European Medicines Agency
Inspections

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CHMP/CVMP/QWP/80473/2004

MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE JOINT CHMP/CVMP QUALITY WORKING PARTY

I. GENERAL CONSIDERATIONS

Introduction.
According to the CHMP and CVMP rules of procedure, the Committees may consult their working parties on any scientific issue related to their specific fields of expertise. The Committees may also delegate certain tasks associated with the scientific evaluation of applications, or drafting of guidelines to the relevant working parties. The tasks identified by the Committees should be included in the work programme of each Working Party to be adopted by the Committees.

The Joint CHMP/CVMP Quality Working Party (QWP) is therefore established to provide recommendations to the Committees on matters relating directly or indirectly to the quality of medicinal products to perform the tasks described under section II.

In view of its responsibility in the areas of both medicinal products for human use and veterinary use, a chairperson and two vice-chairpersons (one specifically responsible for veterinary issues) are considered necessary.

The mandate may be revised to take account of the need for liaison with the Committee for Herbal Medicinal Products (HMPC), once this Committee has established its work programme and priorities.

II. MANDATE AND OBJECTIVES

The general objective of the QWP is to provide a forum for dialogue and understanding between pharmaceutical experts/assessors in the human and veterinary area to reach a harmonised approach to quality issues and to avoid national divergences in assessing quality problems and interpreting quality guidelines.

It provides recommendations to the CHMP/CVMP on matters relating directly or indirectly to the quality of medicinal products including, but not limited to the tasks defined below:

- Preparation, review and update of quality guidelines
- Involvement in the assessment of applications in the centralised procedure on the request of CHMP or CVMP for specific matters related to Quality
- At the request of the CHMP or CVMP, provision of scientific advice on general and product specific matters related to Quality
- Resolution of national divergences in assessing quality problems and interpreting quality guidelines
- Liaison with interested parties (EFPIA. IFAH, AESGP, APIC, and other specific interested parties as appropriate)
- International cooperation on Quality related matters
- Setting up of drafting groups in accordance with point VI.4

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 7418 8400 Fax (44-20) 7418 8595
E-mail: mail@emea.eu.int http://www.emea.eu.int

- Liaison with other CHMP/CVMP Working parties, the HMPC and the ad hoc GMP inspection services meeting on quality related matters
- Advice, through the CHMP or CVMP, to European Commission and Notice to Applicants Working Party on quality related issues
- On request, advice, through the CHMP or CVMP, to MRFG or VMRFG on Quality related matters
- Training of quality assessors
- Contribution to Quality related workshops and training
- Facilitating the introduction of new approaches to manufacturing and control methodologies (PAT) through the EU PAT team
- Interaction with the European Directorate of the Quality of Medicines:
    - European Pharmacopoeia:
        - Monographs and general methods
        - Terminology
        - Certification scheme
        - Impurities

    - Official Medicines Control Laboratories Network:
        - Review and comment on results from testing of centrally authorised products and market surveillance studies

III. COMPOSITION AND RULES OF PARTICIPATION

The QWP is composed of experts selected from the European experts list according to their specific expertise in the area of quality assessment.

CVMP and CHMP members are invited to nominate one expert per Member State for products for Human use and, where there is a separate agency for Veterinary Medicinal Products, one expert per Member State for products for Veterinary use.

The EDQM may nominate an observer to participate in the work of the QWP.

The final composition shall be jointly agreed by the CVMP and CHMP.

Membership of a Working party implies a commitment to participate actively in the work of that Working party and to attend the meeting of the Working Party regularly.
A member may nominate a replacement to participate in those exceptional cases where he or she is unable to attend a meeting.

Members who want to bring additional experts should notify the EMEA secretariat in advance of the meeting, subject to the agreement of the chairperson.

Meeting documentation will be distributed to an agreed list of recipients drawn up by the EMEA with the agreement of the chairperson.
Observers from non-EEA countries may participate with the agreement of the chairperson and the EMEA.

Observers from accession countries and MRA partners may have standing invitations to the CHMP/CVMP QWP.

Specific confidentiality rules will apply to observers.

CHMP and CVMP members are encouraged to take an active role in the activities of the QWP.

IV. MEETING FREQUENCY

The Quality Working Party shall meet at least 4 times per year, in accordance with the adopted Work Programme. The dates of the meetings shall be included in the work programme of the Working party.

QWP drafting groups will meet for a one day session about 3 times per year, in the margins of the plenary meeting of the QWP.

V. DURATION OF ACTIVITY (IN THE CASE OF TEMPORARY WORKING PARTIES)

Not applicable

VI. RULES OF PROCEDURE

1. Responsibilities of Chairperson and Vice-Chairpersons

1. The Chairperson, and in his absence the Vice-Chairperson(s), is responsible for the efficient conduct of the business of the Working Party and shall in particular:

- plan the work of the Working party together with the EMEA Secretariat;
- monitor, together with the EMEA Secretariat, that the rules of procedure are respected;
- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the Working Party;
- aim to achieve consensus on issues discussed by the Working Party;
- decide in exceptional cases, when a vote is necessary;
- ensure, together with the Working Party and the Secretariat, the regulatory and scientific consistency of the Working Party's recommendations;
- co-ordinate together with the EMEA secretariat the work of this Working Party with that of the other relevant Working Parties of the Agency;
- report on the activities of the Working Party to the CXMP or other Working Party as appropriate

2. The Vice-Chairperson will deputise for the Chairperson when the latter is unable to chair either all or part of the Working Party meeting. On such occasions the Chairperson will seek the agreement of the Vice-Chairperson(s) as early as possible, prior to the meeting and the EMEA Secretariat shall be informed immediately. The Vice-Chairperson (vet) will chair the specific veterinary agenda topics.

2. Election of Chairperson and Vice Chairpersons

The Chairperson and the Vice Chairperson (human) of the QWP shall be elected by the members of the CHMP, and shall be subject to approval of the CVMP for a term of the Committees, which may be renewed. The vice chairperson (vet) shall be elected by the CVMP.

A committee member, an alternate or a member of the QWP may be elected by the Committee to fulfil this responsibility. Regardless of the time of election of the Chairperson he/she shall be appointed for the term of the Committee. This appointment may be renewed.

It is considered appropriate to elect two Vice-Chairpersons. See section 1.

Nominations should be submitted in writing to the EMEA secretariat no later than the start of the Committee meeting at which election of Working Party chairpersons 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-Chairpersons, 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 CXMP.

3. Organisation of meetings and reporting arrangements

1.The QWP shall meet regularly at the Agency.

2. The dates of meetings are decided on an annual basis in consultation with the QWP and the relevant Committees.

3. The meetings will be held and minuted in English.

4. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMEA Secretariat, in consultation with the chairperson, at least 14 calendar days before the meeting.

5. When a Member of the QWP is unable to participate to a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the Secretariat in advance in writing.

6. The Working Party may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the Committee(s) for endorsement and shall be preceded by a concept paper to be endorsed by the Committee(s).

7. Any recommendation from the QWP shall be transmitted to the relevant Committee(s) for adoption.

8 When considered appropriate by the QWP, oral presentations by companies can be made during Working Party meetings on matters directly related to the activities of the Working Party, following agreement of the Committee(s).

9. The QWP shall prepare an annual work programme for adoption by the Committee(s) which shall include topics identified in accordance with point 6 above and any specific tasks identified by the Committee(s). The work programme shall be regularly reviewed and updated as necessary with the agreement of the Committee(s).

10. Agenda, table of conclusions and minutes of the meetings of the working party should be circulated to the Committee(s).

11. Where the Chairperson is an alternate or a member of the Working Party, he/she will be invited to attend plenary Committee meetings to report on the activities on the QWP and ensure liaison with the work of the Committee.

12. The mandate of the QWP shall be agreed by the Committee(s). It shall be reviewed, at least at the start of each new term of the Committee(s).

4. Drafting Groups

When further consideration is required in order to prepare proposals on specific topics the Working Party may convene drafting groups constituted of members of the Working Party or experts, as appropriate.

The drafting group will report to its Working Party in direct line.

5. Participation of Experts in meetings

1. When necessary, the Working Party may avail itself of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and be included in the European Experts list. Where appropriate members from patient organisations or other health care professionals may act as experts.

2. The names of these experts shall be notified to the EMEA Secretariat before the meeting which they are due to attend.

6. Guarantees of independence

1. The members of the Working Party and experts 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, and shall make an annual declaration of their financial interests. All indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the Agency which is accessible to the public, on request at the Agency's office.

2 Members of the Working Party and experts attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

3. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interests for Committee Members and Experts, adopted by the Management Board (EMEA/H/31653) are applicable to members of the Working Party and experts participating in the activities of the Working Party.

7. Code of conduct

Members of the Working Party and experts participating in the EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

8. EMEA Secretariat

1. Under the authority of the Executive Director, the EMEA secretariat shall provide technical, scientific and administrative support to the Working Party. This includes the following:

- provide technical and scientific support to rapporteurs (guidelines), and other members of the Working Party;
- provide legal, regulatory and scientific support to the Working Party;
- prepare and co-ordinate the work of the Working Party in consultation with their chairpersons;
- ensure, if appropriate, that the periods laid down by Community legislation for the adoption of the opinions are complied with;
- organise meetings of the Working Party ensuring timely circulation of meeting documents;
- facilitate the necessary contacts between the Working Party and the Committee;
- ensure adequate co-ordination of the work carried out within the Working Party, the scientific Committee(s) and other concerned working parties and/or scientific advisory groups;
- contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents / recommendations of the Working Party in co-operation with the Chairperson or Vice-Chairperson, as appropriate;
- prepare the agenda, table of conclusions and minutes of the meetings of the Working Party in consultation with the Chairpersons;

- communicate when necessary any Committee recommendations relevant to the Working Party to interested parties
- contribute to the identification of experts

2. The Executive Director of the Agency, members of the EMEA secretariat, and representatives of the Commission, may attend all meetings of the Working Party.

9. Contacts with Interested Parties

1. Where relevant, the Working Party will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations.

2. Pharmaceutical industry, health care professionals, patients/consumers or other interested parties have the opportunity to comment in writing on draft guidelines and general regulatory developments during the public consultation of the documents.

3. When considered appropriate by the Working Party, oral presentations by interested parties can be made during Working Party meetings in earlier stages of development of guidelines. The working parties may also meet with interested parties to discuss general matters or specific scientific issues with the agreement of the Committee and under specific conditions to be agreed by the Committee.

4. In any case, the Working Party shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

5. Before any consultation session, interested party representatives and Working Party members will communicate to the EMEA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Working party Chairperson and circulation by the EMEA secretariat.

10. General Provisions

The Members of the Working Party 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 forums on behalf of the Committee(s), members shall ensure that the views expressed are those of the Committee(s).

When participating in international or other for a not specifically on behalf of the Committee(s), members shall make clear that the views expressed are their own views and not those of the Committee(s).