EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Evaluation of competing interests of experts for involvement in Agency activities		
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1. Purpose

To describe the procedure for evaluating competing interests of experts with regard to their involvement in activities of the European Medicines Agency (EMA), in particular meeting attendance, involvement in scientific assessments, guidelines' development and participation in inspections.

2. Scope

This SOP applies to administrators and assistants responsible for handling the involvement of experts in EMA activities. The administrator is responsible for approving, in EMA's Experts Management Tool, the evaluation of competing interests declared by the expert to the Agency.

This SOP relates to the evaluation of competing interests of experts **prior to their involvement in activities falling within the scope of Policy 0044** the 'European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts':

- Chairs, members, alternates and experts attending a scientific committee, working party, drafting group, inspector working group, scientific advisory group, ad hoc expert group, Emergency Task Force (ETF), Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) or Executive Steering Group on Shortages of Medical Devices (MDSSG) meeting at the Agency, i.e. participation in the meeting either in person or virtually (via a remote connection) or participation in a written (consultation) procedure of that body;
- inspectors performing inspections requested by a scientific committee;
- experts proposed by a nominating authority or body as expert for involvement in an Agency activity.

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The SOP does not apply to:

- observers participating in a meeting not requiring a declaration of interest;
- NCA staff and experts participating in the work at national level for services provided to the Agency as covered by the Memorandum of Understanding between the Agency and the NCAs (e.g. meetings in the context of assessment falling under the role of the Rapporteur (pre-submission meeting, (co-)rapporteurs meetings with companies, peer review meetings, FDA teleconference), etc.).
  However, if NCA staff or experts attend a meeting at the Agency falling under the scope of policy 0044, the SOP becomes applicable and an evaluation of competing interests is required;
- meetings with representatives of other EU and/or non-EU regulatory authorities (e.g. cluster meetings) which represent fora for exchange of information on requirements for marketing authorisation application dossiers;
- Chairs, members, alternates and experts attending a training, conference or workshop (e.g. public discussion during guidance development) held at the Agency including participants not pertaining to NCAs (e.g. industry).

3. Responsibilities

It is the responsibility of each Head of Division, Head of Task Force, Head of Department and Head of Office to ensure that this procedure is adhered to within their own organisational entity.

It is the responsibility of the Head of the relevant functions to nominate a member (and a back-up) to compose the DOI/COI community as per the mandate establishing this cross-Agency group.

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

Scope of revision:

- alignment vis-à-vis the latest revision of policy 0044 (resulting from the additional responsibilities for the Agency following its involvement in certain medical device and *in vitro* diagnostic procedures as set out in Regulations (EU) 2017/745 and 2017/746, as well as from its extended mandate in accordance with Regulation (EU) 2022/123);
- reference to the EMA Experts Management Tool that replaced the Experts Database;
- reference to the EMA DOI/COI community that replaced the Declaration of Interest Advisory Group (DIAG);
- alignment vis-à-vis EMA's organisational structure.

5. Documents needed for this SOP

- Nomination for European experts (within the Experts Management Tool)
- Declaration of interest and Confidentiality Undertaking form (within the Experts Management Tool)
- Curriculum vitae (within the Experts Management Tool)
- Record of performed evaluation of competing of interests (within the Experts Management Tool)

- Experts Management Tool
- User Guides and guidance called 'knowledge articles' available within the Experts Management Tool
- SOP/EMA/0076 - Management Board consultation on nominations to the CHMP and CVMP
- Repository of responses to queries on DoI and competing interests
- Template emails 1 to 4 (located at Cabinets/06. Corporate governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*0001 - 0999 EMA (cross-Agency)/0040 SOP)

6. Related documents

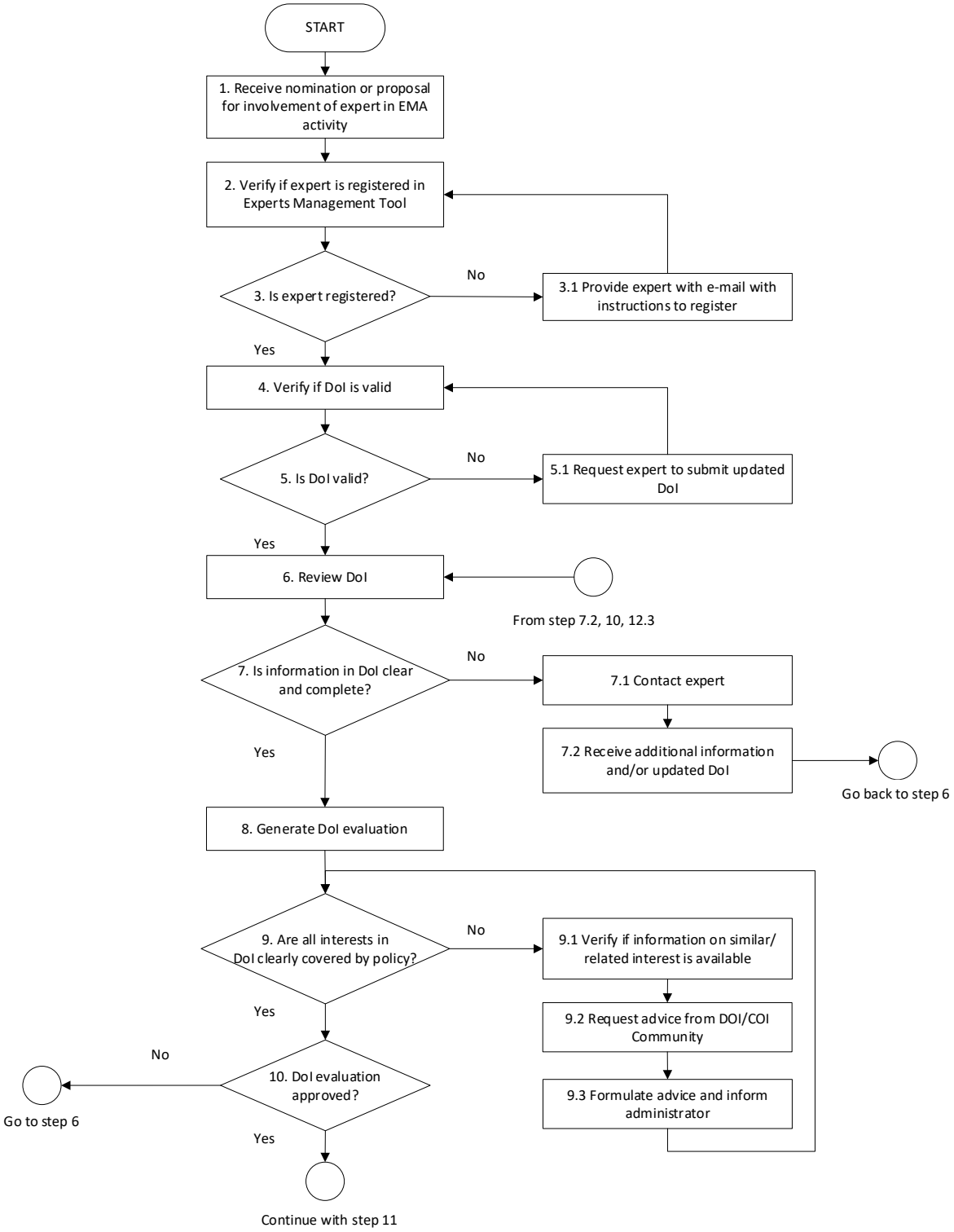
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0726-20190128)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745)
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746)
- Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0123)
- EMA Code of Conduct (EMA/385894/2012 rev.1) (Internet: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78# - Home\About Us\How we work\Handling competing interests)
- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (policy/0044) (Internet: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en-0.pdf - Home\About Us\How we work\Handling competing interests)

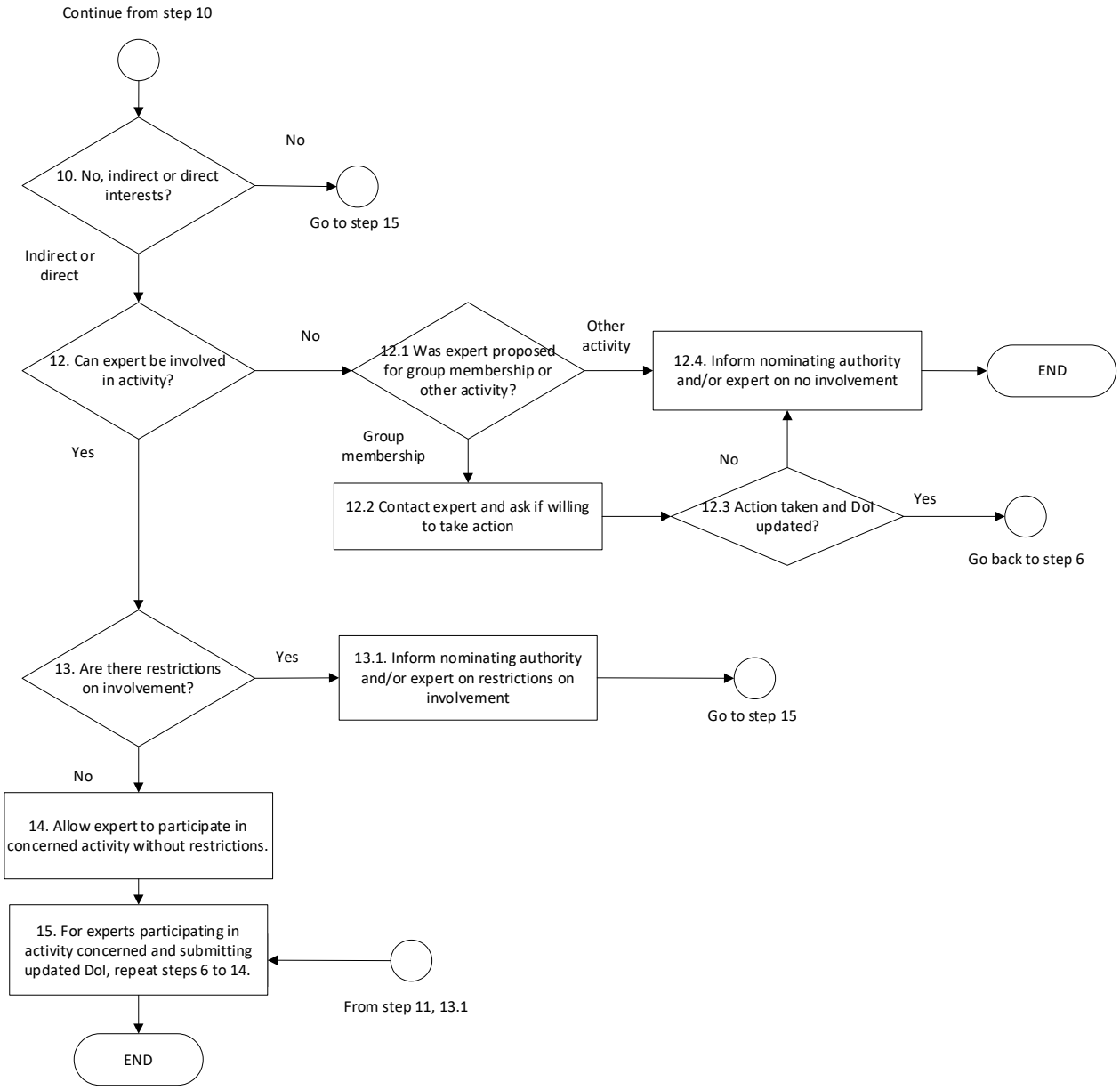
7. Abbreviations

Assistant:	Assistant in the secretariat of the group and any other assistant dealing with experts
Administrator:	Administrator in the secretariat of the group and any other administrator dealing with experts
CHMP:	Committee for Medicinal Products for Human Use
COI:	Competing interest

CV:	Curriculum vitae
CVMP:	Committee for Veterinary Medicinal Products
DoI:	Declaration of Interests (incl. a Confidentiality Undertaking form)
EC:	European Commission
EMA:	European Medicines Agency
ETF:	Emergency Task Force
EU:	European Union
HoO:	Head of Office
MB:	EMA Management Board
MDSSG:	Medical Devices Shortages Steering Group
MS:	Member state
MSSG:	Medicines Shortages Steering Group
NCA:	National competent authority

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




Continue from step 10
10. No, indirect or direct interests?
No
Go to step 15
Indirect or direct
12. Can expert be involved in activity?
No
12.1 Was expert proposed for group membership or other activity?
Other activity
12.4. Inform nominating authority and/or expert on no involvement
END
Yes
Group membership
12.2 Contact expert and ask if willing to take action
12.3 Action taken and DoI updated?
No
Yes
Go back to step 6
13. Are there restrictions on involvement?
Yes
13.1. Inform nominating authority and/or expert on restrictions on involvement
Go to step 15
No
14. Allow expert to participate in concerned activity without restrictions.
15. For experts participating in activity concerned and submitting updated DoI, repeat steps 6 to 14.
From step 11, 13.1
END

9. Procedure

Step	Action	Responsibility
1	Receive information from a nominating authority or body on the nomination of an expert as a member, alternate or expert for a group or for any other EMA activity falling under the scope of policy 0044 (thereafter 'EMA activity'). Receive a proposal from an EMA staff member for an expert to be involved in an EMA activity.	Assistant
2	Before an expert can be involved in any activity, verify if the expert is registered in the Experts Management Tool. *Note: Once the DoI is completed by the expert in the Experts Management Tool, an interest level is automatically assigned for that expert in accordance with policy 0044 (interest level 1 = no interests declared, interest level 2 = indirect interests declared, interest level 3 = direct interests declared).*	Assistant
3	If the expert is not registered in the Experts Management Tool, go to step 3.1. If the expert is registered in the Experts Management Tool, go to step 4.	Assistant
3.1	Send to the expert the template email (available within the Expert Management Tool) with instructions to access and to register in the Experts Management Tool. Return to step 2.	Assistant
4	Verify if the DoI is valid (i.e. not older than 1 year).	Assistant
5	If the DoI is no longer valid (status Amber), go to step 5.1. If the DoI is still valid (status Green), go to step 6.	Assistant
5.1	Request the expert to submit an updated DoI, referring him/her to relevant 'knowledge article' within the Experts Management Tool. Return to step 4.	Assistant
6	Review the DoI in detail and critically: - Verify if clear and complete information is provided in the relevant and appropriate sections of the DoI, considering that the DoI of the expert is already or will be published on the EMA external website; - Verify consistency with the CV (e.g. coherence with the periods of employment); - Verify for existing experts, if necessary, the previous DoI of the expert for previously declared interests.	Assistant

Step	Action	Responsibility
	Liaise with an Administrator in case of doubt.	
7	Is the information in the DoI clear and complete: - to perform the evalution of competing of interests and - to permit an identification of restrictions adequate to the involvement in the EMA activity? If more information from the expert is required or if the DoI needs to be updated to correctly reflect the declared interests, go to step 7.1. If sufficient information is available and the DoI is correctly completed, go to step 8.	Assistant
7.1	Contact the expert to obtain more details and/or clarifications on the declared interests. If necessary, ask the expert to submit an updated DoI, referring him/her to relevant 'knowledge article' within the Experts Management Tool.	Assistant / Administrator
7.2	Receive additional information and/or updated DoI from the expert. Return to step 6.	Assistant
8	Generate the DoI evaluation within the Experts Management Tool, verify the outcome, update the outcome if necessary and select the relevant approver.	Assistant
9	Review the DoI evaluation in the Experts Management Tool. Are all interests clearly covered by policy 0044? If not all interests are clearly covered by policy 0044, go to step 9.1. If all interests are clearly covered by policy 0044, go to step 10.	Administrator
9.1	Verify if a query on a similar/related interest has already been discussed by the DOI/COI community and recorded in the 'Repository of responses to queries on DoI and competing interests'. If no query on a similar/related interest has been answered already, go to step 9.2 If a query on a similar/related interest has been answered already, go to step 10.	Administrator
9.2	Request advice from the DOI/COI community on the categorisation of the interest declared by the expert which is not clearly covered by the policy or its definitions, nor clarified in any procedural guidance.	Administrator

Step	Action	Responsibility
	Provide sufficient background information on the declared interest, on the expert's role (chair, member, etc.), on the intended involvement (medicine's assessment, guidelines, etc.) and on the scientific group concerned (committee, working party, etc.). *Note: Advice from the DOI/COI community should only be sought on a case-by-case basis, not systematically for all experts with declared interests. The administrator remains responsible for the evaluation of the interests declared by the expert and for the decision to involve or not the expert in EMA activities.*	
9.3	Formulate an advice and inform the administrator accordingly. Return to step 9.	DOI / COI community
10	Can the DoI evaluation be approved in the Experts Management Tool? If yes, go to step 11 If not, liaise with the Assistant with a return to step 6.	Administrator
11	For an expert with no declared interests, go to step 15. For an expert with indirect or direct declared interests, go to step 12.	Administrator
12	Can the expert be involved in the activity concerned? If the outcome of the evaluation is that the expert **cannot be involved** due to an incompatibility of the declared interests with the activity concerned, go to step 12.1. If the outcome of the evaluation is that the expert **can be involved** (with or without restrictions) in the activity concerned, go to step 13.	Administrator
12.1	If the expert was nominated for the membership in a group, go to step 12.2. For any other expert nominated for any other activity, go to step 12.4.	Administrator
12.2	Contact the expert informing him/her of the outcome of the evaluation and that on the basis of the declared interest(s) he/she is not allowed to participate as member or alternate of the group. Ask the expert whether he/she intends to take any action with respect to the declared interest(s) and if so, to submit an updated DoI.	Administrator
12.3	If the expert indicates his/her intention to take action and submits an updated DoI, return to step 6.	Administrator

Step	Action	Responsibility
	If the expert does not intend to take actions, continue with step 12.4.	
12.4	**DoI evaluation outcome: no involvement** <u>For appointments as member or alternate of a group:</u> Inform the nominating authority or body and the expert by email (see template 1, with cc to the relevant HoO) of the outcome of the evaluation and that the expert is not allowed to participate as member or alternate. <u>For other appointments for involvement in an EMA activity:</u> Inform the expert by email (see template 2) of the outcome of the evaluation and that he/she is not allowed to participate in the activity concerned (except if already done in step 12.2). End of procedure.	Assistant / Administrator
13	Are there any restrictions on the involvement of the expert in the activity concerned? If the outcome of the evaluation is that the expert can only be involved with restrictions in the activity concerned, go to step 13.1. If the outcome of the evaluation is that there are no restrictions on the involvement of the expert, go to step 14.	Administrator
13.1	**DoI evaluation outcome: involvement with restrictions** <u>For appointments as member or alternate of a group:</u> Inform the nominating authority or body and the expert by email (see template 3, with cc to the relevant HoO) of the restrictions for the expert's involvement in the group. For scientific committees, request whether the nominating authority intends to maintain the nomination of the expert. If the nomination in the scientific committee is maintained, ensure that all required information is available, either in the Experts Management Tool, in relevant documents (e.g. tracking tables) or in EMA's document management system (nomination letter and related correspondence). For CHMP and CVMP members and alternates, request a written consultation of the MB on a new nomination, in accordance with SOP/EMA/0076. <u>For other appointments for involvement in an EMA activity:</u> Inform the expert by e-mail (see template 4) of the restrictions for his/her involvement in the activity concerned.	Assistant / Administrator

Step	Action	Responsibility
	Before involvement of the expert in the activity concerned, ensure that all required information is available, either in the Experts Management Tool, in relevant documents (e.g. tracking tables) or in EMA's document management system (nomination letter and related correspondence). Continue with step 15.	
14	**DoI evaluation outcome: involvement without restrictions** Allow the expert to participate in the activity concerned. Before involvement of the expert in the activity concerned, ensure that all required information is available, either in the Experts Management Tool, in relevant documents (e.g. tracking tables) or in EMA's document management system (e.g. nomination letter and related correspondence). For CHMP and CVMP members and alternates, request a consultation of the MB on a new nomination.	Assistant
15	For experts participating (without or with restrictions) in the activity concerned and submitting an updated DoI at any stage during their participation, repeat steps 6 to 14.	Administrator

10. Records

The DoIs and evaluation of DoIs of experts for involvement in EMA activities are stored in EMA's Experts Management Tool. Documents in support of formal nominations by nominating authorities or bodies are saved in EMA's document management system (retention time: as specified for the meeting concerned in accordance with the business classification scheme).