EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Eligibility to the centralised procedure for medicinal products for human use		
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1. Purpose

To describe the process of handling requests for eligibility to the centralised procedure for medicinal products for human use, including the preparation of the eligibility report, the discussion of the requests and report at the CHMP meeting and the preparation and sending of eligibility letters to applicants.

2. Scope

This SOP applies to the CHMP Secretariat in the Committees Secretariat Service (C-CS-SCS), but with support from the Product and Application Business Support Service (I-BD-BUS), the Regulatory Affairs Office (D-RS-REA), the Quality Office (E-SD-QME) and the Procedure Management Department (C-PM).

It does not apply to eligibility to the centralised procedure for medicinal products for veterinary use.

3. Responsibilities

It is the responsibility of each Head of Department and Service/Office to ensure that this procedure is adhered to within their own department and service/office. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

New SOP.

This SOP replaces WIN/H/3136 on CHMP eligibility report and eligibility outcome letters.

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5. Documents needed for this SOP

- Template 1: Draft CP Eligibility Report
- Template 2: CHMP Sponsors Briefing Note
- Template 3: Eligibility letter
  - NAS wording
  - Art 28
  - Art 29
  - Art 3(1)
  - Art 3(2)a
  - Art 3(2)b
  - Art 31
  - Art 58
  - Art 83
  - Automatic access application
  - Generic application
  - Non eligible 1st round
  - Non eligible 2nd round
- New Active Substance wording decision tree

The above templates and document can be found in: Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/1. Governance/10. Templates/Templates/Eligibility + Rapporteurship/Eligibility 2010 templates

- User Manual 'Preparation of Draft Eligibility Report and Eligibility letters'. This user manual provides guidance on the use of SIAMED for the creation of the draft eligibility report and the eligibility letters. It can be found in: Cabinets/14. Working areas/14.03 C-Division/01. C-Division Administration/01. C-Division IMS and BCP/IQM/User guides C-CS
- SOP/EMA/0101 – Conducting checks for conflicts of interest of Agency employees assigned duties relating to medicinal products for human or veterinary use

6. Related documents

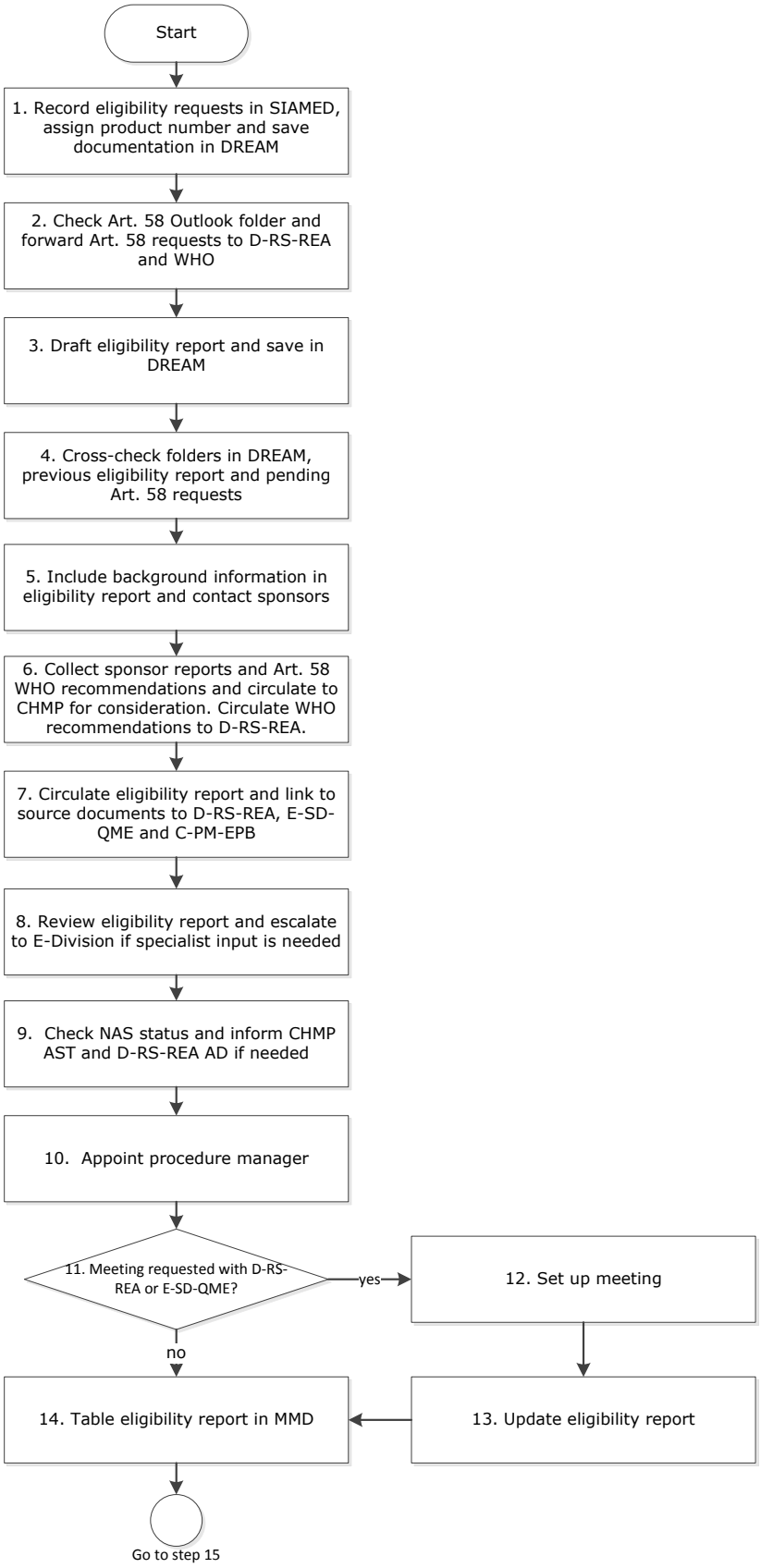
- Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (http://ec.europa.eu/health/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf)
- Regulation (EC) No 1901/2006 on medicinal products for paediatric use (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF)

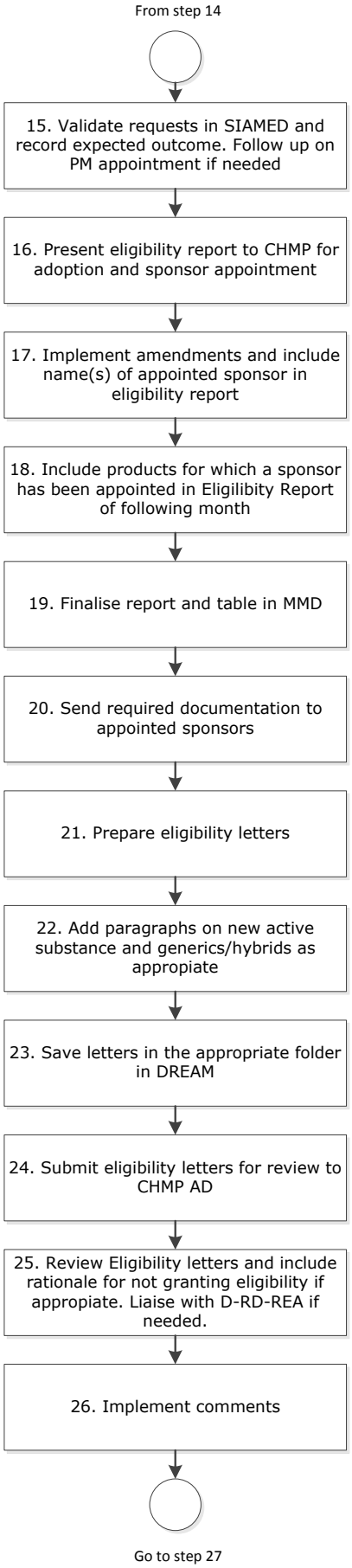
- Regulation (EC) No 1394/2007 on advanced therapy medicinal products (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF)
- Notice to Applicants, Volume 2A (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)
- Questions and answers on pre-submission guidance (EMA website: Home - Human regulatory - Pre-authorisation - Q&A: Pre-submission guidance, link to website)

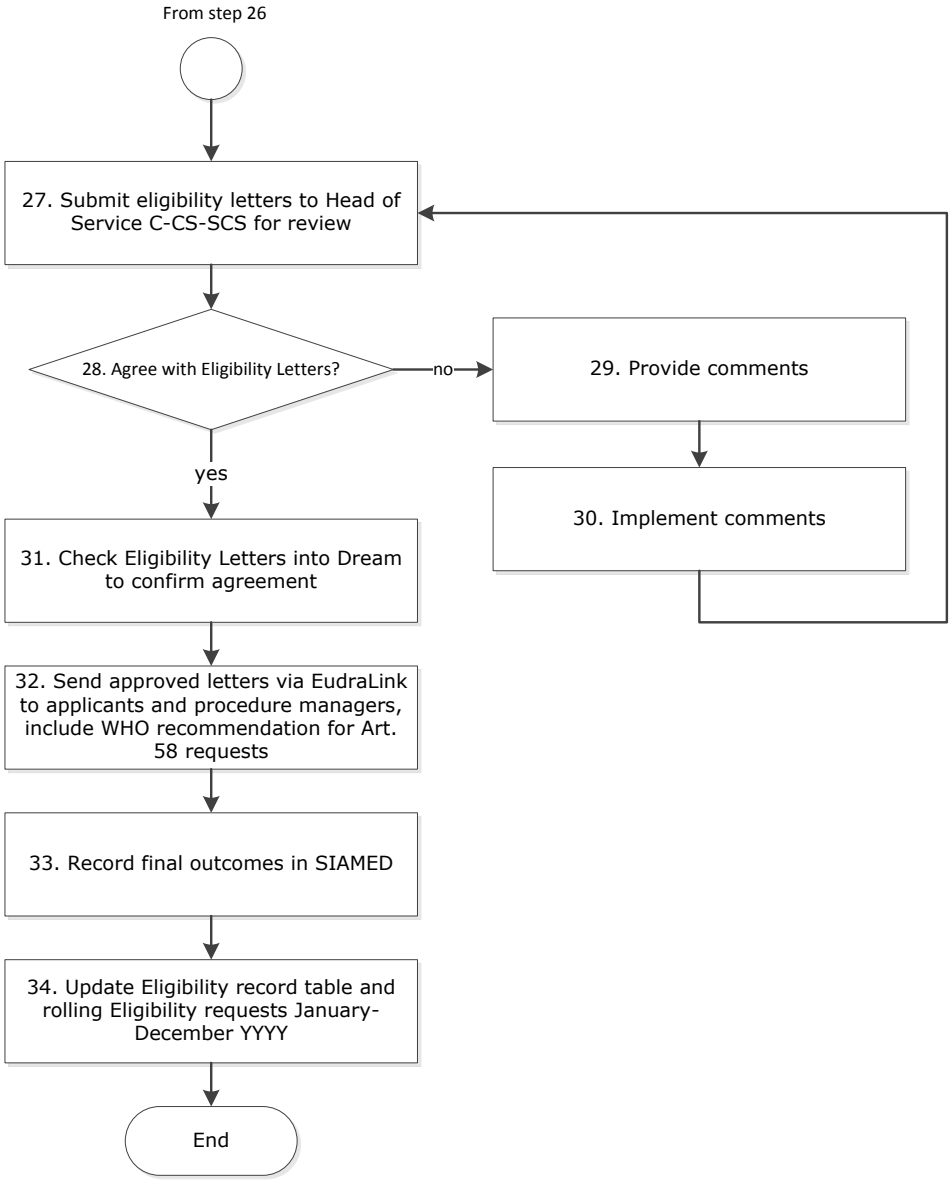
7. Definitions

- C-CS-SCS: Committees Secretariat Service
- CHMP: Committee for Medicinal Products for Human Use
- CHMP AD: Scientific Committee manager to CHMP
- CHMP AST: Scientific Committee assistant to CHMP
- CP: Centralised procedure
- C-PM: Procedure Management Department
- C-PM-EPB: Evaluation Procedures B Service
- DREAM: Agency's Document Records Electronic Archive Management system
- D-RS-REA: Regulatory Affairs Office
- EC: European Commission
- EMA: European Medicines Agency
- E-SD-QME: Quality Office
- I-BD-BUS: Product and Application Business Support Service
- MMD: Agency's Managing Meeting Documents system
- NAS: New active substance
- Q&A: Question and answers
- SIAMED: Agency's product information and application tracking system
- WHO: World Health Organisation

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




From step 14
15. Validate requests in SIAMED and record expected outcome. Follow up on PM appointment if needed
16. Present eligibility report to CHMP for adoption and sponsor appointment
17. Implement amendments and include name(s) of appointed sponsor in eligibility report
18. Include products for which a sponsor has been appointed in Eligilibity Report of following month
19. Finalise report and table in MMD
20. Send required documentation to appointed sponsors
21. Prepare eligibility letters
22. Add paragraphs on new active substance and generics/hybrids as appropiate
23. Save letters in the appropriate folder in DREAM
24. Submit eligibility letters for review to CHMP AD
25. Review Eligibility letters and include rationale for not granting eligibility if appropiate. Liaise with D-RD-REA if needed.
26. Implement comments
Go to step 27


From step 26
27. Submit eligibility letters to Head of Service C-CS-SCS for review
28. Agree with Eligibility Letters?
no
29. Provide comments
30. Implement comments
yes
31. Check Eligibility Letters into Dream to confirm agreement
32. Send approved letters via EudraLink to applicants and procedure managers, include WHO recommendation for Art. 58 requests
33. Record final outcomes in SIAMED
34. Update Eligibility record table and rolling Eligibility requests January-December YYYY
End

9. Procedure

Step	Action	Responsibility
Preparation of Eligibility Report		
1	Record the received eligibility requests in SIAMED, assign a product number and create a link to the documentation from the applicant in a specific product folder on eligibility for the given month in the CHMP meeting folder in DREAM: *Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/2. Meeting Organisation/<Year> Plenary Meetings/<Month>-<Year>/Eligibility requests and intention to submit* *Note: In case of a prior refusal of eligibility, the applicant can appeal the CHMP outcome and re-submit with additional/revised justification on its eligibility request. In this case the same product number is kept.*	I-PD-BUS
2	Check regularly the Art. 58 folder in Outook (All public folders/Chrono In/Workflow/Article 58) for any new submission. Forward any new eligibility request to the responsible colleague in the Regulatory Affairs Office (D-RS-REA) for any comments. Forward the documentation package for an Art. 58 eligibility request to the responsible person at WHO requesting assessment and providing of a recommendation.	CHMP AD/AST
3	Draft the Eligibility Report on the Monday of the week before any given CHMP meeting using SIAMED (see template 1 and user manual). Save the draft Eligibility Report in the relevant meeting folder in DREAM: *Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/2. Meeting Organisation/<Year> Plenary Meetings/<Month-<Year>/Eligibility requests and intention to submit*	CHMP AST
4	Cross check with the DREAM folder containing all eligibility requests (see step 1) that all eligibility requests have been included in the draft Eligibility Report for the given meeting, including Art. 58 requests. *Note: Submissions received up to one day after the official submission deadline can be accepted, as some applicants seeking clarifications last minute.* Cross check with the final Eligibility Report from the previous month and include the eligibility requests for Art.3 (2)b with the sponsor report pending and include the conclusions from the sponsor in the draft Eligibility Report of the current month.	CHMP AST

Step	Action	Responsibility
	Cross check the pending eligibility requests for Art. 58 and include them in the draft Eligibility Report of the current month.	
5	Update the draft Eligibility Report with the relevant background product information from the eligibility request. Identify products requiring sponsor's appointment and contact possible CHMP sponsors as soon as possible. *Note: A sponsor should also be appointed after receipt of an Art. 58 eligibility request. The sponsor receives the eligibility documentation as well as the response from WHO and reports back to the CHMP at the next Plenary.* *Note: In case a company appeals against a negative eligibility outcome, the same sponsor is asked to assess the new justification and reconsider the previous recommendation if appropriate.* Perform the quality check on the content of the draft Eligibility Report (see user manual).	CHMP AD
Pre-meeting phase		
6	Collect all sponsor reports and Art. 58 WHO recommendations for the current month and circulate them to the CHMP members in preparation of and for consideration at the Plenary meeting. Circulate the WHO recommendations also to the responsible colleague in the Regulatory Affairs Office (D-RS-REA) for any comments.	CHMP AD/AST
7	By Tuesday end of business pre-CHMP week (at the latest), circulate the draft Eligibility Report and a link to the source documents in DREAM to the responsible colleague in the Regulatory Affairs Office (D-RS-REA) as well as the responsible colleague in the Quality Office (E-SD-QME) for any comments by Thursday end of business. Send the draft Eligibility Report also to the Head of Service of Evaluation Procedures B (C-PM-EPB) for him/her to appoint the procedure manager for each procedure.	CHMP AST
8	Review of the draft Eligibility Report for any regulatory consistency and plausibility. Escalate an issue to the E-division or other services if needed. Inform the CHMP AST in case of amendments to the report or if a face-to-face meeting is required.	D-RS-REA AD
9	Check the new active substance status of eligibility procedures for Art 3(2)a and Art 3(1) indent 3 if needed. Inform the CHMP AST in case of amendments to the report or if a	E-SD-QME AD

Step	Action	Responsibility
	face-to-face meeting is required. In case of issues concerning the new active substance status are identified, also inform the D-RS-REA AD immediately.	
10	Appoint a procedure manager for each of the products taking into account SOP/EMA/0101 and include the names in SIAMED.	HSer C-PM-EPB
11	Is a meeting requested between the CHMP AD, D-RS-REA colleague and E-SD-QME colleague? If yes, go to with step 12. If no, go to step 14.	CHMP AST
12	Set up the meeting on the Friday before CHMP.	CHMP AST
13	Following the meeting, update the content of the draft Eligibility Report if changes are required and save the document in DREAM.	CHMP AD/AST
14	Table the draft Eligibility Report in MMD.	CHMP AST
Meeting phase		
15	In SIAMED, validate the eligibility requests and record the draft eligibility requests outcomes (expected decision) during the CHMP week (see user manual). Check if the C-PM Procedure Managers have been included in SIAMED for each of the concerned procedures. If not, contact the Head of Service C-PM-EPB.	CHMP AST
16	Present the draft Eligibility Report at the CHMP meeting for adoption and appointment of sponsors. *Note: In case of article 3(2)b conclusions, ensure that the eligibility sponsor is present for the CHMP discussions.*	CHMP AD/AST
17	Implement amendments to the draft Eligibility Report if necessary. Update the content of the draft Eligibility Report with the names of the appointed sponsors if required.	CHMP AST
18	If a sponsor has been appointed by the CHMP, include the product in the Eligibility Report of the following month. *Note: The sponsor report is expected by Friday two weeks before the next CHMP.*	CHMP AST
19	Save the final version of the Eligibility Report in DREAM and table it in MMD.	CHMP AST
Post-meeting phase		
20	For a product where a sponsor has been appointed, send the product details (eligibility request, application documentation	CHMP AST

Step	Action	Responsibility
	received from the applicant) and completed Sponsor Briefing Note (see template 2) to the appointed sponsor reminding him/her of the Friday two weeks pre-CHMP deadline. Save sponsor reports received from the CHMP members in DREAM: *Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/2. Meeting Organisation/<Year> Plenary Meetings/<Month>-<Year>/Eligibility requests and intention to submit /Sponsor reports* (month when eligibility was granted by the CHMP).	
Preparation and distribution of Eligibility Letters		
21	Prepare the Eligibility Letters to be sent to the applicant, during the CHMP week using SIAMED (see template 3 and user manual).	CHMP AST
22	For any product with a legal basis of Article 8(3) – new active substance or known active substance, add the relevant paragraph in accordance with the basis for eligibility and the type of active substance (chemical or biological) to the Eligibility Letter. For any generic or hybrid product (Generic/Hybrid of a Centrally Authorised Medicinal Product (Article 3(3) of Regulation (EC) No 726/2004)), add the paragraph on the confirmation of the legal basis to the Eligibility Letter. (see New Active Substance wording decision tree).	CHMP AST
23	Save the Eligibility Letters in DREAM: *Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/2. Meeting Organisation/<Year> Plenary Meetings/<Month>-<Year>/Eligibility requests and intention to submit /Letters to companies* (month when eligibility was granted by the CHMP).	CHMP AST
24	Submit hard copies of the Eligibility Letters together with the relevant eligibility requests and the final Eligibility Report to CHMP AD for review.	CHMP AST
25	Review the Eligibility Letters and provide comments as appropriate. In case that eligibility is refused, expand in the Eligibility Letter the rationale for not granting eligibility to the centralised procedure. Liaise with the responsible D-RS-REA colleague if needed.	CHMP AD
26	Implement the CHMP AD's comments.	CHMP AST
27	Submit the hard copies of the Eligibility Letters with the comments from the CHMP AD together with the relevant eligibility requests and the final Eligibility Report to the Head of Service Committees Secretariats (C-CS-SCS) for agreement. Furthermore, send the Head of Service C-CS-SCS the link to the folder in DREAM where the letters are saved.	CHMP AST

Step	Action	Responsibility
28	Review the content of the Eligibility Letters (on the screen in DREAM or on the paper copies). If in agreement, go to step 31. If not in agreement, go to step 29.	HSer C-CS-SCS
29	Provide comments to the CHMP AST for correction.	HSer C-CS-SCS
30	Implement the Head of Service's comments. Return to step 27.	CHMP AST
31	Check the letters out in DREAM and check them back into DREAM as a higher version. Write in the version label "seen and agreed" to confirm agreement.	HSer C-CS-SCS
32	Send the WORD versions of the approved Eligibility Letters via EudraLink to the applicant and copy the Procedure Manager, using the eligibility EudraLink account. For Art. 58 eligibility requests, include also the recommendation letter received from the WHO. In the EudraLink message, include the following disclaimer: *Please note that no hard copy of the Eligibility Letter will be sent by post and this electronic copy is the formal correspondence.*	CHMP AST
Record of the final decision of the CHMP in SIAMED		
33	During the week after the CHMP, record the final eligibility requests outcomes (final decision) in SIAMED (see user manual). Ensure that the correct final decision is recorded in case it has changed compared to the expected outcome.	CHMP AST
34	Update the Eligibility record table and the rolling Eligibility requests January-December <YYYY> document accordingly. *Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/1. Governance/11. Secretariat/Statistics* *Cabinets/02b. Administration of Scientific Meeting/CHMP - Administration/2. Meeting Organisation/Rolling Eligibility requests and Rapporteurship per year*	CHMP AST

10. Records

Electronic copies of the relevant documents and letters are saved in the appropriately labelled folders in DREAM: Cabinets/02b. Administration of Scientific Meeting/CHMP-Administration/2. Meeting Organisation/<Year> Plenary Meetings/<Month>-<Year>/Eligibility requests and intention to submit and kept for at least 15 years.

The Eligibility Report adopted by the CHMP and tabled in MMD is considered as the record and kept permanently.