EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Human Medicines Division
EMA/182440/2024

Business process description

Title: Expert management		
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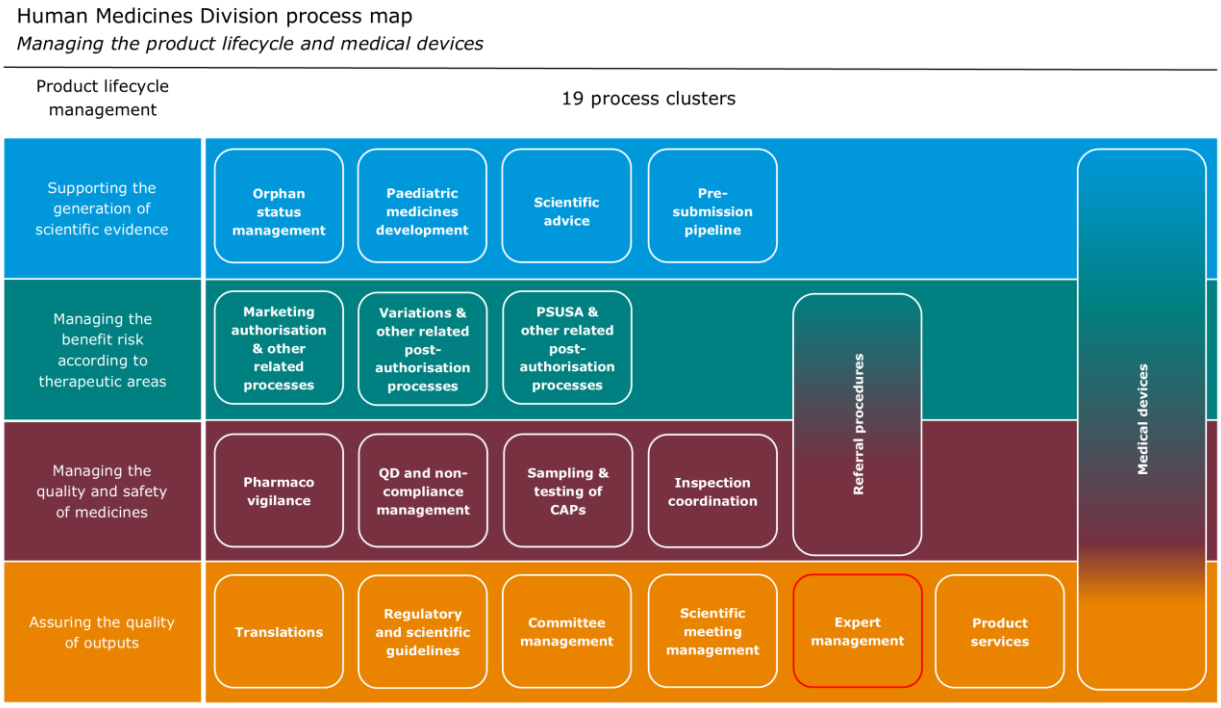
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for managing experts involved in EMA activities and evaluating their declared interests, which ensures impartiality in their involvement in EMA activities.

This process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.



Expert management process:

It covers experts involved in EMA activities falling under EMA policy 0044 on the handling of competing interests of scientific committees' members and experts or the European Commission policy on the management of competing interests of members of experts panels on medical devices and in vitro diagnostic medical devices (EXPAMED).

2. Changes since last revision

New business process description

3. Related documents

Policies

- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts
- European Commission policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical device

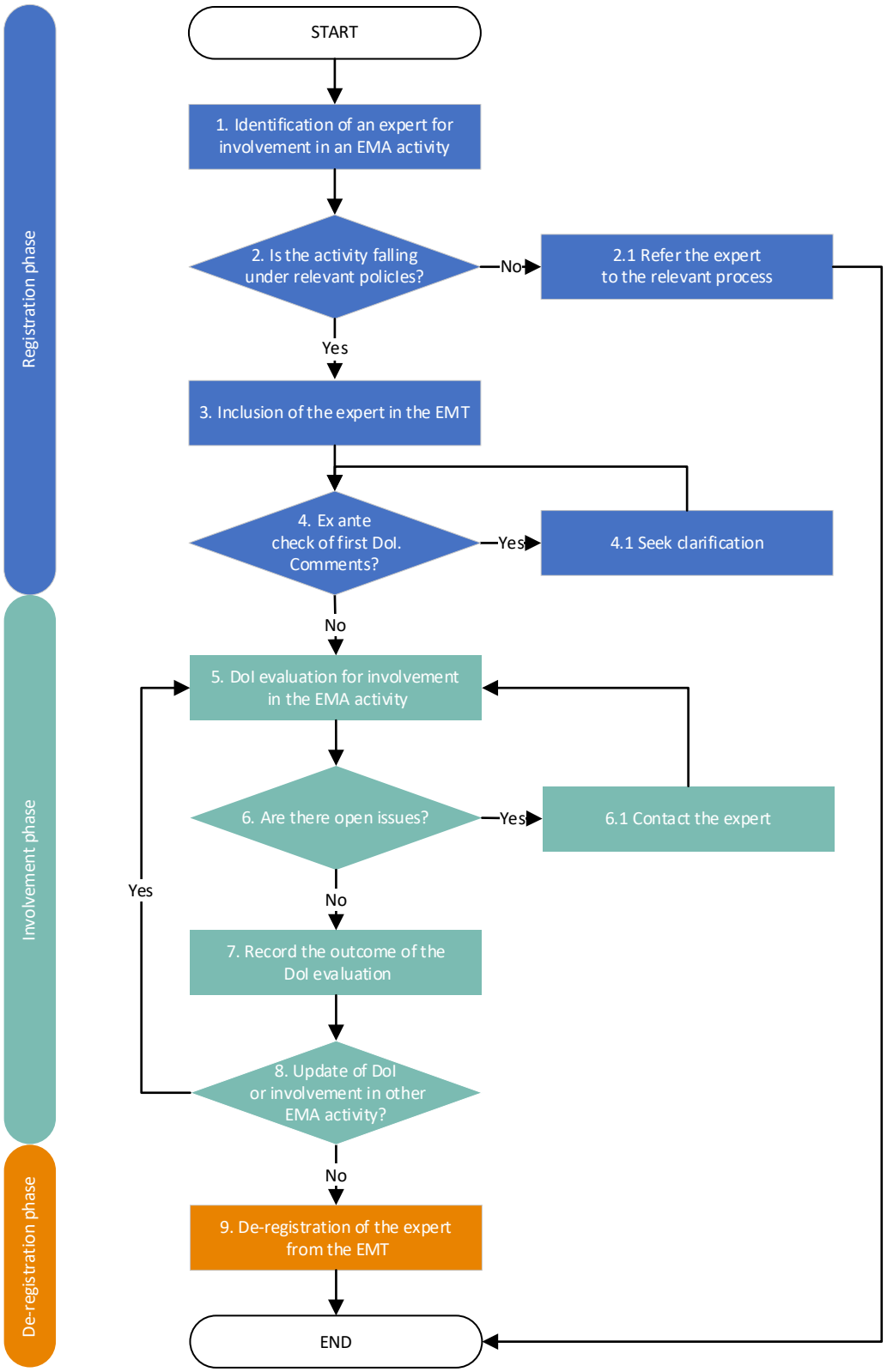
Relevant information

- Handling competing interests
- List of European scientific experts
- Medical Devices - Expert Panels
- Patients, consumers and carers' involvement in EMA activities
- Healthcare professionals' involvement in EMA activities

4. Abbreviations/Definitions

CAPs	Centrally authorised products
CV	Curriculum vitae
DoI	Declarations of interest(s)
EC	European Commission
EMA	European Medicines Agency
EMT	Expert management tool: Dedicated IT system allowing EMA to manage DoI and CV of all medicines experts, EXPAMED experts and Management Board members
PSUSA	Periodic safety update report single assessment
QD	Quality defect

5. Process map(s)



6. Procedure

Step	Description
Registration phase	
1.	**Identification of an expert for involvement in an EMA activity** Identify: • experts to be included in EMA's list of European experts, • experts (to be) nominated for membership in an EMA group in compliance with the mandate and/or Rules of procedure of the group, or • experts to be involved in another EMA activity in compliance with the rules for the activity

2.	**Is the activity falling under relevant policies?**
	• policy 0044 for experts involved in EMA medicines-related and/or medical devices-related activities, or
	• the EC policy for members of the expert panels on medical devices
	  • If yes, go to step 3
	  • If no, go to step 2.1

2.1	**Refer the expert to the relevant process** E.g. invite the person: • to get involved via the network of eligible patients and consumers organisations or eligible healthcare professionals' organisations, • to be included in the individuals' stakeholder database, by completing the online registration form, or • to contact the relevant secretariat or function at EMA Then the process ends.
3.	**Inclusion of the expert in the EMT** • Transmit to the expert instructions to access and submit the request for registration in EMA's EMT, including contact details, areas of expertise, DoI, CV (in English) and/or nominating authority • Assist the expert with any follow-up on the request for registration, in liaison with relevant EMA functions, if necessary • Approve the registration of the expert in the EMT (nominating authority and/or EMA) with, for experts falling under policy 0044, automatic publication of names, DoIs and CVs on the corporate website (EMA's list of European experts)
4.	***Ex ante* check of the first DoI** Perform an *ex ante* check on the first DoI and CV of the new expert. Are there comments? • If yes, go to 4.1

	• If no, go to 5
4.1	**Seek clarification** After receiving clarification, go to step 4.
Involvement phase	
5.	**DoI evaluation for involvement in the EMA activity** Perform the evaluation of the expert's DoI in the EMT for the EMA activity concerned in accordance with the relevant policy: • in the context of adding the expert to a group and prior to its first involvement in the group, or • on an *ad hoc* basis prior to involvement of the expert in the EMA activity
6.	**Are there open issues?** • If yes, go to step 6.1 • If no, go to step 7
6.1	**Contact the expert** Contact the expert if clarifications are required or if submission of an updated DoI is needed. Once input is received, go to step 5.
7.	**Record the outcome of the DoI evaluation** • Update records in relevant EMA tracking systems, including for group membership management • Ensure that names, professional contact details, DoI and/or CV are published on relevant websites in accordance with practice in place
8.	**Update of DOI or involvement in other EMA activity?** Has the expert submitted an updated DoI or is the expert to be involved in a different EMA activity? • If yes, go to step 5 • If no, go to step 9 *Note: Experts can submit an updated DoI either on an annual basis and/or at any time when their interests change*
De-registration phase	
9.	**De-registration of the expert from the EMT** De-registration will occur: • on the request of the nominating authority of the expert, • on the request of the expert, or • if no updated DoI has been submitted for a defined period of time