s).	PTL
17	Discuss the draft LoQ(s) and TT for the procedure with the (co-) rapporteur prior to CHMP discussion. Note that: • the assessment report from the triggering MS is always part of the LoQ and the MAHs are asked to comment on it; • an additional LoQ addressed to the MS(s) or third parties (e.g. investigators, patients organisations) can be needed for	PTL

Step	Action	Responsibility
	collection of additional relevant information for assessment; • based on the urgency of the matter, the CHMP may agree that the LoQ will only be addressed to the brand leader. Liaise with PTM-RM in case the draft LoQ(s) refers to risk management of safety concerns. Liaise with the PTM-RA, if required. Liaise with the Compliance and Inspection (P-CI) Sector in case the Clinical Trials Falicitation Group (CTFG) needs to be contacted. Table the LoQ(s) and TT in MMD for discussion at CHMP.	PTL secretary
18	Attend the discussion on the procedure at the CHMP meeting. Amend the draft LoQ(s) 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
19	Include the start of procedure in the annexes to the CHMP meeting highlights (see WIN/H/3234).	PTL
20	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL
21	Prepare the cover letter on the start of procedure and LoQ(s) and requesting LoR (see templates).	PTL secretary
22	After signature by the SH P-R-CP, send the letters together with the LoQ(s) including the AR from the triggering MS and TT for the procedure to all MAHs, MSs and third parties as applicable in accordance with WIN/H/3145 and verify receipt of the documents. In case it is not possible to contact the MAH, inform the relevant MS that the MAH will be excluded from the procedure (see template).	PTL secretary
23	Receive the LoR from the MAHs. Verify that the letters are correct. • If not correct, go to step 23.1. • If correct, go to step 24.	Administrative assistant
23.1	Request an updated LoR after consultation with the D-LS, if necessary. Go to step 23.	Administrative assistant
24	Prepare/update the table of contact persons from the MAHs including the grouping of MAHs based on the LoR.	Administrative assistant

Step	Action	Responsibility
25	Update the tracking table based on the CHMP ToD.	Administrative assistant
Receipt of responses to list of questions		
26	Receive responses to the LoQs from the MAHS, MS and third parties as applicable. Forward the responses to the PTL and PSM.	V-PD-BUS
27	Inform the PTM-RM about the receipt of responses, if applicable.	PTL
28	Compile a tabular overview of the MAHs/groups of MAHs and of MSs/third parties (e.g. investigators, patients organisations) (if applicable) which submitted responses and checking the date of receipt. Save the responses and the tabular overview in the procedure folder in DREAM.	PTL secretary
29	Forward the table to the (co-)rapporteur and enquire whether they have received the same responses.	PTL
30	Receive feedback from the (co-)rapporteur. • If (co-)rapporteur have not received the same response(s), go to step 30.1. • If (co-)rapporteur have received the same response(s), go to step 31.	PTL
30.1	Request and/or provide the missing information. Upon receipt of information that has not yet been provided to the Agency, update the tabular overview and go to step 29.	PTL
31	Receive (co-)rapporteur's ARs on the responses. Forward the ARs to the PTL and PSM. Save the ARs in the procedure folder in DREAM.	V-PD-BUS PTL secretary
32	Inform the PTM-RM about the receipt of the ARs, if applicable. Redact any confidential information in the ARs (see WIN/EMA/0070) and save the redacted version in the procedure folder in DREAM.	PTL
33	Send the redacted (co-)rapporteur's ARs by Eudralink to the MAHs (see template and WIN/H/3145) and verify receipt of documents.	PTL secretary
34	Receive comments on the (co-)rapporteur's ARs from other CHMP members. Forward the comments to the PTL and PSM.	V-PD-BUS
35	Inform the PTM-RM about the receipt of comments, if applicable.	PTL

Step	Action	Responsibility
	Check with the (co-)rapporteur whether they have received comments and if the comments received are the same. • If yes, go to step 36. • If no, go to step 35.1.	
35.1	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
36	Save the CHMP members' comments in the procedure folder in DREAM. Forward compiled CHMP members' comments to the PSM.	PTL secretary
37	Check with the (co-)rapporteur if a LoOI is required and inform the CHMP secretariat accordingly. *Noting the urgency of the issues raised, this would only be applicable in very exceptional cases.* • If yes, go to step 38. • If no, go to Opinion phase - step 59.	PTL
List of outstanding issues		
38	Generate the draft LoOI (see template) and prepare the administrative parts of the draft LoOI. Generate the TT. Save the draft LoOI and TT in the procedure folder in DREAM.	PTL secretary
39	Prepare the scientific parts of the draft LoOI. Discuss the draft LoOI with the (co-)rapporteur. Note that based on the urgency of the matter, the CHMP may agree that the LoOI will only be addressed to the brand leader. Discuss with the (co-)rapporteur whether there is a need for an oral explanation to the CHMP and incorporate if necessary the specific issues to be addressed at an oral explanation in the LoOI. Liaise with the PTM-RM in case the draft LoOI refers to risk management of safety concerns. Liaise with the PTM-RA, if required. Send the draft LoOI and TT to the (co-)rapporteur for comments and/or agreement.	PTL
40	Receive comments/agreement from the (co-)rapporteur on the draft LoOI and TT. Amend the documents accordingly.	PTL
41	Table the draft LoOI and TT in MMD for discussion at CHMP.	PTL secretary

Step	Action	Responsibility
42	Attend the discussion on the procedure at the CHMP meeting. Update the CTFG on the status of the procedure in liaison with the P-CI Sector, if applicable. Revise the draft LoOI and TT if necessary. Table the revised documents in MMD for adoption by CHMP.	PTL PTL secretary
43	Prepare the cover letter on 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 CHMP secretariat about the need for an oral explanation.	PTL secretary
44	After signature by the SH P-R-CP, send the cover letter and documentation to the MAHs, MSs and third parties as applicable (cc (co-)rapporteur) in accordance with WIN/H/3145 and verify receipt of documents.	PTL secretary
45	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL
46	Update the tracking table based on the CHMP ToD.	Administrative assistant
47	Arrange a time slot for the oral explanation, if necessary. Inform the MAHs 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
Receipt of responses to list of outstanding issues		
48	Receive responses to the LoOI from the MAHS, MS and third parties as applicable. Forward the responses to the PTL and PSM. Inform the PTM-RM about receipt of responses, if applicable.	V-PD-BUS PTL
49	Update the tabular overview with the responses received. Save the responses in the procedure folder in DREAM.	PTL secretary
50	Forward the table to (co-)rapporteur and enquire whether they have received the same responses.	PTL
51	Receive feedback from (co-)rapporteur.	PTL

Step	Action	Responsibility
	• If (co-)rapporteur has not received the same response(s) go to step 51.1. • If (co-)rapporteur has received the same response(s) go to step 52.	
51.1	Request and/or provide the missing information. Upon receipt of information that has not yet been provided to the Agency, update the tabular overview and go to step 50.	PTL secretary
52	Receive (co-)rapporteur's AR on the responses to the LoOI. Forward the AR to the PTL and PSM. Save the AR in the procedure folder in DREAM. Inform the PTM-RM about the receipt of AR, if applicable.	V-PD-BUS PTL secretary PTL
53	Redact any confidential information in the AR (see WIN/EMA/0070) and save the redacted version in the procedure folder in DREAM.	PTL
54	Send the redacted (co-)rapporteur's AR by Eudralink to the MAHs (see template and WIN/H/3145) and verify receipt of documents.	PTL secretary
55	Receive comments on the (co-)rapporteur's AR from other CHMP members. Forward the comments to the PTL and PSM.	V-PD-BUS
56	Inform the PTM-RM about the comments received, if applicable. Check with the (co-)rapporteur whether they have received comments and if the comments received are the same. • If yes, go to step 57. • If no, go to step 56.1.	PTL
56.1	Send the (co-)rapporteur any comment that they have not received and/or ask them to send any comments that have not been sent to the Agency.	PTL
57	Save the CHMP members' comments in the procedure folder in DREAM. Forward compiled CHMP members' comments to the PSM.	PTL secretary
58	Address the status of the comments and possible oral explanation with the CHMP Chairman and Vice-Chairman during the pre-CHMP teleconference, if applicable. Check with the (co-)rapporteur whether the procedure is going for opinion or for a further LoOI. • If a further LoOI is necessary, go to step 38. • If an Opinion is foreseen, go to step 59.	PTL

Step	Action	Responsibility
Opinion		
59	1 week before the CHMP meeting, send the latest version of annex I to the NCA contact points for confirmation and validation of the information. Remind the MSs that no new MA/MAHs/products can be added to the procedure and that the pharmaceutical form(s) must be in line with the standard terms. Follow-up with a reminder if necessary. Receive answers from the NCA contact points. Update annex I with comments received, if necessary.	Administrative assistant
60	In case several MAHs were involved during the assessment of the procedure, initiate discussions on the work sharing process for translations with those MAHs.	PTL
61	Inform V-PD-DIS (translationsrequests@ema.europa.eu) about up-coming translations (annex II and IV).	PTL secretary
62	If an oral explanation is required, make preparations for the oral explanation as per the CHMP guidance to applicants on CHMP oral explanations CPMP/2390/01.	PTL
63	Generate the draft CHMP opinion and assessment report, including relevant annexes (see templates). Prepare the administrative parts of the draft CHMP opinion and assessment report, including relevant annexes. Save the draft CHMP opinion and assessment report, including relevant annexes, in the procedure folder in DREAM.	PTL secretary
64	Prepare the scientific parts of the draft CHMP opinion and assessment report, including the scientific conclusions, relevant annexes and grounds sustaining the proposed action. Consider the need (or not) for the EC to adopt temporary measures and/or for follow-up actions e.g. triggering an Article 31 procedure, conditions for lifting suspension, if applicable. Provide the SH P-R-CP, PTM-RA, PTM-RM and D-LS-LA, if applicable, with the draft documents for review if possible at the latest by Wednesday the week before the CHMP meeting. Send the draft CHMP opinion and assessment report to the (co-) rapporteur for consideration and review. Update the Early Notification table (see SOP/H/3346) and attend the Product Oversight Meeting.	PTL
65	Prepare the draft TT for translations and draft letters for sending out the opinion, including the sign-off slip for checking and signing	PTL secretary

Step	Action	Responsibility
	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.	
66	Provide comments on the draft CHMP opinion and assessment report by Friday the week before CHMP meeting, if applicable.	SH P-R-CP, PTMs
67	Receive comments from the SH P-R-CP, PTMs and (co-)rapporteur and update the draft CHMP opinion and assessment report, as necessary.	PTL
68	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
69	Prepare a draft press release (according to SOP/EMA/0111), if appropriate. Prepare a draft Q&A document (according to SOP/EMA/0111).	D-CM P-MI-PIN
70	Provide comments on the draft press release to D-CM and on the draft Q&A document to P-MI-PIN.	PTL
71	Table the draft opinion and assessment report as well as the draft Q&A and draft press release, if applicable, in MMD for discussion at CHMP.	PTL secretary
72	Attend the discussion at the CHMP meeting including the oral explanation if applicable. Update the CHMP opinion and assessment report as needed to reflect the CHMP discussions, the oral explanation (if applicable), the voting and any divergent positions. Update the CTFG on the status of the procedure in liaison with the P-CI Sector. Table the revised documents in MMD for adoption by CHMP.	PTL PTL secretary
73	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 MAHs and EC if necessary.	PTL secretary
Post opinion phase		
74	Prepare the correspondence (see template) and documentation to be sent to the EC, IS and NO and MAHs (cover letter, CHMP opinion and assessment report, together with all annexes and TT for translations) in accordance with WIN/H/3145. After signature by the SH P-R-CP, send out the correspondence and	PTL secretary

Step	Action	Responsibility
	documentation to EC, IS and NO and to MAHs (cc (co-)rapporteur), in accordance with the Action list for product secretaries, and verify receipt of documents.	
75	Send annexes I, II, III and IV (if applicable) of the CHMP opinion to V-PD-DIS (translationsrequests@ema.europa.eu) and the MAHs for translation, in accordance with SOP/EMA/0048.	PTL secretary
76	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat, if necessary. Update the CTFG on the practical aspects of the outcomes of the procedure in liaison with the P-CI Sector.	PTL
77	Update the tracking table based on the CHMP ToD.	Administrative assistant
78	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 the opinion by the MAH. If yes, go to step 78.1. If no, go to step 79.	PTL
78.1	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 79.	PTL
79	Prepare the correspondence (see template) and documentation (final translations) to be sent to the EC, IS and NO and MAHs. After signature by the SH P-R-CP, send the documents to the EC, IS and No and the MAHs in accordance with WIN/H/3145 and verify receipt of documents.	PTL
Standing Committee and Commission decision phase		
80	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

Step	Action	Responsibility
81	Save the draft Commission Decision in the procedure folder in DREAM and forward the e-mail from the EC to the PSM.	PTL secretary
82	At the end of the SC phase, verify with the PTL if comments have been received. If yes, go to step 82.1. If no, go to step 83.	PTL secretary
82.1	Send the updated translations (if any) to the EC and MAHs on 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 84.	PTL secretary
83	Inform the EC that no comments were received.	PTL secretary
84	Receive information from the EC on the adoption of the final Commission Decision. Retrieve the final Commission Decision documents from the EC website and save them in the procedure folder in DREAM.	PTL secretary
Post Commission decision phase		
85	Update the Q&A by adding the date of the Commission Decision and send it to V-PD-DIS (translationsrequests@ema.europa.eu) for translation. Upon receipt of the Q&A translations from V-PD-DIS (translationsrequests@ema.europa.eu), prepare all documents for publication (see WIN/H/3205). Prepare the folder and sign off slip for publication. Send 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.