Title: Check of expert for product evaluation		Document no.: SOP/H/3022
Applies to: Human Pre-authorisation Unit: Safety & Efficacy Sector and Quality of Medicines Sector		Effective Date: 21-SEP-05
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Prepared by	Approved by	Authorised for issue by
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Date: 12 September 2005	Date: 12-SEP-05; 15-SEP-05	Date: 15-SEP-05

1. Purpose

The purpose of this document and attachments is to provide guidance to Product Team Leaders in the Pre-authorisation Safety & Efficacy Sector, on a procedure for the checking of conflicts of interests of the experts involved in the product evaluation and to ensure a consistent procedure for checking the suitability of experts involved in the product evaluation.

2. Scope

This SOP applies to the Human Pre-authorisation Unit Safety & Efficacy Sector and Quality of Medicines Sector involved in product evaluation procedures.

This SOP is applicable for the following procedures:

- Centralised applications
- Referrals/arbitrations

3. Responsibilities

It is the responsibility of the Head of Sector to ensure that this procedure is adhered to within the sector. The responsibility for the execution of each step of this procedure is identified in the right-hand column under point **7. Procedure.**

4. Forms needed for this SOP

Template 1: E-mail to Rapporteurs asking for experts' names
Template 2: Reminder to Rapporteurs asking for experts' names
Template 3: 2nd reminder to Rapporteurs asking for on experts' names
Template 4: e-mail to experts and national contact points on missing/incomplete documents
Template 5: Fax to Rapporteurs asking for alternative expert as previous one has conflict of interests
Template 6: Letter to Rapporteurs informing of unsuitability of expert due to conflict of interests
Template 7: 'Evaluation Team' form
Template 8: E-mail/Fax to Rapporteurs asking for confirmation of names of the experts (Day 121)
Form: 'Declaration of Interests and Confidentiality Undertaking'
Form: 'Nomination of Expert'
Form: 'Evaluation of Conflict of Interest'
Expert's CV
All of the templates and forms are to be found in: Word/File/New/Experts for centralised procedure

5. Related documents

- Article 62 (2) of Council Regulation (EC) No. 726/04 of 31 March 2004 (O.J. No.L 136 of 30 April 2004)
  http://pharmacos.eudra.org/F2/eudralex/vol-1/REG_2004_726/REG_2004_726_EN.pdf

- EMEA Procedure on the Handling of Conflicts of Interests for EMEA Scientific Committees Members and Experts. (EMEA/H/5475/04/Final).
  http://www.emea.eu.int/pdfs/general/direct/conflicts/ProcedureHandlingofConflictsofInterests.pdf

- EMEA Policy on the Handling of Conflicts of Interests for EMEA Scientific Committees Members and Experts (EMEA/H/31653/03/Final).
  http://www.emea.eu.int/pdfs/general/direct/conflicts/PolicyHandlingofConflictsofInterests.pdf

- Declaration of Interests Assessment Group's 'Rules of Procedure' (EMEA/H/33606/03/Final)'
  http://www.emea.eu.int/pdfs/general/direct/conflicts/Annex4-RulesofProcedure.pdf

- EMEA Code of Conduct EMEA/D/37674/99
  http://www.emea.eu.int/pdfs/general/admin/Conduct/647003en.pdf

- European Experts
  http://www.emea.eu.int/htms/aboutus/experts.htm

- Contact Points and Heads of Nomination
  (Confidential. Available on the Intranet, within the Expert Database)

6. Definitions

PTL: Product Team Leader
HoS: Head of Sector
HoU: Head of Unit
DIAG: Declaration of Interests Assessment Group
DI-CU: Declaration of Interests and Confidentiality Undertaking
CIG: Central Information Group
CAP: Central Application Procedure
LoQ: List of Questions
CV: Curriculum Vitae

7. Procedure

Step/Timeline	Action	Responsibility
Step 1 **3-4 months before submission**	Appointment of Rapporteur and Co-Rapporteur	**CHMP**
Step 2 **4 weeks before submission of MAA**	Send e-mail to Rapporteur/Co-Rapporteur requesting the names of the experts appointed for the evaluation team. Template 1 + Form A, *Nomination form, DI-CU	**PTL's Secretary**
Step 3 **3 weeks before submission of MAA**	Check that the names of the experts (Form A) belonging to the Rapporteur's and Co-rapporteur's evaluation teams have been received. If the names have been received, go to Step 4. If the names have not been received, go to Step 3.1.	**PTL's Secretary** **PTL's Secretary**
Step 3.1	Send reminder. Template 2 + Form A, Nomination form, DI-CU	**PTL's Secretary**
Step 3.2	Check that the names of experts have been received. If the names have been received, go to Step 4. If the names have not been received, go to Step 3.3.	**PTL Secretary**
Step 3.3	Send second reminder (this time signed by HoS) if the names of the experts have not been received, and repeat reminder if necessary. Template 3	**PTL's Secretary**
Step 4 **Submission of MAA**	As soon as the names of experts have been received, check that: 1. the experts are registered; 2. their details are complete and up to date; 3. the risk level is 1 (no risk) in section 14 of the Expert DataBase. If all checks are positive, go to Step 11 If either check 1 or 2 is negative, go to Step 4.1 If check 3 is negative (risk 2 or 3) go to step 5	**Expert-checking secretary**
Step 4.1	If an expert(s) is (are) not found on the Experts DataBase, or any of his/her information is incomplete (e.g. missing forms or DI-CU more than one year old), send an e-mail (choose appropriate template) to the expert with relevant forms for his/her nomination and/or the 'Declaration of Interests and Confidentiality Undertaking' (DI-CU) form to be completed, signed and returned by hard mail along with an up-to-date CV, as appropriate. Template 4a/b + forms	**Expert-checking secretary**
Step 4.2	If the expert's documents have been received, go to Step 5. If the documents have not been received, return to Step 4.1.	**Expert-checking secretary**

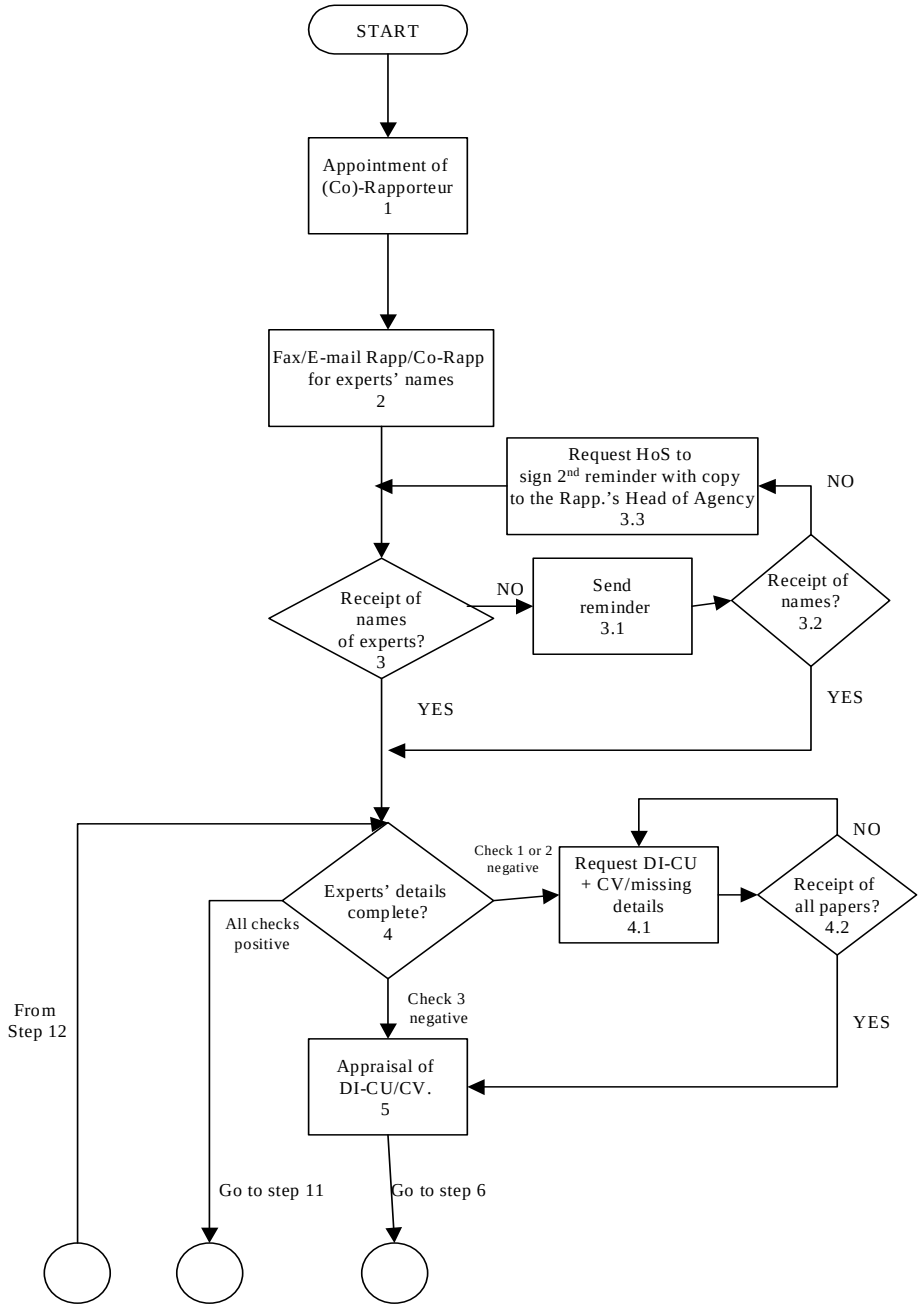
Step/Timeline	Action	Responsibility
Step 5	Perform an appraisal of potential conflicts of interest if: 1. it is a newly nominated expert; 2. it is an updated DI-CU that has not been seen by CIG; 3. the risk level shows as 2 or 3 (at step 1) in section 14 of the Expert DataBase In order to perfom this task, cross-refer to 'EMEA Procedure on the Handling of Conflicts of Interests for EMEA Scientific Committees Membrs and Experts' (EMEA/H/5475/04/Final). Direct link to be found in this SOP under section 5. Related Documents or external webpage under General Reporting/Executive/EMEA Directorate. Form 'Evaluation of Conflict of Interest'	PTL
Step 6	If no conflict of interest has been identified go to Step 11 If potential conflict of interest has been identified go to Step 7	PTL
Step 7	Request a waiver from DIAG if at Step 2 of the 'Evaluation of Conflict of Interest' form **all of the three** points below apply: ▪ a risk level 2 or 3 related to product under evaluation has been identified; ▪ no suitable alternative can be found; ▪ the expert is considered to be irreplaceable Attach the following supporting documents: Form 'Evaluation of Conflict of Interests' + DI-CU + expert's CV	PTL
Step 8	The DIAG informs the PTL of their decision within 24 hours.	DIAG
Step 9	If the expert has been granted a waiver go to Step 11. If a conflict of interest has been identified by the DIAG and the expert is to be excluded from participating in the assessment, go to Step 10	PTL's secretary
Step 10	Send letter from HoS to (Co-)Rapporteur informing him/her of the conflict of interests of the named expert with a copy to the expert. File relevant documents in the Product Master File and Product Working File. Template 6	PTL
Step 11	Complete 'Table of Evaluation Team' and file copies of all documents in the Product Master File and Product Working File. Template 7	PTL's secretary
Step 12 **Day 121 Responses to LoQ** **4 weeks before submission of responses**	Send e-mail to Rapporteur/Co-Rapporteur seeking confirmation of the experts appointed for the evaluation team. Template 8 If named experts are confirmed, procedure ends. If changes to the named experts occur during the procedure, return to Step 4.	PTL's secretary

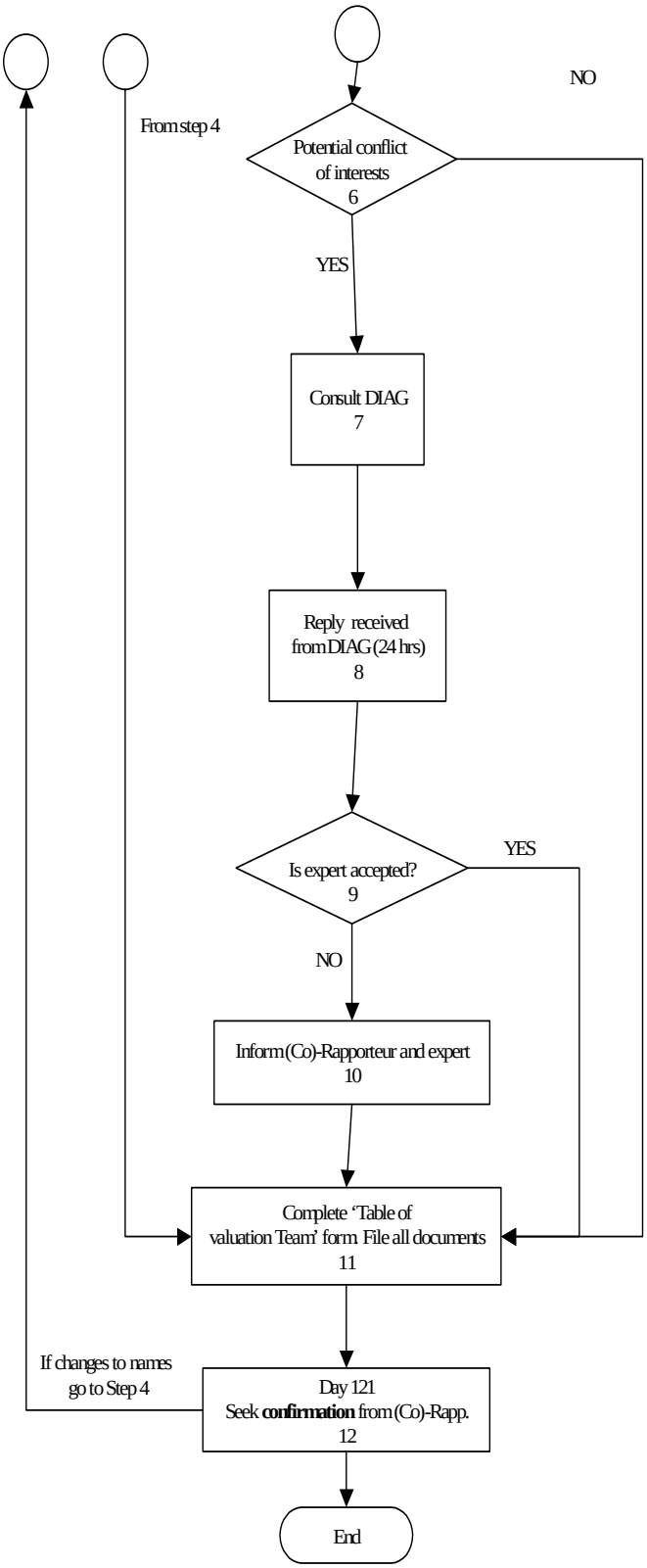
8. Records

All original experts' 'Declaration of Interests and Confidentiality Undertaking' and 'Nomination of Expert' forms and CV will be kept in the Experts Folders by CIG. Copies to be kept in the Product Master folder. It is the PTL's responsibility to decide if copies are needed, also, for the PTL's Product Working File.

All correspondence originated from seeking out experts' documents to be kept in the Product Master folder.

9. Process Map(s)/ Flow Chart(s)




From step 4
Potential conflict of interests 6
NO
YES
Consult DIAG 7
Reply received from DIAG (24 hrs) 8
Is expert accepted? 9
YES
NO
Inform (Co)-Rapporteur and expert 10
Complete 'Table of valuation Team' form. File all documents 11
If changes to names go to Step 4
Day 121 Seek **confirmation** from (Co)-Rapp. 12
End