EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: CHMP rapporteur/co-rapporteur appointment for Community procedures		
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1. Purpose

This SOP describes the procedure for the rapporteur/co-rapporteur appointment for Community procedures in accordance to Articles 29(4), 30, 31, 36, 107(2) of Directive 2001/83/EC, Article 13 of Commission Regulation (EC) 1234/2008 and Article 5(3) of Regulation (EC) No 726/2004.

2. Scope

This SOP applies to the CHMP Secretariat in the Scientific Committee Support Section and the Community Procedure Section in the Patient Health Protection Unit.

3. Responsibilities

It is the responsibility of each Head of Unit/Sector/Section to ensure that this procedure is adhered to within their Unit/Sector/Section. 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 reflect the revised policy on the handling of conflicts of interests of Scientific Committee members and experts.

5. Documents needed for this SOP

- Procedural Advice on CHMP/CAT rapporteur/co-rapporteur appointment principles, objective criteria and methodology in accordance with Article 62 (1) of Regulation (EC) No 726/2004 amended by Regulation (EU) No 1235/2010 (EMA/151751/2010).

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http://www.ema.europa.eu/pdfs/human/regaffair/15175110en.pdf
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- A list of all relevant templates (such letter to inform the MAH of the appointed rapporteur and co-rapporteur) for each Community procedure can be found on the X:\ drive\Templates\Others\H – Referral\Article <art. N°>.
- Template Outcome of evaluation for conflicts of interests form for CHMP rapporteur appointment (located at: Cabinet 6. Corporate governance\06.2 Integrated Management System\2. IMS Manual\5. SOPs and WINs*3000-3999 H (Human)\3176 SOP – CHMP rapporteur/co-rapporteur appointment for Community procedures)

6. Related documents

Legal framework on CHMP Rapporteur /Co-Rapporteur appointment

- Articles 62(1), 61(5), 61(6), 62(3), 62(4) of Regulation (EC) 726/2004 of the European Parliament and of the Council

  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 of the European Parliament and of the Council 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

- Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

  http://ec.europa.eu/health/files/eudralex/vol-1/reg_2008_1234/reg_2008_1234_en.pdf

- "Community Referral", The Rules governing Medicinal Products in the European Union, Notice To Applicants, Volume 2A, Chapter 3

  http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap3_rev09-2007_en.pdf

- EMA Questions and Answers on Referrals

  http://www.emea.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

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- CHMP Rules of Procedure (EMA/CHMP/89672/2009)

  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004628.pdf

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- SOP/H/3144 - SOP on Art 6(12), 6(13), 31 and 36 Referral Procedures
- SOP/H/3177 – Article 29(4) referral procedures (MRP/DCP referrals)
- SOP/H/3215 – Article 30 referrals triggered by the European Commission or a member state

- SOP/H/3250 – Article 107 procedures – Pharmacovigilance urgent measures
- SOP/H/3193 - Master Files for Referrals
- EMA policy on the handling of conflict of Interests for Scientific Committee Members and Experts (policy/0044, EMA/513078/2010)

  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

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- The EMA code of conduct (EMA/6470/03/2368)

  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf

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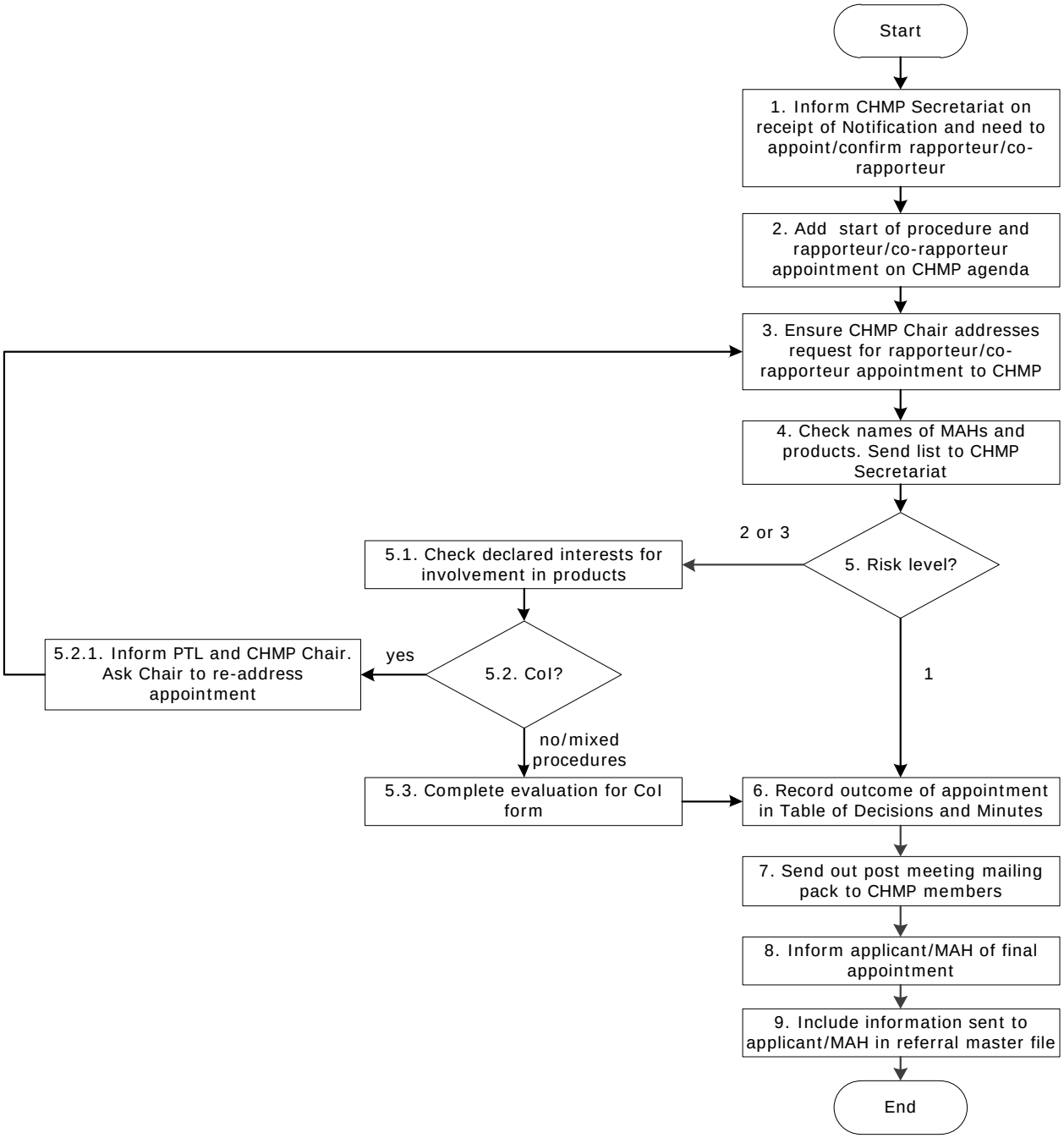
7. Definitions

Assistant	Administrative assistant for the Community procedure
CHMP	Committee for Medicinal Products for Human Use
CHMP AD	Administrator in the CHMP Secretariat
CHMP AST	Assistant in the CHMP Secretariat
CoI	Conflict of interest
DREAM	Document Records and e-Archive Management system
e-DoI	electronic declaration of interests
EEA	European Economic Area
EMA	European Medicines Agency
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
PTL	Product team leader for the Community procedure
P-R-CP	Community Procedures Section
P-R-SCS	Scientific Committee Support Section
SH	Section Head
SOP	Standard operating procedure

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



9. Procedure

Step	Action	Responsibility
	Initiation of the CHMP Rapporteur/Co-Rapporteur appointment procedure	
1	Inform the CHMP Secretariat that a (draft) Notification of referral letter (from an EEA National Competent Authority, the European Commission or an Applicant/MAH) to the CHMP/EMA was received and needs to be added to the agenda of the CHMP meeting. Inform the CHMP Secretariat on the need to appoint or confirm a rapporteur and/or co-rapporteur for the Community procedure.	PTL
2	Add the start of the Community procedure and the appointment of the rapporteur and/or co-rapporteur, if applicable, on the CHMP agenda.	CHMP AST
	Appointment process	
	If the Notification is received in advance of a CHMP meeting, the appointment of rapporteur/co-rapporteur takes place at the next CHMP meeting. *If the Notification is received during a CHMP meeting, and depending on the urgency of the matter (e.g. Notification on safety issue(s)), the rapporteur/co-rapporteur appointment takes place during that meeting.*	
3	*During the CHMP meeting:* Ensure that the CHMP Chairman addresses the request for rapporteur and co-rapporteur appointment for the Community procedure to the CHMP and note the appointment. *In case of a class referral or a referral concerning several issues to be assessed, the CHMP can consider it appropriate to have more than one co-rapporteur.* *If no CHMP member(s) volunteer(s) to be rapporteur/co-rapporteur, the CHMP Chairman designates the rapporteur/co-rapporteur.*	CHMP AD
4	Check the names of the MAHs and medicinal products involved in the Community procedure. Send a complete list of concerned medicinal products including the names of the MAH(s) to the CHMP Secretariat by Wednesday 12:00 am CHMP week.	Assistant
5	Check the risk levels of the proposed rapporteurs and co-rapporteurs in the Experts database. *Only in case of no CoI can the CHMP member or alternate be*	CHMP AST

Step	Action	Responsibility
	appointed as rapporteur or co-rapporteur. For a proposed rapporteur or co-rapporteur with a risk level 1, go to step 6. For a proposed rapporteur or co-rapporteur with a risk level 2 or 3, go to step 5.1.	
5.1	Check the declared interests in the e-DoI of the proposed rapporteur or co-rapporteur with regard to their involvement in the respective medicinal product(s) and assess whether a CoI exists.	CHMP AD
5.2	In case a CoI is identified, go to step 5.2.1. In case no CoI is identified, go to step 5.3. In case of the appointment of co-rapporteurs for Community procedures which involve more than one centrally authorised product, where declared interests are identified with respect to one of the other products in the referral, go to step 5.3, identifying in addition, restrictions with respect to voting on the overall procedure.	CHMP AD
5.2.1	Inform the PTL and the CHMP Chair as soon as possible of the CoI and ask the Chair to re-address the appointment of the rapporteur and/or co-rapporteur for the Community procedure. Go back to step 3.	CHMP AD
5.3	For each assessment of CoI, complete an outcome of evaluation for conflicts of interests form for CHMP rapporteur appointment (see template) and submit it for signature to the CHMP AD.	CHMP AST
6	Record the outcome of the rapporteur and co-rapporteur appointment for the Community procedure, including the risk level of the CHMP members, in the Table of Decisions and Minutes of the CHMP meeting.	CHMP AD
7	*On Thursday of the week after the CHMP meeting:* Send out the post meeting mailing pack to the CHMP members, which includes the final Table of Decisions outlining the final appointment of the rapporteur and co- rapporteur for the Community procedure.	CHMP AST
8	*By the end of the week after the CHMP meeting:* Inform the applicant(s)/MAH(s) in writing on the final appointment of the rapporteur/co-rapporteur for the Community procedure.	PTL
9	Include the information sent to the applicant(s)/MAH(s) in the Referral Master File.	PTL

10. Records

All correspondence related to the procedure and the information to the applicant/MAH on the final appointment of the rapporteur/co-rapporteur is kept in the referral Master File of the concerned procedure in accordance with SOP/H/3193 Master files for referrals.

A scan of the signed outcome of evaluation of conflicts of interest forms for rapporteur appointment is stored in DREAM (Cabinet 2b. Administration of Scientific Meeting/CHMP - Administration/2. Meeting Organisation/<year> Plenary meetings/<month> <year>/Rapporteurships allocation).