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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Table of contents

1. Legal basis 5

2. General considerations 5

2.1. Scope of the mandate, objectives and rules of procedure 5

2.2. Other general considerations 6

3. Mandate and objectives 6

4. Composition and rules of participation 7

4.1. Composition 7

4.2. Nomination and appointment 7

4.3. Rules of participation 7

5. Meeting frequency 8

6. Duration of the WPs 8

7. Rules of procedure of working parties 8

7.1. Responsibilities of chairperson and vice-chairperson(s) 8

7.2. Election of chairperson and vice-chairperson(s) 9

7.3. Responsibilities of EMA secretariat 10

7.4. Organisation of meetings and reporting arrangements 10

7.5. Guarantees of independence 11

7.6. Code of conduct 11

7.7. Contacts with Interested Parties 11

7.8. General provisions 12

Annex 1 – List of WPs under the domains 13

Abbreviations

3RsWP	3Rs Working Party
AWP	Antimicrobials Working Party
BMWP	Biosimilar Medicinal Products Working Party
BWP	Biologics Working Party
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CNSWP	Central Nervous System Working Party
COMP	Committee for Orphan Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
CVSWP	Cardiovascular Working Party
EC	European Community
EEA	European Economic Area
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
ERAWP	Environmental Risk Assessment Working Party
EU	European Union
EWP-V	Efficacy Working Party
HAEMWP	Haematology Working Party
HCPWP	Healthcare Professionals' Working Party
HMPC	Committee on Herbal Medicinal Products
IDWP	Infectious Diseases Working Party
IIWP	Immune and Inflammatory Diseases Working Party
IWP	Immunologicals Working Party
MDSSG	Executive Steering Group on Shortages of Medical Devices
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MWP	Methodology Working Party
NcWP	Non-clinical Working Party
NTWP	Novel Therapies and Technologies Working Party

ONCWP	Oncology Working Party
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee
PhVWP-V	Pharmacovigilance Working Party – Veterinary
PRAC	Pharmacovigilance Risk Assessment Committee
QWP	Quality Working Party
SAWP-H	Scientific Advice Working Party - Human
SAWP-V	Scientific Advice Working Party – Veterinary
SPOC	Single Point Of Contact
SWP-V	Safety Working Party - Veterinary
VWP	Vaccines Working Party
WP	Working Party

1. Legal basis

Article 56(2) of Regulation (EC) No 726/2004[1] provides that the relevant European Medicines Agency (EMA, hereinafter "the Agency" or "EMA") Committees may each establish Working Parties (hereinafter "WPs"). These Committees include:

- Committee for Medicinal Products for Human Use (CHMP);
- Committee for Veterinary Medicinal Products (CVMP);
- Pharmacovigilance Risk Assessment Committee (PRAC);
- Committee for Orphan Medicinal Products (COMP);
- Committee on Herbal Medicinal Products (HMPC);
- Committee for Advanced Therapies (CAT);
- Paediatric Committee (PDCO).

For CVMP, the mandate to establish WPs is based on Article 139(3) of Regulation (EU) 2019/6[2].

As provided in Article 56(2) of Regulation (EC) No 726/2004 and Article 139(6) of Regulation (EU) 2019/6, when establishing WPs, the Committees shall, in their rules of procedure, lay down procedures relating to the appointment and consultation of these WPs.

According to Article 80 of Regulation (EC) No 726/2004, the internal rules and procedures of the Agency, its Committees and its working groups shall be made available to the public.

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 standing WPs established by CHMP and CVMP under the five domains[3]: quality, non-clinical, methodology, clinical and veterinary. These WPs are listed in Annex 1.

This document does not apply to the following WPs, which have dedicated mandates and rules of procedure[4]:

- the Scientific Advice Working Party - Human (SAWP-H) and Scientific Advice Working Party - Veterinary (SAWP-V);
- the Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP);
- the Medicine Shortages Single Point of Contact (SPOC) Working Party and the Medical Device Shortages SPOC Working Party, which were established in line with Regulation (EU) 2022/123[5] to support the work of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Executive Steering Group on Shortages of Medical Devices (MDSSG).

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0726-20220128
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0006-20220128
[3] Information on domains and domain governance is provided on the Agency's website: https://www.ema.europa.eu/en/committees/working-parties-other-groups#overview-and-domains-12260.
[4] All mandates and procedures are published on the Agency's website.
[5] https://eur-lex.europa.eu/eli/reg/2022/123/oj/eng

2.2. Other general considerations

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.

WPs are accountable to their respective Committee (see Annex 1).

WPs that routinely support both CHMP and CVMP, as provided for in their workplan, are referred to as 'joint WPs'[6]. They are accountable to CHMP for human topics, to the CVMP for veterinary topics, and to both CHMP and CVMP for cross-topics. Both CHMP and CVMP are responsible for joint WPs and will adopt the corresponding workplans (see Section 3).

3. Mandate and objectives

WPs are established in consultation with the Agency to complement the work of the Committees and to carry out specific tasks related to their respective fields.

These tasks include, but are not limited to:

- Preparing, reviewing, and updating guidance documents;
- Preparing reflection papers, scientific positions, questions and answers following Committee and/or SAWP-H/SAWP-V requests;
- Contributing to product evaluation;
- Providing support to other Agency's WPs and working groups;
- Offering trainings, webinars and workshops;
- Interacting with stakeholders[7] (as agreed at the domain level, see Section 7.7);
- Participating in European and international cooperation i.e. interacting with partners such as other European institutions and international regulators.

In practice, for each WP or domain as applicable, a workplan[8] is defined to be adopted by CHMP and/or CVMP. The domain governances should review the workplan annually in the light of the progress of delivery and of emerging needs. Updated workplans shall be endorsed by CHMP and/or CVMP.

Any Committee or SAWP-H/SAWP-V may request scientific input from the WPs at any phase of the lifecycle of a product, including certain tasks associated with the scientific evaluation of applications or drafting of guidelines, while retaining ultimate responsibility for the scientific opinions issued. WPs should take into account the procedural timetable provided by the EMA secretariat to ensure legal timelines can be met for the concerned procedure.

[6] Joint WPs are identified in Annex 1 as the WPs with both CHMP and CVMP as responsible Committees.
[7] Stakeholders are defined in the EMA stakeholder relations management framework (EMA/48651/2016) as organisations, associations and parties interacting with EMA, and which have an interest in or are influenced by the work of EMA and its partners. EMA main stakeholders groups are: patients and consumers, healthcare professionals, academia and industry.
[8] The workplan corresponds to the work programme mentioned in Article 15(4) of the CHMP Rules of Procedure/Article 18(4) of the CVMP Rules of Procedure.

4. Composition and rules of participation

4.1. Composition

WPs are composed of experts working for or on behalf of national competent authorities in the European Economic Area (EEA), as well as other experts registered in the Agency's Experts Management Tool. These experts are appointed in their individual capacity.

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

Experts are sought by CHMP/CVMP to provide specific scientific expertise in the area of responsibility of the WP, considering the workplan to be delivered. All experts nominated must be entered in the Agency's Experts Management Tool prior to selection.

The list of members for each WP is publicly accessible on the Agency's website.

At the time of the review of the workplan (see Section 3), the composition of the WPs should be reviewed by the domain governance and any proposed changes shall be brought to CHMP and/or CVMP for endorsement. The review of the composition includes both the compliance of members with the rules of participation (see Section 4.3) and, where necessary, the need for realignment between the domain/WP workplan and the expertise available, with the same process used in case changes are needed.

4.2. Nomination and appointment

Members of the WPs are appointed by CHMP/CVMP.

In constituting the WPs, the best and available expertise should be sought, aiming for the broadest possible geographical spread across the EEA. Preference should be given to experts who have both a high profile (proven expertise, experience in their field) and are committed to dedicate time to contribute to the WP work.

At the time of the review of the workplan (see Section 3), the membership of the WPs should be reviewed by the domain governance, based on compliance with the rules of participation (see Section 4.3) and the evolving needs of the Committees, and any proposed changes shall be brought to CHMP and/or CVMP for endorsement.

However, in order to ensure a wide representation of expertise across the Member States, and given the critical nature of quality-related matters, QWP and BWP are constituted for a period of 3 years. QWP and BWP members are therefore appointed for a term of 3 years, which may be renewed[9].

In view of the specific mandate and responsibilities of the PhVWP-V, which may involve both centrally and non-centrally authorised veterinary medicinal products, the PhVWP-V is composed of one member per Member State. The PhVWP-V, to complement its expertise, may appoint up to five additional members chosen on the basis of their specific scientific competence in surveillance and signal management. These five additional members are appointed for a term of 3 years, which may be renewed.

4.3. Rules of participation

All WP members are expected to:

[9] The membership of QWP and BWP will therefore only be reviewed every 3 years.

- Support the activities described in the workplan of the domain/WP and take on coordination or lead role[10] within the activities of WPs and expert groups[11] supporting that WP;
- Commit to participating actively in the activities outlined in the workplan, regularly attending the entire meetings of the group, and providing written input between meetings when needed;
- Provide scientific leadership across the European Medicines Regulatory Network (EMRN) on relevant topics, including trainings.

Failure to comply with these expectations may lead to the termination of membership of a WP member.

In specific circumstances, members may be temporarily replaced. Appointment of replacement members shall follow the rules described in Section 4.2.

5. Meeting frequency

The meeting frequency of WPs is based on the needs related to the requests received from the Committees and the content of the domain/WP workplan.

6. Duration of the WPs

Standing WPs have an indefinite duration. However, CHMP/CVMP, upon consultation of the domain governance, may review the necessity to abolish, amend or create a specific WP at any time based on needs.

7. Rules of procedure of working parties

7.1. Responsibilities of chairperson and vice-chairperson(s)

In addition to abiding by the rules of participation of the WP members, the chairperson, and in their absence the vice-chairperson(s) if (a) vice-chairperson(s) has/have been elected (see Section 7.2), is responsible for the efficient conduct of the work of the WP and shall in particular be responsible for the following tasks:

- As part of the domain governance, plan the work of the WP based on priorities outlined in the respective workplan;
- Contribute, together with the EMA secretariat, to setting up the agendas for the WP meetings;
- Chair the WP meetings (the Chair may delegate specific sessions to the vice-chairperson(s));
- Ensure that, at the beginning of each meeting, any potential conflict of interest is declared regarding any item to be discussed;

[10] In the context of identification of conflicts of interest, this role is equivalent to the "Rapporteur" role as defined in Policy 0044.
[11] Information on expert (scientific) groups is provided on the Agency's website: https://www.ema.europa.eu/en/committees/working-parties-other-groups#overview-and-domains-12260.

- Aim to promote participation and exchange of positions of all members present and achieve consensus on issues discussed by the WP;
- Ensure, together with the EMA secretariat, the regulatory and scientific consistency of the recommendations;
- Attend and actively participate in the domain governance meetings;
- Report on the activities of the WP to the domain governance and CHMP/CVMP;
- Ensure, together with the EMA secretariat, that the rules of procedure are respected;
- Monitor, together with the EMA secretariat, the compliance of members with the rules of participation (see Section 4.3);
- Coordinate, together with the EMA secretariat, the work of the WP with that of other relevant WPs, expert groups and Committees via the domain governance or the Scientific Coordination Board[12] when coordination is required beyond a specific domain.

The vice-chairperson(s) will deputise for the chairperson in their absence, or for specific topics (e.g. in case of conflict of interest) in all above-mentioned responsibilities and functions.

7.2. Election of chairperson and vice-chairperson(s)

All WPs have a chairperson. WPs can also have a vice-chairperson if considered appropriate by the WP. In addition, for joint WPs, or in justified cases and subject to agreement from CHMP/CVMP, a second vice-chairperson may be nominated. In the case of joint WPs, one vice-chairperson is elected by the CHMP and the other by the CVMP.

A call for interest is launched for the election of the chairperson or vice-chairperson(s). Both WP members and Committee members or alternates can express interest to be a chairperson or vice-chairperson.

The chairperson and vice-chairperson(s) are elected by CHMP/CVMP for a period of 3 years, renewable once[13]. Upon completion of their mandate, the chairperson and vice-chairperson(s) may continue as a WP member if they were elected from the WP. If they were elected from the Committee, they can retain their status as WP member if the size of the group allows.

The start date of the mandate of a new chairperson and vice-chairperson is the day following the end of the mandate of the current chairperson or vice-chairperson. If there is a nomination for a position currently not filled, the start date of the mandate is the last day of the CHMP/CVMP meeting during which the candidate is elected.

If a vice-chairperson was previously elected, they will deputise for the chairperson when the latter is unable to chair either all or part of a WP meeting. They become acting chair in the event of resignation of the chairperson until a new election is concluded.

In the event that there is no WP chairperson or vice-chairperson available to chair a meeting, the CHMP/CVMP chairperson[14] shall appoint a temporary chairperson for a single meeting or until a (vice-)

[12] 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
[13] Reference is made to Article 15(8) to (12) of the CHMP Rules of Procedure/Article 18(8) to (12) of the CVMP Rules of Procedure for the rules of election of the chairperson and vice-chairperson.
[14] In accordance with Article 2 of the CHMP Rules of Procedure/Article 2 of the CVMP Rules of Procedure, the vice-chairperson will deputise for the chairperson in case of unavailability.

chairperson is elected by CHMP/CVMP via the normal election procedure. The temporary chairperson shall be appointed from amongst the WP members or Committee members.

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 the WPs. This includes the following:

- Organise virtual and face-to-face WP meetings and ensure timely preparation (together with the chairperson(s)) and follow-up to the meetings (including drafting of the minutes);
- Confirm participation of additional experts[15] with the chairperson(s) where required;
- Ensure that all members and all additional experts (when contributing to the meeting) have a valid declaration of interests and that this is evaluated in accordance with EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044)[16]. Reference is made to Section 7.5 for independence provisions;
- Ensure, together with the chairperson(s), the regulatory and scientific consistency of the recommendations;
- Contribute to and prepare WP response documents following requests received, in consultation with the chairperson(s), and share with the respective requestor;
- Provide feedback from the WP discussions to the plenary Committee meetings, when requested;
- Coordinate the nominations of chairpersons, vice-chairperson(s) and members;
- Contribute to the preparation, drafting, finalisation and publication of guidelines, including collection of comments from consultations and ensuring consistency;
- Ensure, together with the chairperson(s), that the rules of procedure are respected;
- Monitor, together with the chairperson(s), the compliance of members with the rules of participation (see Section 4.3);
- Coordinate, together with the chairperson(s), the work of the WP with that of other relevant WPs, expert groups and Committees via the domain governance or the Scientific Coordination Board when coordination is required beyond a specific domain.

7.4. Organisation of meetings and reporting arrangements

The WPs meet virtually or face-to-face based on needs. The meetings are held in English and any output from the WP meetings is provided in English.

Additional experts may be invited to participate in specific discussions or to listen to the meetings.

Observers from international organisations with interests in the harmonisation of regulations applicable to medicinal products[17], from non-EEA regulatory agencies or bodies[18], and from decentralised agencies of the EU may also be invited to observe WP meetings.

[15] For the purpose of this document, "additional experts" means EEA experts registered in the Agency's Experts Management Tool who are not members of the concerned WP.
[16] EMA policies are published on the following webpage: https://www.ema.europa.eu/en/about-us/how-we-work/governance-reporting/policies-procedures.
[17] Reference is made to Article 24(1) of the CHMP Rules of Procedure/Article 27(1) of the CVMP Rules of Procedure for these observers.
[18] Reference is made to Article 24(2) of the CHMP Rules of Procedure/Article 27(3) of the CVMP Rules of Procedure for these observers.

The WP will report back to the Committee or SAWP-H/SAWP-V that has issued the request for scientific input.

7.5. Guarantees of independence

EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) applies to all WP members, as well as to any additional experts attending WP meetings[19].

WP members and any other experts attending WP meetings shall declare at the beginning of each meeting, or where applicable before their contribution to the 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.

Any incomplete and/or incorrect declarations of interests 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[20].

7.6. Code of conduct

WP members and all other attendees to their meetings and activities shall abide by the principles set out in the Agency's Code of Conduct[21].

7.7. Contacts with Interested Parties

Where relevant and as agreed at the domain level, lists of stakeholders for consultation, also referred to as "interested parties", will be established in line with each domain/WP workplan.

WPs may meet with interested parties to discuss general matters or specific scientific topics as foreseen in their workplan, and/or emerging topics with the agreement of the CHMP/CVMP/domain.

WPs may establish links with[22]:

- Patient and consumer organisations;
- Learned societies and healthcare professional organisations;
- Academia, such that it acts as a hub for information flow from key European academic stakeholders into WPs, in those areas falling under the remit of the WP;
- Industry stakeholder organisations; such an interaction should primarily be carried out at EU industry (trade) organisation level, and only exceptionally at company level;
- Public-private partnerships and consortia;
- Other stakeholders which have an interest in or are influenced by the work of the specific WP.

The WP should not reach any formal decisions in the presence of interested parties.

[19] Reference is made to the Procedural guidance to scientific committees' members and experts on completing the European Medicines Agency's declaration of interests in the Experts Management Tool, Section 2, for provisions applying to observers from the European Commission and from non-EU/EEA regulators.
[20] 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
[21] https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf
[22] Relevant frameworks for engagement can be found on the Agency's website for each stakeholder group: https://www.ema.europa.eu/en/partners-networks.

7.8. General provisions

WP members, as well as any other participating experts and observers, 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[23].

When participating in meetings or other fora on behalf of EMA/CHMP/CVMP, WP members shall get prior agreement from EMA/CHMP/CVMP and ensure that the views expressed are those of 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[24].

When preparing a scientific publication related to EMA activities, WP members shall comply with EMA Policy 0015[24].

[23] Article 76 of Regulation (EC) No 726/2004.
[24] EMA policies are published on the following webpage: https://www.ema.europa.eu/en/about-us/how-we-work/governance-reporting/policies-procedures.

Annex 1 – List of WPs under the domains

WPs provide recommendations and advice through the tasks listed in Section 3, in their respective area of expertise. The list of WPs under the domains and their respective area of expertise is the following:

Domain	Responsible Committee (s)	WP abbreviation	WP full name	Area of expertise
Quality	CHMP	BWP	Biologics Working Party	Quality aspects relating to biological and biotechnological medicinal products
	CHMP and CVMP	QWP	Quality Working Party	Quality aspects relating to human or veterinary medicinal products with chemical active substances
	CHMP	BMWP	Biosimilar Medicinal Products Working Party	Clinical or non-clinical aspects relating directly or indirectly to biosimilar medicinal products, and conduct of pharmaceutical tests on biosimilar medicinal products
Non-clinical	CHMP	NcWP	Non-clinical Working Party	Non-clinical aspects
	CHMP and CVMP	3RsWP	3Rs Working Party	Use of animals in the regulatory testing of human and veterinary medicinal products, with particular focus on the application of the so-called 3Rs principles - replace, reduce and refine
Methodology	CHMP	MWP	Methodology Working Party	Biostatistics, modelling and simulation, clinical pharmacology and pharmacokinetics, pharmacogenomics and diagnostics, artificial intelligence and data science, and real-world evidence

Domain	Responsible Committee (s)	WP abbreviation	WP full name	Area of expertise
Clinical	CHMP	CNSWP	Central Nervous System Working Party	Central nervous system
	CHMP	CVSWP	Cardiovascular Working Party	Cardiovascular system, diabetes and obesity
	CHMP	HAEMWP	Haematology Working Party	Non-malignant haematology
	CHMP	IDWP	Infectious Diseases Working Party	Infectious diseases
	CHMP	ONCWP	Oncology Working Party	Oncology (including haematological malignancies)
	CHMP	IIWP	Immune and Inflammatory Diseases Working Party	Rheumatology, immunology (allergy, transplant and primary immunodeficiencies), pulmonology, gastroenterology, hepatology, nephrology, dermatology, urology
	CHMP	VWP	Vaccines Working Party	Vaccines
Veterinary	CVMP	AWP	Antimicrobials Working Party	Antimicrobials and antimicrobial resistance
	CVMP	EWP-V	Efficacy Working Party	Efficacy of veterinary medicinal products, including target animal safety
	CVMP	ERAWP	Environmental Risk Assessment Working Party	Environmental risk assessment of veterinary medicinal products
	CVMP	IWP	Immunologicals Working Party	Immunological veterinary medicinal products

Domain	Responsible Committee (s)	WP abbreviation	WP full name	Area of expertise
	CVMP	NTWP	Novel Therapies and Technologies Working Party	Veterinary novel therapies and technologies
	CVMP	PhVWP-V	Pharmacovigilance Working Party - Veterinary	Co-ordination and supervision of the pharmacovigilance of centrally authorised veterinary medicinal products, as well as of nationally authorised products or products authorised through the mutual recognition/decentralised procedure
	CVMP	SWP-V	Safety Working Party - Veterinary	User safety and consumer safety of veterinary medicinal products.