EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Preparation, dissemination and publication of safety-related EMA press releases and question-and-answer documents		
Status: **PUBLIC**		Document no.: SOP/EMA/0111
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1. Purpose

To ensure that the Agency prepares and publishes safety-related press releases and question-and-answer documents in a timely and consistent manner, and disseminates this information within the EU regulatory network (EMA, NCAs and EC) and to international partners prior to publication.

This SOP does not cover communication through other communication tools such as CHMP press release and CHMP monthly report.

2. Scope

This SOP applies to the Human Medicines Development and Evaluation Unit, the Patient Health and Protection Unit and the Office of the Executive Director.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within his or her sector. The responsibility for the execution of each step of this procedure is identified in the right-hand column of Heading **9. Procedure**.

Depending on time constraints during this procedure, steps can be merged or timelines adjusted on a case-by-case basis. In exceptional cases timing will also depend on a possible co-ordination with international authorities.

As the documents described in this procedure [i.e. press releases (PRs) and question-and-answer documents (Q&As)] are European Medicines Agency (EMA) documents, the ultimate responsibility for their wording and content lies with the Agency. However, consensus should be sought from all parties

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concerned wherever possible, and all views and comments received from the various parties involved will be taken into account during the preparation of the documents.

The Office of the Executive Director is responsible for the preparation, sign-off and publication of press releases and for the publication of question-and-answer documents while the Medical Information Sector is responsible for the preparation and sign-off of the question-and-answer documents. The Medical Information Sector is also responsible for the dissemination of the press releases and question-and-answer documents within the EU regulatory network (EMA, NCAs and EC) and to international partners prior to publication.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

Templates for EMA PRs and Q&As, templates for sending the draft documents to the Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Working Party (PhVWP), and the web content transmission slip used for this SOP are available in Microsoft Word under File/New and can be found on the X: drive in the 'templates' folder.

6. Related documents

SOP/T/1040 - Publication of documents produced by the EMA

WIN/H/3210 – Sending of lines to take and safety-related information to the European Union regulatory network and international partners

SOP/H/3346 - Early Notification System: procedure for advanced notification of emerging safety issues to EU regulatory network and international partners

SOP/H/3347 – Preparation of 'lines-to-take' documents for use within the EU regulatory network to answer external queries in a consistent manner

Principles of EMEA press release (EMA/213289/2007)

Procedure for review of information on products by patients'/consumers' organisations (EMA/279083/06)

European Medicines Agency Communication on (emerging) safety related issues for medicines for human use – practical arrangements (EMA/785792/2009)

Policy on European Medicines Agency communication on (emerging) safety related issues for medicines for human use (EMA/170165/2010)

The European Union regulatory system incident management plan for medicines for human use (for use in the context of a pilot) (EMEA/579383/2008).

WIN/EMA/0031 – Sending of press releases

7. Definitions

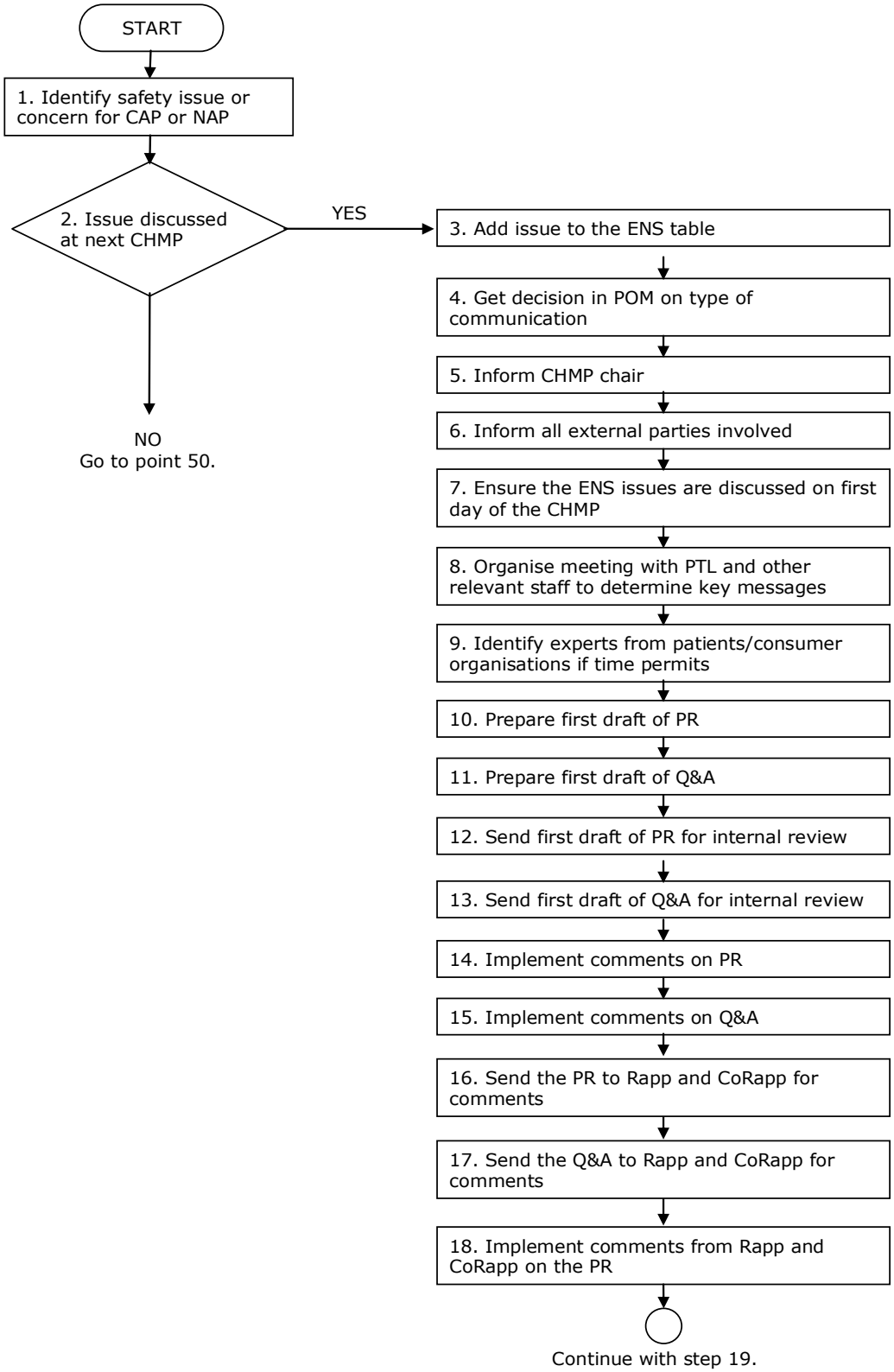
CAP: Centrally authorised medicinal product

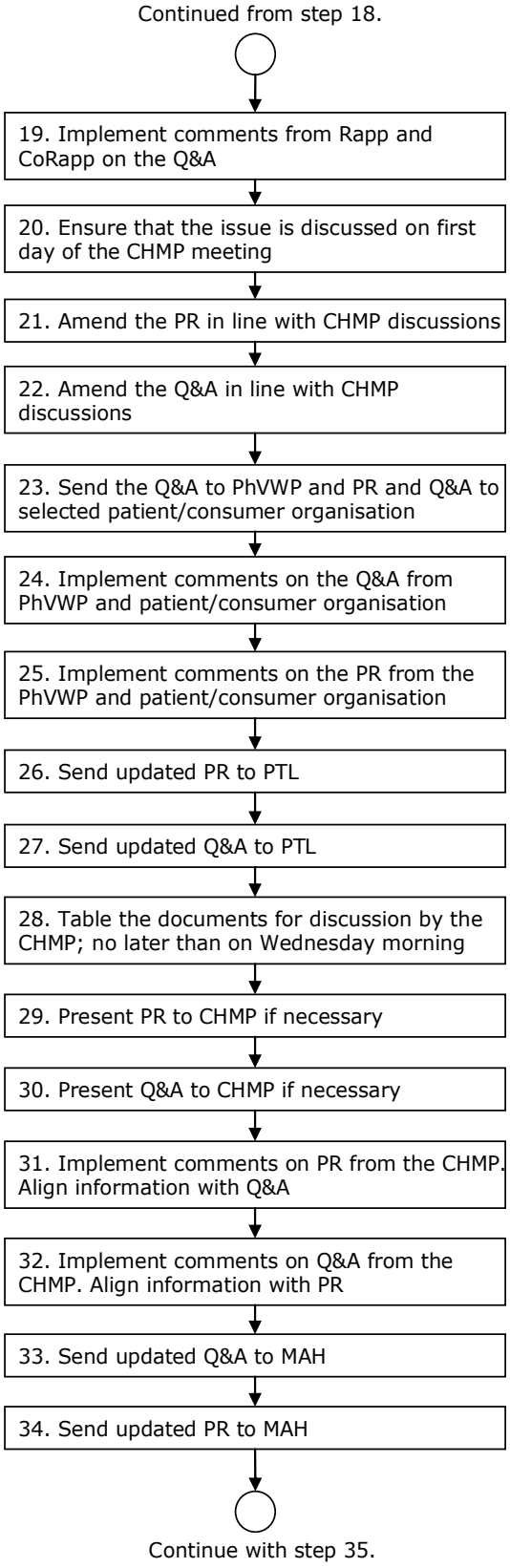
CoRapp: Co-rapporteur

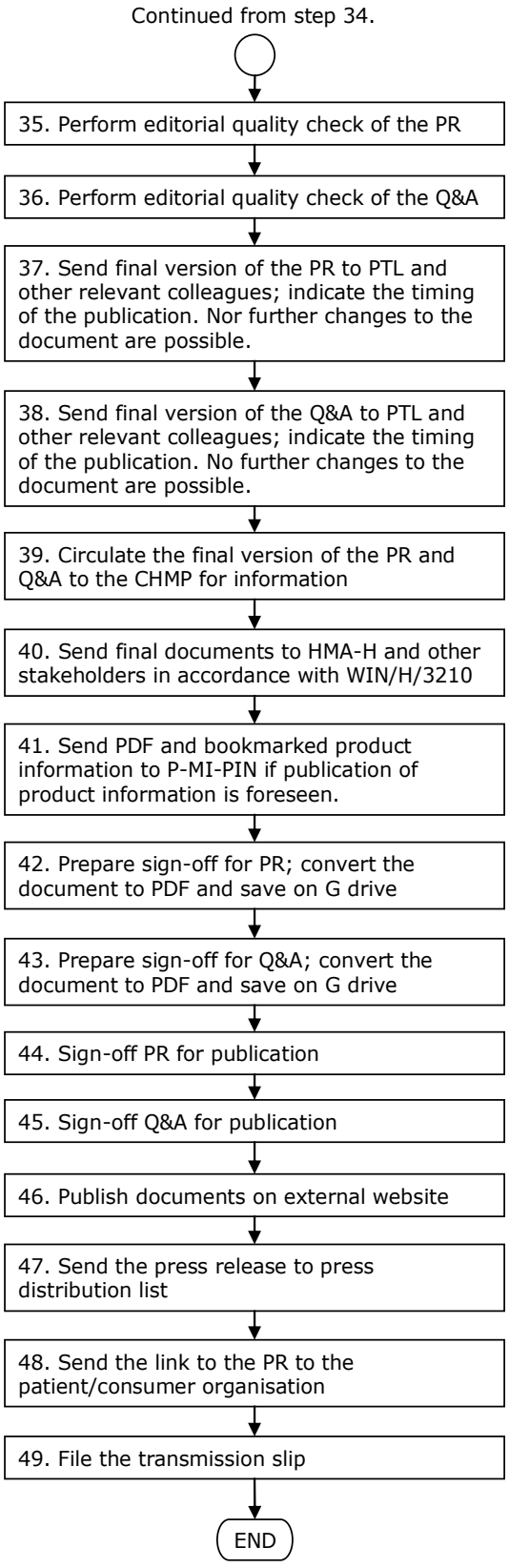
CHMP:	Committee for Medicinal Products for Human Use
D-ED:	Office of the Executive Director
D-ED-COM:	Communications and Media
DREAM:	Document Records Electronic Archive Management
EC:	European Commission
EMA:	European Medicines Agency
ENS:	Early Notification System
EU:	European Union
HMA-H:	Heads of Medicines Agencies - Human
HoS:	Head of Sector
HoU:	Head of Unit
IRN:	Incidence Review Network
LTTs:	Lines to take
MA:	Marketing authorisation
MAH:	Marketing authorisation holder
MedW:	Medical writer
NCA:	National competent authority
NAP:	Nationally authorised medicinal product
P:	Patient Health Protection Unit
P-MI:	Medical Information Sector
P-MI-PIN	Section for Public Information and Stakeholder Networking
H-SE:	Safety and Efficacy of Medicines Sector
P-PV:	Pharmacovigilance and Risk Management Sector
PhVWP:	Pharmacovigilance Working Party
POM:	Product Oversight Meeting
P-R	Regulatory, Procedural and Committee Support Sector
PR:	Press release
PTL:	Product team leader
PTL Sec:	Product team leader’s secretary
PTM:	Product team member
Q&A:	Question-and-answer document
Rapp:	Rapporteur
SH:	Section Head

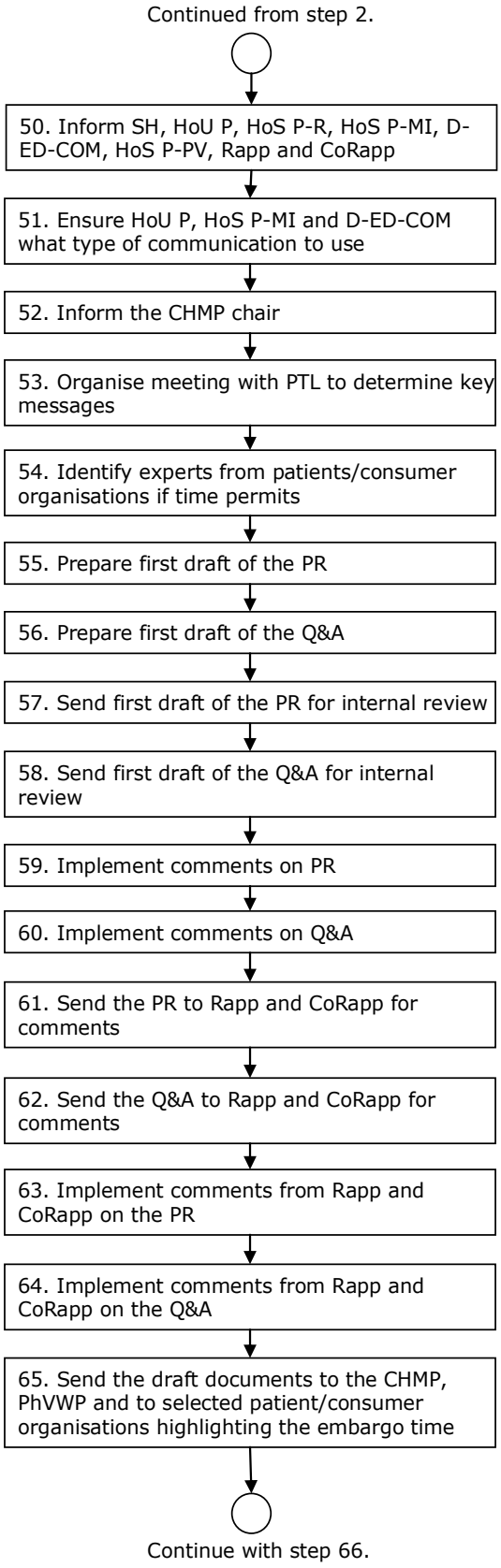
SOP:	Standard operating procedure
WIN:	Work instructions

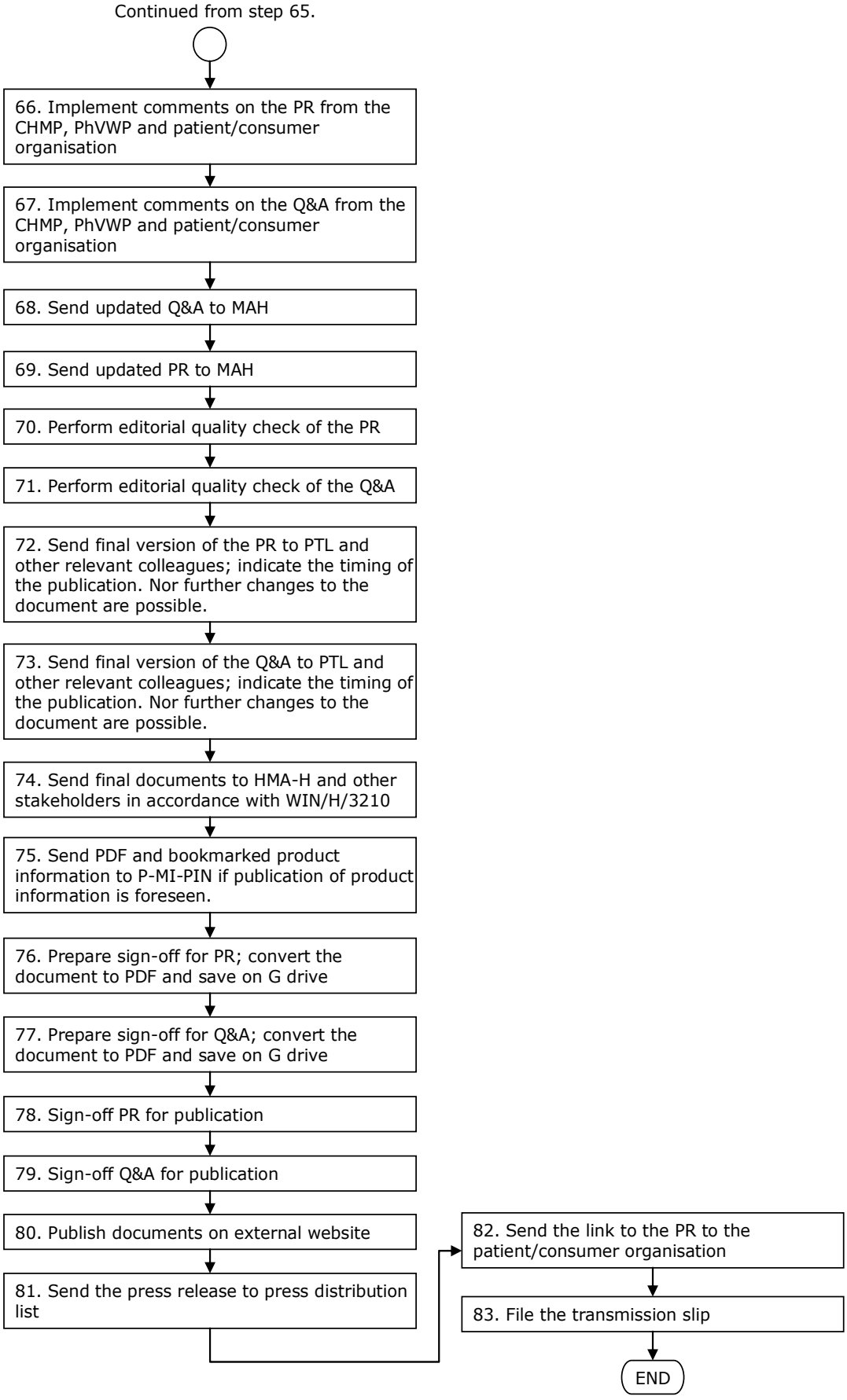
8. Process map(s)/ flow chart(s)




Continued from step 18.
19. Implement comments from Rapp and CoRapp on the Q&A
20. Ensure that the issue is discussed on first day of the CHMP meeting
21. Amend the PR in line with CHMP discussions
22. Amend the Q&A in line with CHMP discussions
23. Send the Q&A to PhVWP and PR and Q&A to selected patient/consumer organisation
24. Implement comments on the Q&A from PhVWP and patient/consumer organisation
25. Implement comments on the PR from the PhVWP and patient/consumer organisation
26. Send updated PR to PTL
27. Send updated Q&A to PTL
28. Table the documents for discussion by the CHMP; no later than on Wednesday morning
29. Present PR to CHMP if necessary
30. Present Q&A to CHMP if necessary
31. Implement comments on PR from the CHMP. Align information with Q&A
32. Implement comments on Q&A from the CHMP. Align information with PR
33. Send updated Q&A to MAH
34. Send updated PR to MAH
Continue with step 35.


Continued from step 34.
35. Perform editorial quality check of the PR
36. Perform editorial quality check of the Q&A
37. Send final version of the PR to PTL and other relevant colleagues; indicate the timing of the publication. Nor further changes to the document are possible.
38. Send final version of the Q&A to PTL and other relevant colleagues; indicate the timing of the publication. No further changes to the document are possible.
39. Circulate the final version of the PR and Q&A to the CHMP for information
40. Send final documents to HMA-H and other stakeholders in accordance with WIN/H/3210
41. Send PDF and bookmarked product information to P-MI-PIN if publication of product information is foreseen.
42. Prepare sign-off for PR; convert the document to PDF and save on G drive
43. Prepare sign-off for Q&A; convert the document to PDF and save on G drive
44. Sign-off PR for publication
45. Sign-off Q&A for publication
46. Publish documents on external website
47. Send the press release to press distribution list
48. Send the link to the PR to the patient/consumer organisation
49. File the transmission slip
END


Continued from step 2.
50. Inform SH, HoU P, HoS P-R, HoS P-MI, D-ED-COM, HoS P-PV, Rapp and CoRapp
51. Ensure HoU P, HoS P-MI and D-ED-COM what type of communication to use
52. Inform the CHMP chair
53. Organise meeting with PTL to determine key messages
54. Identify experts from patients/consumer organisations if time permits
55. Prepare first draft of the PR
56. Prepare first draft of the Q&A
57. Send first draft of the PR for internal review
58. Send first draft of the Q&A for internal review
59. Implement comments on PR
60. Implement comments on Q&A
61. Send the PR to Rapp and CoRapp for comments
62. Send the Q&A to Rapp and CoRapp for comments
63. Implement comments from Rapp and CoRapp on the PR
64. Implement comments from Rapp and CoRapp on the Q&A
65. Send the draft documents to the CHMP, PhVWP and to selected patient/consumer organisations highlighting the embargo time
Continue with step 66.


Continued from step 65.
66. Implement comments on the PR from the CHMP, PhVWP and patient/consumer organisation
67. Implement comments on the Q&A from the CHMP, PhVWP and patient/consumer organisation
68. Send updated Q&A to MAH
69. Send updated PR to MAH
70. Perform editorial quality check of the PR
71. Perform editorial quality check of the Q&A
72. Send final version of the PR to PTL and other relevant colleagues; indicate the timing of the publication. Nor further changes to the document are possible.
73. Send final version of the Q&A to PTL and other relevant colleagues; indicate the timing of the publication. Nor further changes to the document are possible.
74. Send final documents to HMA-H and other stakeholders in accordance with WIN/H/3210
75. Send PDF and bookmarked product information to P-MI-PIN if publication of product information is foreseen.
76. Prepare sign-off for PR; convert the document to PDF and save on G drive
77. Prepare sign-off for Q&A; convert the document to PDF and save on G drive
78. Sign-off PR for publication
79. Sign-off Q&A for publication
80. Publish documents on external website
81. Send the press release to press distribution list
82. Send the link to the PR to the patient/consumer organisation
83. File the transmission slip
END

9. Procedure

Step	Action	Responsibility
1	Identify safety issues that may require communication (as proposed in the Policy on European Medicines Agency communication on (emerging) safety related Issues for medicines for human use (EMA/170165/2010)) or receive information on safety issues as identified by the IRN. As a guide, the following types of safety issues should be included: • Suspension, withdrawal or revocation of a marketing authorisation for safety reasons; • Start or finalisation of a community referral or review procedure initiated for safety reasons (e.g. article 5(3), 20, 31 or 107); • New safety information such as new contraindications, warnings or undesirable effects; • Supply shortages; • Product defects that may lead to safety concerns; • Restrictions of indication or reductions of dose; • Any other emerging safety concerns that may give rise to media interest.	PTL
2	Is the issue or concern to be discussed at the next CHMP meeting? If yes go to 3; If no go to 50.	PTL
	The safety issue or concern is to be discussed at the next CHMP meeting	
3	Add safety issue to the Early Notification System table in line with the SOP/3346, and inform Rapp and CoRapp.	PTL
4	Unless the IRN has taken a decision before, ensure that during the POM that takes place on Tuesday prior to the CHMP, a decision is made on whether the Agency will communicate and which communication tools will be used (i.e. PR, Q&A or LTTs). If LTTs are considered necessary, follow the separate SOP on LTTs (SOP/H/3347). If a Q&A is needed, nominate MedW responsible from P-MI-PIN and inform the PTL accordingly. If a PR is needed, nominate person responsible from D-ED-COM and inform the PTL accordingly. Ensure that tentative embargo for publication is agreed (usually Thursday of the CHMP week at 16:00h UK time).	PTL SH P-MI-PIN D-ED-COM D-ED-COM
5	Inform the CHMP Chair about the upcoming communication during the teleconference with Chair and Vice-chair. This usually takes	PTL

Step	Action	Responsibility
	place on the Thursday prior to CHMP week.	
6	Send the Early Notification System table to HMA-H, EC, CHMP, PhVWP and international partners (in accordance with WIN/H/3210) to inform them about the upcoming potential communication by Thursday prior to CHMP week.	P-MI sec
7	Ensure in collaboration with the CHMP secretariat that safety issues included in the Early Notification System are scheduled for discussion on Monday of CHMP meeting.	PTL
8	Organise a meeting with PTL and other concerned staff to determine the key messages.	MedW/ or D-ED-COM
9	Identify experts from eligible patient/consumer organisations to be involved in the review, when possible.	P-MI-PIN
10	Prepare first draft of the PR.	D-ED-COM
11	Prepare first draft of the Q&A.	MedW
12	Send first draft of the PR for internal review to relevant EMA staff (PTL, PTM and P-MI).	D-ED-COM
13	Send first draft of the Q&A for internal review to relevant EMA staff (PTL, PTM and D-ED-COM).	MedW
14	Implement comments on the PR as appropriate.	D-ED-COM
15	Implement comments on the Q&A as appropriate.	MedW
16	Send the updated PR to the Rapp and CoRapp for comment.	D-ED-COM
17	Send the updated Q&A to the Rapp and CoRapp for comment.	MedW
18	Implement comments from Rapp and CoRapp on the PR as appropriate.	D-ED-COM
19	Implement comments from Rapp and CoRapp on the Q&A as appropriate.	MedW
20	Ensure in collaboration with the CHMP secretariat that the safety issue is discussed on Monday of the CHMP week and that the PR and/or Q&A are discussed by Wednesday morning.	PTL
21	Amend the PR in line with the CHMP discussion and the expected final opinion/outcome of the CHMP's deliberations.	D-ED-COM
22	Amend the Q&A in line with the CHMP discussion and the expected final opinion/outcome of the CHMP's deliberations.	MedW
23	Send the amended Q&A to the PhVWP contact point and the amended Q&A (and amended PR as appropriate) to the patient/consumer organisation (selected at step 9).	P-MI-PIN
24	Implement comments on the Q&A from PhVWP and	MedW

Step	Action	Responsibility
	patient/consumer organisation as appropriate, liaising with PTL as necessary.	
25	Implement comments on the PR from the PhVWP and patient/consumer organisation as appropriate, liaising with PTL as necessary.	D-ED-COM
26	Send updated PR to PTL.	D-ED-COM
27	Send updated Q&A to PTL.	MedW
28	Table documents for discussion at CHMP plenary meeting, no later than Wednesday morning of the CHMP week, and inform D-ED-COM and P-MI-PIN when the topic is to be discussed.	PTL
29	Present PR to CHMP, if necessary, no later than Wednesday morning, noting comments.	D-ED-COM
30	Present Q&A to CHMP, if necessary, no later than Wednesday morning, noting comments.	MedW
31	Implement comments on PR from CHMP as appropriate, liaising with PTL as necessary. Ensure that the information in the PR and Q&A is aligned.	D-ED-COM
32	Implement comments on Q&A from CHMP as appropriate, liaising with PTL as necessary. Ensure that the information in the PR and Q&A is aligned.	MedW
33	Send updated Q&A to the MAH(s) for information, if feasible. Only factual corrections suggested by the MAH(s) can be accepted.	MedW
34	Send updated PR to the MAH(s) for information, if feasible. Only factual corrections suggested by the MAH(s) can be accepted.	PTL
35	Perform an editorial quality check of the PR (e.g. check spelling and grammar).	D-ED-COM
36	Perform an editorial quality check of the Q&A (e.g. check spelling and grammar).	MedW
37	Send final version of the PR to PTL, copying in PTM, SH, P-MI Sec and other concerned EMA staff. Indicate the timing for publication. No additional changes are possible at this time.	D-ED-COM
38	Send final version of the Q&A to PTL, copying in PTM, SH, P-MI Sec and other concerned EMA staff. Indicate the timing for publication. No additional changes are possible at this time.	MedW
39	Circulate final version of PR and Q&A to CHMP for information.	PTL
40	Send final documents (Q&A and/or PR) to HMA-H, EC, CHMP, PhVWP and international partners and inform EMA concerned staff	P-MI Sec

Step	Action	Responsibility
	in accordance with WIN/H/3210.	
41	Once adopted by the CHMP and no later than the evening prior to the day of publication, book-mark and PDF final product information and send to P-MI-PIN, if publication of the product information is foreseen at this stage.	PTL sec
42	Prepare sign-off for PR, convert it into PDF format and save it in G-drive (G:\External Information Draft\SIGN OFF\Directorate) for web publication. Specify the location of the file on the transmission slip.	D-ED-COM
43	Prepare sign-off for Q&A, convert it into PDF format and save in G-drive (G:\External Information Draft\SIGN OFF\Human Unit\Safety Q&A) for web publication. Specify the location of the file on the transmission slip.	P-MI Sec
44	Sign-off PR for publication.	D-ED-COM
45	Sign-off Q&A for publication.	HoS P-MI
46	Publish documents on the EMA external web site at the agreed embargo date and time.	Web team
47	Send the PR to the press group (WIN/EMA/0031).	D-ED-COM
48	Send a link to the published documents to the patient/consumer organisation involved.	P-MI-PIN
49	File original transmission slips.	Web team
	The safety issue needs to be addressed before the next CHMP meeting	
50	Inform the SH, HoU P, HoS P-R, HoS P-MI, D-ED-COM, HoS P-PV, Rapp and CoRapp. If necessary, make sure that an ad hoc POM will take place.	PTL
51	Ensure in collaboration with HoU P, HoS P-MI and HoS D-ED that a decision is made on whether the Agency will communicate and which communication tools will be used (i.e. PR, Q&A or LTTs). If LTTs are considered necessary, follow the separate SOP on LTTs (SOP/H/3347). If a Q&A is needed, nominate MedW responsible from P-MI-PIN and inform the PTL accordingly. If a press release is needed, nominate person responsible from D-ED-COM and inform the PTL accordingly. Ensure that embargo for publication is agreed.	PTL SH P-MI-PIN D-ED-COM D-ED-COM
52	Inform the CHMP Chair about the upcoming communication.	PTL

Step	Action	Responsibility
53	Organise a meeting with PTL and other concerned staff to determine the key messages.	MedW/ or D-ED-COM
54	Identify experts from eligible patient/consumer organisations to be involved in the review, when possible.	P-MI-PIN
55	Prepare first draft of the PR.	D-ED-COM
56	Prepare first draft of the Q&A.	MedW
57	Send first draft of the PR for internal review to relevant EMA staff (PTL, PTM and P-MI).	D-ED-COM
58	Send first draft of the Q&A for internal review to relevant EMA staff (PTL, PTM and D-ED-COM).	MedW
59	Implement comments on the PR as appropriate.	D-ED-COM
60	Implement comments on the Q&A as appropriate.	MedW
61	Send the updated PR to the Rapp and CoRapp for comment.	D-ED-COM
62	Send the updated Q&A to the Rapp and CoRapp for comment.	MedW
63	Implement comments from Rapp and CoRapp on the PR as appropriate.	D-ED-COM
64	Implement comments from Rapp and CoRapp on the Q&A as appropriate.	MedW
65	Send the draft documents to the CHMP, PhVWP contact point (if applicable) and patient/consumer organisation (selected in step 54) for comments, highlighting the embargo.	P-MI Sec
66	Implement comments on PR from CHMP, PhVWP and patient/consumer organisation as appropriate, liaising with PTL as necessary. Ensure that the information in the PR and Q&A is aligned.	D-ED-COM
67	Implement comments on Q&A from CHMP, PhVWP and patient/consumer organisation as appropriate, liaising with PTL as necessary. Ensure that the information in the PR and Q&A is aligned.	MedW
68	Send updated Q&A to the MAH(s) for information, if feasible. Only factual corrections suggested by the MAH(s) can be accepted.	MedW
69	Send updated PR to the MAH(s) for information, if feasible. Only factual corrections suggested by the MAH(s) can be accepted.	PTL
70	Perform an editorial quality check of the PR (e.g. check spelling and grammar).	D-ED-COM
71	Perform an editorial quality check of the Q&A (e.g. check spelling and grammar).	MedW

Step	Action	Responsibility
72	Send final version of the PR to PTL, copying in PTM, SH, P-MI Sec and other concerned EMA staff. Indicate the timing for publication. No additional changes are possible at this time.	D-ED-COM
73	Send final version of the Q&A to PTL, copying in PTM, SH, P-MI Sec and other concerned EMA staff. Indicate the timing for publication. No additional changes are possible at this time.	MedW
74	Send final documents (Q&A and/or PR) to HMA-H, EC, CHMP, PhVWP and international partners and inform EMA concerned staff in accordance with WIN/H/3210.	P-MI Sec
75	No later than the evening prior to the day of publication, book-mark and PDF final product information and send to P-MI-PIN, if publication of the product information is foreseen at this stage.	PTL sec
76	Prepare sign-off for PR, convert it into PDF format and save it in G-drive (G:\External Information Draft\SIGN OFF\Directorate) for web publication. Specify the location of the file on the transmission slip.	D-ED-COM
77	Prepare sign-off for Q&A, convert it into PDF format and save in G-drive (G:\External Information Draft\SIGN OFF\Human Unit\Safety Q&A) for web publication. Specify the location of the file on the transmission slip.	P-MI Sec
78	Sign-off PR for publication.	D-ED-COM
79	Sign-off Q&A for publication.	HoS P-MI
80	Publish documents on the EMA external web site at the agreed embargo date and time.	Web team
81	Send the PR to the press group (WIN/EMA/0031).	D-ED-COM
82	Send a link to the published documents to the patient/consumer organisation involved.	P-MI-PIN
83	File original transmission slips.	Web team

10. Records

Original EMA PR, Q&A and correspondence are filed in the Master File. Electronic copies are saved in DREAM.