EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: CHMP/CAT/PRAC rapporteur/co-rapporteur/peer reviewer appointment in the centralised procedure		
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1. Purpose

To describe the procedure for the CHMP/CAT/PRAC rapporteur/co-rapporteur/peer reviewer appointment in the centralised procedure and under the PRIME scheme for medicinal products for human use, as well as the CHMP/PRAC liaison appointment. This procedure applies to the following application types:

- New marketing authorisation applications (MAAs), including generic medicinal products, hybrid medicinal products, similar biological medicinal products, advanced therapy medicinal products, non-prescription medicinal products, MAAs under exceptional circumstances, conditional marketing authorisations, applications under Article 58 of Regulation (EC) 726/2004, compassionate use applications, applications in accordance with Article 28, 29 and 31 of Regulation No 1901/2006
- Consultation on ancillary medicinal substances
- PRIME scheme.

2. Scope

This SOP applies to the CHMP Secretariat in the Committees Secretariat Service (P-CI-SCS), but with support from the Product and Application Business Support Service (I-BD-BUS), the Human Medicines Research and Development Support Division and the Human Medicines Evaluation Division.

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3. Responsibilities

It is the responsibility of each Head of Division/Department/Service/Office to ensure that this procedure is adhered to within their Division/Department/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

Major revision to include the principle of multinational teams, the appointment of the CHMP/CAT rapporteur under the PRIME scheme and the appointment of the CHMP/PRAC liaison. Furthermore, the new organisational structure of the EMA was taken into account and the preparation and sending of the outcome letters was added (previously WIN/H/3260 – CHMP rapporteur, co-rapporteur and peer reviewer appointment – sending outcome letters).

5. Documents needed for this SOP

- Procedural Advice on CHMP/CAT/PRAC Rapporteur/Co-Rapporteur appointment principles, objective criteria and methodology in accordance with Article 62 (1) of Regulation (EC) No 726/2004 (EMA/151751/2010) (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004163.pdf)
- Template 1 – CHMP Rapporteurship and assessment team nomination form
- Template 2 – CAT Rapporteurship and assessment team nomination form
- Template 3 – PRAC Rapporteurship and assessment team nomination form
- Template 4 – Communication to multinational teams

The above templates are located in: Cabinets/6. Corporate governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*3000-3999 H (Human)/3143 SOP – CHMP/CAT/PRAC rapporteur co-rapporteur peer reviewer appointment in the centralised procedure.

6. Related documents

Legal framework on CHMP rapporteur/co-rapporteur appointment

- Articles 62(1) and 61(5), 61(6), 62(3), 62(4) of Regulation (EC) 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_cons/reg_2004_726_cons_en.pdf)

Other related documents

- Directive 2001/83/EC on the community code relating to medicinal products for human use (http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf)
- Regulation (EC) No 1901/2006 on medicinal products for human use (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF)

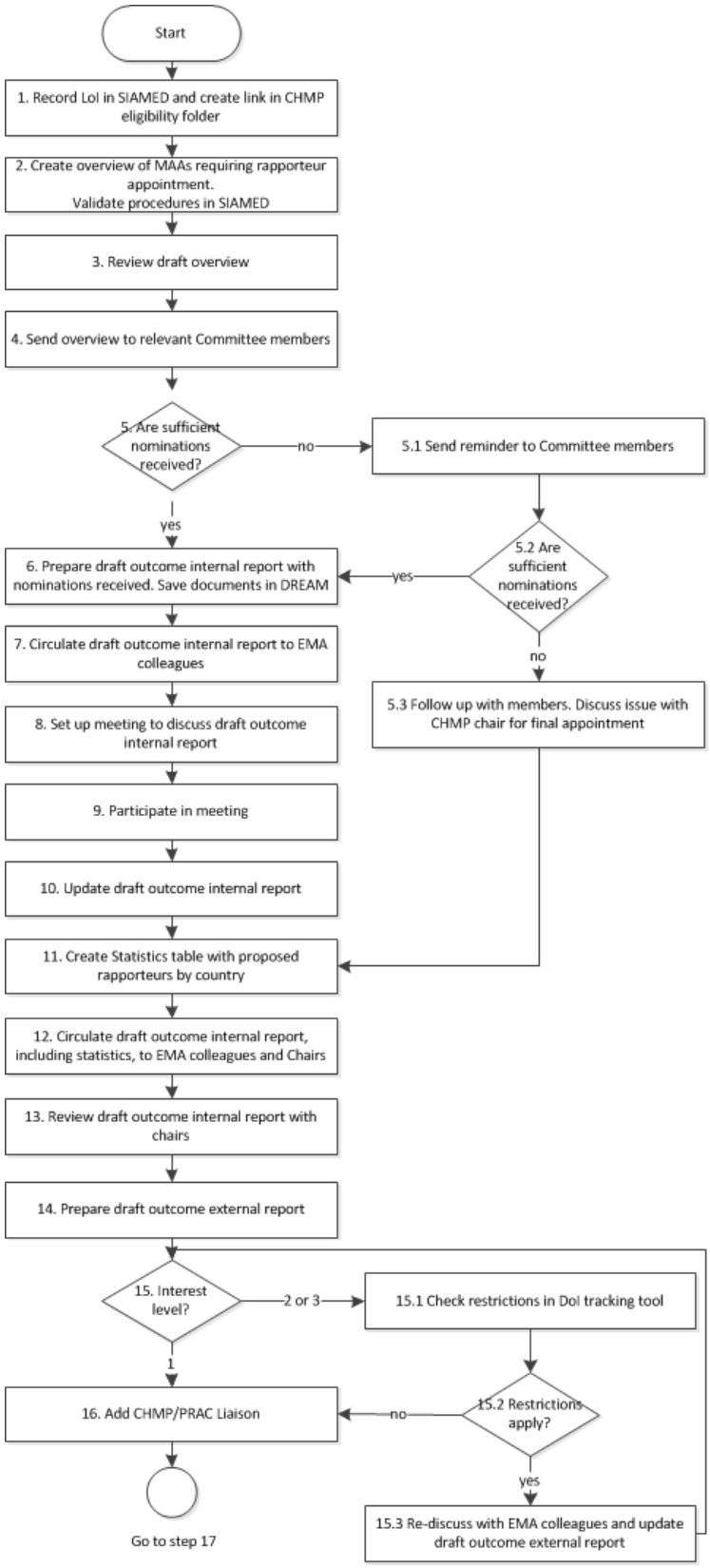
- Notice to Applicants, Volume 2A (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)
- CHMP Rules of Procedure (EMA/MB/87146/2007) (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004628.pdf)
- CAT Rules of Procedure (EMA/CAT/454446/2008) (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004761.pdf)
- PRAC Rules of Procedure (EMA/PRAC/567515/2012) (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/03/WC500139609.pdf)
- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (policy/0044, EMA/626261/2014) (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216190.pdf)
- EMA code of conduct (EMA/385894/2012) (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf)
- Guideline on Similar Biological Medicinal Products (CHMP/437/04 Rev 1) (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/10/WC500176768.pdf)
- EMA Pre-authorisation guidance for users of the centralised procedure (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000167.jsp&mid=WC0b01ac0580b18196)
- Good Pharmacovigilance Practices (GVP) (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c)
- Recommended submission dates for Applicants/MAHs for full applications (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000330.jsp&mid=WC0b01ac05803d8b9c)

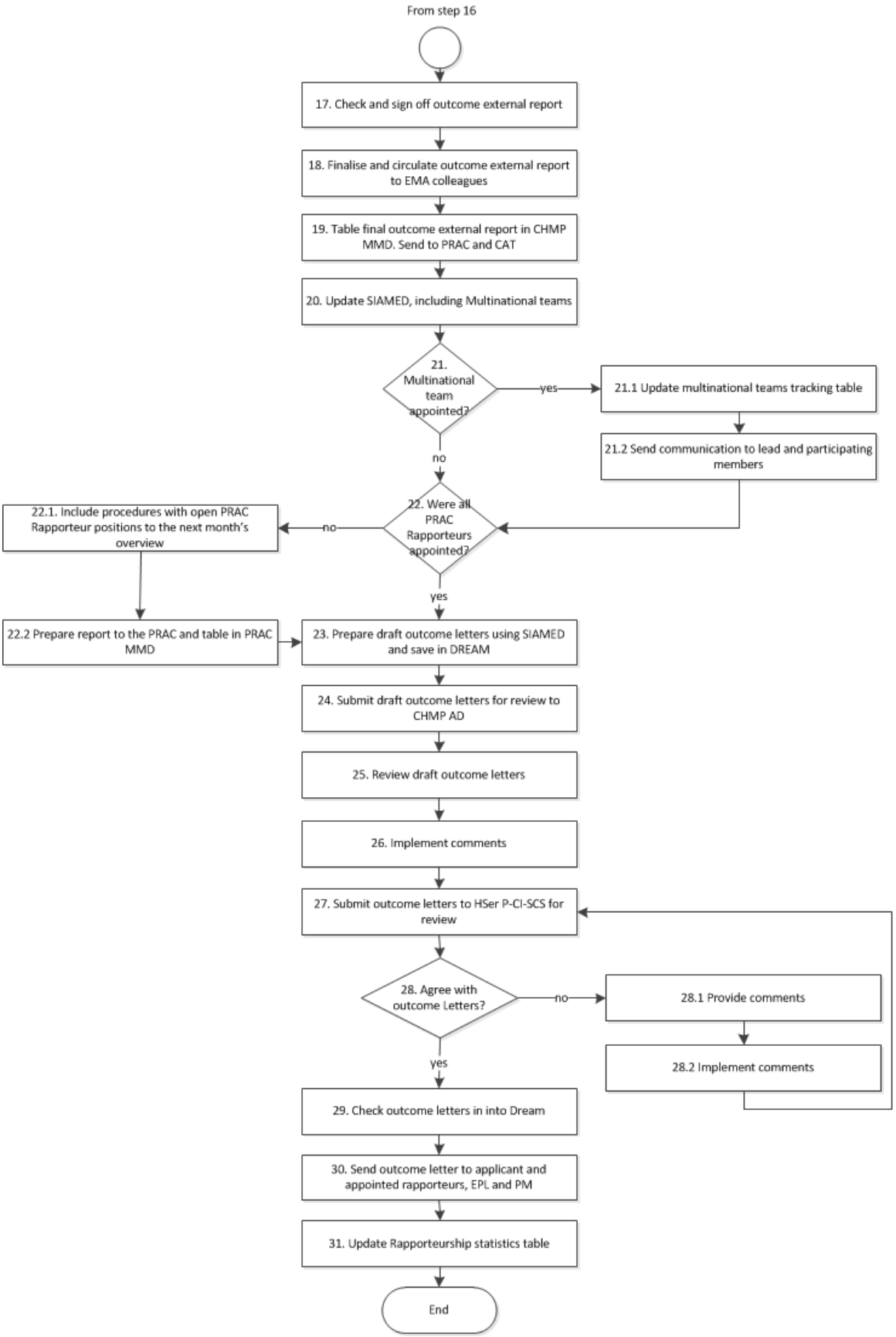
7. Definitions

ATMP	Advanced therapies medicinal product
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CHMP AD	Scientific Committee manager to CHMP
CHMP AST	Scientific Committee assistant to CHMP
DREAM	Document Records and Electronic Archive Management system
D-SD-QME	Specialised Scientific Discipline Department, Quality office
e-DoI	electronic declaration of interests
EMA	European Medicines Agency
EPL	EMA Evaluation Product Leader

E-SR	Scientific and Regulatory Management Department
HDep	Head of Department
HOff	Head of Office
HSer	Head of Service
I-BD-BUS	Product and Application Business Support Service
LoI	Letter of intent
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
Members	Committee members including alternates, co-opted members and/or EC nominated members
MMD	Managing Meeting Documents system
P-CI	Committees and Inspections Department
P-CI-SCS	Scientific Committee Secretariat Service
PM	Procedure Manager
PRAC	Pharmacovigilance Risk Assessment Committee
PRIME	Priority Medicines

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




From step 16
17. Check and sign off outcome external report
18. Finalise and circulate outcome external report to EMA colleagues
19. Table final outcome external report in CHMP MMD. Send to PRAC and CAT
20. Update SIAMED, including Multinational teams
21. Multinational team appointed?
yes
21.1 Update multinational teams tracking table
21.2 Send communication to lead and participating members
no
22. Were all PRAC Rapporteurs appointed?
no
22.1. Include procedures with open PRAC Rapporteur positions to the next month's overview
22.2 Prepare report to the PRAC and table in PRAC MMD
yes
23. Prepare draft outcome letters using SIAMED and save in DREAM
24. Submit draft outcome letters for review to CHMP AD
25. Review draft outcome letters
26. Implement comments
27. Submit outcome letters to HSer P-CI-SCS for review
28. Agree with outcome Letters?
no
28.1 Provide comments
28.2 Implement comments
yes
29. Check outcome letters in into Dream
30. Send outcome letter to applicant and appointed rapporteurs, EPL and PM
31. Update Rapporteurship statistics table
End

9. Procedure

Step	Action	Responsibility
	Initiation of the CHMP/CAT/PRAC rapporteurs/co-rapporteurs/peer reviewer and CHMP/PRAC liaison appointment procedure	
1	*When the LoI (Pre-submission form – Scope of Request: Centralised Procedure – Intent to submit a MAA) is received:* Record the "Intent to submit an initial application" in SIAMED and create a link to the letter of intent (LoI) 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). *Notes:* • *When requesting a rapporteur/co-rapporteur appointment, applicants should follow the timetable from Q2.5 of the Pre-authorisation guidance.* • *In case of eligibility to the centralised procedure request, the CHMP/CAT/PRAC rapporteurs, co-rapporteurs, peer reviewer and CHMP/PRAC liaison appointment is performed after the eligibility process. In case of duplicates or informed consent applications, the appointment can be done in parallel to the eligibility process.* • *The actual appointment takes place at the earliest 6 months prior to the intended submission date.* *For example: If the MAA intended submission date is in December, then the applicant should submit a LoI 7 months in advance, i.e. by May the same year. Appointment of the CHMP/CAT/PRAC rapporteurs, co-rapporteurs, peer reviewer and CHMP/PRAC liaison takes place at the June CHMP meeting. Even if the LoI is submitted earlier than 7 months before the intended submission date, the appointment takes place at the June CHMP meeting at the earliest.* • *Rapporteur appointment for PRIME products: Once the eligibility to the PRIME scheme at proof of concept stage has been granted by CHMP, regardless of the intended submission date, the appointment of the CHMP Rapporteur or of the CAT Rapporteur and the corresponding CHMP Coordinator is initiated for appointment the following month. The appointment of the CHMP or CAT Co-Rapporteur, PRAC rapporteur/co-rapporteur, peer reviewer and CHMP/PRAC liaison will be initiated at the time of receipt of the letter of intent and 7*	I-BD-BUS

Step	Action	Responsibility
	months in advance of the intended submission date at the earliest.	
2	*During the CHMP week, after the expected outcome has been recorded in SIAMED for each procedure from the final outcome Rapporteurship external report for the current month:* Create an overview of all MAAs for which a rapporteurs/co-rapporteurs/peer reviewer/CHMP/PRAC liaison appointment is required for the next month using SIAMED. Check if procedures without appointed PRAC Rapporteurs need to be included from the previous month and check any outstanding requests from PMs/EPLs or applicants. Validate all procedures in SIAMED with as validation date the day after the submission deadline for the current month. In addition, add all procedures to the list which have been granted eligibility to the PRIME scheme at proof of concept stage during the CHMP week.	CHMP AST
3	Review the draft overview of all MAAs for which a rapporteurs/co-rapporteurs/peer reviewer/CHMP/PRAC liaison appointment is required. Check that the requested biddings correspond to the required resources for the concerned product type and update the overview if needed.	CHMP AD
4	*On Monday the week after the CHMP week*: Send an e-mail via EudraNet and an EudraLink message to all CHMP and PRAC members and in case of an ATMP also to all CAT members and CC to *Rapporteurship@ema.europa.eu* with the following documents attached: • The overview of all MAAs for which a rapporteurs/co-rapporteurs/peer reviewer/CHMP/PRAC liaison appointment is required at the next month's CHMP meeting. • A nomination form for rapporteurship and their assessment team (a separate nomination form for the CHMP, CAT and PRAC Rapporteurships – Templates 1, 2 and 3). • The final outcome of rapporteur/co-rapporteur/peer review/CHMP/PRAC liaison appointments for the current month. • The statistics on rapporteur/co-rapporteur/peer reviewer appointment for the current year (<Year> CHMP-PRAC Rapporteurship Stats). • Member State profiles for multinational teams (only for CHMP and CAT). *Note: CHMP, PRAC and CAT members are requested to complete*	CHMP AST

Step	Action	Responsibility
	the overview document, to indicate their priority order for rapporteurship, co-rapporteurship and/or peer review, to indicate their priority order for CHMP, CAT or PRAC and to return the form electronically to the CHMP Secretariat (Rapporteurship@ema.europa.eu) within the given deadline (two weeks), together with a completed assessors nomination form for each application they are nominating a rapporteur or co-rapporteur for.	
	Nomination process	
5	*On Friday 2 weeks before the next CHMP meeting:* Are sufficient nominations received from CHMP and CAT members? If sufficient nominations for rapporteur/co-rapporteur are received for all MAAs from the overview by the nomination process deadline (i.e. at least three nominations for CHMP rapporteur and co-rapporteur for each MAA from three different NCAs to also identify one peer reviewer), go to step 6. If insufficient nominations for rapporteur and/or co-rapporteur are received for a MAA from the overview by the nomination process deadline, inform the CHMP AD and go to step 5.1.	CHMP AST
5.1	Send a reminder to all CHMP and CAT members if appropriate. *Note: This reminder is sent by Tuesday closure of business 1 week before the next CHMP meeting. CHMP and CAT members are requested to provide their nominations as soon as possible and no later than Friday before the CHMP meeting.*	CHMP AD
5.2	Are sufficient nominations received from CHMP and CAT members? If sufficient nominations are received, go to step 6. If after this second deadline (still) insufficient nominations are received for a MAA, inform the CHMP AD and go to step 5.3.	CHMP AST
5.3	Follow up with members who have Rapporteurships for similar products whether they can take the required rapporteurship or peer review, considering multinational teams. Discuss the issue with the CHMP Chairman who will decide on the final appointment of the rapporteur/co-rapporteur/peer reviewer based on the objective criteria outlined in the procedural advice. Go to step 11.	CHMP AD
	Appointment process	
6	*By Tuesday of the week before the CHMP meeting:* Compile all priorities indicated in the overviews by the CHMP, PRAC	CHMP AST

Step	Action	Responsibility
	and CAT members by the process deadline into the draft outcome rapporteurship internal report. Indicate clearly nominations for multinational teams, mentioning the lead and the participating NCA(s). If no CHMP/PRAC/CAT member's name is stated in the overview, send an e-mail to the person from the NCA who provided the overview requesting clarification on the member nominated. Save the e-mails of the CHMP, PRAC and CAT members with the completed overviews and the assessment team nomination forms as well as the draft outcome rapporteurship internal report in DREAM (Cabinets/02b. Administration of Scientific Meeting/CHMP – Administration/2. Meeting Organisation/<year> Plenary meetings/<month> - <year>/Rapporteurships allocation/Correspondence). Save each nomination form in the appropriate product folder in the CHMP, CAT or PRAC subfolder with the file name starting with the two letter country code of the nominating NCA.	
7	*By Wednesday lunchtime of the week before the CHMP meeting week:* Circulate links to the draft outcome rapporteurship internal report and the folder with the assessment team nomination forms received to the designated colleagues in the E-SR and D-SD-QME Offices, the HSer P-CI-SCS and the HOff in E-SR and E-SD to evaluate the scientific expertise of the various assessment teams mentioned in the assessment team nomination forms.	CHMP AST
8	*On Friday of the week before the CHMP meeting:* Set up a meeting between the CHMP AD, PRAC AD, CAT AD if applicable, HSer P-CI-SCS and the designated colleagues in the E-SR and D-SD-QME Offices to discuss the draft outcome rapporteurship internal report, the assessment team nomination forms received and the best expertise available. *Note: This recurrent meeting is set up in August of the previous year on a monthly basis (Friday prior the CHMP meeting week).*	CHMP AST
9	Participate in the meeting and take notes of the proposals for rapporteur/co-rapporteur/peer reviewer appointment agreed during the meeting. Provide an update to the CHMP AST.	CHMP AD
10	Based on the outcome of the meeting, update the draft outcome rapporteurship internal report with the names of the proposed rapporteurs, co-rapporteurs and peer reviewers.	CHMP AST

Step	Action	Responsibility
11	Create a table with the proposed rapporteurs/co-rapporteurs/peer-reviewers allocated by country.	CHMP AST
12	Send the draft outcome rapporteurship internal report and the table by e-mail to the HSer P-CI-SCS, HOff in E-SR and D-SD-QME, the designated colleagues in the E-SR and D-SD-QME Offices and the CHMP Chair, PRAC Chair and if applicable CAT Chair.	CHMP AST
13	*On Monday morning of CHMP week*: Review the draft outcome rapporteurship internal report with the CHMP and PRAC Chairs, the designated colleagues in the E-SR and D-SD-QME Offices, as well as the CAT Chair in case of ATMP applications. Note the decisions taken by the Chairs on the rapporteur/co-rapporteur/peer reviewer appointment and inform the CHMP AST accordingly. Follow up with CHMP, CAT and PRAC members during the CHMP Plenary week if needed.	CHMP AD
14	Prepare the outcome rapporteurship external report with the rapporteurs/co-rapporteurs/peer reviewers as per the Chairs' decision, removing the priorities. Check the e-DoI of the rapporteurs, co-rapporteurs and peer reviewers in the EDM DoI tracking tools and include their interest levels in the draft outcome rapporteurship external report.	CHMP AST
15	*Only in case no restrictions are applicable (declared interests do not prevent appointment for a specific product from a specific company) can the CHMP, PRAC and CAT member be appointed as rapporteur, co-rapporteur, peer reviewer or CHMP/PRAC liaison.* For rapporteurs, co-rapporteurs and peer reviewers with an interest level 1 (no interests declared), go to step 16. For rapporteurs, co-rapporteurs and peer reviewers with an interest level 2 (indirect interests declared) or 3 (direct interests declared), go to step 15.1.	CHMP AST
15.1	Check in the EDM DoI tracking tools the restrictions for the CHMP, CAT and PRAC members nominated as rapporteurs, co-rapporteurs and peer reviewers and verify if the restrictions apply to the concerned medicinal product.	CHMP AD
15.2	In case no restrictions apply, go to step 16. In case a restriction applies, go to step 15.3.	CHMP AD
15.3	Contact the designated colleagues in the E-SR and D-SD-QME Offices as soon as possible to re-discuss the rapporteurs, co-	CHMP AD

Step	Action	Responsibility
	rapporteurs and peer reviewers for the concerned medicinal product. Agree on a revised draft outcome rapporteurship external report via e-mail and confirm it with the CHMP, CAT and PRAC chairs. Go back to step 15 for checking the restrictions of the new rapporteur, co-rapporteur and peer reviewer.	
16	Include the CHMP/PRAC liaison once the PRAC Rapporteur is decided. *Note:* *The CHMP/PRAC liaison is responsible for the review of comments on the PRAC Rapporteurs Assessment Report received from the CHMP, the presentation of the comments to the CHMP if applicable and for the review and update of the Request for Supplementary Information (RSI) and PRAC Assessment Report, if applicable.* *The CHMP/PRAC liaison is the CHMP member from the same NCA as the PRAC rapporteur. If this member has an interest level 2 or 3, he is replaced by the CHMP alternate of the same NCA. If this alternate has an interest level 2 or 3, ask the CHMP AD to identify a suitable CHMP/PRAC liaison.*	CHMP AST
17	*During the CHMP meeting*: Check the draft outcome rapporteurship external report and update as necessary. Ensure that all restrictions have been checked for all nominated members with an interest level 2 or 3. Sign the external report off at the end of the document and check it in into DREAM.	CHMP AD
18	Ensure that the outcome rapporteurship external report in the rapporteurship folder has been signed off by the CHMP AD before making the report final. Send the final outcome rapporteurship external report by e-mail to the HSer P-CI-SCS, HOff in E-SR and D-SD-QME and the designated colleagues in the E-SR and D-SD-QME Offices.	CHMP AST
19	Table in MMD the final outcome rapporteurship external report for adoption at the CHMP. Send the final outcome rapporteurship external report to the PRAC for endorsement and in case of ATMP applications to the CAT secretariat for information.	CHMP AST
20	Update SIAMED (at product level) and record the final outcome with the appointed rapporteurs, co-rapporteurs, peer reviewer and CHMP/PRAC liaison for each MAA.	CHMP AST

Step	Action	Responsibility
	In case of a multinational team, include the details on the lead and the participating member state(s) in SIAMED.	
21	In case of the appointment of a multinational team, go to 21.1. If no multinational team is appointed, go to step 22.	CHMP AST
21.1	Update the Multinational teams tracking table in DREAM (Cabinets/ 02b. Administration of Scientific Meeting/CHMP – Administration/1. Governance/11. Secretariat/Statistics).	CHMP AST
21.2	Send an e-mail to the lead/participating CHMP members with general information on multinational teams (Template 4).	CHMP AST
22	Were PRAC Rapporteurs appointed for all procedures requiring PRAC Rapporteurs? If no, go to step 22.1. If yes, go to step 23.	CHMP AST
22.1	Include procedures without appointed PRAC rapporteurs in the next month's overview of all MAA for which an appointment is required (see step 2).	CHMP AST
22.2	Include procedures without appointed PRAC rapporteurs in a report to the PRAC. Table the report under section 12.01 in the PRAC MMD for discussion at the following PRAC meeting.	CHMP AD
	Preparation and distribution of outcome letters	
23	Prepare the outcome letters of rapporteurship appointment using SIAMED (file share: \\fs-prod.eudra.org\OracleBI\Siamed2\Rapporteurship Outcome letters). Save the draft outcome letters in DREAM (Cabinets/02b. Administration of Scientific Meeting/CHMP – Administration/2. Meeting Organisation/<year> Plenary Meetings/<month> - <year>/ Rapporteurships allocation/Rapporteurship letters (month when Rapporteurs were appointed by the CHMP)).	CHMP AST
24	Submit hard copies of the outcome letters of rapporteurship appointment together with the relevant pre-submission form (LoI) to the CHMP AD for review.	CHMP AST
25	Review the outcome letters for compliance with the final outcome rapporteurship external report and pre-submission forms and provide comments as necessary to the CHMP AST.	CHMP AD
26	Implement the CHMP AD's comments.	CHMP AST
27	Send the P-CI-SCS HSer the link to the folder in DREAM where the	CHMP AST

Step	Action	Responsibility
	letters are saved for electronic sign off.	
28	Review the content of the outcome letters. If in agreement, go to step 29. If not in agreement, go to step 28.1.	HSer P-CI-SCS
28.1	Provide comments to the CHMP AST for correction.	HSer P-CI-SCS
28.2	Implement the HSer's comments. Return to step 27.	CHMP AST
29	Check the letters out in DREAM and check them back in into DREAM as a higher version. Write in the version label "seen and agreed" to confirm agreement.	HSer P-CI-SCS
30	Send the WORD version of the outcome letter of rapporteurship appointment via EudraLink, using the Rapporteurship Eudralink account to the applicant and copy the appointed CHMP, PRAC and CAT rapporteurs, co-rapporteurs and peer reviewers, the EPL and the PM. In the EudraLink message include the following disclaimer: *"Please note that no hard copy will be sent by post and this WORD document is the formal correspondence."*	CHMP AST
31	Update the statistics table '<year>-CHMP-PRAC Rapporteurship Stats' in DREAM (Cabinets/02b. Administration of Scientific Meeting/CHMP – Administration/1. Governance/11. Secretariat/Statistics).	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>/Rapporteurships allocation\Rapporteurship letters and kept for at least 15 years.

The rapporteurship outcome external report adopted by the CHMP and tabled in MMD is considered as the record and kept permanently.

Application tracking system is provided by SIAMED.