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Mandate, objectives, and rules of procedure for expert groups under the quality, non-clinical, methodology, clinical and veterinary domains

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Abbreviations

AHEG	Ad Hoc Expert Group
CHMP	Committee for Medicinal Products for Human Use
CNSWP	Central Nervous System Working Party
CVMP	Committee for Veterinary Medicinal Products
DOI	Declaration of Interest
EEA	European Economic Area
EMA	European Medicines Agency
EMANS	European Medicines Agencies Network Strategy
EMRN	European Medicines Regulatory Network
EMT	Experts Management Tool
ESEC	European Specialised Expert Community
EU	European Union
MB	Management Board
NCA	National Competent Authority
(t)OEG	(temporary) Operational Expert Group
RSS	Regulatory and Science Strategy
SAG	Scientific Advisory Group
SAWP-H	Scientific Advice Working Party - Human
SAWP-V	Scientific Advice Working Party - Veterinary
SIA	Specialised Interest Area
tDG	temporary Drafting Group
WP	Working Party

1. Legal basis and background

1.1. Legal basis

The mandate to establish Working Parties (WPs) is provided for in Article 56(2) of Regulation (EC) No 726/2004 and Article 139(3) of Regulation (EU) No 2019/6. The mandate to establish scientific advisory groups (SAGs)[1] is provided for in Article 56(2) of Regulation (EC) No 726/2004 and Article 139(3) of Regulation (EU) No 2019/6. Other types of expert groups are not foreseen in the current legislation.

Drafting groups are foreseen in the Committee for Medicinal Products for Human Use (CHMP) and Committee for Veterinary Medicinal Products (CVMP) rules of procedure, Articles 17 and 20, respectively.

1.2. Background on operational model

A review of the activities of the European Medicines Agency (EMA, hereinafter "the Agency" or "EMA") WPs was initiated in 2015 and endorsed by EMA's Management Board (MB) in October 2019. A high-level implementation plan was endorsed by the MB in March 2021[2]. The outcome was the proposal for a new operational model introducing the concept of domains and domain governance presented in Section 1.3, and including the expert groups listed in Section 2.

1.3. Background on domains and domain governance

There are five domains: quality, non-clinical, methodology, clinical and veterinary[3].

The Scientific Coordination Board[4] is responsible for the oversight and overarching coordination of the work across all domains (see Figure 1).

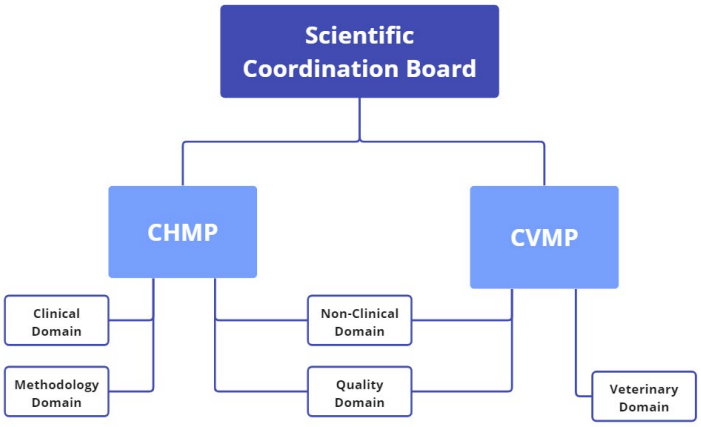


Figure 1: Governance structure of domains

[1] There are Scientific Advisory Groups (SAGs) and Ad Hoc Expert Groups (AHEGs) under the Clinical domain. They are not in the scope of this document. Their mandate, objectives and rules of procedure, including composition, are described in a separate document (SAGs mandate, objectives and rules of procedure).
[2] https://www.ema.europa.eu/en/documents/minutes/minutes-111th-meeting-management-board-11-march-2021_en.pdf
[3] Information on domains is provided on EMA's website: https://www.ema.europa.eu/en/committees/working-parties-other-groups#overview-and-domains-12260
[4] Information on the Agency's Scientific Coordination Board is provided at the following link: https://www.ema.europa.eu/en/news/european-medicines-agencys-scientific-coordination-board-starts-reflection-best-cooperation-between-scientific-committees

The domain governances were constituted to provide strategic oversight of the relevant WPs and their expert groups, linked to the Agency's Regulatory and Science Strategy (RSS) – up to 2025 - and the European Medicines Agencies Network Strategy (EMANS) – which as of 2026 incorporates the RSS.

Primary objectives of the domains include:

- Generating a 3-year rolling strategic plan linked to RSS/ EMANS;
- Coordinating and overseeing the activities of WPs and expert groups;
- Introducing systematic and structured engagement with stakeholders and partners at the appropriate level, to underpin strategic priority planning and individual guideline generation/revision.

2. General considerations

2.1. Scope of the mandate, objectives and rules of procedure

The present mandate, objectives and rules of procedure apply to the following expert groups established under the quality, non-clinical, clinical, methodology and veterinary domains:

- Operational Expert Groups (OEGs) – divided in standing OEGs and temporary OEGs (tOEGs);
- Temporary Drafting Groups (tDGs);
- European Specialised Expert Communities (ESECs).

The term "expert groups" used in this document collectively refers to OEGs, tDGs, and ESECs.

OEGs, tDGs and ESECs operate under the governance of the five domains (see Section 1.3). They are established either under one specific domain, or cross-domain where necessary.

The focus of each of these expert groups is provided in Section 2.2.

This mandate, objectives and rules of procedure shall be agreed by CHMP and CVMP and reviewed by CHMP and CVMP as needed and at least every 3 years, upon consultation of the Agency.

Unless otherwise specified, any reference to a Committee in this document should be understood as a reference to CHMP and/or CVMP as appropriate.

2.2. Governance, focus and oversight

Table 1 below describes the governance, accountability and primary focus for each of the expert groups. **WPs are included for reference and to provide context, but are not in the scope of this document**[5].

As a general rule, tasks in scope of a WP should preferably be conducted within the WP, and there is no obligation to establish one of the below expert groups for specific tasks. However, the operational model allows for this possibility should this be necessary. Of note, proposed new tasks for a WP arising from its oversight of one of the expert groups should be discussed with, and endorsed by, the relevant domain governance and CHMP/CVMP, in line with the WPs mandate, objectives and rules of procedure.

[5] The mandate, objectives and rules of procedure for WPs is published at the following link: https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-working-parties-under-quality-non-clinical-methodology-clinical-veterinary-domains_en.pdf

Expert group	Established by[6]	Accountable to	Primary focus	Notes
WP (not in scope of this document)	*CHMP and/or CVMP*	*CHMP and/or CVMP*	*Complement the work of Committees, including guidance documents and product evaluation*	*WPs are the main scientific groups advising EMA's Committees based on their expertise in specific scientific fields. WP tasks are listed in Section 3 of the dedicated WPs mandate (EMA/299541/2025).*
OEG	WP(s)	WP(s)	Advice on specific or groups of products/ procedures/ evaluation topics	Complement WP expertise. Can be both standing and temporary (tOEG).
tDG	CHMP/CVMP[7] or WP	CHMP/CVMP or WP depending on who established the tDG	Drafting guidelines/ guidance documents	These groups are only temporary, disbanded once guideline/ guidance is final.
ESEC	WP(s); or domain governance where necessary and justified	N/A	Education, knowledge-sharing/ mining and training	ESECs are also a source of expertise when constituting WPs, OEGs and tDGs, complementing domain-contained knowledge.

Table 1. Governance, accountability and focus of the expert groups

3. Mandate and objectives

3.1. Operational expert groups

OEGs may be established to complement expertise for medicinal product-specific recommendations or other operational activities when there is not sufficient expertise in the WP. OEGs are responsible for providing:

[6] See Section 6 for further details on the involvement of the Agency and CHMP/CVMP in the establishment of expert groups. It is acknowledged that some of the expert groups may have been established by other parties prior to publication of the present document, but the establishment rules should be followed as of the date of publication.
[7] Article 17 of the CHMP Rules of Procedure; Article 20 of the CVMP Rules of Procedure (see Section 1.1).

- Product-specific recommendations to the Scientific Advice Working Party-Human/-Veterinary (SAWP-H/SAWP-V) upon their request;
- Product-specific recommendations following the delegation of some of the Committee's evaluation duties;
- Recommendations on scientific matters relating directly or indirectly to medicinal products (e.g. class/ type of products or substances) and technologies.

Temporary and standing OEGs can be created according to the needs of the WPs.

- **Standing** OEGs are constituted in order to provide regular and continuous product support, and/or support recurring activities.
- **Temporary** OEGs are created on an *ad hoc* basis for specific, non-recurrent tasks (e.g. a question from a Committee over a particular procedure). They are decommissioned when the task is complete (see also Section 6).

Unless otherwise specified, OEG provisions in this document apply to both standing and temporary OEGs.

Standing OEGs may be established to routinely support a Committee or SAWP-H/SAWP-V, in which case they may report directly to the Committee or SAWP-H/SAWP-V; however, these OEGs remain accountable to their WP(s), and should inform their respective WP(s) of the performed task(s) accordingly. For any *ad hoc* request to a standing OEG, and for all requests to temporary OEGs, the request for scientific input should be made to the WP, and the WP will report back to the Committee or SAWP-H/SAWP-V.

The scientific input provided to Committees or SAWP-H/SAWP-V may be at any phase of the lifecycle of a product, including certain tasks associated with the scientific evaluation of applications. The Committees and SAWP-H/SAWP-V retain ultimate responsibility for the scientific opinions issued. The OEG should take into account the procedural timetable provided by the EMA secretariat to ensure legal timelines can be met for the procedure concerned.

3.2. Temporary Drafting Groups

tDGs may be established to draft or revise specific guidelines or other types of guidance documents. tDGs are set up by CHMP/CVMP or by WPs with a view to fulfil one of the objectives set out in the CHMP/CVMP or domain/WP workplan.

The tDG mandate is limited to the specific task commissioned by the CHMP/CVMP or WP.

Discussions occurring in tDGs are limited to topics relevant to the drafting or revision of guidance documents. tDGs should not provide advice on ongoing product/ evaluation procedures.

3.3. European specialised expert communities

ESECs are communities of experts with knowledge and/or interest in certain areas of expertise, that can support the European Medicines Regulatory Network (EMRN) and the delivery of workplans of the various WPs. They:

- allow efficient exchange of information and expertise, with EMA and between ESEC members;
- facilitate collaboration, including as appropriate with external stakeholders, and exploration of new ideas;

- facilitate development and training of assessors across the EMRN.

ESECs are also a source of expertise when constituting other groups, i.e. members of the ESECs may become members of tDGs and OEGs (as well as WPs) or be involved as an expert in other EMA activities, according to the respective nomination and endorsement procedure.

It is not within the scope of the ESECs themselves to initiate or contribute in any way to any regulatory action/advice/procedure on product-related activities, to contribute to the assessment of products, or to comment or advise on the need for specific guidelines.

Consistent with this and the fact that ESECs can include experts external to the EMRN, ESECs do not handle or have access to commercially confidential information.

Any access an ESEC member may have to procedure-related EMA tools and/or confidential information derives solely from a separate capacity (e.g. as a National Competent Authority [NCA] employee or as a member of a WP, OEG or tDG upon completion of the necessary conflict of interest checks).

Non-confidential information may be shared with ESEC members, including for training purposes.

4. Composition and rules of participation

4.1. Provisions applicable to all expert groups

Table 2 provides information on the composition of each expert group, as well as on the expertise, nomination and endorsement of the members in each expert group.

All experts nominated to these groups must be registered in the Agency's Experts Management Tool (EMT).

EMA staff members provide support (scientific, technical, legal, regulatory and administrative) to such groups, however they cannot serve as members.

The duration of appointment of expert group members is linked to the duration of the expert group, provided for in Section 6.

Expert group	Composition	Expertise	Nomination	Endorsement
OEG	Experts working for or on behalf of NCAs in the European Economic Area, as well as other experts registered in EMT	Specific scientific expertise considering the task(s) in question	- WP members - CHMP/CVMP members or alternates - Other Committee members or alternates - SAWP-H/V members or alternates - EMA, in agreement with the chairperson(s) of the	WP chairperson(s)
tDG **established by WP**				
tDG **established by CHMP/CVMP**				CHMP/CVMP

Expert group	Composition	Expertise	Nomination	Endorsement
			WP/Committee (where EMRN members are unable to nominate experts or for experts from specific organisations/ agencies/ institutions)	
ESEC	- Assessors working for or on behalf of NCAs - Staff members of other EU agencies - Staff members from specific organisations/ agencies/ institutions relevant for EMA activities, including intergovernmental organisations - Researchers or employees in the academic sector - Committee members - SAWP-H/SAWP-V members - WP members - Expert group members - SAG/AHEG members from the same therapeutic area	Experts with special knowledge and/or interest in certain areas of expertise	- WP members - CHMP/CVMP members or alternates - SAWP-H/V members or alternates - EMA, in agreement with the chairperson(s) of the WP (where EMRN members are unable to nominate experts or for experts from specific organisations/ agencies/ institutions)	WP chairperson(s)

Table 2. Composition of the expert groups; expertise, nomination and endorsement of the expert group members

CHMP/CVMP are periodically informed of the composition of the expert groups.

4.2. Operational expert groups

The number of members for each OEG is based on the needs related to the requests received and the content of the domain/WP workplan.

OEG members are expected to:

- Support the activities described in the workplan of the domain/WP or delegated by the WP, Committee or SAWP-H/SAWP-V, and where appropriate take on coordination or lead role[8] within the activities of the OEG;
- Commit to participating actively in the activities, regularly attending the entire meetings of the group, and providing written input between meetings when needed.

4.3. Temporary Drafting Groups

The number of members for each tDG is based on the needs related to the requests received and the content of the domain/WP workplan.

tDG members are expected to commit to participating actively in the drafting or revising of the guideline or guidance, and in follow-up training activities.

4.4. European Specialised Expert Communities

Additional requirements on the composition may be specified by each ESEC.

ESEC members are nominated based on expertise.

Experts can be part of more than one ESEC.

5. Meeting frequency

The meeting frequency of OEGs, tDGs and ESECs is defined on a case-by-case basis depending on the needs related to their assigned tasks and the content of the domain/WP workplan.

6. Duration of the expert groups

Standing OEGs and ESECs do not have a predefined duration. The creation or abolishment of a standing OEG or ESEC is under the responsibility of the WP(s) or domain governance as defined in Table 1. It should also be discussed at the domain governance level and with the Agency, and is ultimately endorsed by the CHMP/CVMP.

CHMP/CVMP can also suggest the creation or abolishment of a specific expert group for the consideration of the WP(s) or domain governance.

tOEGs and tDGs are constituted for the time period needed to complete the tasks assigned by the CHMP/CVMP or WP.

CHMP/CVMP are periodically provided with a list of all current expert groups, for information.

[8] In the context of identification of conflicts of interest, this role is equivalent to the "Rapporteur" role as defined in Policy 0044.

7. Rules of procedure of expert groups

Standing OEGs may have a chairperson if it is deemed necessary for its functioning. Otherwise, it is recommended that standing OEG members appoint a lead member who acts as the link with the overarching WP(s) and report to the WP(s). This lead member should endorse the relevant responsibilities listed in Section 7.1.

tOEGs, tDGs and ESECs do not have chairpersons. It is mandatory for tDGs and recommended for tOEGs to appoint one member who will lead the group[9], act as the link with the overarching WP(s) and report to the WP(s).

EMA staff members provide support (scientific, technical, legal, regulatory and administrative) to such groups.

7.1. Responsibilities of standing OEG chairperson (where present)

In addition to abiding by the rules of participation of the standing OEG members, the chairperson of a standing OEG is responsible for the efficient conduct of the work of the standing OEG and shall in particular be responsible for the following tasks:

- Contribute, together with the EMA secretariat, to setting up the agendas for the standing OEG meetings;
- Chair the standing OEG meetings;
- Ensure that, at the beginning of each meeting, any potential conflict of interest is declared regarding any item to be discussed;
- Aim to promote participation and exchange of positions of all members present and achieve consensus on issues discussed by the OEG;
- Ensure, together with the EMA secretariat, the regulatory and scientific consistency of the recommendations;
- Report on the activities of the standing OEG to the WP(s)/Committees as appropriate;
- Ensure, together with the EMA secretariat, that the rules of procedure are respected;
- Monitor and supervise, together with the EMA secretariat and (where appropriate) the chairperson of the respective WP(s), the fulfilment of the tasks assigned to the OEG.

7.2. Election of standing OEG chairperson

A call for interest is launched for the election of the chairperson. Standing OEG members can express interest to be a chairperson.

The chairperson is elected by the standing OEG and formally endorsed by the responsible WP(s). CHMP/CVMP is/are informed.

The election is for a period of 3 years, renewable once.

The start date of the mandate of a new chairperson is the day following the end of the mandate of the current chairperson. If there is a nomination for a position currently not filled, the start date of the mandate is the last day of the (last) WP meeting during which the candidate is formally endorsed.

[9] In the context of identification of conflicts of interest, this role is equivalent to the "Rapporteur" role as defined in Policy 0044.

7.3. Responsibilities of EMA secretariat

Under the authority of the executive director, the EMA secretariat shall provide technical, scientific, legal, regulatory and administrative support to expert groups. This includes the responsibilities listed in the following sections.

For all groups, EMA is responsible for ensuring that all members and all additional experts (EEA experts registered in the Agency's Experts Management Tool who are not members of the expert group concerned) have a valid declaration of interests and that this is evaluated as relevant, prior to appointment to a group, prior to participation in a meeting or prior to the start of a product-specific task, in accordance with EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044)[10]. Reference is made to Section 7.5 for independence provisions.

7.3.1. Standing OEGs

Responsibilities of the EMA secretariat include but are not limited to the following:

- Support the process for the creation of the group;
- Organise meetings and ensure timely preparation (together with the standing OEG chairperson where there is one) and follow-up to the meetings (including drafting of minutes);
- Maintain membership and access to the group workspace;
- Ensure, together with the standing OEG chairperson where there is one, the regulatory and scientific consistency of the recommendations;
- Contribute to and prepare response documents following requests received, in consultation with the standing OEG chairperson where there is one, and share with the respective requestor;
- Monitor and supervise, together with the standing OEG chairperson where there is one and (where appropriate) the chairperson of the respective WP(s), the fulfilment of the tasks assigned to the OEG;
- Coordinate the assignment of new tasks to the standing OEG;
- Coordinate the nominations of members;
- Ensure, together with the standing OEG chairperson where there is one, that the rules of procedure are respected;
- Support the closing process of the group when disbanded.

7.3.2. tOEGs and tDGs

Responsibilities of the EMA secretariat include but are not limited to the following:

- Support the process for the creation of the group;
- Maintain membership and access to the group workspace;
- Provide administrative support when organising meetings including but not limited to external stakeholder engagement;

[10] EMA policies are published on the following webpage: https://www.ema.europa.eu/en/about-us/how-we-work/governance-reporting/policies-procedures.

- Ensure, together with the member leading the group (as relevant), the regulatory and scientific consistency of the recommendations and guidance documents;
- Contribute to the preparation, drafting, finalisation and publication of guidance documents, including collection of comments from consultations and ensuring consistency;
- Monitor and supervise, together with the member leading the group (as relevant) and (where appropriate) the chairperson of the respective WP(s), the fulfilment of the tasks assigned to the tOEG or tDG;
- Ensure, together with the member leading the group (as relevant), that the rules of procedure are respected;
- Support the closing process of the group when disbanded.

7.3.3. ESECs

Responsibilities of the EMA secretariat include but are not limited to the following:

- Support the process for the creation of the ESEC;
- Support nominations to the ESECs;
- Maintain membership and access to the ESEC workspace;
- Provide administrative support when organising meetings;
- Ensure that the rules of procedure are respected;
- Provide information on initiatives relevant to the ESEC and of upcoming events that may be organised by the EMA or by other stakeholders (such as EU Network Training Centre training, webinars, stakeholders' workshops and symposium, studies and projects).

7.4. Organisation of meetings and reporting arrangements

7.4.1. OEGs and tDGs

Standing OEGs meet based on needs. Standing OEGs usually meet virtually; face-to-face meetings may be considered where appropriate.

tOEGs and tDGs meet virtually, based on needs.

The meetings are held in English and any output from the meetings is provided in English.

Standing OEG, tOEG and tDG meetings require meeting objectives set in advance and in line with the WP workplan and agreed outputs. In addition, for OEGs, product-specific topics should be clearly identified to allow evaluation of conflicts of interest ahead of each meeting.

Relevant stakeholders can be invited to give oral presentations during meetings on matters directly related to the activities of an OEG or tDG, as appropriate.

Independence provisions are described in Section 7.5 and confidentiality provisions in Section 7.7.

Standing OEGs, tOEGs and tDGs regularly report to the entities they are accountable to (see Table 1).

7.4.2. ESECs

ESECs have no established meetings. Depending on the topic and on the strategic, operational, and tactical goals of the WP as set out in the domain/WP workplan, meetings can be organised for and by ESEC members, and webinars can be organised specifically for and by ESEC members. EMA is involved in the organisation of these meetings.

As a general principle, all communication within the ESEC should be transparent and available to all ESEC members. However, in some cases, a Specialised Interest Area (SIA) within an ESEC may function as a content group that facilitates the dissemination of information on specific scientific topics. SIAs prove particularly useful when the ESEC comprises members with a broad range of expertise in various scientific and medical areas. ESEC members can express interest in certain SIAs to receive communication tailored to those specific topics and can also express interest in taking a leading role in a SIA to shape and coordinate activities.

Independence provisions are described in Section 7.5.

7.5. Guarantees of independence

EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044)[10] applies to all expert group chairpersons and members, as well as to any additional experts attending expert group meetings.

For OEG and tDG members, the DOI is evaluated at the time of nomination of the member (and whenever the DOI is updated) and against tasks and/or meeting agendas to ensure that there are no conflicts that would be incompatible with membership or impact on the participation in discussion, deliberation and voting on a specific topic. This evaluation is performed against the matrix for WP members.

OEG and tDG members and any other experts attending OEG or tDG meetings shall declare at the beginning of each meeting any interests which may be prejudicial to their independence with respect to the points of the agenda. This will be documented in the meeting minutes.

For ESECs, the DOI evaluation is performed at the time of nomination of the member (and whenever the DOI is updated). Experts who have current direct interests in the pharmaceutical or medical device industry, i.e. current employment, current general matters consultancy/strategic advisory role or current financial interests; or experts who have current direct interests in a research organisation, i.e. involvement in a unit that acts as a marketing authorisation applicant or holder for a medicinal product, or involvement in a unit that manufactures medicinal products or medical devices, cannot be a member of an ESEC. ESECs do not handle or have access to procedure-related EMA tools and/or commercially confidential information as described in Section 3.3.

Any incomplete and/or incorrect DOI as well as any disclosure of confidential information will be handled according to EMA's breach of trust procedure for competing interest of and disclosure of confidential information by scientific committees' members and experts[11].

7.6. Code of conduct

Expert group members and all other attendees to their meetings and activities shall abide by the principles set out in the Agency's Code of Conduct[12].

[11] https://www.ema.europa.eu/en/documents/other/breach-trust-procedure-competing-interests-disclosure-confidential-information-european-medicines-agencys-scientific-committees-members-experts_en.pdf
[12] https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf

7.7. General provisions

Expert group members, as well as any other participating experts, shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy[13].

When participating in meetings or other fora on behalf of EMA/CHMP/CVMP, expert group members shall get prior agreement from the EMA/CHMP/CVMP and ensure that the views expressed are those of the EMA/CHMP/CVMP. When they are not participating on behalf of EMA/CHMP/CVMP, they shall make clear that the views expressed are their own, in compliance with EMA Policy 0029[10].

When preparing a scientific publication related to EMA activities, expert group members shall comply with EMA Policy 0015[10].

[13] Article 76 of Regulation (EC) No 726/2004.