EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Mandate, objectives and rules of procedure for the CHMP Biologics Working Party (BWP)

1. General considerations

According to the Committee for Medicinal Products for Human Use (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 plan of each working party to be adopted by the Committee.

The Working Party on Biotechnology and Pharmacy was first constituted in 1986 to advise the CPMP on quality aspects of emerging medicinal products produced by biotechnological processes. In 1995 the Biotechnology Working Party was established as a permanent working party of the CPMP.

The BWP provides on request of the CHMP a forum for discussion and harmonisation amongst quality and other experts to maintain and reinforce a uniform approach to the understanding of biotechnology and biological issues and to avoid/eliminate divergences in assessing biotechnology problems and interpreting biotechnology guidelines. The forum of the BWP should facilitate the efficient use of European expertise in the development and maintenance of the scientific review of applications for marketing authorisations for biotechnology or biological derived medicinal products including those from emerging technologies and therapies.

Apart from the European Commission (DG SANTE), the European Directorate for the Quality of Medicines (EDQM) would have direct interest in most of these activities. In specific cases other sectors of the European Commission (e.g. DG Research and Innovation) or of the Council of Europe might have a common interest, e.g. blood transfusions, biomedical research, bioterrorism. The BWP provides on request of CHMP input into international co-operation activities e.g. with WHO and into the ICH process.

The Biologics Working Party (BWP) is therefore established to provide recommendations to the Committee(s) on all matters relating directly or indirectly to quality aspects and safety in relation to quality of biological and biotechnological medicinal products and to perform the tasks described under section 2.

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2. Mandate and objectives

The BWP is established to provide recommendations to the Committee(s) on all matters relating directly or indirectly to quality aspects and safety aspects related to the quality of biological and biotechnological medicinal products including, but not limited to the tasks defined below:

- Support to dossier evaluation. The BWP, based on the evaluation and conclusions from the rapporteur and co-rapporteur, will support the CHMP to maintain consistent evaluation of the pharmaceutical dossier of biotechnological and biological medicinal products. The BWP contribution to dossier evaluation should facilitate consistency in assessments, and thereby in the coherence of the CHMP opinion. The BWP shall provide reports to CHMP which contain recommendations whether or not the application for marketing authorisation should be granted on quality grounds, and where relevant identify major issues and provide a list of questions, commitments or follow-up measures. The BWP shall provide reports to the CHMP (and other Committees (e.g. CAT), where applicable) for all marketing authorisation applications (MAAs) prior to opinion. The BWP may, particularly where new scientific issues are raised, provide reports to CHMP for maintenance aspects of marketing authorisations such as line extensions, variations etc. Where deemed necessary by the BWP/CHMP, oral clarification meetings may be held with applicants or marketing authorisation holders (MAHs).
- At the request of the CHMP, provision of scientific advice on general and product-specific matters related to quality aspects of biological and biotechnological medicinal products. The BWP shall provide reports to SAWP (and other working parties and Committees (e.g. VWP, CAT), where applicable).
- Preparation, review and update of guidelines in conjunction with other appropriate working parties.
- Liaison with interested parties (pharmaceutical industry associations such as EFPIA-EBE, Vaccines Europe, Medicines for Europe, Europa-Bio, AESGP, GME, EPFA, PPTA etc., learned society, public health-care professional organisations, patient organisations, etc. See point 6.9.).
- International cooperation on quality aspects and safety aspects related to quality of biological and biotechnological medicinal products related matters, in conjunction with other relevant working parties.
- Provide CHMP with a contribution to ICH on quality and safety aspects related to the quality of biological and biotechnological medicinal products.
- Contribution to CHMP scientific opinions in the context of collaboration with WHO for the evaluation of medicinal products intended exclusively for markets outside the community for quality and safety aspects related to the quality of biological and biotechnological medicinal products.
- Setting up of drafting groups (see point 6.4).
- Liaison with other working parties and ad-hoc GMP inspection services meetings on quality and safety aspects related to the quality of biological and biotechnological medicinal products.
- Advise as appropriate on other applications of biological/biotechnological methods in relation to medicinal products and their use.
- Advice, through the CHMP, to the European Commission on quality aspects of biological and biotechnological medicinal product-related matters in relation to medicinal products.

- On request, advice, through the CHMP, to other Committees and working parties/working groups on quality aspects of biological and biotechnological medicinal product-related matters in relation to medicinal products.
- Focus and catalyst for training for quality aspects and safety aspects related to quality of biological and biotechnological medicinal products assessment.
- Contribution to and organisation of workshops and training sessions on quality and safety aspects related to the quality of biological and biotechnological medicinal products.
- Interaction with the European Directorate of the Quality of Medicines (EDQM) particularly in relation to European Pharmacopoeia activities, biological standardisation and the Official Medicines Control Laboratory Network activities.
- Preparation of public statements on general and/or product-specific matters for information to the public.
- On request of the CHMP, constitute a rapid-acting crisis group to take on board specific issues related to the quality and related safety aspects of biological/biotechnological medicinal products with the objective of exchanging information on a European level and to co-ordinate responses to the public in a timely manner.

3. Composition and rules of participation

The BWP is composed of experts selected from the European experts list according to their specific expertise.

All members of the CHMP are invited to nominate one expert to be a member of the working party (one member per Member State) on the basis of their specific expertise and/or regulatory experience on the subjects covered within the scope of the BWP mandate.

A chairperson and vice-chairperson shall be appointed by the CHMP.

The final composition shall be agreed by CHMP.

Where specific topics are under discussion, a group of relevant experts will form a drafting group.

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 member may nominate an alternate to participate in those exceptional cases where he/she is unable to attend a meeting.

Whenever possible, any given member should be replaced by the same person (alternate) in order to maintain continuity. The member shall inform the EMA secretariat at the latest one week in advance of the meetings if he/she will be replaced by the alternate. Alternates are encouraged to attend all BWP meetings. The list of alternates will be made available to the CHMP.

Representatives of the Commission may attend meetings of the BWP.

Members who want to bring additional experts should consult the EMA Secretariat and chairperson in advance of the meeting.

Meeting documentation will be distributed to an agreed list of recipients drawn up by EMA with the agreement of the chairperson.

An observer from EDQM may attend meetings of the BWP. A representative of WHO could be invited to attend the meetings as appropriate, as an observer for non-product related issues.

Observers from non-EEA countries may participate with the agreement of the chairperson and EMA.

Observers from accession countries and Mutual Recognition Agreement (MRA) partners may have standing invitations to participate in certain working parties' meetings.

Specific confidentiality rules will apply to observers.

CHMP members are encouraged to take an active role in the activities of the BWP.

Certain BWP members may be designated as contact persons vis-a-vis 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.

The working party will agree on the responsibilities and role of the contact person.

4. Meeting frequency

The BWP shall meet up to 11 times per year in accordance with the adopted work plan. The dates of the meetings shall be included in the work plan of the working party.

5. Duration of activity (in the case of temporary working parties)

Not applicable.

6. Rules of procedure

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

The chairperson, and if appointed, in his/her 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 BWP together with the EMA Secretariat
- Monitor, 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 regarding any particular item to be discussed by the BWP
- Aim to achieve consensus on issues discussed by the BWP
- Decide in exceptional cases, when a vote is necessary
- Ensure, together with the BWP and the EMA Secretariat, the regulatory and scientific consistency of the BWP's recommendations
- Co-ordinate together with the EMA Secretariat the work of the BWP with that of other relevant working parties of the Agency

- Report on the activities of the BWP to the CHMP or other working party as appropriate

The vice-chairperson (if appointed) 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 EMA Secretariat shall be informed immediately.

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

The chairperson of a working party shall be elected by the members of the CHMP for a term of three years, which may be renewed once. 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 a term of three years. This appointment may be renewed once.

A vice-chairperson may be elected by the CHMP if the BWP and the CHMP consider it appropriate.

Nominations should be submitted in writing to the EMA Secretariat no later than the start of the CHMP 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(s), where appropriate, shall follow the same procedure as that for the election of the chairperson and vice-chairperson of the CHMP as stated in Article 3, paragraphs 1 to 6, of the Rules of Procedure of the CHMP.

6.3. Organisation of meetings and reporting arrangements

- The BWP shall meet regularly at the Agency.
- The dates of meetings are decided on an annual basis in consultation with the BWP and the CHMP.
- The meetings will be held and minuted in English.
- The draft agenda for every meeting shall be circulated, together with the related documents, by the EMA Secretariat, in consultation with the chairperson, 9-14 calendar days before the meeting.
- When a member of the BWP is unable to participate in a meeting, part of meeting, or discussion topic due to a conflict of interest, he/she must inform the Secretariat in advance in writing.
- The working party may identify and propose topics for its consideration. Any proposal for a guideline, providing adequate justification, shall be transmitted to the CHMP for endorsement and shall be preceded by a concept paper to be endorsed by the CHMP.
- Any recommendation from the working party shall be transmitted to the relevant Committee(s) for adoption.
- When considered appropriate by the BWP, 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 CHMP.
- The BWP shall prepare an annual work plan for adoption by the CHMP, which shall include topics identified in accordance with point 6 above and any specific tasks identified by the Committee(s).

The work plan shall be regularly reviewed and updated as necessary with the agreement of the CHMP.

- Agenda and minutes of the meetings of the BWP should be circulated to the CHMP.
- Where the chairperson is an alternate or a member of the BWP, he/she will be invited to attend plenary CHMP meetings to report on the activities of the BWP and ensure liaison with the work of the CHMP.
- The mandate of the BWP shall be agreed by the CHMP. It shall be reviewed, at least at the start of each new term of the Committee.

6.4. Drafting groups

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

Drafting groups will report to the BWP in direct line.

6.5. Participation of experts in meetings

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.

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

6.6. Guarantees of independence

The members of the BWP 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 interests. The Declarations of Interests of the working party's members and alternates shall be made available on the Agency's website.

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.

The specific provisions for handling Declarations of Interests and confidentiality undertakings as defined in the European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (EMA/626261/2014) are applicable to members of the BWP and experts participating in BWP activities.

6.7. Code of conduct

Members of the BWP and experts participating in EMA's activities shall abide by the principles set out in the 'EMA Code of Conduct' (EMA/385894/2012).

6.8. EMA Secretariat

Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the BWP. This includes the following:

- Provide technical and scientific support to rapporteurs and other members of the BWP;
- Provide legal, regulatory and scientific support to the BWP;
- Prepare and co-ordinate the work of the BWP in consultation with the chairperson(s);
- Ensure, if appropriate, that the timelines laid down by EU legislation for the adoption of the opinions are complied with;
- Organise meetings of the BWP ensuring, together with the respective rapporteurs, the timely circulation of meeting documents;
- Facilitate the necessary contacts between the BWP, CHMP and other concerned working parties and/or scientific advisory groups;
- Ensure adequate co-ordination of the work carried out within the BWP, the EMA scientific committees 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 BWP in cooperation with the chairperson or vice-chairperson, as appropriate;
- Prepare the agenda and minutes of BWP meetings in consultation with the chairperson(s);
- Communicate when necessary any Committee recommendations relevant to the BWP to interested parties;
- Contribute to the identification of experts

The Executive Director of the Agency, members of the EMA Secretariat, and representatives of the European Commission may attend all meetings of the BWP.

6.9. Contacts with interested parties

Where relevant, the BWP 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.

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

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

In any case, the BWP shall neither conduct any deliberations nor reach any formal decisions in the presence of interested parties.

Before any consultation session, interested party representatives and BWP members will communicate to the EMA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the BWP chairperson and circulated by the EMA Secretariat.

6.10. General Provisions

The members of the BWP 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 professional secrecy.

When participating in international or other fora on behalf of the CHMP, members shall ensure that 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.