



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE

RULES OF PROCEDURE

Article 55 of Parliament and Council Regulation (EC) No 726/2004 of 30 April 2004 establishes the European Medicines Agency with the responsibility for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Committee for Medicinal Products for Human Use (Committee), being part of the Agency, is responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for human use, relying on the scientific evaluation and resources available to national marketing authorisation bodies.

When a medicinal product containing a herbal substance is referred to the Committee, the Committee for Herbal Medicinal Products shall be requested to give an opinion on the herbal substance, where appropriate. Appropriate co-ordination with the Committee for Herbal Medicinal Products will be ensured through a procedure to be developed by the EMEA.

The Executive Director, in close consultation with the scientific committee, shall / has set up the administrative structures and procedures allowing the development of advice for undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products particularly regarding the development of new therapies.

Since the Committee is part of the Agency, the Integrated Quality Management System, endorsed by the Agency Management Board on 11 March 2004, applies to the Committee, its working parties and scientific advisory groups.

Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitate the activities of nominated members and experts. Member States shall refrain from giving Committee members and experts any instruction, which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.

Having regard to Article 61(8) of Regulation (EC) No 726/2004;

Having regard to Parliament and Council Directive 2001/83/EC, as amended, on the Community Code relating to medicinal products for human use;

Having regard to the EEA Joint Committee Decision No 74/1999 of 28 May 1999 regarding the participation of the EEA-EFTA states in the work of the EMEA;

Having consulted the Commission and the Management Board of the Agency on the basis of Article 61(8) of Regulation (EC) No 726/2004;

The Committee adopts the following rules of procedure:

Composition

Article 1

1. The Committee consists of one member appointed by each of the EU Member States, after consultation of the Management Board, for a term of three years, which may be renewed, and a chairperson.
2. The Committee shall also include one member appointed by each of the EEA-EFTA States, for a term of three years, which may be renewed.
3. The Committee, in order to complement its expertise, may appoint up to five co-opted members chosen on the basis of their specific scientific competence, among the experts nominated by Members States or the Agency. Co-opted members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

Responsibilities of Chairperson and Vice-Chairperson

Article 2

1. The Chairperson, and in his absence the Vice-Chairperson, is responsible for the efficient conduct of the business of the Committee and shall in particular:
 - plan the work of the Committee meetings 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 Committee;
 - decide when a vote is necessary;
 - ensure, together with the Committee and the Secretariat, the regulatory and scientific consistency of the Committee's opinions and recommendations;
 - ensure that scientific grounds are adequately reflected in the Committee opinions.
 - Co-ordinate together with the EMEA secretariat the work of this Committee with that of the other Committees of the Agency
2. The Vice-Chairperson will deputise for the Chairperson when the latter is unable to chair either all or part of the Committee 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.

3. If the Vice-Chairperson takes the chair, his/her place and vote will be assigned to his/her alternate.

Election of Chairperson and vice Chairperson

Article 3

1. The Chairperson and Vice-Chairperson of the Committee shall be elected by and from amongst its members for a term of three years, which may be renewed once.
2. Nominations for Chairperson and Vice-Chairperson should be submitted in writing to the EMEA secretariat no later than the start of the Committee's meeting at which the election is to take place.
3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

4. The election of the Chairperson and the Vice-Chairperson shall be by absolute majority of the Members (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. In the case of a tie in the decisive round, another round is organised with two remaining candidates. If, at the decisive round, the candidate with the highest number of votes does not get an absolute majority, a further voting is organised with this candidate only, where he/she needs favourable votes by at least half of the total number of Committee members eligible to vote plus one, to be elected Chairperson or Vice-Chairperson, as the case may be.

5. After the election of the Chairperson, the Member State who appointed him or her will designate a new member to replace the Chairperson as a member of the Committee. From the date of this appointment, the Chairperson shall lose his/her vote.

6. In the event of resignation of the Chairperson, the Vice-Chairperson shall take the chair until a new election is convened.

7. The members appointed by the EEA-EFTA States may not vote nor be elected Chairperson or Vice-Chairperson of the Committee.

Appointment of co-opted members

Article 4

1. Members shall decide if co-opted members should be appointed and shall agree on their profile and number. The Committee shall also agree on the procedure for the selection of co-opted members.

2. The Committee shall take the necessary steps to identify and appoint any such co-opted members forthwith.

3. The members and alternates appointed by EEA-EFTA States may not be elected co-opted members.

Alternates to nominated Committee members

Article 5

1. Each member of the Committee referred to under Article 1, paragraphs 1 and 2 shall have an alternate appointed by their Member State or EEA-EFTA State for a term of three years, which may be renewed.

2. Alternates shall represent and vote for the nominated member in the absence of the member, when he/she is not in attendance at the meeting. They may act as rapporteurs at any time. At the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for urgent advice from members between meetings.

3. Alternates may not be elected as Chairperson or Vice-Chairperson of the Committee.

Rapporteur, Co-Rapporteur and Assessment Team

Article 6

1. For any scientific evaluation in respect of a procedure a rapporteur shall be appointed from amongst the members of the Committee or alternates. The appointment of the rapporteur shall be made on the basis of objective criteria, which will allow the use of the best available expertise in the EU on the relevant scientific area.

2. The role of the rapporteur is to perform the scientific evaluation and to prepare an assessment report to the Committee according to the timetable agreed for the evaluation procedure, taking into account the timeframe laid down in the relevant legislation.

3. For the evaluation of new marketing authorisations, Type II variation applications involving a new indication and referral procedures the rapporteur is supported by a co-rapporteur, as agreed by the Committee. The involvement of the co-rapporteur in other major variations will be decided by the CHMP on a case-by-case basis. A co-rapporteur shall be appointed from amongst the members of the Committee or alternates and shall prepare a critique of the rapporteur's report or prepare a separate full report at the discretion of the Committee. The Committee may also appoint (a) peer reviewer(s) from amongst the members or alternates. In addition, the Committee may at any time ask for a peer review of any critical issues by the appropriate Committee's working party or scientific advisory group.

4. The rapporteur, and when appropriate, co-rapporteur chooses amongst the experts included in the European experts list available at the EMEA, those who will form his/her/their assessment team. He/she/they notify his/her/their choice to the EMEA prior to the start of the procedure. Members of the Committee or alternates and experts responsible for the evaluation of applications shall rely on the scientific evaluation and resources made available by national competent authorities and the EMEA.

5. Whenever meetings between rapporteurs or co-rapporteurs with applicants or marketing authorisation holders take place, minutes of all contacts shall be made available to the rapporteur, co-rapporteur and the EMEA secretariat. Contacts by other members and alternates with applicants and marketing authorisation holders are not considered appropriate and should be avoided during assessment procedures. Should such contacts take place, these shall be reported to the rapporteur and co-rapporteur and to the EMEA.

6. Rapporteurs may establish contacts on an advisory basis, with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned. Any such contacts should be organised in liaison with the EMEA Secretariat with the prior agreement of the Committee. The Rapporteur should provide a report on the outcome of such contacts to the Committee.

7. The provision of services by rapporteurs or experts shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and his/her employer. The person concerned, or his/her employer, shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board.

8. The Committee may (if and when established) consult the relevant scientific advisory group in particular in relation to the evaluation of a specific product without prejudice of the legal deadlines established. In such case the draft assessment report(s) prepared by the rapporteur and co-rapporteur, where appropriate, shall be forwarded to the group for advice in accordance with the procedure to be agreed by the Committee. The Committee may consult the relevant working party and/or relevant experts from the European expert list as appropriate.

9. The format and quality of the assessment report should be determined and judged by the Committee.

Scientific advice

Article 7

1. The Executive Director, in close consultation with the Committee for Medicinal Products for Human Use and with the Commission, shall set up the administrative structures and procedures allowing the development of advice for undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products particularly regarding

the development of new therapies.

2. For any procedure regarding the provision of advice for undertakings on the conduct of tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products, the Committee shall liaise with its working party on scientific advice, which shall appoint (a) co-ordinator(s) amongst its members for the evaluation.

3. The provisions under Article 6, paragraphs 7 to 9 equally apply regarding the provision of services of co-ordinators, consultation with the scientific advisory groups and assessment reports.

Scientific opinions and recommendations

Article 8

1. The quorum required for the adoption of scientific opinions or recommendations by the Committee shall be reached when two thirds of the total members of the Committee eligible to vote are present. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied).

2. Whenever possible, scientific opinions or recommendations of the Committee shall be taken by consensus. If such a consensus cannot be reached, the scientific opinion or recommendation will be adopted if supported by an absolute majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).

3. The divergent positions of and the names of the members expressing the divergent positions shall be mentioned in the opinion of the Committee, and where relevant, the minutes of the Committee. Members having divergent positions shall provide them in writing, stating clearly the reasons on which they are based. They will be appended to the opinion. The reasons for the divergent opinions shall be publicly available together with the documentation made publicly available in relation to the evaluation of applications.

4. The members from the EEA-EFTA States may not vote but their positions shall be stated separately in the opinion, where relevant, in the minutes of the Committee and in case of divergent opinions appended to the Committee's opinion. Their position is not counted in reaching the Committee's opinion.

5. In the event of no absolute majority position in favour of the granting, variation, suspension or withdrawal of a marketing authorisation, the Committee's opinion is deemed to be negative.

Procedure for urgent adoption of opinions

Article 9

1. In some instances, it may be necessary to take an urgent decision with regard to pharmacovigilance, serious concerns on public health or quality defects. This may be done by:

- Adoption of an opinion during the course of a scheduled meeting (using an accelerated timeframe if necessary), when the need for adoption of the urgent opinion /agreement on course of action has been identified during the course of the meeting (or within 48 hours before the meeting);
- The convening of an extraordinary meeting, if considered necessary and if feasible to organise within the necessary short timeframe. This meeting should take place in the presence of a quorum allowing the Committee to adopt an opinion i.e. when at least two thirds of the members are available to participate. A separate full report of this meeting, formally recording the adoption of the opinion should be prepared;
- Written procedure in accordance with Article 10.

2. Where the action to be taken requires an urgent change in product information, this may be carried out by an urgent safety restriction either within a scheduled meeting if the timeframe allows or by a written procedure.

3. The decision on the need for the adoption of an urgent opinion outside of a scheduled Committee meeting will be taken by the EMEA Secretariat in discussion with the Committee Chairperson and Vice-Chairperson. The procedure for the adoption of such urgent opinions should be in line with the EMEA incident management arrangements.

Written procedure

Article 10

1. Draft opinions and recommendations can, after approval of the Chairperson, be submitted by the EMEA Secretariat to the Committee for adoption by written procedure. However, such written procedures should be restricted to measures required to be taken between scheduled meetings

2. Draft opinions or recommendations are addressed to members of the Committee, who may raise objections within a specified time period, to be established in agreement with the Chairperson. The Secretariat shall present a full report on the outcome of the written procedure at the following meeting of the Committee.

3. In the case of serious objections, the Chairperson decides whether the written procedure should be suspended and the adoption of the draft opinion or recommendation postponed to the next meeting of the Committee.

Re-examination of opinions

Article 11

1. For the implementation of the procedures for the re-examination of opinions mentioned in Article 9(2) of Regulation (EC) No 726/2004, in Article 32(4) of Directive 2001/83/EC, as amended, a different rapporteur and where previously appointed, a different co-rapporteur from those appointed for the initial evaluation, will be appointed to assess the grounds for the re-examination of opinions. This re-examination shall be made by using the best endeavours to ensure a new examination, independent from the first opinion.

2. The re-examination may deal only with the points of the opinion initially identified by the applicant and is based only on the scientific data available when the Committee adopted the initial opinion. The applicant may request that the Committee consult a scientific advisory group (if and when established) in connection with the re-examination. In this case, the Committee shall request the advice of additional available expertise.

Organisation of meetings

Article 12

1. The Committee shall meet monthly at the Agency with the exception of the month of August during which no meeting is convened unless explicitly required. The meeting shall be convened by the Executive Director or his/her representative after consultation with the Chairperson.

2. The dates of meetings are decided on an annual basis in consultation with the Committee. In exceptional circumstances and on motivated grounds agreed with the Chairperson an extraordinary meeting may be convened at short notice.

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. This draft agenda shall enable the Committee to perform its duties as defined in Article 57 of Regulation (EC) No 726/2004.
5. When a Member of the Committee 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. Such declarations will be recorded in the minutes of the respective meeting.

Hearings - Oral Explanations

Article 13

1. The Committee shall invite an applicant or marketing authorisation holder to provide oral explanations in connection with an evaluation procedure where requested by the applicant or marketing authorisation holder, unless urgent measures need to be adopted for reasons of public health. The Committee may also invite on its own initiative an applicant or marketing authorisation holder to provide oral explanations. Oral explanations may also be provided by the applicant or marketing authorisation holder to working parties or scientific advisory groups when the Committee has delegated tasks associated with the scientific evaluation to a working party or a scientific advisory group.
2. The Committee may also invite on its own initiative or may consider a request of any other relevant third party for a hearing in connection with an evaluation procedure. With the agreement of the Committee, hearings may also be provided by any other relevant third party in connection with an evaluation procedure to working parties or scientific advisory groups.
3. Oral explanations/hearings shall be indicated clearly in the draft agenda of the meeting. .
4. The Committee, working party or scientific advisory group as appropriate shall not make any conclusions during these presentations in the presence of the company representatives or the third parties.
5. In all cases the applicant/marketing authorisation holder is informed of the trend at CHMP level at the end of the scientific discussion ahead of any formal vote to conclude the evaluation process.

Coordination with national authorities

Article 14

In addition to their task of providing objective scientific opinions to the Community and Member States on the questions which are referred to them, the members of the Committee shall ensure that there is appropriate coordination between the tasks of the Agency and the work of national competent authorities including the consultative bodies concerned with the marketing authorisation, and the Committee may consult national competent authorities and consultative bodies regarding specific scientific expertise.

Working parties

Article 15

1. In addition to the Scientific Advice Working Party, the Committee may establish other standing working parties.
2. Temporary working parties may also be established when work of a temporary or ad hoc nature is required such as preparation of proposals on a specific scientific topic, preparation of responses to specific questions raised by the Committee, drafting of new guidelines or revision of existing ones in relation to specific scientific fields.
3. Working parties are composed of experts selected from the European experts list according to their specific expertise.
4. The document establishing the mandate and objectives of each working party shall include its composition and meeting frequency and in the case of temporary working parties, also the duration of their activity. The Committee shall review the mandate and objectives of each standing working party at least every three years. Those of the temporary working parties should be reviewed either at the end of the period for which they have been created or after three years, whichever comes first. Where amendments are introduced in the mandate, of any working party, the Committee shall consider if the composition of the working party should be re-visited in order to ensure that scientific experience is available to execute the respective mandate. The work programmes of each working party shall be reviewed at least annually and will be made publicly available.
5. Whenever considered appropriate the Committee shall 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 Committee.
6. The working parties 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. The recommendation from the working parties shall be transmitted to the Committee for adoption (For Pharmacovigilance Working Party, c.f. the working party mandate).
8. The chairperson of a working party shall be elected by the members of the Committee for a term of three years, 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. The chairperson 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.
9. A vice-chairperson may be elected by the Committee if the working party considers it appropriate (For Pharmacovigilance Working Party, c.f. the working party mandate).
10. 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.
11. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
12. 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 these Rules of Procedure
13. Agenda, table of conclusions and minutes of the meetings of the working parties should be circulated to the Committee.

14. The Committee shall put in place measures to ensure that there is coordination of work and exchange of information between the standing and temporary working parties.

Scientific advisory groups

Article 16

1. Scientific advisory groups shall be established to provide advice to the Committee in connection with the evaluation of specific types of medicinal products or treatments, as appropriate.
2. The group shall consist of a core panel of members. The group may also include additional experts who may be called upon depending on the required expertise by the Committee or the core panel. The Committee shall appoint the members of the group on the basis of nominations from Committee members or the EMEA from the European experts list.
3. The scientific advisory group shall appoint a chairperson for the group, who may either be a member of the group, a member of the Committee or an alternate, for endorsement by the Committee. A Vice-Chairperson may also be appointed if the group considers it appropriate.
4. The Committee shall establish the mandate and objectives of each scientific advisory group and the duration of their activity shall be determined and reviewed when appropriate by the Committee.
5. When considered appropriate the Committee may delegate certain tasks associated with drawing up scientific opinions regarding the evaluation of medicinal products to the appropriate scientific advisory group.
6. When a scientific advisory group is consulted to provide advice to the Committee in relation to the evaluation of a specific product, the opinion of the group further to the consideration of the draft assessment report(s) prepared by the rapporteur and co-rapporteur, where appropriate shall be forwarded to the chairperson of the Committee according to the timetable established in order to ensure that the legal deadlines for evaluation of applications are met.
7. Agenda and minutes of the meetings of the scientific advisory groups shall be circulated to the Committee. Activity reports/tables of conclusions are presented by the chairperson or vice-chairperson of the scientific advisory groups or by the Secretariat at a subsequent Committee meeting.

Drafting Groups

Article 17

When further consideration is required in order to prepare proposals on specific topics the Committee or the working parties may convene drafting groups constituted by members or alternates of the Committee, members of the working parties or experts involved in the assessment of an application, as appropriate.

Participation of experts in meetings

Article 18

1. When necessary, the Committee, its working parties and scientific advisory groups may avail themselves 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.

2. Specialised experts included in the European experts list may be invited to support the Committee in queries or recommendations regarding clinical safety issues for centrally authorised medicinal products further to a proposal from the rapporteur, co-rapporteur(s), any member of the Committee or the Agency and with the agreement of the Committee in accordance with the procedure established by the Committee.

3. In addition members of the Committee may be accompanied by the experts mentioned in paragraph 1 (at their own expense). The names of these experts shall be notified to the EMEA Secretariat before the meeting which they are due to attend.

Guarantees of independence

Article 19

1. The names of the members and alternates of the Committee shall be made public. When each appointment is published, the professional qualifications of each member and alternate shall be specified.

2. The members of the Committee and alternates, members of working parties, scientific advisory groups and experts mentioned in various articles of the present Rules of Procedure, 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. In addition, the Declarations of Interest of the members and alternates of the Committee shall be made available on the Agency's website.

3. Members of the Committee and alternates, members of working parties and scientific advisory groups (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.

4. 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 Managements Board (EMEA/H/31653) are applicable to members of the Committee, working parties, scientific advisory groups and experts participating in the scientific activities of the Agency

5. The Members of the Committee, working parties, or scientific advisory groups shall not accept from the Member States any instructions incompatible with the tasks incumbent upon them within the Agency. It is essential for these tasks to remain strictly scientific in nature.

Code of conduct

Article 20

Members of the Committee, working parties, scientific advisory groups and experts participating in the EMEA's activities shall abide by the principles set out in the EMEA Code of Conduct.

Call for expression of interest

Article 21

The performance of scientific services for which there are several potential providers may result in a call for an expression of interest, if the scientific and technical context allows, and if it is compatible with the tasks of the Agency, in particular the need to provide a high level of public health protection.

EMEA Secretariat

Article 22

1. Under the authority of the Executive Director, the EMEA secretariat shall provide technical, scientific and administrative support to the Committee, its working parties and scientific advisory groups with a view to the performance of its duties as defined in Article 57 of Regulation (EC) No 726/2004. This includes the following:

- Provide technical and scientific support to rapporteurs, and other members of the Committee, working parties and scientific advisory groups;
- Provide legal and regulatory support to the Committee, working parties and scientific advisory groups;
- Prepare the Committee's assessment reports on the basis of rapporteur's and co-rapporteurs assessment reports or critique, as appropriate;
- Prepare and communicate relevant public information related to the activities of the Committee such as press releases, public statements, Q&A documents and EPARs after consultation of the Committee, where appropriate;
- Prepare and co-ordinate the work of the Committee, its working parties, scientific advisory groups and ad hoc groups in consultation with their chairpersons;
- Ensure that the periods laid down by Community legislation for the adoption of the opinions are complied with;
- Organise meetings of the Committee, working parties and scientific advisory groups ensuring timely circulation of meeting documents;
- Carry out the administrative validation of the applications submitted to the Agency;
- Facilitate the necessary contacts between the Committee, the Rapporteur and the applicant or person responsible for the placing on the market of the product;
- Ensure adequate co-ordination of the work carried out within this Committee, its working parties and scientific advisory groups and between them;
- Ensure scientific and regulatory consistency of the opinions / recommendations of the Committee in co-operation with the Chairperson or Vice-Chairperson, as appropriate;
- Organise, when necessary, joint meetings with the Committee for Medicinal Products for Veterinary Use, the Committee for Orphan Medicinal Products and the Committee for Herbal Medicinal Products;
- Prepare the minutes of the meetings of the Committee, its working parties and, scientific advisory groups in consultation with the Chairpersons;
- Communicate to applicants the relevant opinions or recommendations of the Committee;
- Communicate to interested parties relevant recommendations of the Committee;
- Communicate the views of the Committee in international *fora*.

2. The Executive Director of the Agency, members of the EMEA secretariat, and representatives of the Commission, may attend all meetings of the Committee, its working parties and scientific advisory groups.

Contacts with interested parties

Article 23

1. The Committee and its working parties and scientific advisory groups 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 Committee may agree to invite representatives of such interested parties to address a plenary meeting.

2. Concept papers, draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, health care professionals, patients/consumers or other).

3. When considered appropriate by the Committee, oral presentations by interested parties can be made during working party or scientific advisory group 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 Committee, working parties or scientific advisory groups 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 Committee 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 Committee Chairperson and circulation by the EMEA secretariat.

Observers

Article 24

1. At the initiative of the European Commission and in agreement with the Management Board, the Committee may admit representatives of international organisations with interests in the harmonisation of regulations applicable to medicinal products as observers at the Committee and working parties' meetings or meetings arranged for this purpose to discuss topics of common interest. The conditions for participation shall be determined beforehand by the European Commission.

2. For the purposes of regulatory cooperation, and particularly within the framework of mutual recognition agreements, visiting experts or other representatives from non-EEA regulatory authorities may also participate as observers to the Committee and its working parties. Participation shall be agreed with the respective Chairperson in advance of the meeting.

3. The observers shall be bound by the rules of confidentiality mentioned in Article 19.

General Provisions

Article 25

For tasks incumbent on the Agency, other than those of evaluation, the Committee may propose that the Agency has recourse to rapporteurs within the meaning of Article 6 paragraph 1 or to experts within the meaning of Article 18.

Article 26

The Committee may if, they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 27

The Members of the Committee, working parties and scientific advisory groups 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.

Article 28

The decision to adopt or to amend these rules of procedure shall be taken by an absolute majority of the Members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).

Article 29

The rules of procedure or any amendment to them shall enter into force after receiving a favourable opinion from the Commission and the EMEA Management Board and will be made publicly available.

Adopted by the Committee on 29 July 2004

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