

Coordination group for Mutual recognition and Decentralised procedure (human)

RULES OF PROCEDURE

Article 27 of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use¹ as amended by Directive 2004/27/EC² establishes the Coordination Group for examination of any question relating to marketing authorisation of a medicinal product in two or more Member States. 'Any question related to marketing authorisations of medicinal products in two or more Member States' covers a variety of issues related to new applications, variations and renewals which should be defined by the group itself.

The Coordination group shall consider points of disagreement raised by Member States during Mutual recognition or Decentralised procedures, in relation to the assessment report, Summary of Product Characteristics, labelling and package leaflet of a medicinal product on the grounds of potential serious risk to public health and make every effort to resolve issues to avoid referral to the Committee for Medicinal Products for Human Use (CHMP) or the Committee on Herbal Medicinal Products (HMPC) for arbitration.

In order to promote harmonisation of authorisations for medicinal products authorised in the Community the Coordination group shall lay down a list of products, taking into account proposals from Member States, and forward the list to the Commission.

The Coordination group for Mutual recognition and Decentralised procedure for human medicinal products, CMD(h),

Having regard to Directive 2001/83/EC laying down Community procedures for the authorisation of medicinal products for human use in the framework of mutual recognition and decentralised procedure, the CMD(h),

Has adopted the following rules of procedure:

COMPOSITION

ARTICLE 1

1. The members of the CMD(h) shall be appointed by the Member States, one per Member State, for a term of three years, which may be renewed. A Chairperson shall be elected as mentioned in Article 3.

In addition the CMD(h) shall include one member nominated by each of the EFTA States concerned, for a term of three years which may be renewed.

¹ *Official Journal L 311, 28/11/2001 p. 67 - 128*

² Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (*Official Journal L 136, 30/4/2004 p. 34 - 57*)

2. The members should be from the national competent authorities and have adequate regulatory and/or scientific expertise. They also should have sufficient delegated authority to express final positions and confirm their regulatory authority's intention to implement the final outcome (see also Article 8).
3. When a member of the CMD(h) is not able to attend, a substitute may attend in his/her place. The Competent Authority of the member shall advise the Secretariat of the name of the substitute prior to the meeting concerned.

GUARANTEES OF INDEPENDENCE

ARTICLE 2

1. The membership of the CMD(h) shall be made public. When each appointment is published the professional qualifications of each member shall be specified.
2. In accordance with national rules and EU legal framework, the members of the CMD(h) and European experts mentioned in various articles of the Rules of Procedure shall not have any direct interests, financial or otherwise, in the pharmaceutical industry, which could affect their impartiality. All indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the EMEA which is accessible to the public, on request at the EMEA office. Experts shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests.
3. The specific provision for handling declarations of interests and confidentiality undertakings as defined in the EMEA Policy on the Handling of Conflicts of Interest for Committee Members and Experts, adopted by the Management Board (EMEA/H/31653) are applicable to members of the CMD(h), working parties and experts participating in the activities of the CMD(h).
4. The discussion within the CMD(h) may raise potential conflict of interests for a participant. He/she should remind the meeting of his/her interests before the start of the discussion and should refrain from participation in the discussion. He/she may be asked by the Chairperson to leave the meeting for that item or only answer direct questions from the Chairperson.

CHAIRPERSON AND VICE-CHAIRPERSON

ARTICLE 3 (ELECTION)

1. The Chairperson of the CMD(h) shall be elected by and from amongst its members for a term of three years, renewable once.. Members from the EFTA States can not be elected as Chairperson.

Every nomination, together with a short CV of the candidate should be submitted to the EMEA secretariat no later than 7 days prior to the CMD (h) meeting at which the election is to take place.

The Vice-Chairperson shall be appointed from among the members of CMD(h) by the Member State which has the presidency of the Council of the European Union for the duration of the term of the presidency.

2. The election of the Chairperson shall be by absolute majority of the members and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. If an absolute majority vote is not obtained when only two candidates remain, further rounds of voting are organised with the two remaining candidates, if it is considered that an absolute majority vote may be achieved. If an absolute majority vote for one of the candidates is not considered feasible a further voting is held with the candidate who has received the highest number of votes in the latest round only. This candidate is elected Chairperson if he/she receives a majority of votes.

3. After the election of the Chairperson, the Member State, which appointed him/her will appoint a new member to replace the Chairperson as a member of the CMD(h). (From the date of this appointment, the Chairperson shall lose his/her vote.) This provision also applies to the Vice-Chairperson whenever he/she takes the chair and replaces the Chairperson. His/her vote will be assigned to the member of his/her delegation attending the meeting.

ARTICLE 4 (ROLE OF CHAIRPERSON AND VICE-CHAIRPERSON)

1. The Chairperson will be responsible for the efficient conduct of the business of the CMD(h). The Chairperson has, in particular, the following responsibilities in collaboration with the Vice-Chairperson:
 - i. to liaise regularly with the EMEA secretariat to plan the work of the CMD(h);
 - ii. to monitor and promote compliance with the rules of procedure;
 - iii. to convene each month a meeting of the CMD(h);
 - iv. to ensure that any potential conflict of interests is declared before any particular item is discussed by the CMD(h);
 - v. to manage the business of the agenda by:
 - giving the floor to all members equitably, taking into account time constraints,
 - formulating questions and proposals,
 - summing up discussions,
 - concluding on all items of discussions.
 - vii. to decide when a vote is necessary;
 - viii. to ensure consistency of agreements;
 - ix. to ensure that the best possible advice is given by the CMD(h) on regulatory matters.
2. The Vice-Chairperson will replace the Chairperson of the CMD(h) in his/her absence and support the Chairperson. The CMD(h) may give more detailed instructions of the duties of the Vice-Chairperson.
3. In case of resignation of the Chairperson, the Vice-Chairperson shall take the chair until a new election is convened.

PARTICIPATION OF EXPERTS

ARTICLE 5

1. When necessary, the CMD(h) or the members of the CMD(h) may avail themselves of the services of other experts. The names of these experts shall be notified to the Chairperson and the secretariat before the meeting which they are due to attend.
2. When experts accompanying members of the CMD(h) cannot adequately cover a specific field of expertise, the CMD(h) itself may request the contribution of other experts.

MEETINGS AT THE EMEA

ARTICLE 6 (DATES AND AGENDA)

1. The CMD(h) shall normally meet monthly at the EMEA.
2. The dates of meetings are decided and published on an annual basis. In exceptional circumstances and on motivated grounds agreed with the Chairperson an exceptional meeting may be convened at short notice.

3. The draft agenda for every regular meeting shall be agreed upon in advance of the meeting. It is recommended that the EMEA secretariat shall circulate a draft agenda together with all relating documents in consultation with the Chairperson.
4. The working language of the CMD(h) is English.

ARTICLE 7 (PARTICIPATION AT MEETINGS)

1. All agreements to be adopted by the CMD(h) mentioned in legislation shall be reached when at least two thirds of the members are present. This covers all agreements except for applications for marketing authorisations or referrals in Mutual Recognition or Decentralised procedures where consensus is needed, as set out in article 9.
2. The Heads of the national agencies, the Executive Director of the EMEA, members of the EMEA secretariat, and representatives of the Commission, may take part in all meetings of the CMD(h) and its working parties.

AGREEMENTS

ARTICLE 8 (GENERAL PROVISIONS)

1. Each member shall have one vote.
2. Whenever possible, agreements on the list of products for harmonisation, guidelines, SOPs, recommendations, procedural or regulatory practices or position statements of the CMD(h) shall be adopted by consensus. In the absence of consensus they are deemed to be adopted if supported by an absolute majority of the members of the CMD(h).
3. The agreement adopted shall, where necessary, be concluded in a formal binding decision by the regulatory authorities of the representatives of the CMD(h) (see also Article 1).
4. Any divergent positions shall be mentioned in the agreements of the CMD(h) upon request of those members concerned. They shall state clearly the reasons on which they are based.
5. In the absence of a majority position of the CMD(h), the discussion is deemed inconclusive and hence the group can not publish any (external or internal) statements.
6. Advice formulated by the CMD(h) should be referred to the Heads of Medicines Agencies group (HMA) for endorsement and implementation in cases where consistent practices and communications are considered to be in the interests of the Community. HMA should also be consulted in matters which are resource-related, concerns policy or have a considerable national impact.

ARTICLE 9 (AGREEMENTS CONCERNING APPLICATIONS FOR MARKETING AUTHORISATIONS, ARTICLE 29(3), (4) OF DIRECTIVE 2001/83/EC)

Agreements are to be reached by consensus among all EEA Member States concerned by the procedure. In the absence of consensus of the EEA Member States concerned, the EMEA shall be immediately informed with a view to the application of the procedure laid down under Articles 32, 33 and 34.

ADVICE

ARTICLE 10

Requests for advice submitted by companies or by one or more EEA Member State shall be dealt with in accordance with a defined procedure to be adopted by CMD(h) including the criteria for acceptance of such a request. Advice on scientific matters should be referred to the EMEA to be dealt with as a scientific advice.

WRITTEN PROCEDURE

ARTICLE 11

1. Between two meetings of the CMD(h), the EMEA secretariat can submit draft agreements to the CMD(h) after approval of the Chairperson for adoption by written procedure.
2. Such written procedures should be restricted to measures deemed urgent by the Chairperson, the adoption of draft agreements previously discussed by the CMD(h) or the implementation of measures adopted earlier by the CMD(h).
3. A full report on the outcome of the written procedure should be made at the following meeting.
4. Draft agreements are addressed to members of the CMD(h), who may raise objections within a specified time period, to be established in agreement with the Chairperson.
5. In case of serious objections, the Chairperson will decide whether the written procedure should be suspended and the adoption of the draft statement postponed to the next meeting of the CMD(h).

HEARINGS

ARTICLE 12

1. Any request for a hearing by a pharmaceutical company wishing to make an oral presentation in connection with the evaluation procedure of one of its products shall be respected
2. Any hearing shall be indicated clearly in the draft agenda of the meeting during which it is deemed to take place. The scientific and/or regulatory argumentation on which a presentation will be based shall be sent to the members of the CMD(h) in advance in accordance with the defined procedure.

The CMD(h) shall not express any final positions during a hearing.

WORKING PARTIES

ARTICLE 13

1. When necessary, the CMD(h) may decide to create ad-hoc temporary working parties (defined as working parties). Such working parties should not duplicate the work of other working parties already established by the EMEA or its Committees.
2. Members of a working party and its chairperson will be appointed by the CMD(h). They should preferably be members of the CMD(h) but may include members of any of the EMEA Committees or its working parties. National competent authorities could also propose a non-member of CMD(h) as a member or a chairperson of a working party.

3. The CMD(h) shall adopt the mandate and objectives of each working party and the duration of their activity.
4. Participation in working parties will be limited to one delegate per EEA Member State, either a member of the CMD(h) or another expert. When required by the agenda, additional experts might however participate in the meeting.
5. The draft agenda of each meeting of any working party shall be circulated for endorsement by the CMD(h). The chairperson must ensure that any potential conflict of interest is declared before the particular item is discussed by the working party.
6. The written minutes will be circulated to all CMD(h) members as soon as possible and no later than the next scheduled working party meeting.
7. Reports are presented at the following CMD(h) meeting by the chairperson. The chairperson may delegate this task to another member of the working party.
8. In agreement with the CMD(h), oral presentations by companies or other interested parties can be made during working party meetings.
9. Joint human-veterinary working parties could be envisaged if needed.

CONTACTS WITH REPRESENTATIVE ORGANISATIONS

ARTICLE 14

1. Contacts with representative organisations may be held under the conditions to be defined by the CMD(h).
2. The CMD(h) shall neither conduct any deliberations nor reach any formal positions in the presence of members of representative organisations.

OBSERVERS

ARTICLE 15

1. The Heads of Medicines Agencies may propose that the CMD(h) invite representatives of international organisations with interests in the harmonisation of regulations applicable to medicinal products as observers at the CMD(h) and working parties' meetings or meetings arranged for this purpose to discuss topics of common interest.
2. The observers shall be bound by the rules of confidentiality as provided by Article 17.

EMEA SECRETARIAT

ARTICLE 16

Under the authority of the Executive Director, the EMEA secretariat shall provide assistance to the CMD(h) and its working parties with a view to the performance of its duties as defined by Article 27(1) of Directive 2001/83/EC and shall provide secretarial services as follows:

- To propose an agenda for each meeting to the Chairperson and to circulate the agenda;
- To circulate the relevant documents in due time for each meeting;
- To set up and maintain a database for all regulatory and scientific agreements.

- To facilitate liaison with EMEA Committees/working groups and interested parties;
- To assist the responsible CMD(h) member and/or CMD(h) expert(s) in the preparation of the texts of the agreements, and of any other texts related to the role of the CMD(h);
- To produce the minutes and table of decisions for each meeting;
- To prepare for each meeting, taking into account the proposed agenda, a list of positions taken on similar issues;
- To assist the Chairperson in the preparation of the annual reports on mutual recognition and decentralised procedure;
- To assist the Chairperson in monitoring compliance with the time periods laid down by legislation in relation to referrals to the CMD(h);
- Facilitate the necessary contacts between the CMD(h) and the person responsible for the placing a product on the market;
- Prepare monthly statistics related to the mutual recognition and decentralised procedures;
- Provide support from regulatory/legal staff with experience in the mutual recognition and decentralised procedures.

GENERAL PROVISIONS

ARTICLE 17

The members of the CMD(h) and all the 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 18

The decision to adopt or to amend these rules of procedure shall be taken by an absolute majority of the members of the CMD(h).

ARTICLE 19

The Rules of Procedure or any amendment to them shall enter into force after receiving a favourable opinion from the European Commission and will be made publicly available.

Agreed by the CMD(h) on 15 November 2005

Favourable opinion by the Commission on 18 January 2006

Date of entry into force: 20 February 2006