EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Standard operating procedure

| Title: Establishment of European Union herbal monographs and European Union list entries and related documents | | |
|---|---|---|
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## 1. Purpose

To describe the processes related to the establishment and publication of European Union herbal monographs (monographs) and entries to the 'European Union list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (list entries), based on Committee on Herbal Medicinal Products (HMPC) assessments.

The SOP does not describe the steps for the identification of priority herbal substances/preparations to be covered by a monograph and/or list entry, nor the compilation of the scientific data/literature prior to the start of the assessment nor the compilation of the content of the monographs and/or list entries.

## 2. Scope

This SOP applies to the HMPC secretariat within the Committee Secretariat Service (P-CI-SCS).

## 3. Responsibilities

It is the responsibility of the Head of Service P-CI-SCS to ensure that this procedure is adhered to within the HMPC secretariat. 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

Updated to reflect major changes in the process.

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# 5. Documents needed for this SOP

- Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs (EMA/HMPC/328575/2007 Rev. 1)
- Procedure for call for scientific data for use in Committee on Herbal Medicinal Products assessment work (EMA/305056/2006 Rev. 4 *Corr.*)
- Template for a European Union herbal monograph (EMA/HMPC/107436/2005 Rev. 7)
- Template for a European Union list entry (EMA/HMPC/439705/2006 Rev. 5)
- Assessment report template for the development of European Union herbal monographs and European Union list entries (EMA/HMPC/418902/2005 Rev. 5)
- Template for overview of comments received during the public consultation on a draft European Union herbal monograph/European Union list entry (EMA/HMPC/411398/2006 Rev. 1 *Corr*.)
- HMPC opinion template for entry to the European Union list (EMA/HMPC/107749/2006)
- HMPC opinion template for European Union herbal monographs (EMA/HMPC/207141/2006)
- Inventory of herbal substances for assessment (EMA/HMPC/494079/2007)
- Overview of status of HMPC and MLWP assessment work (EMA/HMPC/519580/2007)
- Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)
- Seed file (EMA/HMPC/367569/2009)
- Editorial checklist for draft/final of European Union herbal monographs, list entries and related documents (EMA/612917/2011)
- Web publication template e-mail (EMA/666445/2015)
- User manual on HMPC/MLWP meetings and related activities (EMA/HMPC/321041/2016)
- Checklist for List Entry translation and transmission to the Commission (EMA/350470/2016)
- Checklist for ARSP (EMA/548762/2016)

# 6. Related documents

- Procedure for the appointment by the HMPC of a Rapporteur responsible for a scientific evaluation or for the establishment of a Community herbal monograph and/or Community list entry (EMA/HMPC/108877/2005/Rev. 1)
- Procedure for the preparation of Community monographs for traditional herbal medicinal products (EMA/HMPC/182320/2005 Rev. 2)
- Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use (EMA/HMPC/182352/2005 Rev. 2)
- Procedure for the preparation of an entry to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMA/HMPC/57137/2007)

- Procedure on the publication of HMPC public statements when Community herbal monographs on herbal substances, preparations and combinations thereof are not established (EMA/HMPC/84530/2010 Rev. 2)
- Template for the submission of comments on a draft European Union herbal monograph/European Union list entry (EMA/HMPC/384286/2006 Rev. 2 *Corr*.)
- Herbal summary for the public – template with guidance (EMA/289537/2012)
- Guide to Rapporteurs and Peer-reviewers for the establishment of monographs, list entries, public statements and related documents (EMA/HMPC/287394/2009)
- User Manual on compiling scientific data/literature to support HMPC assessment work (EMA/197774/2016)

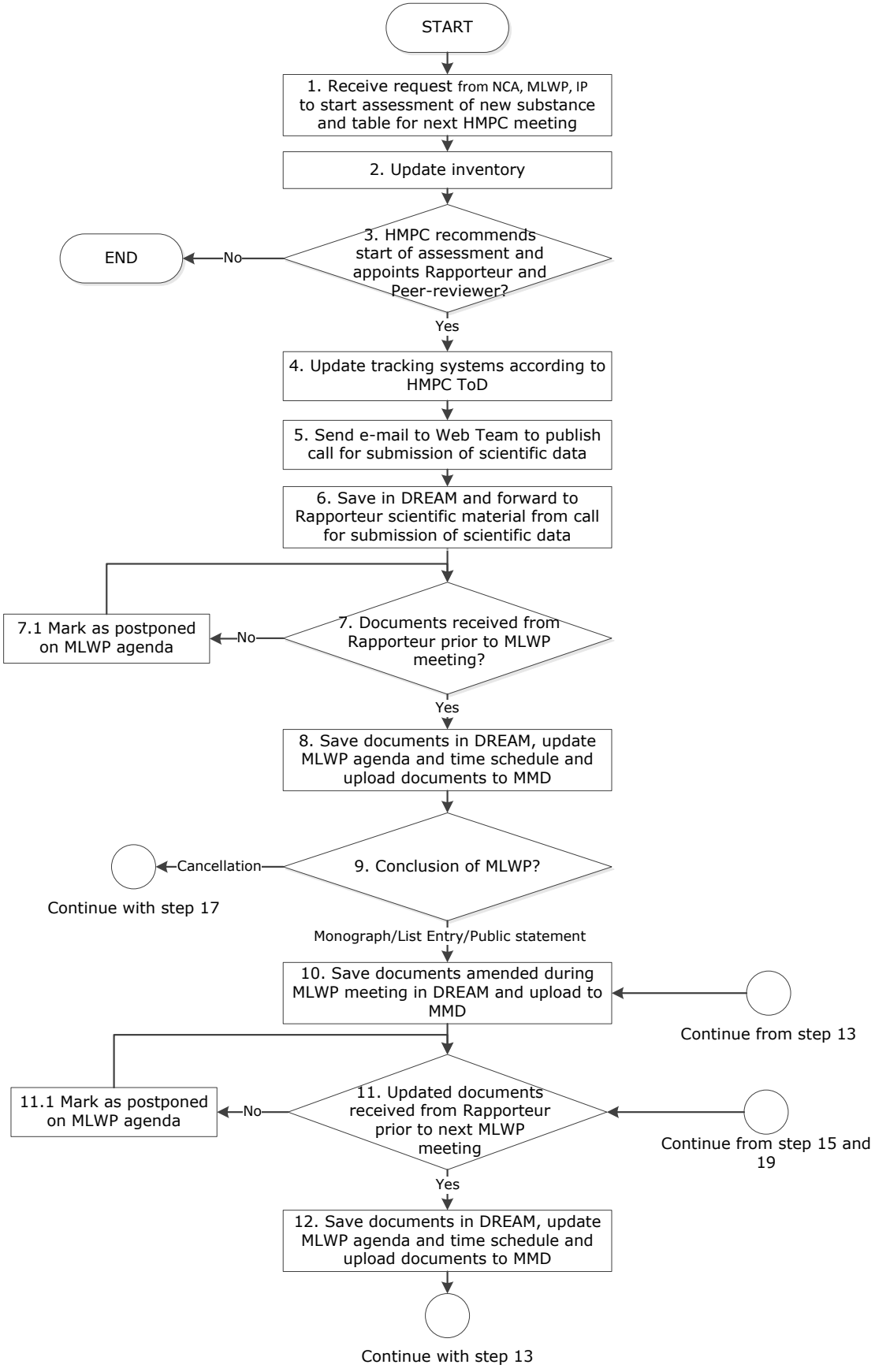
# 7. Definitions

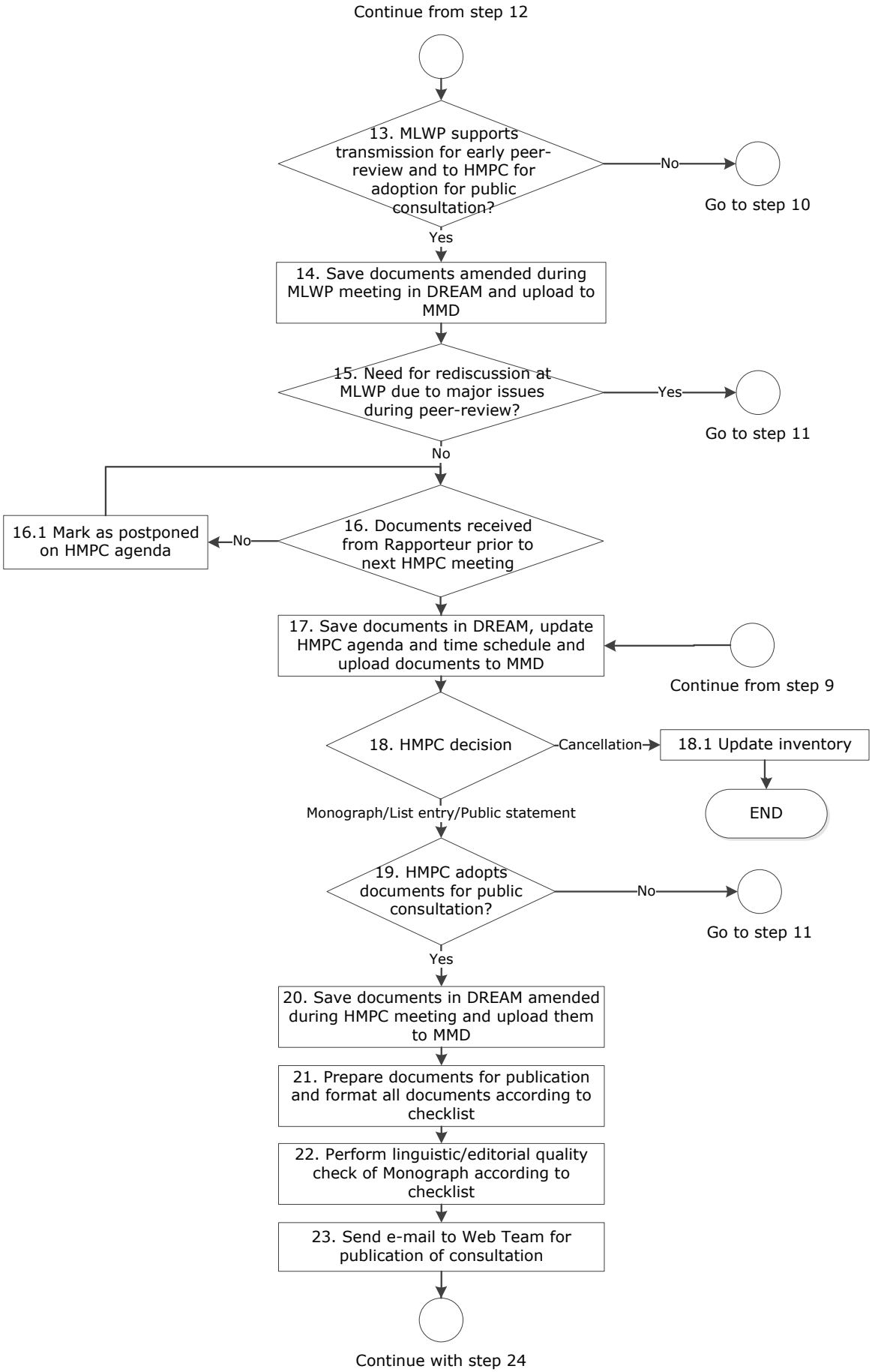
- Agency: European Medicines Agency
- AESGP: Association of the European Self-Medication Industry
- AR: assessment report (underpinning a monograph and/or list entry)
- ARSP: assessment report summary for the public (2-3 pages summary of the assessment conducted, written in language understandable by the general public)
- CdT: Translation Centre for the Bodies of the European Union (Luxembourg)
- DREAM: Document, Records and Electronic Archive Management system
- EC: European Commission
- EEA: European Economic Area
- EU: European Union
- European Union herbal monograph (monograph): document whose purpose is to provide a scientific summary of all data available on the safety and efficacy of a herbal substance/preparation intended for medicinal use, as referred to in Article 16h(3) of Directive 2001/83/EC
- European Union list: the 'list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products', which is established in accordance with Article 16f(1) of Directive 2001/83/EC
- European Union list entry (list entry, LE): document whose purpose is to provide structured information, including information laid down in Article 16f(1) of Directive 2001/83/EC, relating to specific herbal substances or herbal preparations or combinations of substances and preparations from a given plant[1] for use in traditional herbal medicinal products
- HMPC: Committee on Herbal Medicinal Products
- IP: Interested parties - parties concerned with the use of (herbal) medicinal products such as pharmaceutical industry associations, health care professional groups, scientific, consumers and patients' associations, governmental institutions as well as EU Member States and EEA-EFTA States
- IRCH: International Regulatory Cooperation for Herbal Medicines

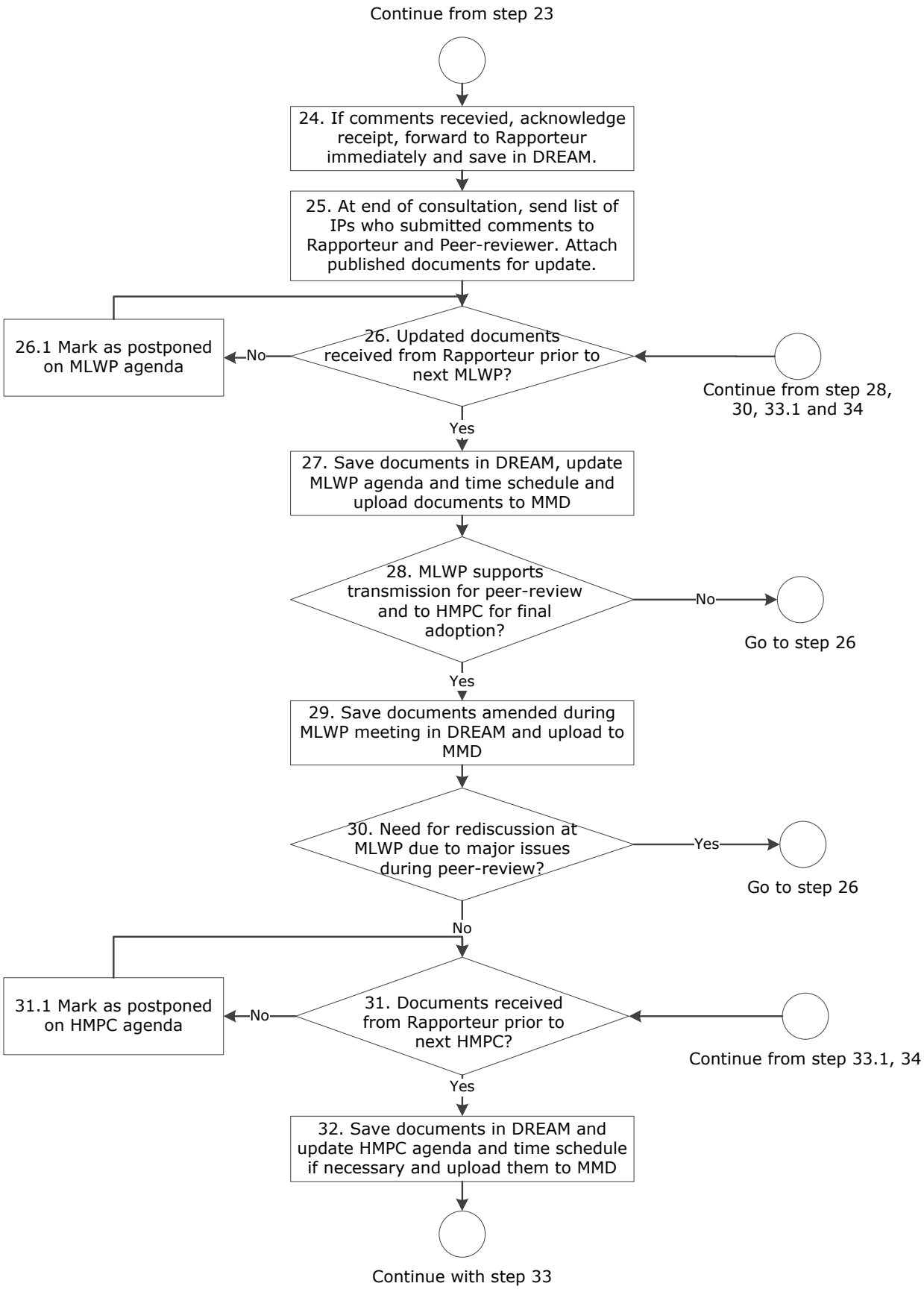
[1] It will be indicated if more than one plant is used and if hybrids are also used.

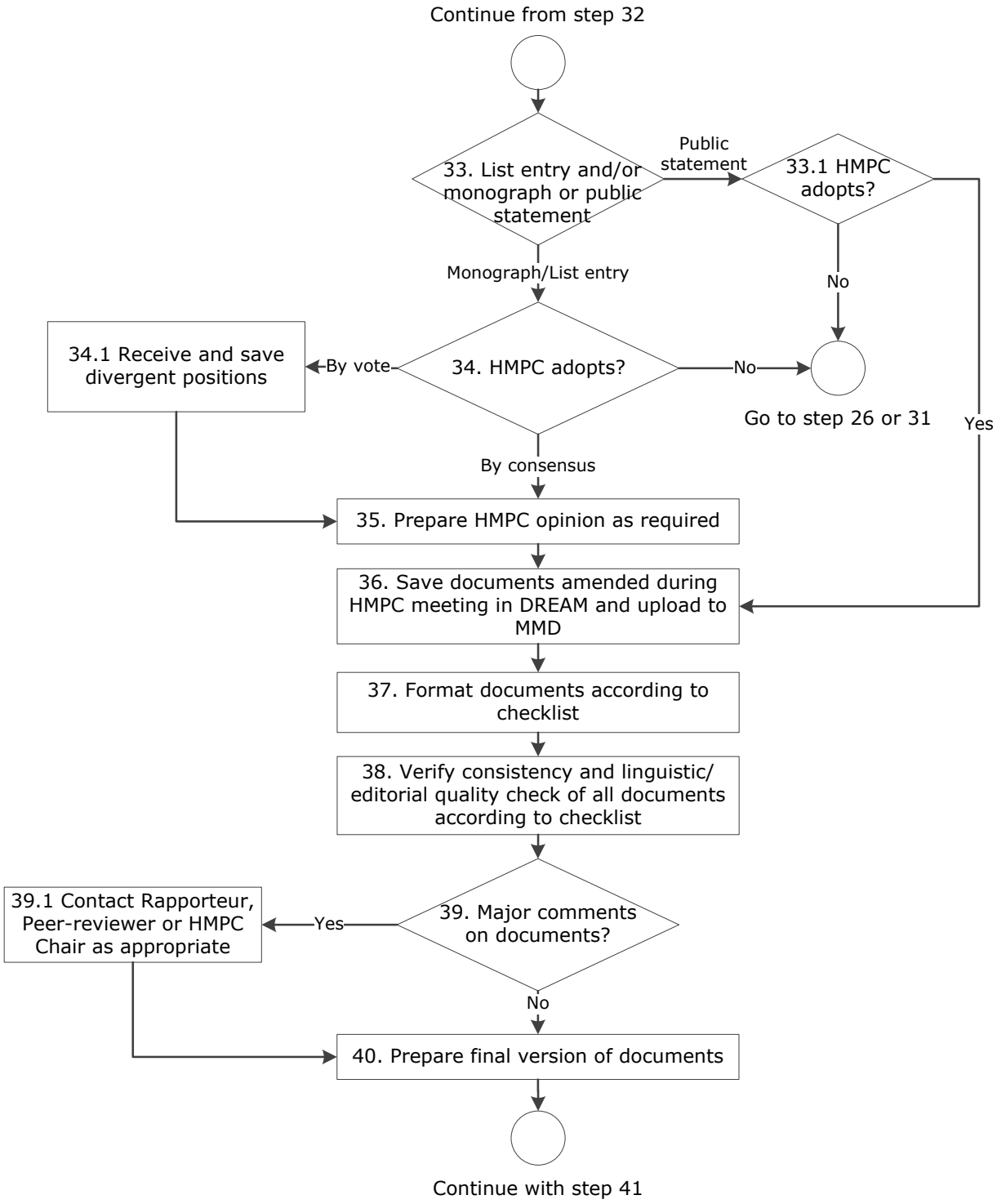
- List of references: list of references supporting the assessment report
- Majority:
  - Simple majority: more than half of the valid votes cast
  - Absolute majority: favourable votes by at least half of the total number of Committee members eligible to vote plus one
- MLWP: HMPC Working Party on European Union Monographs and European Union List
- MMD: Managing Meeting Documents system
- NCA: National Competent Authority
- Overview of comments: overview of comments received during the public consultation
- P-CI-SCS: Committee Secretariat Service
- Public statement: document presenting the opinion of the HMPC as to why no European Union herbal monograph could be established on a given herbal substance and/or preparations thereof
- Rapporteur (Rapp.): MLWP or HMPC member responsible for a given assessment work
- S-CO-MHI: Medical and Health Information Office
- ToC: Table of Conclusions (as defined under Article 14(13) of the HMPC rules of procedure)
- ToD: Table of Decisions (as defined under Article 11(4) of the HMPC rules of procedure)

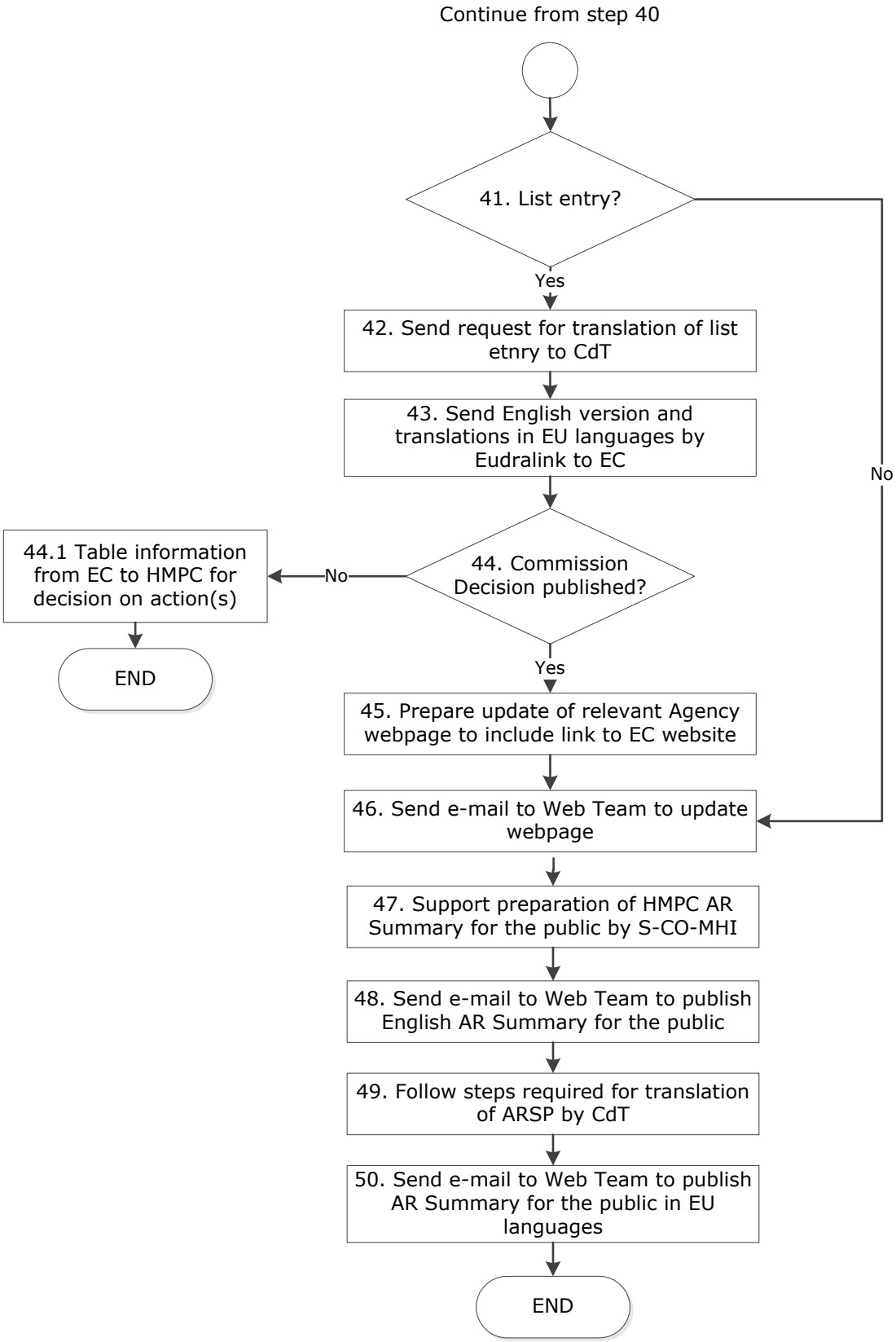
# 8. Process map(s)/ flow chart(s)




Continue from step 12
13. MLWP supports transmission for early peer-review and to HMPC for adoption for public consultation?
No
Go to step 10
Yes
14. Save documents amended during MLWP meeting in DREAM and upload to MMD
15. Need for rediscussion at MLWP due to major issues during peer-review?
Yes
Go to step 11
No
16. Documents received from Rapporteur prior to next HMPC meeting
No
16.1 Mark as postponed on HMPC agenda
17. Save documents in DREAM, update HMPC agenda and time schedule and upload documents to MMD
Continue from step 9
18. HMPC decision
Cancellation
18.1 Update inventory
END
Monograph/List entry/Public statement
19. HMPC adopts documents for public consultation?
No
Go to step 11
Yes
20. Save documents in DREAM amended during HMPC meeting and upload them to MMD
21. Prepare documents for publication and format all documents according to checklist
22. Perform linguistic/editorial quality check of Monograph according to checklist
23. Send e-mail to Web Team for publication of consultation
Continue with step 24


Continue from step 23
24. If comments recevied, acknowledge receipt, forward to Rapporteur immediately and save in DREAM.
25. At end of consultation, send list of IPs who submitted comments to Rapporteur and Peer-reviewer. Attach published documents for update.
26. Updated documents received from Rapporteur prior to next MLWP?
No
26.1 Mark as postponed on MLWP agenda
Continue from step 28, 30, 33.1 and 34
Yes
27. Save documents in DREAM, update MLWP agenda and time schedule and upload documents to MMD
28. MLWP supports transmission for peer-review and to HMPC for final adoption?
No
Go to step 26
Yes
29. Save documents amended during MLWP meeting in DREAM and upload to MMD
30. Need for rediscussion at MLWP due to major issues during peer-review?
Yes
Go to step 26
No
31. Documents received from Rapporteur prior to next HMPC?
No
31.1 Mark as postponed on HMPC agenda
Continue from step 33.1, 34
Yes
32. Save documents in DREAM and update HMPC agenda and time schedule if necessary and upload them to MMD
Continue with step 33


Continue from step 32
33. List entry and/or monograph or public statement
Public statement
33.1 HMPC adopts?
Monograph/List entry
No
34.1 Receive and save divergent positions
By vote
34. HMPC adopts?
No
Go to step 26 or 31
Yes
By consensus
35. Prepare HMPC opinion as required
36. Save documents amended during HMPC meeting in DREAM and upload to MMD
37. Format documents according to checklist
38. Verify consistency and linguistic/ editorial quality check of all documents according to checklist
39.1 Contact Rapporteur, Peer-reviewer or HMPC Chair as appropriate
Yes
39. Major comments on documents?
No
40. Prepare final version of documents
Continue with step 41


Continue from step 40
41. List entry?
Yes
No
42. Send request for translation of list etnry to CdT
43. Send English version and translations in EU languages by Eudralink to EC
44. Commission Decision published?
No
44.1 Table information from EC to HMPC for decision on action(s)
END
Yes
45. Prepare update of relevant Agency webpage to include link to EC website
46. Send e-mail to Web Team to update webpage
47. Support preparation of HMPC AR Summary for the public by S-CO-MHI
48. Send e-mail to Web Team to publish English AR Summary for the public
49. Follow steps required for translation of ARSP by CdT
50. Send e-mail to Web Team to publish AR Summary for the public in EU languages
END

# 9. Procedure

| Step | Action | Responsibility |
|---|---|---|
| 1 | Receive a request from NCAs, MLWP or IPs to start assessment of a new herbal substance and table it for the next HMPC meeting (together with background documents, if applicable).<br>Where applicable, follow the 'Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs' (EMA/HMPC/328575/2007 Rev 1.). | HMPC Assistant |
| 2 | Update the document 'Inventory of herbal substances for assessment' (EMA/HMPC/494079/2007). | HMPC Assistant |
| 3 | Does the HMPC recommend starting the assessment and appoint a Rapporteur and Peer-reviewer?<br>If YES: go to step 4.<br>If NO: End of procedure.<br>Record the HMPC decision in the HMPC ToD, minutes and meeting report. | HMPC Committee manager |
| 4 | Update the following "tracking" systems and documents according to the HMPC Table of Decisions: | |
| | • Overview of status of HMPC and MLWP assessment work (EMA/HMPC/519580/2007) (non-public) | HMPC Assistant |
| | • Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006) (public) | HMPC Assistant |
| | • Seed file (to support publication of HMPC documents on Agency website) (EMA/HMPC/367569/2009) | HMPC Assistant |
| | • HMPC public meeting report of the month when the Rapporteur appointment and/or the start of the assessment work was endorsed by the HMPC. | HMPC Committee manager |
| 5 | Prepare and send the standard e-mail (Web publication template e-mail – EMA/666445/2015) to the Web team to publish a call for submission of scientific data (see template in: Procedure for call for scientific data EMA/305056/2006 Rev. 4 *Corr.*) on the Agency website and make a reference to such call in the HMPC public meeting report.<br>Check that the documents are published correctly on the webpage for submission of scientific data on the Agency's website.<br>Make a reference to the call in the HMPC public meeting report. | HMPC Assistant<br><br>HMPC Committee manager |
| 6 | Record and acknowledge receipt of information and scientific data received in response to the call for submission of scientific data and | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| | transmit to the Rapporteur. Save the received e-mails with attachments in DREAM in the '02 Call for scientific data' subfolder for the concerned herbal substance. | |
| 7 | Are a draft monograph and/or list entry and/or related documents received from the Rapporteur prior to the MLWP meeting?<br><br>If NO: go to step 7.1.<br><br>If YES: go to step 8.<br><br>*Note: Send reminders before the MLWP meeting as appropriate. Send one e-mail on week-2 of the MLWP meeting and on e-mail on week-1 to MLWP members that the agenda is uploaded MMD and informing them on the deadlines.*<br>*(See User manual on HMPC/MLWP meetings and related activities EMA/HMPC/321041/2016).*<br><br>*Save the correspondence in DREAM in the '07 Correspondence – 01 Versions' subfolder of the concerned herbal substance.* | HMPC Assistant |
| 7.1 | Mark the topic as postponed on the MLWP agenda.<br><br>Return to step 7. | HMPC Assistant |
| 8 | Save documents received from the Rapporteur in DREAM in the folder of the concerned herbal substance, update the MLWP agenda and time schedule if necessary and upload the documents to MMD. | HMPC Assistant |
| 9 | If the MLWP supports the establishment of the monograph and/or list entry or public statement, go to step 10.<br><br>If the MLWP supports the cancellation of the assessment work, go to step 17.<br><br>Record the MLWP conclusions in the MLWP ToC and minutes. | HMPC Committee manager |
| 10 | Save documents amended during the MLWP meeting in DREAM in the subfolder of the concerned herbal substance and upload them to MMD. | HMPC Assistant |
| 11 | Are the updated documents received from the Rapporteur prior to next the MLWP meeting?<br><br>If YES: go to step 12.<br><br>If NO: go to step 11.1.<br><br>*Note: Send reminders before the MLWP meeting as appropriate. Send one e-mail on week-2 of the MLWP meeting and on e-mail on week-1 to MLWP members that the agenda is uploaded MMD and informing them on the deadlines. (See User manual on HMPC/MLWP meetings and related activities EMA/HMPC/321041/2016).*<br><br>*Save the correspondence in DREAM in the '07 Correspondence – 01* | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| | *Versions' subfolder of the concerned herbal substance.* | |
| 11.1 | Mark the topic as postponed on the MLWP agenda.<br><br>Return to step 11. | HMPC Assistant |
| 12 | Save documents received from the Rapporteur in DREAM in the folder of the concerned herbal substance, update the MLWP agenda and time schedule if necessary and upload the documents to MMD. | HMPC Assistant |
| 13 | Does the MLWP support the transmission of the documents for 'early' peer-review and to HMPC for adoption for public consultation?<br><br>If YES (for 'early' peer-review): go to step 14.<br><br>If NO (for rediscussion by MLWP): go to step 10.<br><br>Record the MLWP conclusions in the MLWP ToC and minutes. | HMPC Committee manager |
| 14 | Save documents amended during the MLWP meeting in DREAM in the subfolder of the concerned herbal substance and upload them to MMD. | HMPC Assistant |
| 15 | Do the Rapporteur and Peer-reviewer identify the need for re-discussion by MLWP as a result of the peer-review?<br><br>If YES (for rediscussion by MLWP): go to step 11.<br><br>If NO (for adoption by HMPC): go to step 16.<br><br>*Note: Save the updated versions received during peer-review from the Rapporteur and Peer-reviewer in DREAM and save the correspondence in the '06 Peer-review' subfolder for the concerned herbal substance.* | HMPC Assistant |
| 16 | Are the updated documents received from the Rapporteur prior to next HMPC meeting?<br><br>If YES: go to step 17.<br><br>If NO: go to step 16.1.<br><br>*Note: Send reminders before the HMPC meeting as appropriate. Send one e-mail on week-2 of the HMPC meeting and on e-mail on week-1 to HMPC members that the agenda is uploaded MMD and informing them on the deadlines. (See User manual on HMPC/MLWP meetings and related activities EMA/HMPC/321041/2016).*<br><br>*Save the correspondence in DREAM in the '07 Correspondence – 01 Versions' subfolder of the concerned herbal substance.* | HMPC Assistant |
| 16.1 | Mark the topic as postponed on the HMPC agenda.<br><br>Return to step 16. | HMPC Assistant |
| 17 | Save documents received from the Rapporteur in DREAM in the folder of the concerned herbal substance, update the HMPC agenda | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| | and time schedule if necessary and upload the documents to MMD. | |
| 18 | Decision by HMPC.<br>If cancellation of assessment work, go to step 18.1.<br>If monograph/list entry/public statement, continue with step 19.<br>Record the HMPC decision in the HMPC ToD, minutes and meeting report. | HMPC Committee manager |
| 18.1 | Update the document 'Inventory of herbal substances for assessment' (EMA/HMPC/494079/2007).<br>End of procedure. | HMPC Assistant |
| 19 | Have the draft AR, list of references, monograph and/or list entry or draft public statement been adopted by the HMPC for release for 3 months public consultation?<br>If YES: go to step 20.<br>If NO: go to step 11.<br>Record the HMPC decision in the HMPC ToD, minutes and meeting report. | HMPC Committee manager |
| 20 | Save documents amended during HMPC meeting in DREAM in the folder of the concerned herbal substance and upload them to MMD. | HMPC Assistant |
| 21 | Prepare the draft documents for release on the Agency website for 3-month public consultation and format all documents using the 'Editorial checklist for draft/final of EU herbal monographs, list entries and related documents' (EMA/612967/2007). | HMPC Assistant |
| 22 | Perform the linguistic/editorial quality check of the monograph using the 'Editorial checklist for draft/final of EU herbal monographs, list entries and related documents' (EMA/612967/2007). | HMPC Committee manager |
| 23 | Prepare and send the standard e-mail (Web publication template e-mail – EMA/666445/2015) to the Web team to publish the documents for consultation.<br>Check that the documents are published correctly on the website. | HMPC Assistant |
| 24 | If comments are received during the public consultation (including confirmation e-mail from associations that they have no comments), acknowledge receipt of each message received, forward them to the Rapporteur immediately (with the Peer-reviewer in copy) and save all comments received in DREAM in the '05 Public consultation' subfolder for the concerned herbal substance. | HMPC Assistant |
| 25 | At the end of the consultation period, send a list of the IPs who submitted comments to the Rapporteur and Peer-reviewer. Attach to this e-mail the Word version of the monograph/list entry/public | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| | statement and supporting documents as published on the Agency website for public consultation (for the Rapporteur to use them when preparing a new version).<br><br>*Note: At the end of the consultation period, in case there were no comments received from them, enquire whether relevant associations (i.e. AESGP as a minimum) have any comment.* | |
| 26 | Are the updated documents received from the Rapporteur prior to next MLWP meeting?<br><br>If YES: go to step 27.<br><br>If NO: go to step 26.1.<br><br>*Note: Send reminders before the MLWP meeting as appropriate. Send one e-mail on week-2 of the MLWP meeting and on e-mail on week-1 to MLWP members that the agenda is uploaded MMD and informing them on the deadlines. (See User manual on HMPC/MLWP meetings and related activities EMA/HMPC/321041/2016).*<br><br>*Save the correspondence in DREAM in the '07 Correspondence – 01 Versions' subfolder of the concerned herbal substance.* | HMPC Assistant |
| 26.1 | Mark the topic as postponed on the MLWP agenda.<br><br>Return to step 26. | HMPC Assistant |
| 27 | Save documents received from the Rapporteur in DREAM in the folder of the concerned herbal substance, update the MLWP agenda and time schedule if necessary and upload the documents to MMD.<br><br>*Note: The full set of references (in electronic format) should be received before final adoption by HMPC. Mark references on the MLWP agenda with xx/yy as a reminder.* | HMPC Assistant |
| 28 | Does the MLWP support the transmission of the documents for the peer-review and to HMPC for final adoption?<br><br>If YES (for peer-review): go to step 29.<br><br>If NO (for rediscussion by MLWP): go to step 26.<br><br>Record the MLWP conclusions in the MLWP ToC and minutes. | HMPC Committee manager |
| 29 | Save documents amended during the MLWP meeting in DREAM in the subfolder of the concerned herbal substance and upload them to MMD. | HMPC Assistant |
| 30 | Do the Rapporteur and Peer-reviewer identify the need for re-discussion by MLWP as a result of the peer-review?<br><br>If YES (for rediscussion by MLWP): go to 26.<br><br>If NO (for adoption by HMPC): go to 31.<br><br>*Note: Save the updated versions received during peer-review from* | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| | *the Rapporteur and Peer-reviewer in DREAM and save the correspondence in the '06 Peer-review' subfolder for the concerned herbal substance.* | |
| 31 | Are the updated documents received from the Rapporteur prior to next HMPC meeting?<br><br>If YES: go to step 32.<br><br>If NO: go to step 31.1.<br><br>*Note: Send reminders before the HMPC meeting as appropriate. Send one e-mail on week-2 of the HMPC meeting and on e-mail on week-1 to HMPC members that the agenda is uploaded MMD and informing them on the deadlines. (See User manual on HMPC/MLWP meetings and related activities EMA/HMPC/321041/2016).*<br><br>*Save the correspondence in DREAM in the '07 Correspondence – 01 Versions' subfolder of the concerned herbal substance.* | HMPC Assistant |
| 31.1 | Mark the topic as postponed on the HMPC agenda.<br><br>Return to step 31. | HMPC Assistant |
| 32 | Save documents received from the Rapporteur in DREAM in the folder of the concerned herbal substance, update the HMPC agenda and time schedule if necessary and upload the documents to MMD. | HMPC Assistant |
| 33 | For public statement, go to step 33.1.<br><br>For monograph/list entry, go to step 34. | HMPC Assistant |
| 33.1 | Does the HMPC adopt the public statement?<br><br>If YES: go to step 36.<br><br>If NO: go to step 26 (rediscussion at the MLWP) or 31 (rediscussion at HMPC), depending on the HMPC decision.<br><br>Record the HMPC decision in the HMPC ToD, minutes and meeting report. | HMPC Committee manager |
| 34 | Does the HMPC adopt the monograph/list entry?<br><br>If by CONSENSUS: go to step 35.<br><br>If by VOTE: go to step 34.1.<br><br>If NOT ADOPTED: go to step 26 (rediscussion at MLWP) or 31 (rediscussion at HMPC), depending on the HMPC decision.<br><br>Record the HMPC decision in the HMPC ToD, minutes and meeting report. | HMPC Committee manager |
| 34.1 | Receive the divergent positions via e-mail from the HMPC members during the HMPC meeting and save them in DREAM. Collect the signatures (dated and signed version, with the name of the | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| | member).<br><br>Go to step 35.<br><br>*Note: The dated and signed original (paper) of the divergent position(s) is(are) filed in a dedicated binder.* | |
| 35 | Prepare the HMPC opinion as required. Allocate a number according to the 'Final HMPC opinions' tab in the 'Overview of status of HMPC and MLWP assessment work' (EMA/HMPC/152126/2006).<br><br>*Note: See templates of opinion on a monograph (EMA/HMPC/207141/2006) and/or opinion on a list entry (EMA/HMPC/107749/2006). The divergent positions are added as an appendix in the Word version of the HMPC opinion.* | HMPC Assistant |
| 36 | Save documents amended during the HMPC meeting in DREAM in the folder of the concerned herbal substance and upload them to MMD. | HMPC Assistant |
| 37 | Prepare the final documents for publication on the Agency website and format all documents using the 'Editorial checklist for draft/final of EU herbal monographs, list entries and related documents' (EMA/612967/2007). | HMPC Assistant |
| 38 | Verify consistency and linguistic/editorial quality of all documents, using the 'Editorial checklist for draft/final of EU herbal monographs, list entries and related documents' (EMA/612967/2007). | HMPC Committee manager |
| 39 | Are there any major comments on the documents?<br><br>If YES: go to step 39.1.<br><br>If NO: go to step 40. | HMPC Committee manager |
| 39.1 | Contact the Rapporteur, Peer-reviewer or HMPC Chair as appropriate to finalise the documents.<br><br>Go to step 40. | HMPC Committee manager |
| 40 | Prepare the final version of the documents. | HMPC Assistant |
| 41 | Does the set of documents include a list entry?<br><br>If YES: go to step 42.<br><br>If NO: go to step 46. | HMPC Assistant |
| 42 | Send the request for translation of the list entry documents to CdT according to 'Checklist for List Entry translation and transmission to the Commission' (EMA/350470/2016). | HMPC Assistant |
| 43 | Send the English version and the translations of the list entry in the other EU languages with the supporting documents by Eudralink to the European Commission. | HMPC Assistant |

| Step | Action | Responsibility |
|---|---|---|
| 44 | Has the Commission Decision been published?<br><br>If YES: go to step 45.<br><br>If NO: go to step 44.1. | HMPC Assistant |
| 44.1 | Table information received from the European Commission to the HMPC for decision on relevant action(s).<br><br>End of procedure. | HMPC Assistant |
| 45 | Prepare the update of the relevant Agency webpage to include a link to the European Commission website. | HMPC Assistant |
| 46 | Prepare and send the standard e-mail (Web publication template e-mail – EMA/666445/2015) to the Web Team to update the webpage.<br><br>Check that the webpage is updated correctly on the website. | HMPC Assistant |
| 47 | Support the preparation of the HMPC assessment report summary for the public (ARSP) by S-CO-MHI. | HMPC Committee manager |
| 48 | Prepare and send the standard e-mail (Web publication template e-mail – EMA/666445/2015) to the Web Team to publish the English ARSP.<br><br>Check that the documents are published correctly on the website. | HMPC Assistant |
| 49 | Follow the steps required for translation of the ARSP by CdT, according to 'Checklist for ARSP (EMA/548762/2016). | HMPC Assistant |
| 50 | Prepare and send the standard e-mail (Template e-mail – EMA/666445/2015) to the Web Team to publish the ARSP in all EU languages.<br><br>Check that the documents are published correctly on the website. | HMPC Assistant |

# 10. Records

All versions of ARs, monographs and/or list entries and related documents submitted by the Rapporteur are saved in DREAM (Cabinets/01. Evaluation of Medicines/H–Herbal Monographs/<X>-<Y>/<herbal substance/preparation>).

Progress with the establishment of monographs and/or list entries, public statements and related documents as well as HMPC decisions on cancellation of assessment works are reflected after each MLWP and HMPC meeting in the following documents:

- Overview of status of HMPC and MLWP assessment work (EMA/HMPC/152126/2006)
- Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)
- Inventory of herbal substances for assessment (EMA/HMPC/494079/2007)
- Cumulative figures for final and draft monographs, list entries and public statements over time (EMA/HMPC/642131/2008)

- Excel Overview of content of final monographs (EMA/HMPC/308308/2009)
- Seed file (to support publication of HMPC documents on Agency website) (EMA/HMPC/367569/2009)

The 'Overview of status of HMPC assessment work – priority list' is published on the Agency website after each HMPC meeting. The 'Inventory of herbal substances for assessment' is published in case of any changes.

HMPC Opinions are tracked in the 'Overview of status of HMPC and MLWP assessment work' (EMA/HMPC/152126/2006).

The common names of herbal substances in all EU official languages are provided by HMPC/MLWP members if required and compiled by the HMPC secretariat in an Excel document: 'Common names of HS – All languages' (EMA/HMPC/95087/2011).

Rapporteur(s) shall provide copies of all references supporting a monograph/list entry to the HMPC secretariat, no later than the time when documents are tabled for final adoption by HMPC.

Scientific data in electronic format are saved under the appropriate folders in DREAM (Cabinets/01. Evaluation of Medicines/H–Herbal Monographs/<X>-<Y>/<herbal substance/preparation>).

The following documents are considered records (retention time: 50 years):

- Opinion on monograph
- Monograph
- Assessment report
- Overview of comments received on draft monograph
- List of references
- References
- Public statement in case no monograph could be established
- Draft monograph as published for consultation
- Opinion on list entry
- List entry in English and all other EU official languages
- Overview of comments received on draft list entry
- Letter to European Commission on list entry
- Corrigenda for list entry