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Human medicines development and evaluation

Mandate, objectives and rules of procedure for the temporary working parties and drafting groups

1. General considerations

In accordance with Article 56 (2) of EC Regulation 726/2004 as amended, the CHMP may establish temporary working parties. The Mandate, objectives and rules of procedure for the Temporary Working Parties and Drafting Groups follow the proposals made at the document adopted by CHMP in May 2010 "Reflection Paper on Working Parties (WP) CHMP/EMA group analysis and proposals". It shall be agreed by the CHMP and reviewed at least at the start of each new term of the CHMP.

2. Mandate and objectives

Temporary WPs are convened by the CHMP in order to carry out specific tasks related to their respective fields according to the following mandate:

- Preparation, review and update of guidelines/concept papers.
- Contribution to Scientific Advice Working Party activities upon request.
- Contribution to product-related assessment following specific CHMP request.
- Preparation of specific positions / Q&As following specific CHMP request.
- Interaction with stakeholders under supervision of CHMP.
- European and International cooperation under supervision of CHMP.
- Contribution to other Committee's needs.
- Training of assessors
- Accountable to CHMP for all activities, via coordination group as appropriate

The tasks identified by the CHMP should be included in the work programme of each WP to be adopted by the CHMP. The work programme shall be regularly reviewed (at least annually) in the light of WP's performance and updated as necessary with the agreement of the CHMP.

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3. Drafting groups

When a request for reviewing or developing a particular guideline is adopted and the area is not covered by any of the existing (temporary) WPs, the CHMP may create a Drafting Group (DG) rather than a new Temporary WP.

The DG mandate will be limited to the specific task commissioned by the CHMP and the rules of procedures will follow those of the Temporary WPs where applicable. In general terms, a DG rather than a WP will be set up when the tasks are limited to drafting 1 or 2 guidelines or to provide occasional support to scientific advice. Accountable to CHMP for all activities, via coordination group as appropriate

4. Composition and rules of participation

Some of the CHMP responsibilities could be delegated to the Coordination Group and therefore this will apply when WPs/DGs require CHMP endorsement.

WPs and DGs should be composed of assessors from or associated to National Agencies with specific expertise in the area of interest.

It is recommended that relevant number of the WPs' members should be senior assessors with accredited experience. One of the senior assessors should act as a Chair. For DGs the Rapporteur of the Guideline will act as Chair and if there are more than one, the most senior will be appointed as Chair.

It is highly desirable that at least one CHMP member or alternate should be part of each WP.

In case that a WP considers that it should be composed by members from each National Agency a justified request should be adopted by CHMP.

There should be a maximum of 10 members per WP, however by exception more than 10 may be permitted by CHMP and EMA.

DGs composition could be limited to very few members as agreed by the CHMP.

The nominations for WPs and DGs will be adopted by the CHMP in accordance with the membership profile previously agreed and following proposals from CHMP members and EMA Secretariat.

Specific requirements on the composition of each WP require adoption by CHMP (i.e. inclusion of members from other WPs or Committees).

Additional experts may be invited for particular topics for which specific expertise is required and these should be appointed by the CHMP and they will be reimbursed by EMA. If such a topic (e.g. guideline) involves paediatric patients and none paediatrician is member of the WP/DG, at least one additional expert should be appointed by the PDCO.

Additional assessors, who have been proposed by individual National Agencies and agreed by the CHMP could participate as observers, however, there will not be reimbursement by the EMA. Their participation aims to ensure information exchange within the European regulatory network. However, observers cannot act as Rapporteurs for drafting guidelines or position papers.

Observers from the European Commission, other EU Agencies, non-EEA Regulatory bodies or international institutions may participate with the agreement of the CHMP. Specific confidentiality rules will apply.

Membership of a WP or DG implies a commitment to participate actively in the work and to attend the meetings and tele/videoconferences regularly. If a member does not participate in 3 consecutive meetings without reasonable justification, EMA Secretariat may ask CHMP, in consultation with the WP or DG Chairperson, to reconfirm his/her membership or to nominate a new one.

5. Meeting frequency

The maximum number of face-to-face meetings per year will be 3 with a maximum of 2 days each.

Additional meetings will require specific approval from the CHMP and EMA.

One of the main characteristics of the regular work of the WPs and DGs should be based in the use of IT facilities in order to improve efficiency and minimising costs. Use of tools such as tele/videoconference (including websharing and VITERO) should ensure the ability of WPs to hold dynamic discussions, keeping assessors properly involved and replying to CHMP, other Committees and SAWP requests in a timely basis.

6. Duration of activity

Temporary WPs and DGs are constituted for the period of time needed to complete tasks committed by the CHMP. Continuity of each Temporary WP and DG should be confirmed by the CHMP at least once a year at the time of the adoption of the annual Work Programme.

Temporary WPs and DG can be put on hold and/or their composition modified at any time depending on the ongoing needs.

Chairpersons will be nominated for a term of 3 years, which may be renewed once, in case that the WP is required for a longer period of time. No time limit is proposed for the term of WP members, however in case of continuing activities (re)nominations should take place every 3 years.

7. Rules of procedure

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

The Chairperson is responsible for the scientific conduct of the business of the WP in efficient manner and shall in particular:

- Plan the work of the WP together with the EMA Secretariat.
- Ensure, together with the EMA Secretariat, that the rules of procedure are respected.
- Ensure that at the beginning of each meeting any potential conflict of interest is declared.
- Aim to achieve consensus on issues discussed by the WP.
- Ensure, together with the EMA Secretariat, the regulatory and scientific consistency of the recommendations.
- Attend the monthly teleconference of the Coordination Group.
- Liaise with the Consistency Group regarding the guidelines produced by the WP.
- Coordinate together with the EMA secretariat the work with that of the other relevant WPs, DGs and Committees.
- Report on the activities of the WP to the CHMP.

The Vice-Chairperson will deputise for the Chairperson in his/her absence in all above mentioned responsibilities and functions.

7.2. *Election/nomination of chairperson and vice chairperson(s)*

The Chairperson and Vice Chairperson shall be appointed by the CHMP for a term of 3 years, which may be renewed once, in case that the WP is required for a longer period of time.

Nominations should be submitted in writing to the EMA secretariat no later than the start of the Committee meeting at which election of the working party chairperson is to take place.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

The election of the Chairperson and the Vice-Chairperson, where appropriate, shall follow the same procedure as that for the election of the chairperson of Committee as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CHMP.

7.3. *Organisation of meetings and reporting arrangements*

Meetings refer to both face to face and tele/videoconference meetings. The face to face meetings shall take place at the Agency. The dates of meetings are decided on an annual basis. The meetings will be held and minuted in English.

The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the chairperson, at least 7 calendar days before the meeting.

Agenda and Table of conclusions/minutes of the meetings should be circulated for information to the CHMP.

When considered appropriate by the WP, oral presentations by companies, expert groups, representatives of professional bodies, patients associations or other interested parties can be made during a meeting on matters directly related to the activities of the WP, following prior agreement of the CHMP. The WP shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

WPs and DGs report to CHMP and are represented in the Coordination Group.

7.4. *Guarantees of independence*

The members of the WPs and DGs, other assessors, experts or observers referred to above shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. The specific provisions for handling declaration of interests and confidentiality undertakings are as defined in the EMA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (in the current version).

When a member is unable to participate to a meeting or part of meeting, due to conflict of interest, he/she must inform the Secretariat in advance.

All attendees of WPs and DGs meetings shall declare at the beginning of each meeting any specific interest, which could be considered to be prejudicial to their independence with respect to the points of the agenda.

7.5. *Code of conduct*

Members of the WPs and DGs and all other attendees to their meetings shall abide by the principles set out in the Agency Code of Conduct.

8. Agency secretariat

Under the authority of the Executive Director, the Agency secretariat shall provide technical, scientific and administrative support to the WPs and DGs. This includes the following:

- Provide technical and scientific support to Rapporteurs/Co-ordinators and other members.
- Provide legal, regulatory and scientific support.
- Prepare and co-ordinate the work of the WP/DG in consultation with the Chairperson.
- Organise meetings as described in 7.3 ensuring timely circulation of meeting documents to an agreed list of recipients.
- Responsible for the coordination of WP/DG with regard to planning, producing guidelines and reporting on progress /deviations from plans.
- Facilitate the necessary contacts between the WP/DG, the Committees and other concerned WPs/DGs or scientific advisory groups.
- Facilitate the necessary contacts and co-ordination between the WP/DG and the Coordination Group, Consistency Group and CHMP.
- Contribute to the overall quality and assurance of scientific and regulatory consistency of the documents / recommendations of the WP/DG in co-operation with the Chairperson.

- Prepare the agenda, Table of conclusions/minutes of the meetings in consultation with the Chairperson.
- Communicate when necessary any Committees recommendations relevant to the WP/DG to interested parties.
- Contribute to the identification of assessors and experts.

The Executive Director of the Agency and members of the Agency may attend all meetings.

9. Coordination group and consistency group

The Coordination Group is created in order to ensure an integrated management of Scientific Committees and WPs/DGs operations. The Coordination Group has only functional objectives, such as coordination of activities among the WPs, avoiding overlapping and ensuring the efficient integration of common horizontal activities such as ICH, training of assessors and relationship with stakeholders. Each Chair of the WP/DG will attend the monthly teleconference.

The Consistency group will peer review all concept papers, draft guidelines and reflection papers before they are discussed at the CHMP in order to maintain regulatory and scientific consistency. The Group will be composed by a few CHMP members or assessors or members from other Committees and EMA staff.

The CHMP will adopt Mandate, Objectives and rules of procedures for both Groups.

When a WP/DG adopts a final draft guideline, EMA will circulate it to Consistency Group. A predefined time for review and comments is 1 month. The group will interact directly with the WP/DG Chair, EMA secretariat and – if applicable – the guideline's Rapporteur and they can also be involved in the WP discussions. If there are no major issues, the guideline will be submitted to the CHMP for release for consultation or for adoption. If there are major discrepancies, a presentation to the CHMP will be carried out by a member of the Consistency Group and the chair of WP/DG or by the Rapporteur.

10. Relationship with other WPs, committees and groups

WPs/DGs interact with each other as needed through the Coordination Group. The Chairs of the WPs/DGs raise at the Coordination Group monthly teleconferences requests for interaction with an appropriate justification. After agreement of such Group the respective WP/DG interact each other directly and the Coordination Group will be kept informed. If for drafting of a particular guideline/concept paper continuous contribution from another WP/DG is desirable, such need will be managed at the stage of guideline/concept paper planning.

Requests from SAWP will be sent directly to the relevant WP/DG and in case that it is not covered by any of the existing WP/DG, it will be sent to the CHMP and managed by the Coordination Group, for the appropriate expertise to be made available. The response will be sent directly to the SAWP.

WPs/DGs provide service to Scientific Committees other than CHMP, and to other groups (e.g.CMDh). All requests should be sent directly to the relevant WP/DG and simultaneously to the Coordination Group for agreement as described above for WP/DG interactions.

11. General provisions

The Members of the WPs and DGs, as well as observers and all 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.

When participating in international or other fora on behalf of the EMA/CHMP, members shall ensure that the views expressed are those of the EMA/CHMP. It is noted that such participation requires prior agreement by the EMA/CHMP.

When participating in international or other fora not specifically on behalf of the EMA/CHMP, members shall make clear that the views expressed are their own views and not those of the EMA/CHMP.