EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Article 29 procedures according to the Paediatric Regulation No 1901/2006		
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1. Purpose

To describe the procedure for handling of procedures under Article 29 of the Paediatric Regulation No. 1901/2006 as amended 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
- Human Medicines Special Areas Sector: Paediatric Medicines Section
- Pharmacovigilance and Risk Management Sector: Risk Management Section
- Quality of Medicines Sector
- Communications Sector
- Legal Service Sector
- Product Data Management Sector: Product and Application Business Support Section, Product Database Management Section, Document and Information Services Section
- Medical Information Sector: Product Information Quality Section, Public Information and Stakeholder Networking Section

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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 29 Paediatrics) and on the X:\ drive (X:\Templates\Filenew\H-Opin QRD).

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.

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 transmission slip for referral publications (Located at: Word/File/New/Transmissions Slips/TS – Referrals)

6. Related documents

Legislation

- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (http://ec.europa.eu/health/files/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf).
- Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (http://ec.europa.eu/health/files/eudralex/vol-1/reg_2006_1902/reg_2006_1902_en.pdf).
- 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).

Guidance documents

- Commission Guideline on the format and content of applications for agreement or modification of a Paediatric Investigation Plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies (2008/C 243/1) (http://www.ema.europa.eu/pdfs/human/paediatrics/Guideline_2008_C243_01.pdf path: Home \ Regulatory \ Human medicines \ Paediatric medicine \ Guidance \ Paediatric Investigation Plan (PIP) and waivers)
- Question and answers on the procedure of PIP compliance verification at EMA (EMA/PDCO/179892/2011) (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000088.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580025ea3# path: Home \ Regulatory \ Human medicines \ Paediatric medicine \ Application guidance \ Compliance)
- Information on medicines for children available on the Agency's website (http://www.ema.europa.eu/htms/human/paediatrics/introduction.htm path: Home \ Regulatory \ Human medicines \ Paediatric medicine)
- 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/pdfs/human/regaffair/239001en.pdf path: Home \ Regulatory \ Human medicines \ Pre-authorisation \ Guidance \ Application and Evaluation \ Evaluation)
- 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)
- Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents (EMEA/45422/2006) (http://www.ema.europa.eu/pdfs/human/euleg/4542206en.pdf path: Home \ Regulatory \ Human medicines \ Post-opinion \ EPAR)

SOPs and WINs

- SOP/EMA/0047 QRD post-opinion review of product information initial applications and Annex II applications
- SOP/EMA/0048 QRD post-opinion review of product information for post-authorisation procedures affecting the annexes, excluding Annex II applications
- WIN/EMEA/0070 Redaction of documents in relation to access to documents
- SOP/EMA/0073 PIQ-QRD pre-opinion review of product information for referral procedures and Art. 29 Paediatric procedures
- SOP/EMA/0101 Conducting checks for conflicts of interest of Agency employees assigned duties relating to medicinal products for human or veterinary use.

- SOP/EMA/0111 Preparation, dissemination and publication of safety-related EMA press releases and question-and-answer documents
- SOP/H/3101 Determination of fees (medicinal products for human use)
- SOP/H/3129 Organisation of Scientific Advisory Group (SAG) meetings and reporting of SAG position to the CHMP
- 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/H/3193 Master file for referrals
- 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/3347 Preparation of 'lines-to-take' documents for use within the EU regulatory network to answer external queries in a consistent manner
- WIN/H/3111 Pre-submission meetings
- WIN/H/3136 CHMP eligibility report and eligibility outcome letters
- SOP/H/3133 CHMP activities: meeting organisation, document distribution and related activities
- SOP/H/3181 Assessment of similarity of medicinal products
- WIN/H/3234 Preparation for publication of annexes to the CHMP meeting highlights by the CHMP Secretariat and CP Section.

7. Definitions

Article 29 of Regulation (EC) No 1901/2006, as amended

The article 29 paediatric procedure is an optional procedure triggered by a marketing authorisation holder to apply for an extension of indication, new pharmaceutical form or new route of administration for use in the paediatric population for a product authorised according to Directive 2001/83/EC, as amended.

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 Quality of Medicines sector, the Paediatric Medicines Section, the Risk Management Section and the Legal Service Sector as appropriate.

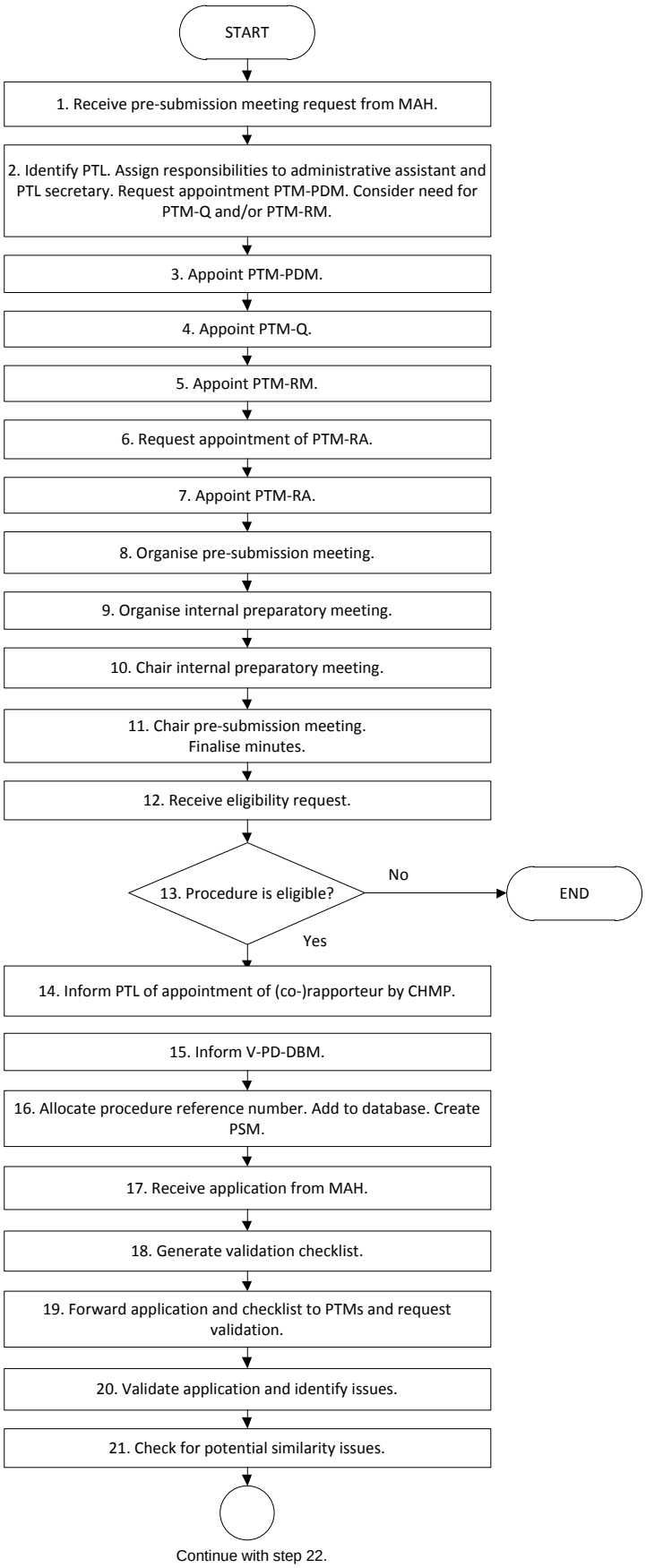
Abbreviations:

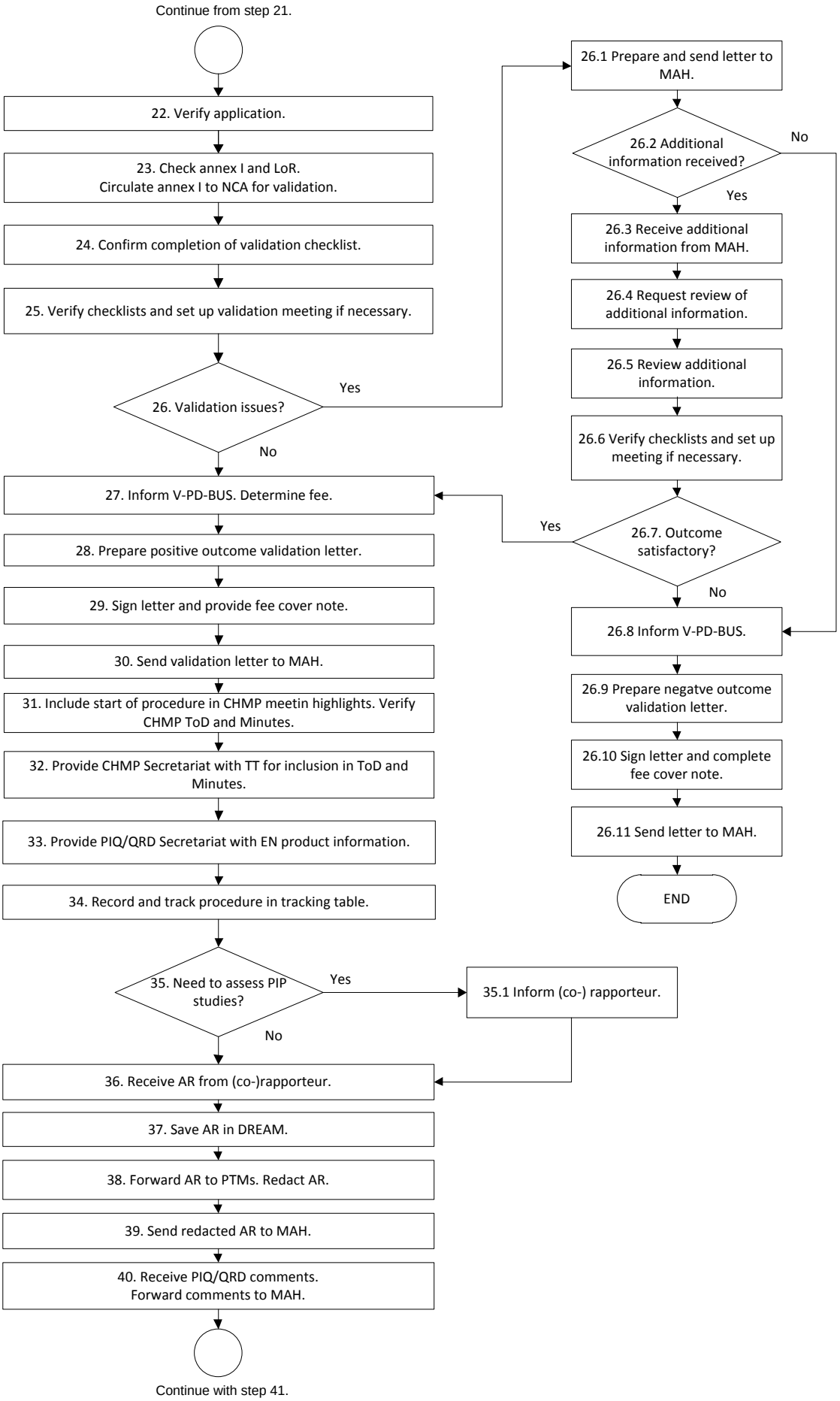
AR:	Assessment report
CdT:	Centre de Traduction
CHMP:	Committee for Medicinal Products for Human Use
D-CM:	Communications Sector
D-LS:	Legal service Sector
DREAM:	Document Records and Electronic Archive Management system

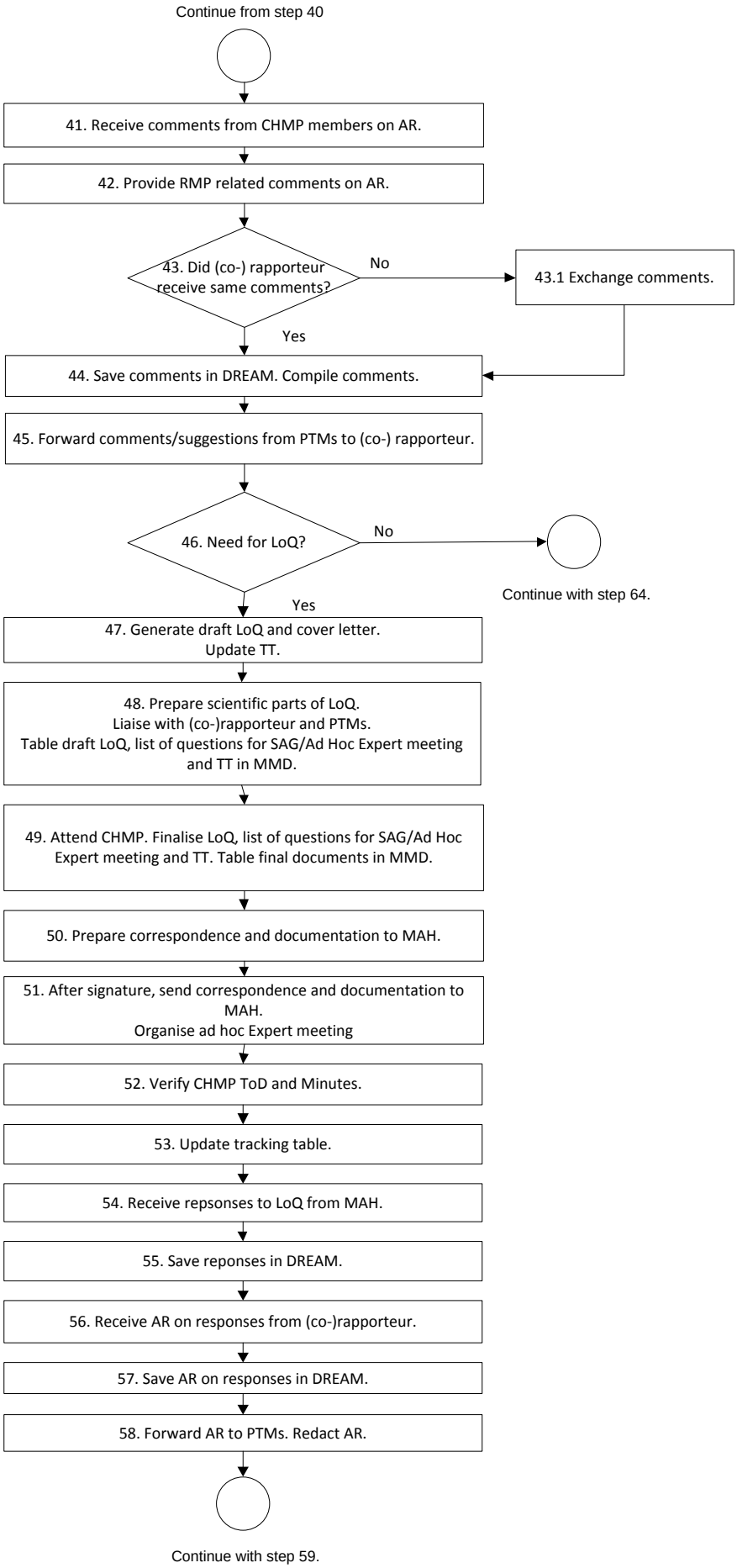
EC:	European Commission
EMA:	European Medicines Agency
EPAR:	European public assessment report
H-HM-OM:	Orphan Medicines Section
H-HM-PDM:	Paediatric Medicines Section
HoS:	Head of Sector
H-QM:	Quality of Medicines Sector
H-SE	Safety and Efficacy of Medicines Sector
LoOI:	List of outstanding issues
LoQ:	List of questions
LoR:	Letter of representation
MAH:	Marketing authorisation holder
MMD:	Meeting Management Document system
MS:	Member State
NCA:	National competent authority
P-MI-PIN:	Product Information and Stakeholder Networking Section
P-PV-RM:	Risk Management Section
P-R:	Regulatory, Procedural and Committee Support Sector
P-R-CP:	Community Procedures Section
P-R-RA:	Regulatory Affairs Section
PDCO:	Paediatric Committee
PIP:	Paediatric investigation plan
PIQ:	Product information quality review
POM	Product oversight meeting
PSM:	Product shared mailbox
PTL:	Product team leader for the procedure
PTM:	Product team member
PTM-PDM:	PTM from the Paediatric Medicines Section
PTM-Q:	PTM from the Quality of Medicines Sector
PTM-RA:	PTM from the Regulatory Affairs Section
PTM-RM:	PTM from the Risk Management Section
Q&A:	Question and answer
QRD:	Quality review of documents

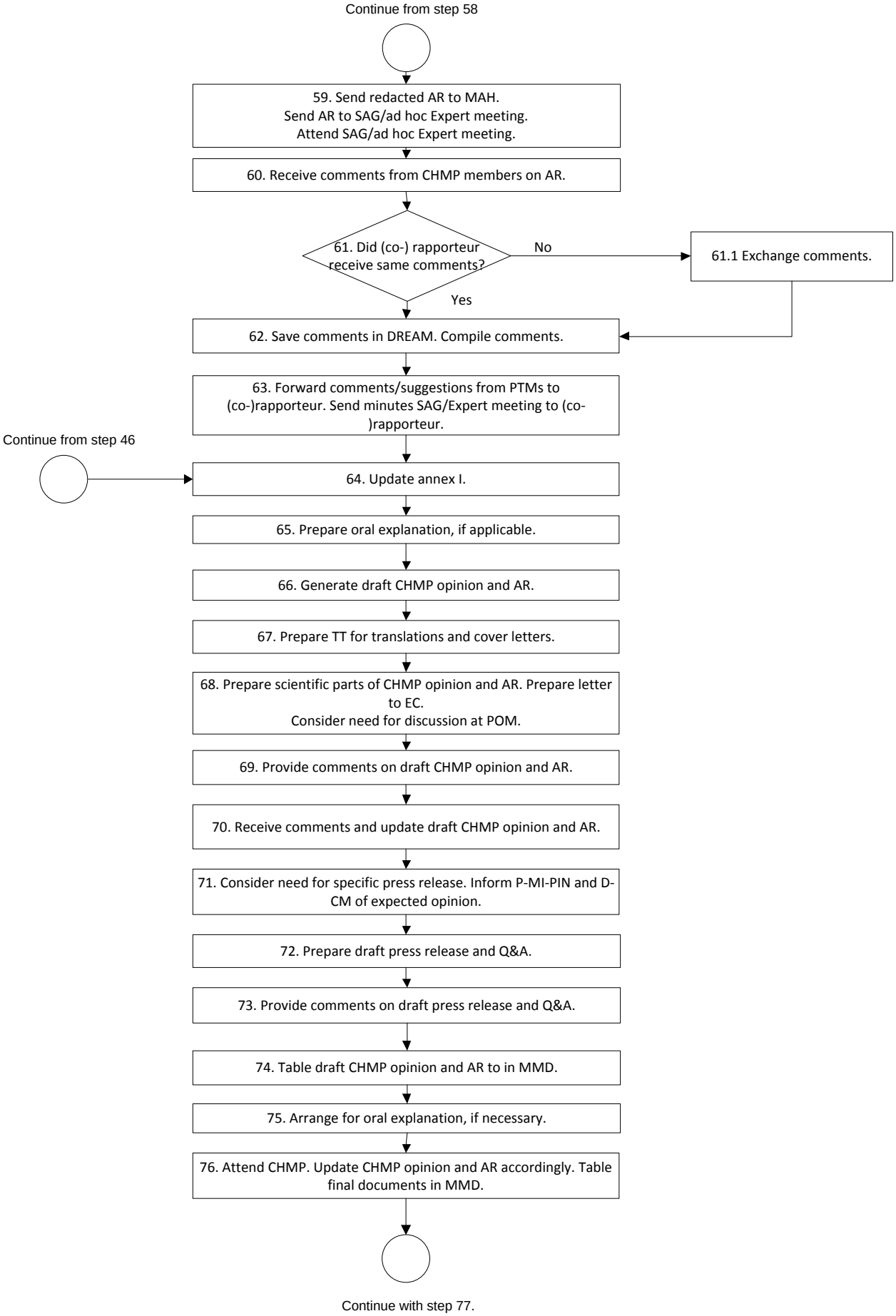
r-MF:	Referral master file
RMP:	Risk management plan
SAG:	Scientific Advisory Group
SC:	Standing Committee
SH:	Section Head
SOP:	Standard operating procedure
ToD:	Table of decisions
TT:	Time table
V-PD-BUS:	Product and Application Business Support Section
V-PD-DBM:	Product Database Management Section
V-PD-DIS:	Document and Information Services Section
WIN:	Work instructions

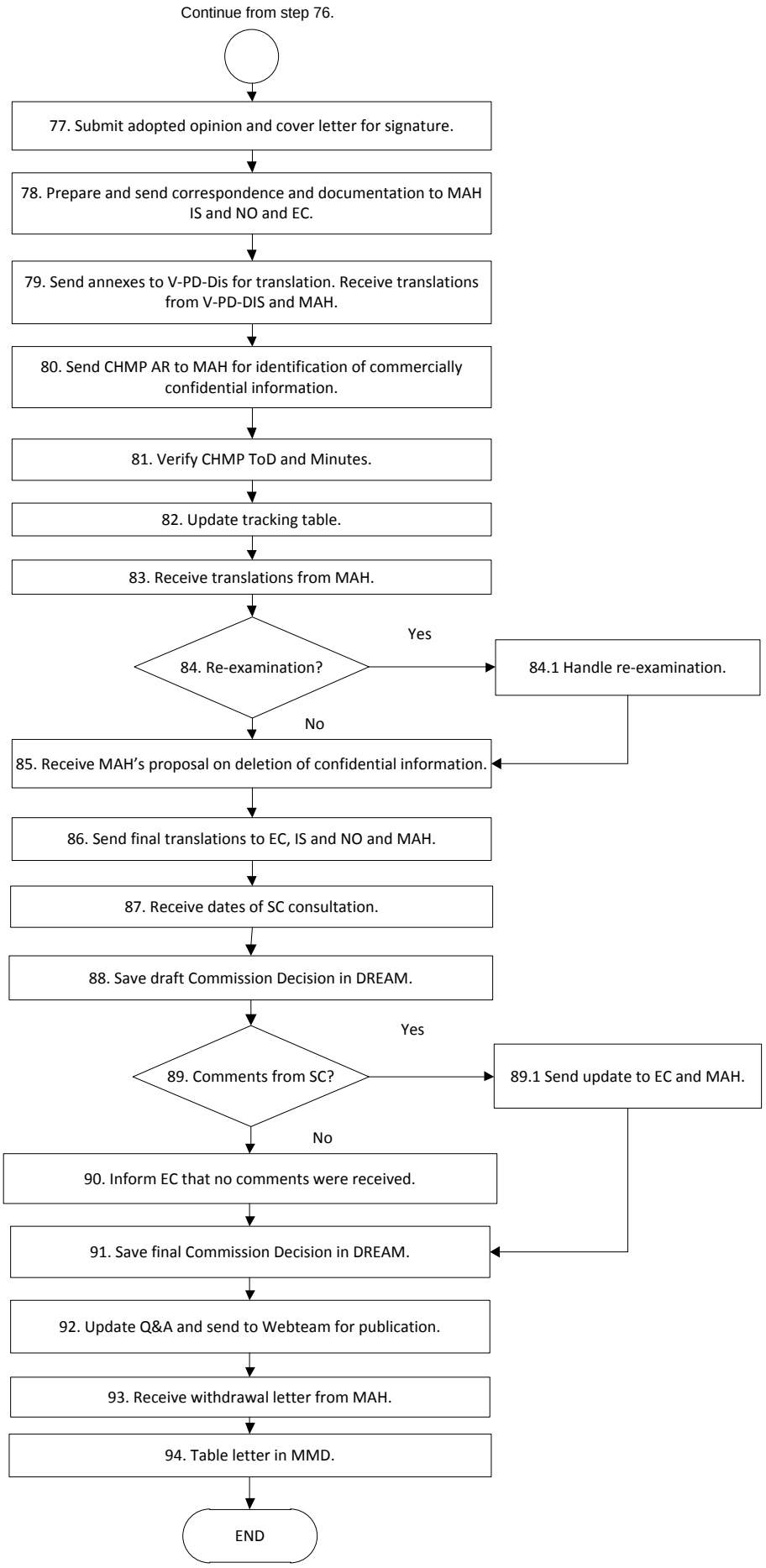
8. Process map(s)/ flow chart(s)




Continue from step 21.
22. Verify application.
23. Check annex I and LoR.
Circulate annex I to NCA for validation.
24. Confirm completion of validation checklist.
25. Verify checklists and set up validation meeting if necessary.
26. Validation issues?
Yes
No
26.1 Prepare and send letter to MAH.
26.2 Additional information received?
No
Yes
26.3 Receive additional information from MAH.
26.4 Request review of additional information.
26.5 Review additional information.
26.6 Verify checklists and set up meeting if necessary.
26.7. Outcome satisfactory?
Yes
No
26.8 Inform V-PD-BUS.
26.9 Prepare negatve outcome validation letter.
26.10 Sign letter and complete fee cover note.
26.11 Send letter to MAH.
END
27. Inform V-PD-BUS. Determine fee.
28. Prepare positive outcome validation letter.
29. Sign letter and provide fee cover note.
30. Send validation letter to MAH.
31. Include start of procedure in CHMP meetin highlights. Verify CHMP ToD and Minutes.
32. Provide CHMP Secretariat with TT for inclusion in ToD and Minutes.
33. Provide PIQ/QRD Secretariat with EN product information.
34. Record and track procedure in tracking table.
35. Need to assess PIP studies?
Yes
No
35.1 Inform (co-) rapporteur.
36. Receive AR from (co-)rapporteur.
37. Save AR in DREAM.
38. Forward AR to PTMs. Redact AR.
39. Send redacted AR to MAH.
40. Receive PIQ/QRD comments.
Forward comments to MAH.
Continue with step 41.


Continue from step 40
41. Receive comments from CHMP members on AR.
42. Provide RMP related comments on AR.
43. Did (co-) rapporteur receive same comments?
No
43.1 Exchange comments.
Yes
44. Save comments in DREAM. Compile comments.
45. Forward comments/suggestions from PTMs to (co-) rapporteur.
46. Need for LoQ?
No
Continue with step 64.
Yes
47. Generate draft LoQ and cover letter.
Update TT.
48. Prepare scientific parts of LoQ.
Liaise with (co-)rapporteur and PTMs.
Table draft LoQ, list of questions for SAG/Ad Hoc Expert meeting and TT in MMD.
49. Attend CHMP. Finalise LoQ, list of questions for SAG/Ad Hoc Expert meeting and TT. Table final documents in MMD.
50. Prepare correspondence and documentation to MAH.
51. After signature, send correspondence and documentation to MAH.
Organise ad hoc Expert meeting
52. Verify CHMP ToD and Minutes.
53. Update tracking table.
54. Receive repsonses to LoQ from MAH.
55. Save reponses in DREAM.
56. Receive AR on responses from (co-)rapporteur.
57. Save AR on responses in DREAM.
58. Forward AR to PTMs. Redact AR.
Continue with step 59.


Continue from step 58
59. Send redacted AR to MAH.
Send AR to SAG/ad hoc Expert meeting.
Attend SAG/ad hoc Expert meeting.
60. Receive comments from CHMP members on AR.
61. Did (co-) rapporteur receive same comments?
No
61.1 Exchange comments.
Yes
62. Save comments in DREAM. Compile comments.
63. Forward comments/suggestions from PTMs to (co-)rapporteur. Send minutes SAG/Expert meeting to (co-)rapporteur.
Continue from step 46
64. Update annex I.
65. Prepare oral explanation, if applicable.
66. Generate draft CHMP opinion and AR.
67. Prepare TT for translations and cover letters.
68. Prepare scientific parts of CHMP opinion and AR. Prepare letter to EC.
Consider need for discussion at POM.
69. Provide comments on draft CHMP opinion and AR.
70. Receive comments and update draft CHMP opinion and AR.
71. Consider need for specific press release. Inform P-MI-PIN and D-CM of expected opinion.
72. Prepare draft press release and Q&A.
73. Provide comments on draft press release and Q&A.
74. Table draft CHMP opinion and AR to in MMD.
75. Arrange for oral explanation, if necessary.
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 MAH IS and NO and EC.
79. Send annexes to V-PD-Dis for translation. Receive translations from V-PD-DIS and MAH.
80. Send CHMP AR to MAH for identification of commercially confidential information.
81. Verify CHMP ToD and Minutes.
82. Update tracking table.
83. Receive translations from MAH.
84. Re-examination?
Yes
84.1 Handle re-examination.
No
85. Receive MAH's proposal on deletion of confidential information.
86. Send final translations to EC, IS and NO and MAH.
87. Receive dates of SC consultation.
88. Save draft Commission Decision in DREAM.
89. Comments from SC?
Yes
89.1 Send update to EC and MAH.
No
90. Inform EC that no comments were received.
91. Save final Commission Decision in DREAM.
92. Update Q&A and send to Webteam for publication.
93. Receive withdrawal letter from MAH.
94. Table letter in MMD.
END

9. Procedure

Step	Action	Responsibility
Before the start of procedure – pre-submission meeting 6 months before submission		
1	Receive the pre-submission meeting request for an Art. 29 paediatric procedure from the MAH. Forward documents received electronically to the SH P-R-CP. Create subfolders in DREAM under 01. Evaluation of medicines\Referrals\H - Article 29 Paediatric and save any documents received on CD-ROM (see SOP/H/3193).	V-PD-BUS
2	Identify a scientific administrator from P-R-CP to act as PTL for the upcoming Art. 29 Paediatric 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. Assign responsibilities to an administrative assistant and PTL secretary from P-R-CP and inform them accordingly. Inform the SH H-HM-PDM about the receipt of the pre-submission request from the MAH and request the nomination of a PTM-PDM. 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. Consider the need for involvement of a PTM-RM. If involvement is needed, contact the SH P-PV-RM and request the nomination of a PTM-RM.	SH P-R-CP
3	Appoint the PTM-PDM and inform the PTM-PDM and PTL accordingly.	SH H-HM-PDM
4	Appoint the PTM-Q and inform the PTM-Q and PTL accordingly.	SH H-QM
5	Appoint the PTM-RM and inform the PTM-RM and PTL accordingly.	SH P-PV-RM
6	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
7	Appoint the PTM-RA and inform the PTM-RA and PTL accordingly.	SH P-R-RA
8	Organise the pre-submission meeting in accordance with WIN/H/3111.	V-PD-BUS
9	Organise an internal preparatory meeting (at least 1 day prior to the pre-submission meeting) with relevant PTMs, if necessary.	PTL Secretary
10	Chair the internal preparatory meeting.	PTL
11	Chair the pre-submission meeting and request minutes of the	PTL

Step	Action	Responsibility
	meeting from the MAH. Receive the draft minutes from the MAH and forward them to the EMA attendees for comments. Finalise the minutes, integrating comments received from the EMA attendees, and send them to the MAH and the EMA attendees.	
Before the start of procedure – eligibility request 5 months before submission		
12	Receive the eligibility request from the MAH. Forward documents received electronically to the CHMP secretariat and PTL.	V-PD-BUS
13	Add the request for eligibility to the agenda of the next CHMP meeting. Subsequent to the discussion at CHMP, inform the MAH and PTL about the outcome of the eligibility in accordance with WIN/H/3136. If the procedure is eligible, continue with step 14. If the procedure is not eligible, end of procedure.	CHMP secretariat
14	Add the request for appointment of a rapporteur and co-rapporteur to the agenda of the next CHMP meeting. Subsequent to the discussion at CHMP, inform the PTL about the (co-) rapporteur appointment.	CHMP secretariat
15	Inform V-PD-DBM about the eligibility of the procedure.	PTL secretary
16	Allocate a procedure reference number with 'A-29-PAE' as prefix. Add the procedure to the referral database. Create a PSM for the procedure.	V-PD-PDM
Submission and validation phase		
If at any time during the evaluation procedure the MAH decides to withdraw the application, go to step 93.		
17	Receive the application from the MAH. Forward the application documents received electronically to the PTL and PSM. Request the PTL to determine the fee for the application by completing the appropriate fee cover note.	V-PD-BUS
18	Generate and save the validation checklist in the procedure folder in DREAM.	PTL
19	Forward the application and validation checklist to PTMs as appropriate, indicating the timeline for validation (15 working days).	PTL

Step	Action	Responsibility
20	Validate the documentation and identify any difficulties or issues, which would prevent validation of the dossier. Fill in the validation checklist.	PTL/PTMs
21	Check for potential similarity issues. Check the claimed indication for potential overlap with the indication of authorised orphan medicinal products using: • The community register of designated orphan medicinal products • SIAMED. If potential similarity is identified, see SOP/H/3181. If necessary, discuss the outcome of the overlap check with the relevant SH in H-SE and the SH H-HM-OM.	PTL
22	Verify whether the application includes: • An overview of the authorised products (annex I) in the different Member States. • A declaration that the products are protected either by a supplementary protection certificate under Regulation (EEC) No 1768/92, or by a patent which qualifies for the granting of the certificate. • Letters of representation (LoR). • Evidence that the PDCO has performed the PIP compliance check.	PTL
23	Check annex I and LoR. Circulate annex I to MS involved requesting validation of the list.	Administrative assistant
24	Send an email to the PTL and other PTMs confirming completion of the checklist and the outcome of the validation in the concerned area of responsibility.	PTMs
25	Verify that all PTMs have completed their respective checklists. If needed, set up a validation meeting to discuss validation findings and agree on the issues that need to be raised to the MAH.	PTL
26	Have issues been identified during the validation? If issues have been identified, go to step 26.1. If no issues have been identified, go to step 27.	PTL
26.1	Prepare and send a letter to the MAH regarding the validation issues based on the completed validation checklists and the outcome of the validation meeting (see template).	PTL
26.2	Check if additional information from the MAH has been received.	PTL

Step	Action	Responsibility
	If yes, go to step 26.3. If no, go to step 26.8.	
26.3	Receive additional information from the MAH and forward it to the PTL and PSM.	V-PD-BUS
26.4	Forward the additional information to the PTMs as appropriate and request the PTMs to review the additional information within a set deadline.	PTL
26.5	Review the additional information and identify any difficulties or issues, which would prevent validation of the dossier. Update the validation checklist. Send an email to the PTL and other PTMs confirming update of the checklist and the outcome of the validation in the concerned area of responsibility.	PTMs
26.6	Verify that all PTMs have updated their respective checklists. If needed, set up a validation meeting to discuss final validation findings.	PTL
26.7	Is the outcome of the validation satisfactory? If yes, go to step 27. If not, go to step 26.8.	PTL
26.8	**Negative outcome of validation** Upon the MAH's failure to provide the requested additional information or an unsatisfactory outcome of the validation, inform V-PD-BUS by e-mail with copy the Administrative assistant, PTL secretary, PTMs, CHMP secretariat, V-PD-DBM and PSM.	PTL
26.9	Prepare the negative outcome of validation letter (see template). Send the letter to the PTL for signature.	V-PD-BUS
26.10	Consult the PTM-RA on the negative outcome of validation letter, if applicable. Complete the appropriate fee cover note (an administrative fee will be invoiced to the MAH) (see SOP/H/3101). Sign the validation letter and return it together with the fee cover note to V-PD-BUS.	PTL
26.11	Check that all required documents and signatures have been obtained. Scan the negative outcome of validation letter and send it to the MAH and (co-)rapporteur by Eudralink, with the PTL in cc. Send the original letter by postal mail to the MAH. Proceed with financial procedures according to SOP/H/3101.	V-PD-BUS

Step	Action	Responsibility
	End of procedure.	
27	**Positive outcome of validation**	
	Inform V-PD-BUS by email about the positive validation outcome and of the timetable for the procedure.	PTL
	Determine the fee for the application and complete the appropriate fee cover note.	
28	Prepare the validation letter, including the timetable (see template).	V-PD-BUS
	Send the letter to the PTL for signature.	
29	Sign the validation letter and return it together with the fee cover note to V-PD-BUS.	PTL
30	Check that all required documents and signatures have been obtained. Scan the positive outcome of validation letter and send it to the MAH and (co-)rapporteur by Eudralink, with the PTL in cc. Send the original letter by postal mail to the MAH.	V-PD-BUS
	Proceed with financial procedures according to SOP/H/3101.	
31	Include the start of the procedure in the annexes to the CHMP meeting highlights (see WIN/H/3234).	PTL
	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	
32	Forward the procedure timetable to CHMP secretariat for inclusion in the ToD and minutes of the next CHMP meeting.	PTL
33	Provide the PIQ/QRD secretariat with the proposed EN product information annexes for QRD review in accordance with SOP/EMA/0073.	PTL
34	Record and track the procedure in the tracking table based on the CHMP ToD.	Administrative assistant
Start of procedure (day 1) and initial assessment		
35	Check in the PDCO Opinion whether there will be a need to assess the significance of the studies included in the PIP.	PTL
	If yes, go to step 35.1.	
	If no, go to step 36.	
35.1.	Inform the (co-)rapporteur about the requirement to assess significance of the studies.	PTL
36	Receive the (co-)rapporteur's assessment reports.	V-PD-BUS
	Forward the reports to the PTL and PSM.	

Step	Action	Responsibility
37	Save the (co-)rapporteur's assessment reports in the procedure folder in DREAM.	PTL secretary
38	Forward the assessment reports to PTMs as appropriate. Redact any confidential information in the (co-)rapporteur's assessment reports (see WIN/EMA/0070) and save the redacted version in the procedure folder in DREAM.	PTL
39	Send the redacted (co-)rapporteur's assessment reports by Eudralink to the MAH (see template and WIN/H/3145) and verify receipt of documents.	PTL secretary
40	Receive comments on the proposed EN product information from the PIQ/QRD secretariat. Ensure that comments are compatible with the (co-)rapporteur's comments in the assessment reports. Liaise with the (co-) rapporteur and PIQ/QRD secretariat in case of contradictions. Forward the QRD comments to the MAH requesting implementation of the comments.	PTL
41	Receive comments on the (co-)rapporteur's assessment reports from other CHMP members. Forward the comments to the PTL and PSM.	V-PD-BUS
42	Provide comments on the (co-)rapporteur's assessment reports in relation to the risk management plan to the PTL and (co-) rapporteur as appropriate.	PTM-RM
43	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 44. If no, go to 43.1.	PTL
43.1	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
44	Save the CHMP members' comments in the procedure folder in DREAM. Forward compiled CHMP members' comments to the PSM.	PTL secretary
45	Forward to the (co-)rapporteur any comments/suggestions from the PTMs involved in the procedure, if applicable.	PTL
46	Discuss with the (co-)rapporteur whether a list of questions will be needed. If yes, go to step 47.	PTL

Step	Action	Responsibility
	If not, go to step 64.	
List of questions (day 30)		
47	Generate the draft LoQ and cover letter (see templates) and prepare the administrative parts of the draft LoQ. Generate the TT (including recalculation of number of active days). Save the draft LoQ, TT and cover letter in the procedure folder in DREAM.	PTL secretary
48	Prepare the scientific parts of the draft LoQ. Liaise with the (co-)rapporteur to agree on the draft LoQ and TT. Liaise with PTM-RM in case the draft LoQ refers to risk management of safety concerns or if documentation submitted by MAH contains a RMP. Liaise with the PTM-RA, if required. Discuss with the (co-)rapporteur whether there will be a need for an oral explanation to the CHMP and reflect the proposal in the draft LoQ. Discuss with the (co-)rapporteur whether a Scientific Advisory Group (SAG) or an ad hoc Expert meeting needs to be convened, and inform the CHMP secretariat accordingly. If applicable, inform the SAG secretariat about the need to organise a SAG meeting according to SOP/H/3129. Liaise with or send to the (co-)rapporteur (and PTMs, as applicable), the draft LoQ, draft list of questions for the SAG/ ad hoc Expert meeting, if relevant, for comments and amend the document accordingly. *NOTE: due to the strict procedural timelines, it is important that the need for an oral explanation or a SAG/ ad hoc Expert meeting be considered at this stage.* Discuss with the (co-)rapporteur whether there is the need for PDCO involvement. If applicable, liaise with the PTM-PDM. Table the draft LoQ, TT and draft list of questions for the SAG/ ad hoc Expert meeting, if relevant, in MMD for discussion at CHMP.	PTL PTL secretary
49	Attend the CHMP discussion on the procedure, including discussions where the list of attendees for the SAG/ ad hoc Expert meeting is adopted, if relevant. Amend the draft LoQ, TT and draft list of questions for the SAG/ ad hoc Expert meeting, if relevant, taking into account the CHMP discussion. Inform the PTL secretary about the adoption of the LoQ, TT and	PTL

Step	Action	Responsibility
	draft list of questions for the SAG/ ad hoc Expert meeting, if relevant.	
	Table the final documents in MMD for adoption by CHMP.	PTL secretary
50	Prepare the correspondence informing the MAH of the LoQ adopted by CHMP. 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 for a SAG/ ad hoc Expert meeting, if relevant.	PTL secretary
51	After signature by the SH P-R-CP, send the LoQ and TT to the MAH (cc (co-)rapporteur) in accordance with WIN/H/3145 and verify receipt of documents.	PTL secretary
	Organise the ad hoc Expert Meeting, if appropriate.	PTL
52	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL
53	Update the tracking table based on the CHMP ToD.	Administrative assistant
Responses to list of questions		
54	Receive responses to the LoQ from the MAH.	V-PD-BUS
	Forward the responses to the PTL and PSM.	
	Inform the PTM-RM and other PTMs about the receipt of responses, if applicable.	PTL
55	Save responses to the LoQ from the MAH in the procedure folder in DREAM.	PTL secretary
56	Receive the (co-)rapporteur's assessment reports on the responses.	V-PD-BUS
	Forward the reports to the PTL and PSM.	
57	Save the (co-)rapporteur's assessment reports in the procedure folder in DREAM.	PTL secretary
58	Forward the assessment reports to the PTMs as appropriate.	PTL
	Redact any confidential information in the (co-)rapporteur's assessment reports (see WIN/EMA/0070) and save the redacted version in the procedure folder in DREAM.	
59	Send the redacted (co-)rapporteur's assessment reports to the MAH (see template and WIN/H/3145) and verify receipt of documents.	PTL secretary
	Forward the (co-)rapporteur's assessment reports to the SAG/ ad hoc Expert meeting members in preparation of their meeting, if	PTL

Step	Action	Responsibility
	applicable.	
	Attend the SAG/ ad hoc Expert meeting.	PTL
60	Receive comments on the (co-)rapporteur's assessment reports from other CHMP members.	V-PD-BUS
	Forward the comments to the PTL and PSM.	
61	Forward the comments to the PTMs as appropriate.	PTL
	Check with the (co-)rapporteur whether they have received comments and if the comments received are the same.	
	If yes, go to step 62.	
	If no, go to step 61.1.	
61.1	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
62	Save the CHMP members' comments in the procedure folder in DREAM. Forward compiled CHMP members' comments to the PSM.	PTL secretary
63	Forward to the (co-)rapporteur any comments/suggestions from the PTMs involved in the procedure, if applicable.	PTL
	Send the minutes of the SAG/ad hoc Expert meeting to the (co-) rapporteur, if applicable.	
Opinion (day 60)		
64	Plan the mailing of the opinion documents in advance (see templates and action list for secretaries).	PTL secretary
	1 week before the CHMP week, confirm with the MAH and NCA contact points that during the procedure no changes occurred to the contents of annex I.	Administrative assistant
	Update annex I with comments received, if necessary.	
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 assessment report, including relevant annexes (see templates).	PTL secretary
	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.	
67	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.	
68	Prepare the scientific parts of the draft CHMP opinion including the proposed amendments to the product information and the assessment report. Prepare the letter to the EC including the compliance statement (if applicable). Provide the SH P-R-CP, PTM-RA, PTM-Q, PTM-PDM and PTM-RM, if applicable, with the draft documents for review if possible at the latest by Wednesday the week before the CHMP meeting. Consider whether the procedure needs to be added to the agenda of the Product Oversight Meeting and attend the meeting, if relevant.	PTL
69	Provide comments on the draft CHMP opinion and assessment report if possible by Friday before the CHMP meeting, if applicable.	SH P-R-CP, PTMs
70	Receive comments and update the draft CHMP opinion and assessment report as necessary. Inform V-PD-DIS (translation inbox – translationsrequest@ema.europa.eu) about upcoming translations (annex II and IV).	PTL PTL secretary
71	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
72	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
73	Provide comments on the draft press release to D-CM and on the draft Q&A document to P-MI-PIN.	PTL
74	Table the draft CHMP opinion and assessment report in MMD for discussion at CHMP.	PTL secretary
75	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. Inform the CHMP secretariat	PTL

Step	Action	Responsibility
	accordingly.	
76	Attend the CHMP discussion on the procedure, including the oral explanation and/or the presentation of the outcomes of the SAG/ ad hoc Expert meeting if applicable. Update the CHMP opinion and assessment report as needed to reflect the CHMP discussion, and if applicable the outcome of the SAG/ ad-hoc Expert group meeting and oral explanation, the voting and/or divergent positions.	PTL
	Table the revised documents in MMD for adoption by CHMP.	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 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 assessment report, 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 correspondence and documentation to the EC and 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	Send annexes I, II, III and IV (if applicable) of the CHMP opinion to V-PD-DIS (translation inbox – translationsrequest@ema.europa.eu) for translation. Receive translations from V-PD-DIS (translation inbox – translationsrequest@ema.europa.eu). Receive sets of annexes translated into all EU languages from the MAH. If multiple procedures are running in parallel, request the MAH to provide also a consolidated version of the annexes in all languages.	PTL secretary
80	Send the CHMP assessment report to the MAH contact point for identification of commercially confidential information. Any proposal for deletion/alternative wording should contain relevant justifications and be sent to the PTL within 15 calendar days.	PTL
81	Verify the CHMP ToD and CHMP minutes with regard to the procedure and provide comments to the CHMP secretariat if necessary.	PTL

Step	Action	Responsibility
82	Update the tracking table based on the CHMP ToD.	Administrative assistant
83	Receive translations from the MAH. In case of an extension of indication, follow the procedure described in SOP/EMA/0048 for the post opinion check of translations for a type II variation. In the case of an annex II application, follow the procedure described in SOP/EMA/0047 for the post opinion check of translations for an annex II application.	PTL secretary
84	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 86.1. If no, go to step 87.	PTL
84.1	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 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 85.	PTL
85	Receive the MAH's proposal for deletion of confidential information and check its acceptability with the SH P-R-CP and PTM-Q (if applicable). Consult the rapporteur only if proposals for deletion go beyond the established principles (EMEA/45422/2006) and/or if it impacts on the scientific integrity of the report. If the proposal is not acceptable, discuss with the MAH until a common position can be reached.	PTL
86	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		

Step	Action	Responsibility
87	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
88	Save the draft Commission Decision in the procedure folder in DREAM and forward the e-mail from the EC to the PSM.	PTL secretary
89	At the end of the SC phase, verify with the PTL if comments have been received. If yes, go to step 89.1. If no, go to step 90.	PTL secretary
89.1	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 91.	PTL secretary
90	Inform the EC whether or not comments were received.	PTL secretary
91	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		
92	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 it to the Webteam for publication. *NOTE: the procedure should be published in the referrals section of the Agency's website, with a link to the PIP table in the paediatrics section.*	PTL secretary
	Withdrawal of the procedure *The MAH may withdraw the application at any time during the evaluation procedure, in which case the procedure shall be stopped.*	
93	Receive a withdrawal letter from the MAH and circulate it to the D-CM, P-MI-PIN, PTMs, (co-)rapporteur, CHMP secretariat, V-PD-BUS,	PTL

Step	Action	Responsibility
	HoS P-R and SH P-R-CP.	
	Save the withdrawal letter in the procedure folder in DREAM.	PTL secretary
94	Table the withdrawal letter in MMD for information to the CHMP.	PTL
	Check the press release prepared by D-CM reflecting the withdrawal and closure of the procedure and provide comments if necessary.	
	End of procedure.	

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.