EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Human Medicines Division
EMA/228156/2024

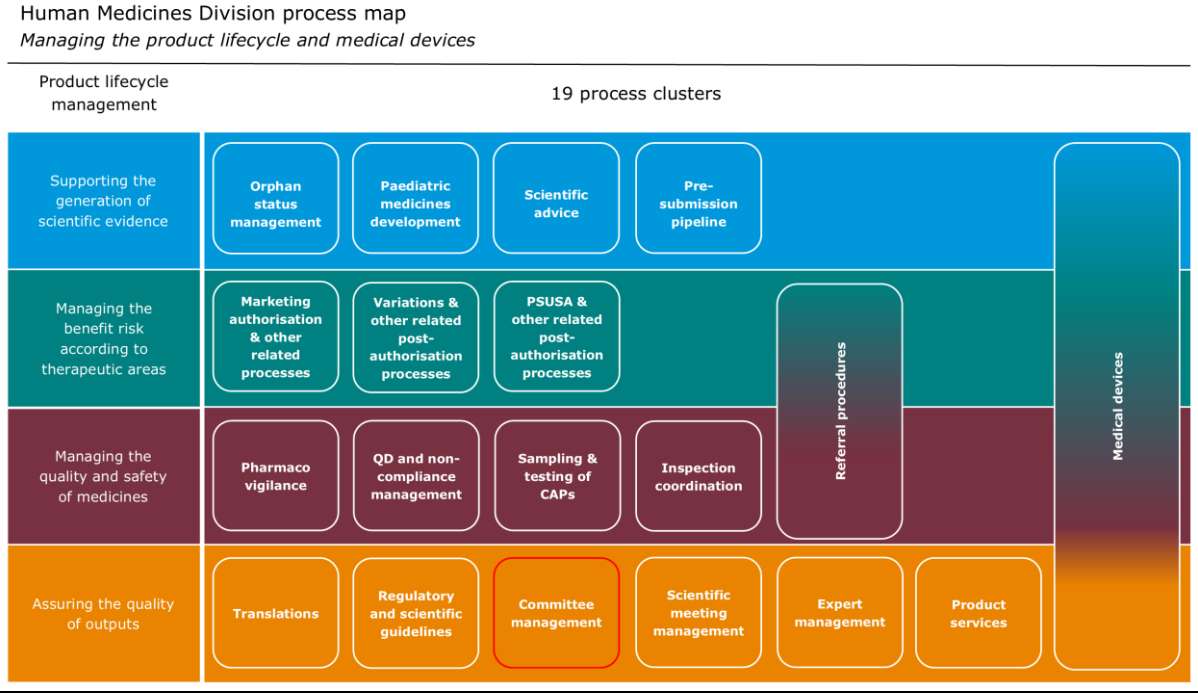
Business process description

Title: Committee management		
Status: **PUBLIC**		Document no.: BPD/H/001
Author: Process Lead	Approver: Lead Process Manager	Effective date: 25-OCT-24
Name: [On file]	Name: [On file]	Review date: 25-OCT-27
Signature: [On file]	Signature: [On file]	Supersedes: N/A

1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the committee management, ensuring a consistent approach for establishing a committee and performing essential activities for its function. In this document, 'committee' covers also the two coordination groups for human and veterinary medicines established under the auspices of the Heads of Medicines Agencies.

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.



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Committee management process:

It describes the formation of EMA's scientific committees, and the support provided for their function.

EMA's committees are:

- Committee for Medicinal Products for Human Use
- Committee for Veterinary Medicinal Products
- Pharmacovigilance Risk Assessment Committee
- Committee for Orphan Medicinal Products
- Paediatric Committee
- Committee for Advanced Therapies
- Committee on Herbal Medicinal Products

The coordination groups established under the auspices of the Heads of Medicines Agencies are:

- Co-ordination group for Mutual recognition and Decentralised procedures – human
- Co-ordination group for Mutual recognition and Decentralised procedures for veterinary medicinal products

2. Changes since last revision

New business process description

3. Related documents

Relevant information:

- Committees, working parties and other groups | European Medicines Agency (europa.eu)
- How the committees work
- Procedure for nomination and appointment of Co-opted members Rev 2 (europa.eu)

Related SOPs and procedures

- SOP/EMA/0076 Management Board consultation on new nominations to the CHMP and CVMP
- Guidance on handling scientific committee/other (scientific) expert group member's declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector (EMA/267183/2015 Rev 1)

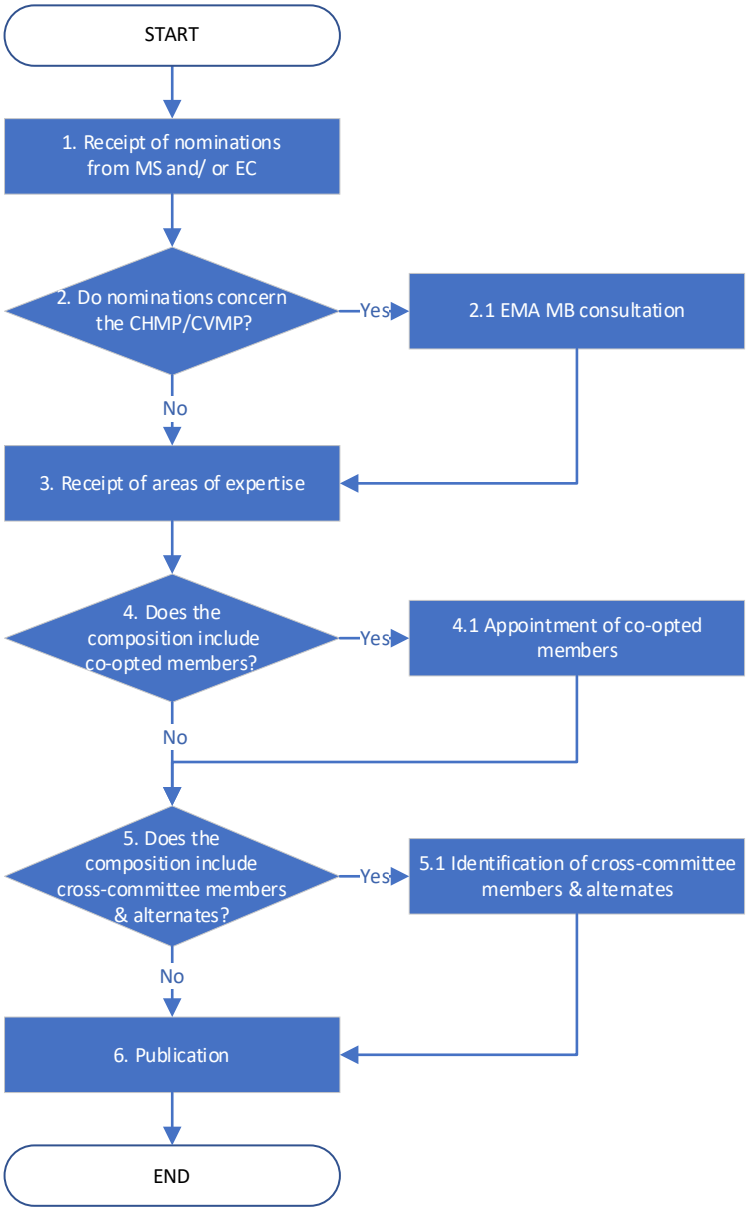
4. Abbreviations/Definitions

CAPs	Centrally authorised products
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CMDh	Co-ordination group for Mutual recognition and Decentralised procedures – human
CMDv	Co-ordination group for Mutual recognition and Decentralised procedures for veterinary medicinal products
COMP	Committee for Orphan Medicinal Products
CV	Curriculum vitae

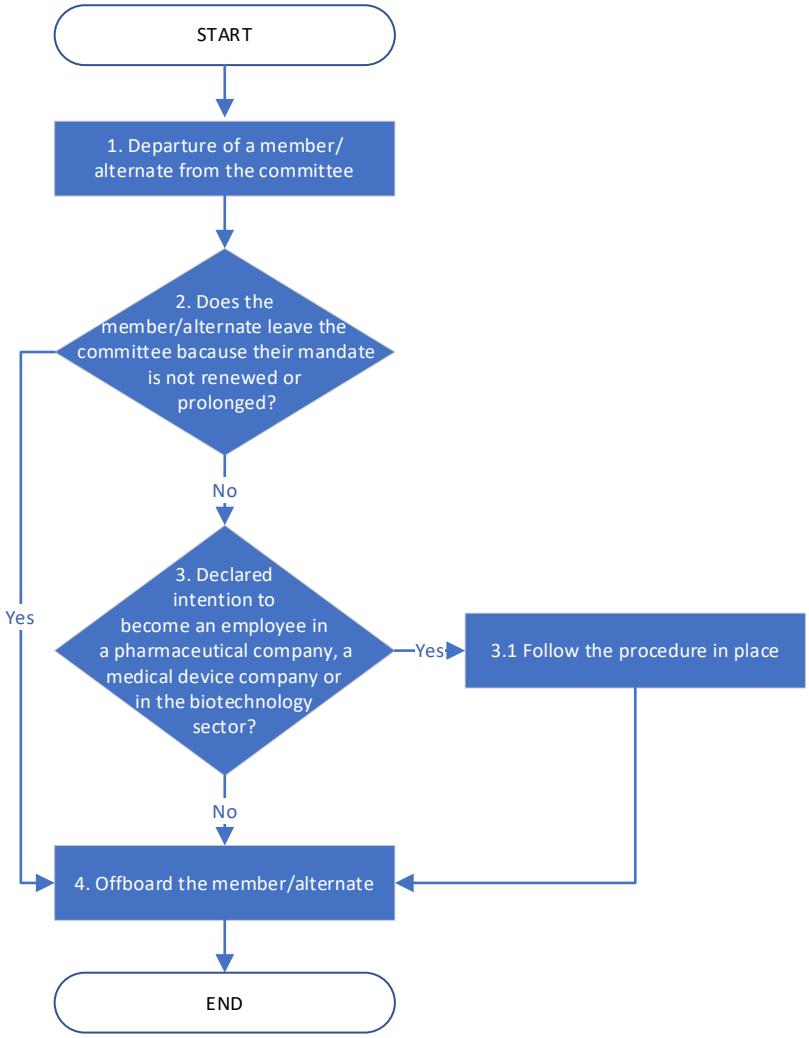
CVMP	Committee for Veterinary Medicinal Products
DoI	Declaration of interests
EC	European Commission
EMA	European Medicines Agency
EU/EEA	European Union/European Economic Area
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
MB	Management Board
MS	Member State
NCA	National competent authority
PDCO	Paediatric Committee
PRAC	Pharmacovigilance Risk Assessment Committee
PSUSA	Periodic safety update report single assessment
QD	Quality defect
RoP	Rules of procedure

5. Process map(s)

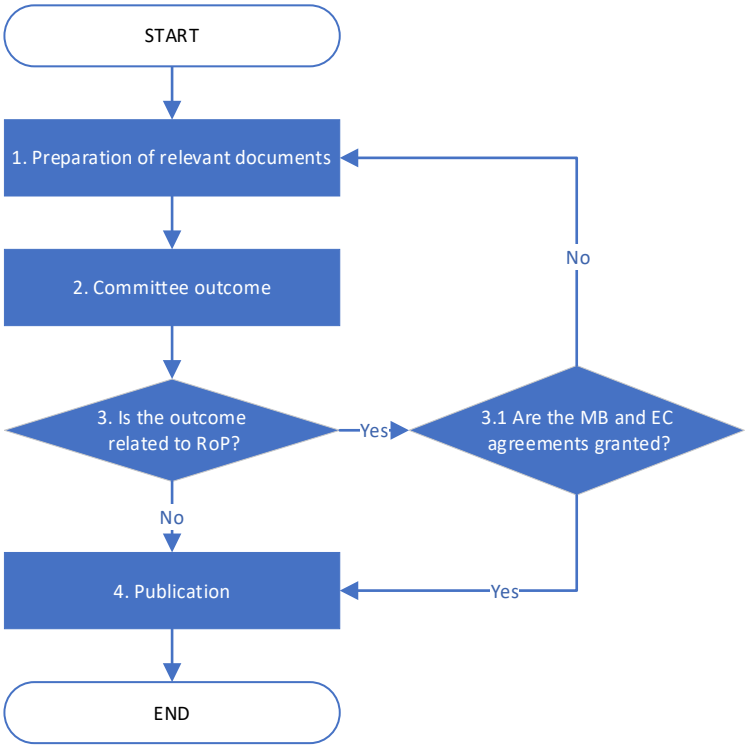
5.1 Committee composition



5.2 Committee member off-boarding



5.3 Committee functioning



6. Procedure

6.1 Committee composition

Step	Description
1.	**Receipt of nominations from MS and/or EC** • Liaise with Nominating Authority to receive nominations (including DoI and CV) for EU/EEA Member States appointed members (and alternates where applicable) and to approve registration in Experts Management Tool • Liaise with EC to receive nominations (including DoI and CV) for EC appointed members (and alternates where applicable) and approve registration in Experts Management Tool
2.	**Do nominations concern the CHMP/CVMP?** • If yes, go to step 2.1 • If no, go to step 3
2.1	**EMA MB consultation** • Organise the MB written consultation on new nominations for CHMP and CVMP, in accordance with SOP/EMA/0076 (go to step 3)
3.	**Receipt of areas of expertise** • Ask appointed members and alternates to indicate their areas of expertise

4.	**Does the composition include co-opted members?** • If yes, go to step 4.1 • If no, go to step 5
4.1	**Appointment of co-opted members** • Identify the missing areas of expertise • Prepare and circulate the call for expression of interest • Support the appointment (vote) Go to step 5
5.	**Does the composition include cross-committee members and alternates?** • If yes, go to step 5.1 • If no, go to step 6
5.1	**Identification of cross-committee members and alternates** • Liaise with NCAs with interest and capacity to nominate experts for double membership • Support the appointment Go to step 6
6.	**Publication** • Publish committee's composition, with DoI and CV, on EMA corporate website or on HMA website for CMDh and CMDv • Update all relevant internal records

6.2. Committee member off-boarding

Step	Description
1.	**Departure of a member/alternate from the committee**
2.	**Does the member/alternate leave the committee because their mandate is not renewed or prolonged?** • If yes, go to step 4 • If no, go to step 3
3.	**Does the member/alternate leave the committee after having declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector?** • If yes, go to step 3.1 • If no, go to step 4

3.1	**Follow the procedure in place** • Follow the procedure (EMA/267183/2015 Rev 1) (go to step 4)
4.	**Offboard the member/alternate** • Remove the member/alternate from the committee's composition • Update all relevant internal records • Update EMA corporate website or HMA website for CMDh and CMDv

6.3 Committee functioning

Step	Description
1.	**Preparation of relevant documents** • Prepare, and revise as appropriate, the RoP • Prepare and circulate the call for expression of interest for committee's chair and vice-chair elections • Prepare and establish a three-year meeting dates schedule • Prepare the annual (or multi-annual) work plan
2.	**Committee outcome** • Record the committee's adoption of the RoP/ meeting dates/ workplan • Record the elections' result (vote)
3.	**Is the outcome related to RoP?** • If yes, go to step 3.1 • If no, go to step 4
3.1	**Are the MB and EC agreements granted?** • If yes, go to step 4 • If no, go to step 1 (i.e. revise RoP as appropriate)
4.	**Publication** Publish on the EMA corporate website or on HMA website for CMDh and CMDv: • the RoP • the names of the elected chair and vice-chair • the three-year meeting dates schedule • the (multi)-annual workplan *Note: These documents are prepared, adopted and published according to their respective timelines*