European Medicines Agency
*Evaluation of Medicines for Human Use*

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# MANDATE, OBJECTIVES AND RULES OF PROCEDURE FOR THE WORKING PARTY ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS (BMWP)

## I. GENERAL CONSIDERATIONS

According to the CHMP rules of procedure, the Committee may consult its Working Parties on any scientific issue related to their specific fields of expertise. The Committee 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 Committee should be included in the work programme of each Working Party to be adopted by the CHMP.

Changes to a biological medicinal product are frequent during its life cycle. Such changes may have consequences to its quality, safety and efficacy. Therefore, a series of suitable tests have to be carried out in order to ensure the comparability of the new and the old version. A company may also choose to develop a new biological medicinal product with the understanding that the new biological medicinal product is "similar" to another already on the market for which intellectual protection rights have expired.

Guidance has been and will be progressively issued by the CHMP concerning the scientific information to be provided to substantiate the claim of comparability, including similar biological medicinal products (e.g. medicinal products containing biotechnology derived proteins as active substance, blood products, monoclonal antibodies, etc.).

This exercise shall be carried out in context with a number of other CHMP guidelines currently in force and therefore would require the consultation of some CHMP working parties.

The temporary working party on similar biological medicinal products is therefore established to provide recommendations to the Committee on non-clinical and clinical matters relating directly or indirectly to similar biological medicinal products and to perform the tasks described under section

The CHMP Biologics Working Party (BWP) shall maintain its responsibility for quality and quality related safety aspects in relationship to similar biological medicinal products as well as quality and quality-related safety aspects in relation to comparability of biological/biotechnological medicinal products.

BMWP is represented at the Bio-Coordination Group, established to facilitate the sharing of information on quality aspects of biotech, biological and emerging technologies and therapies for human use (see VI. Rules of procedure, point 3.13).

## II. MANDATE AND OBJECTIVES

The Working Party on similar biological medicinal products (BMWP) is established to provide recommendations to the Committee on non-clinical and clinical matters relating directly or indirectly to CHMP including, but not limited to the tasks defined below:

- Preparation, review and update of guidelines, in conjunction with other appropriate working parties, to ensure that similarity/comparability specific issues are fully addressed;

- International cooperation, in collaboration with other appropriate working parties, on similar biological medicinal products/comparability. Provide CHMP with scientific contribution on

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ICH and other international activities, reinforcing the networking and exchange of experience with FDA, Japan, Canada, Australia, etc.;

- Advice, through the CHMP, to European Commission on similar biological medicinal products related issues;

- At the request of the CHMP provision of scientific advice on general and product specific matters related to efficacy and safety aspects related to similar biological medicinal products and to comparability of biological/biotechnological medicinal products;

- At the request of the scientific advice working party provision of scientific advice on general and product specific matters related to efficacy and safety aspects related to similar biological medicinal products and comparability of biological/biotechnological medicinal products;

- Liaison with other Working parties on comparability related matters;

- Focus and catalyst for training for assessment of comparability of similar biological medicinal products;

- Contribution to comparability related workshops and training;

- Liaison with interested parties (identify specific interest parties as appropriate) See VI.

## III. COMPOSITION AND RULES OF PARTICIPATION

The Working Party on similar biological medicinal products (BMWP) is composed of experts selected from the European experts list according to their specific expertise. Up to eight experts, identified by the CHMP on the basis of their specific scientific expertise and/or regulatory experience on the subjects covered within the scope of the working party's mandate, shall constitute the core group including:

- The chair of the temporary working party on similar biological medicinal products;
- Two members representing BWP;
- Two members, one of them a statistician, representing EWP;
- Two members representing SWP.

The CHMP may also appoint additional experts as appropriate.

PhVWP and SAWP representatives will be invited as appropriate.

In addition, experts from any of the other CHMP Working Parties and/or Scientific Advisory Groups may be invited as appropriate

The final composition shall be agreed by CHMP.

 

Membership of a working party implies a commitment to participate actively in the work of that working party and to attend the entire meeting of the working party regularly.

A core member shall identify an alternate who shall participate at the BMWP meeting when the core member is not able to attend. Whenever possible, any given member should be replaced by the same person (alternate), in order to maintain continuity. The list of alternates should be made available to the CHMP. The core member shall inform the EMEA secretariat at the latest 1 week in advance of the meeting if she/he will be replaced by the alternate. Alternates are encouraged to attend the BMWP meetings.

Members who want to bring additional experts should notify the EMEA Secretariat in advance to 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.

A representative from the European Commission may attend all meetings of the BPWP.

Observers from accession countries and MRA partners may have standing invitations to participate at certain working parties.

Specific confidentiality rules will apply to observers.

CHMP members are encouraged to take an active role in the activities of the working party and to ensure information of the activities of the group is disseminated at national level.

Certain BMWP members may be designated as contact persons with other Working Parties and/or scientific advisory groups to ensure good communication in areas of common interest. The concerned Working Parties will agree on the responsibilities of the contact person.

## IV. MEETING FREQUENCY

The Working Party on similar biological medicinal products shall meet at least 3 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.

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

To be reviewed on an annual basis.

## VI. RULES OF PROCEDURE

### 1. Responsibilities of Chairperson and Vice-Chairperson

1. The Chairperson, and in his absence the Vice-Chairperson, 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 CHMP 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 as early as possible, prior to the meeting and the EMEA Secretariat shall be informed immediately.

**2. Election of Chairperson and vice Chairperson**

The Chairperson and the Vice-Chairperson of the working party shall be elected by the members of the CHMP (Committee) for a term of the Committee, which may be renewed. A Committee member, an alternate or a member of the working party 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.

A Vice-Chairperson may be elected by the Committee.

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-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.

**3. Organisation of meetings and reporting arrangements**

1. The working party shall meet regularly at the Agency.

2. The tentative dates of meetings are decided on an annual basis in consultation with the working party and the relevant Committee.

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 working party 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 consideration by the working party. Any proposal for a guideline, providing adequate justification, shall be transmitted to the Committee for endorsement and shall be preceded by a concept paper to be endorsed by the Committee.

7. Any recommendation from the working party shall be transmitted to the relevant Committee for adoption.

8. When considered appropriate by the working party, 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.

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

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

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 working party and ensure liaison with the work of the Committee.

12. The mandate of the working party shall be agreed by the Committee. It shall be reviewed, at least at the start of each new term of the committee.

 

13. The BMWP Chairperson or its delegate and the EMEA Secretary will participate, on a regular basis, in the meetings of the BCG.

**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 / co-ordinators (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, the CHMP and other concerned Working Parties and/or scientific advisory groups.

 

- 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 working party in consultation with the Chairperson;
- 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 and members of the EMEA secretariat 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 fora on behalf of the CHMP, members shall ensure the views expressed are those of the CHMP. When participating in international or other fora not specifically on behalf of the CHMP, members shall make clear that the views expressed are their own views and not those of the CHMP.

 