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**Management of scientific committees I**

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**INTERNAL RULES OF PROCEDURE OF THE SCIENTIFIC COMMITTEE ON  
MEDICINAL PRODUCTS AND MEDICAL DEVICES**

Adopted at its meeting on 18 February 1998

## **INTERNAL RULES OF PROCEDURE OF THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES**

At its meeting on 18 February 1998,

### **THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES**

adopted the following rules of procedure:

Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety<sup>1</sup> requires the Scientific Committee on Medicinal Products and Medical Devices (hereinafter the SCMPMD) to adopt rules of procedure. These rules of procedure shall ensure that the Scientific Committee performs its task in the best possible way, in compliance with the principles of excellence, independence and transparency, while respecting the legitimate requirements of commercial confidentiality. In particular, they shall ensure close co-operation with the other Scientific Committees and with the Scientific Steering Committee.

#### **1 ELECTION OF THE CHAIRPERSON AND THE TWO VICE-CHAIRPERSONS OF THE SCMPMD**

The SCMPMD shall elect from among its members a Chairperson and two Vice-Chairpersons

##### **1.1 Election of the Chairperson**

The election procedure shall be chaired by the Commission.

The members of the SCMPMD shall propose candidates from among the members of the Committee. The candidates must, prior to the vote, declare that they are prepared to accept the post of Chairperson of the SCMPMD and at the same time become a member of the Scientific Steering Committee.

The ballot shall be secret and in writing. Subject to a unanimous decision by the SCMPMD, the secrecy requirement for the ballot may be waived.

The candidate receiving the majority of the votes of the members of the SCMPMD shall be elected Chairperson.

If no candidate receives an absolute majority, a second ballot shall be held between the two candidates with the highest individual totals of votes in the first ballot. The procedure shall be repeated until one candidate obtains the majority required.

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<sup>1</sup> OJ No L 237 of 28.8.1997, p. 18.

## 1.2 Election of the two Vice-Chairpersons

The election procedure for the two Vice-Chairpersons is identical to that for the Chairperson of the SCMPMD.

The Vice-Chairpersons shall be elected separately.

## 1.3 Separate minutes shall be kept of the election procedure.

## 1.4 The names of the Chairperson and the two Vice-Chairpersons of the SCMPMD shall be recorded in the minutes of the meeting of the SCMPMD and shall be made public.

## 2. INDEPENDENCE

The members of the SCMPMD shall carry out their duties free of any outside influence.

### 2.1 Each year, the members shall inform the Commission in writing of any interests which could be regarded as prejudicial to their independence (see the declaration in Annex 1).

### 2.2 At each meeting of the SCMPMD, or of a Working Party, members shall declare any particular interests which could be regarded as prejudicial to their independence in the light of the topics on the agenda for that meeting. This declaration shall be made in writing or verbally.

### 2.3 Any member concerned that his or her interests may undermine independence shall inform the Chairperson who shall, together with the other members of the SCMPMD or of the Working Party present at the meeting, evaluate the situation and give an opinion on it.

### 2.4 Any member who, in accordance with the member's declaration or in the opinion of the SCMPMD or of the Working Party, is not able to act independently shall not be authorised to act as rapporteur or as Chairperson, or to participate in decision-making. The extent of the member's participation in the Committee's work shall be laid down by the Chairperson in agreement with the Committee members.

### 2.5 The declaration, and where appropriate the opinion issued by the SCMPMD or the Working Party, and any abstention from voting, shall be noted in the minutes of the meeting.

## 3. CONFIDENTIALITY

Members of the SCMPMD and the external experts shall sign an initial written declaration that they are aware of their obligation not to divulge information obtained in the course of their work where they have been informed that this information is subject to a confidentiality request (the declaration may be found in Annex 2).

## 4 DELEGATION OF RESPONSIBILITIES

The members of the SCMPMD are nominated by the Commission in a personal capacity. It is not possible to delegate these responsibilities to another member or to a third party. One of the Vice-Presidents may act as Chairperson of the SCMPMD and as a member of the Scientific Steering Committee if the Chairperson of the SCMPMD is not able to carry out these duties.

## **5 WORKING PARTIES**

The SCMPMD may create ad-hoc Working Parties to deal with questions submitted by the Commission.

- 5.1 The SCMPMD shall entrust the Working Party with tasks which are clearly defined and directly linked to the question submitted by the Commission. In particular, it shall ask the Working Party to draw up a report on its conclusions and, if appropriate, to prepare a draft scientific opinion. The SCMPMD can require that these tasks be completed within a set period.
- 5.2 The Working Parties shall comprise at least one member of the SCMPMD, as well as external experts and shall be chaired by a member of the SCMPMD
- 5.3 The members of the Working Party and its Chairperson shall be designated by the SCMPMD. The members (see heading 6, external experts) shall be invited by the Commission.
- 5.4 The Working Party shall report to the SCMPMD, providing it with such reports or draft opinions as the Committee has requested.

## **6 EXTERNAL EXPERTS**

External experts possessing particular and relevant scientific knowledge may be invited by the Commission to contribute to the work of the SCMPMD and its Working Parties.

- 6.1 The Secretariat of the SCMPMD shall, with the agreement of the Chairperson of the SCMPMD or the Chairperson of the Working Party, invite the most suitable experts. These may be chosen from a list of experts available from the Secretariat of the SCMPMD. If an expert is invited but is not available, the Secretariat may, in agreement with the Chairperson, invite another suitable expert featuring on the list.
- 6.2 External experts are subject to the rules covering independence (see heading 2.2-2.4) and confidentiality (see heading 3).

## **7 NOTICE OF MEETINGS, AGENDA, DEADLINES**

- 7.1 The Secretariat shall draw up, in accordance with the Chairperson, a provisional timetable of meetings.
- 7.2 The SCMPMD and the Working Parties shall receive notice of the meetings in agreement with their respective Chairpersons, taking account of a notice period which will normally be ten working days before the date of the meeting. In cases of urgency, the Secretariat may shorten this notice period.
- 7.3 The Secretariat shall draw up a draft agenda for the SCMPMD or the Working Party, in agreement with their Chairpersons. The agenda shall comprise questions submitted by the Commission. As soon as possible, the Secretariat shall supply all appropriate supplementary information of relevance to the questions submitted. The definitive agenda shall be adopted by the SCMPMD or the Working Party at the meeting itself.

- 7.4 As far as possible, the documents shall be made available to the members or external experts a week before each meeting of the SCMPMD or of the Working Party. Rapporteurs and members are obliged to respect this deadline when distributing documents or presenting reports and drafts opinions.
- 7.5 The Commission may insist that an opinion be adopted by a specific deadline. The SCMPMD shall take the necessary measures to ensure that the deadline is respected.

## **8 ACCELERATED PROCEDURE**

In urgent cases, an accelerated procedure is possible if this is requested by the Secretariat and this is sanctioned by the Chairperson.

- 8.1 The Secretariat shall request, with the agreement of the Chairperson of the SCMPMD, that a member, an external expert or a Working Party draw up a draft opinion and submit this to the Secretariat of the SCMPMD within a specified, short period. The Secretariat shall place the draft on the agenda for the next meeting of the SCMPMD.
- 8.2 With the agreement of the Chairperson, the draft opinion may be adopted by means of the written procedure (see heading 13.2). In this case, the Secretariat shall send the draft opinion to the members of the SCMPMD, asking them to approve it by a specified date. The draft shall be adopted if the majority of the members of the SCMPMD have expressed their approval. If this majority is not reached, the draft opinion must be placed on the agenda for the next meeting of the SCMPMD.

## **9 QUESTIONS SUBMITTED BY THE COMMISSION**

Should the SCMPMD consider that the question submitted by the Commission is not sufficiently precise for a scientific answer to be given, the SCMPMD may ask the Commission to make the question more explicit and/or supply additional information. The Commission may, however, retain unaltered the wording of the question.

## **10 CO-OPERATION BETWEEN THE SCIENTIFIC COMMITTEES AND THE SCIENTIFIC STEERING COMMITTEE**

The SCMPMD shall co-operate closely with the other Scientific Committees and the Scientific Steering Committee.

In order to ensure that this co-operation is effective

- the Chairperson of the SCMPMD shall notify the Scientific Steering Committee of the activities undertaken by his own Committee;
- the SCMPMD may ask for the assistance of members of other Scientific Committees as external experts if the question submitted has a bearing on the field of competence of one or more of the other Scientific Committees. This involvement is mandatory if it has been requested by the Scientific Steering Committee;

- In agreement with the Scientific Steering Committee, the SCMPMD may form a joint Working Party with one or more other committees. This involvement is mandatory if it has been requested by the Scientific Steering Committee. The Joint Working Party may draw up reports and/or draft scientific opinions, these then be adopted by each of the Committees concerned. However, the reports and/or scientific opinions shall not be made public until after they have been examined by the Scientific Steering Committee. In case of major differences of opinion, the Scientific Steering Committee will produce a synthesis.

## **11 RAPPORTEUR**

The SCMPMD or the Working Party shall designate rapporteurs from among its members. The rapporteur may also be an external expert.

- 11.1 Rapporteurs may be asked to assemble information packages and documentation and to prepare draft reports and scientific opinions within a set period.
- 11.2 Rapporteurs must carry out their duties in accordance with the provisions under heading 2 (Independence). If necessary, the SCMPMD may revoke the appointment as rapporteur.

## **12 CONFIDENTIALITY OF MEETINGS**

- 12.1 Meetings of the SCMPMD, and those of Working Parties, shall not be open to the public. Commission services with responsibilities relating to the topics on the agenda shall be invited to the meeting.
- 12.2 The scientific opinions expressed by members or external experts during discussions within the SCMPMD or a Working Party shall be confidential.

## **13 DECISIONS**

With the exception of elections for the posts of Chairperson and the Vice-Chairpersons, the adoption of scientific opinions and the adoption of any amendment to the rules of procedure, the SCMPMD shall vote by a majority of members present, provided that the quorum of half of the members of the SCMPMD is obtained.

A Working Party shall vote decisions by a majority of its members present, including external experts, provided that the quorum of half of the members of the SCMPMD is obtained.

## **14 ADOPTION OF SCIENTIFIC OPINIONS**

- 14.1 The SCMPMD shall adopt its scientific reports at its plenary meetings and by a majority of the members comprising it.
- 14.2 The SCMPMD may adopt a draft opinion, previously discussed in a Committee meeting, using the written procedure as set out under heading 8.2.

## **15 SCIENTIFIC OPINIONS**

The scientific opinion comprises the response given to a question posed by the Commission, a scientific explanation and any minority opinions. The latter shall be attributed to members only at their request. The opinion must be supplemented by a summary setting out the reply and the main elements of the scientific explanation. The full scientific opinion shall be made public. Legitimate requests for commercial confidentiality are to be respected.

## **16 MINUTES**

The minutes of meetings of the SCMPMD and the Working Parties shall be written by the Secretariat and shall contain at least:

- the agenda as adopted;
- the list of persons attending;
- decisions taken or draft decisions, together with opinions adopted or draft opinions to be adopted;
- the summary report of discussions;
- any declarations by members and the opinions of the SCMPMD or of the Working Party concerning independence of the members, and any abstentions during voting.

The minutes shall be approved at the following meeting of the SCMPMD

Minutes shall be made public after their adoption. Legitimate requests for commercial confidentiality are to be respected.

## Annex 1

### ANNUAL STATEMENT OF MEMBER'S INTERESTS

#### Scientific Committee on Medicinal Products and Medical Devices

**Name:**

In accordance with Article 6(2) of Commission Decision 97/579/EC of 23 July 1997, I hereby notify the Commission that I have interests<sup>1</sup> which I view as being prejudicial to my independence:

**Interests:**

I hereby notify the Commission that I do not have any interests<sup>2</sup> which I view as being prejudicial to my independence.

I shall immediately and explicitly inform the Scientific Committee of any specific interests<sup>3</sup> concerning any question submitted by the Commission on the occasion of the meeting at which the relevant question is to be examined by the Committee. I shall inform the Commission of any change with regard to my interests which could be prejudicial to my independence.

This information is confidential.

**I agree** that it should be accessible to the public and communicated or made available to third parties.

**I do not agree** that it should be accessible to the public and communicated or made available to third parties.

Done at \_\_\_\_\_ on \_\_\_\_\_

Signature

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<sup>1</sup> Links which could be considered interests might include:  
- one's job (university, institute, public service, enterprise);  
- being a member of a board of directors, board of management or any other supervisory body within a company, association, etc.;  
- having carried out scientific research or provided an expert opinion at the request of a company, public service, etc.

<sup>2</sup> see 1.

<sup>3</sup> see 1; a special interest could, in particular, comprise any prior activity concerning the subject of the question.



**Annex 2**

**DECLARATION CONCERNING CONFIDENTIALITY**

**Scientific Committee on Medicinal Products and Medical Devices**

**Name:**

**Position:**     **Member of the Committee**                   **[ ]**

**External expert**                                     **[ ]**

I hereby declare that I am aware of my obligation to respect confidentiality. I know that I am obliged not to divulge information acquired as a result of the work of the Committee if this information is subject to a request for confidentiality. I shall also respect the confidential nature of the scientific opinions expressed by members of the Committee or the external experts during discussions in committee.

Done at   on

Signature