EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Rapporteur/co-rapporteur appointment for re-examination of a CHMP opinion		
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1. Purpose

This SOP describes the procedure for the CHMP rapporteur/co-rapporteur appointment in a re-examination of an opinion. 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, applications in accordance with Article 28, 29 and 31 of Regulation No 1901/2006
- Type II variations and extension applications falling within the scope of Commission Regulation (EC) No 1234/2008
- Renewal applications and annual re-assessments
- Referrals (Article 29(4), 30, 31, 36, 107(2) of Directive 2001/83/EC and Article 13 of Commission Regulation (EC) 1234/2008).

2. Scope

This SOP applies to the CHMP Secretariat in the Patient Health Protection Unit and the staff in the Human Medicines Development and Evaluation and Patient Health Protection Units.

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.

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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)".

  http://www.ema.europa.eu/pdfs/human/regaffair/15175110en.pdf

  (path: Home \ Regulatory \ Human medicines \ Pre-authorisation \ Q&A: Innovative products \ Questions 1-10).

- 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)\3175 SOP - Rapporteur/co-rapporteur appointment for re-examination of a CHMP opinion).

6. Related documents

Legal framework on CHMP rapporteur/co-rapporteur appointment for re-examination of CHMP opinions

- Articles 62(1) 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

- Article 32(4) of Directive 2001/83/EC

  http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf

Other related documents

- 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

- "Centralised Procedure", The Rules governing Medicinal Products in the European Union, Notice To Applicants, Volume 2A, Chapter 4

  http://ec.europa.eu/health/files/eudralex/vol-2/a/chap4rev200604_en.pdf

- Procedural advice on the re-examination of CHMP opinions (EMEA/CHMP/50745/2005)

  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004024.pdf

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

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

(path: Home \ About us \ Committees \ CHMP \ Overview)

- EMA pre-submission procedural advice for users of the centralised procedure

  http://www.ema.europa.eu/htms/human/raguidelines/pre.htm

  (path: Home \ Regulatory \ Human medicines \ Pre-authorisation \ Q&A: Innovative products)

- EMA Post authorisation Guidance – Human Medicinal Products

  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003981.pdf

  (path: Home \ Regulatory \ Human medicines \ Post-authorisation)

- EMA policy on the handling of conflict of Interests of 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

  (path: Home \ About us \ Committees \ Handling conflicts of interests)

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

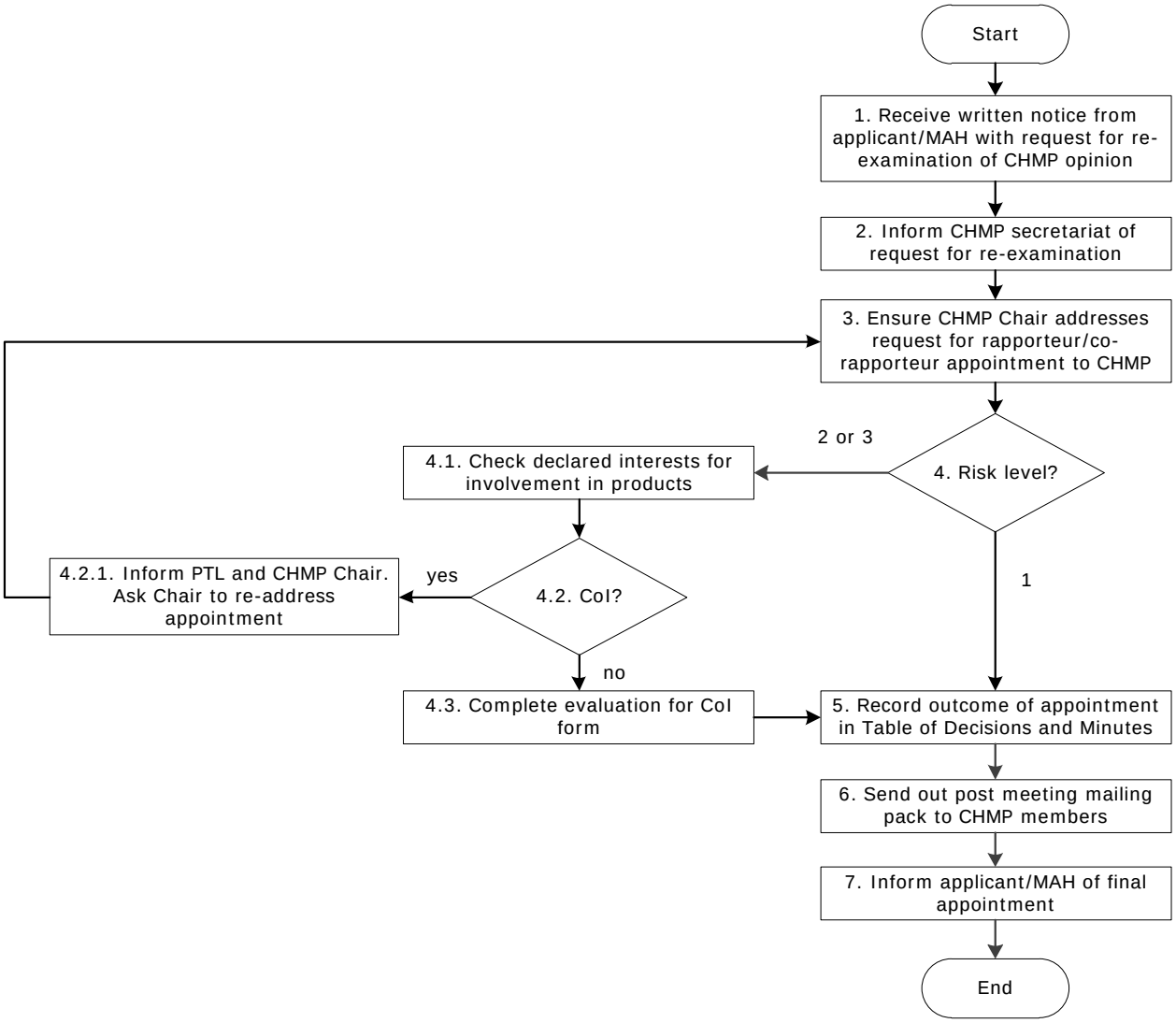
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf

  (path: Home \ About us \ Committees \ Handling conflicts of interests)

7. Definitions

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
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MMD	Meeting Management Document system
PTL	Product team leader

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



9. Procedure

Step	Action	Responsibility
	Re-examination of a CHMP opinion of a centralised MA-MAA /CHMP opinion of a referral	
1	Receive a written notice from the applicant/MAH with a request for a re-examination of the CHMP opinion.	PTL
2	Inform the CHMP Secretariat that the request for re-examination of the CHMP opinion needs to be added to the agenda of the CHMP meeting.	PTL
	Appointment process	
	If the request for re-examination of the CHMP opinion is received in advance of a CHMP meeting, the appointment of rapporteur/co-rapporteur takes place at the next CHMP meeting. *If the request for re-examination of the CHMP opinion is received during a CHMP meeting, 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 re-examination of the CHMP opinion to the CHMP and note the appointment. *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 risk level of the proposed rapporteurs and co-rapporteurs in the Experts database. *Only in case of no CoI can the CHMP member or alternate be appointed as rapporteur or co-rapporteur.* For a proposed rapporteur or co-rapporteur with a risk level 1, go to step 5. For a proposed rapporteur or co-rapporteurs with a risk level 2 or 3, go to step 4.1.	CHMP AST
4.1	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 and assess whether a CoI exists.	CHMP AST
4.2	In case a CoI is identified, go to step 4.2.1. In case no CoI is identified, go to step 4.3.	CHMP AST
4.2.1	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	CHMP AD

	and/or co-rapporteur for the re-examination of the CHMP opinion. Go back to step 3.	
4.3	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
5	Record the outcome of the rapporteur and co-rapporteur appointment of the re-examination of the CHMP opinion, including the risk level of the CHMP members from the Experts database, in the Table of Decisions and Minutes of the CHMP meeting.	CHMP AD
6	*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 appointment of the rapporteur and co- rapporteur for the re-examination of the CHMP opinion.	CHMP AST
7	*By the end of the week after the CHMP meeting:* Inform the applicant/MAH in writing on the final appointment of the rapporteur/co-rapporteur for the re-examination of the CHMP opinion of their MAA/MA.	PTL

10. Records

If appropriate, 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 core Master File of the concerned product in accordance with SOP/PDM/1004 Core master files of medicinal products for human and veterinary use following the centralised procedure or 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).