

**CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND
DECENTRALISED PROCEDURES – HUMAN (CMDh)**

RULES OF PROCEDURE

*Doc. Ref.: CMDh/044/2006/Rev1
July 2011*

Article 27 of Directive 2001/83/EC of the European Parliament and of the Council on the Union 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. According to Article 27 para. 3 of Directive 2001/83/EC, the coordination group shall draw up Rules of procedure.

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 referrals to the Committee for Medicinal Products for Human Use (CHMP) or the Committee on Herbal Medicinal Products (HMPC) for arbitration.

In accordance with Article 30 of Directive 2001/83/EC, in order to promote harmonisation of authorisations for medicinal products authorised in the Union the coordination group shall lay down a list of products, for which a harmonised summary of product characteristics should be drawn up, taking into account proposals from Member States, and forward the list to the Commission.

According to the Commission Regulation (EC) No 1234/2008³ the coordination group shall provide recommendations on the classification of unforeseen variations, use their best endeavours to reach agreements in case of Member States disagreements in variation applications and choose a reference authority for worksharing in specified cases of variation procedures.

The coordination group shall support worksharing between Member States where appropriate, and as provided for in legislation.

The coordination group for mutual recognition and decentralised procedure for human medicinal products, CMDh, has adopted the following Rules of procedure:

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (*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*)

³ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (*Official Journal L 334, 12/12/2008 p. 7 – 24*)

COMPOSITION

ARTICLE 1

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

In addition the EFTA States shall be fully associated with the work of CMDh.

Member States are recommended to appoint an alternate to share the workload with the CMDh member and replace the CMDh member in case of absence.

2. The members should be from the national competent authorities and have adequate regulatory and/or scientific expertise. They also should have 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 CMDh is not able to attend a meeting, the alternate may attend in his/her place and represent the Member State and act on behalf of the member of CMDh. The competent authority of the member or the CMDh member shall advise the secretariat in writing of the name of the alternate prior to the meeting concerned.

GUARANTEES OF INDEPENDENCE

ARTICLE 2

1. The membership of the CMDh including the alternate shall be made public. When each appointment is published the professional qualifications of each member shall be specified.
2. The members of the CMDh, alternates and European experts included in the EMA list of 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 European Medicines Agency which is accessible to the public, on request at the European Medicines Agency secretariat. Members, alternates and 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 European Medicines Agency Policy on the Handling of Conflicts of Interest for Committee Members and Experts, adopted by the Management Board (European Medicines Agency/H/31653) are applicable to members and alternates of the CMDh, working parties and experts participating in the activities of the CMDh.
4. The discussion within the CMDh 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 CMDh shall be elected by and from amongst its members for a term of three years, renewable once. Members from the EEA-EFTA States cannot be elected as chairperson.

Every nomination, together with a short CV of the candidate should be submitted to the European Medicines Agency secretariat no later than 7 days prior to the CMDh meeting at which the election is to take place.

The vice-chairperson shall be appointed from among the members of CMDh 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 EU-members (i.e. favourable votes by at least half of the total number of CMDh EU-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. If a 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 a majority vote may be achieved. If a 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 of EU members.
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 CMDh. (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 CMDh. The chairperson has, in particular, the following responsibilities in collaboration with the vice-chairperson:
 - to liaise regularly with the European Medicines Agency secretariat to plan the work of the CMDh;
 - to monitor and promote compliance with the rules of procedure together with the European Medicines Agency secretariat;
 - to convene each month a meeting of the CMDh;
 - to ensure that any potential conflict of interests is declared before any particular item is discussed by the CMDh;
 - 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.
 - to decide when a vote is necessary;
 - to ensure consistency of agreements;
 - to ensure that the best possible advice is given by the CMDh;

- to liaise with the Heads of Medicines Agencies (HMA) Management Group and the European Commission and
 - to represent the CMDh.
2. The vice-chairperson will replace the chairperson of the CMDh in his/her absence and support the chairperson. The CMDh 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.

CMDh MEMBERS

ARTICLE 5 (ROLE OF MEMBERS)

1. CMDh members are responsible for active contribution for the efficient conduct of the business of the CMDh, including participation in the development of guidance documents, in work-sharing activities and in regulatory and scientific discussions in the CMDh.
2. CMDh members are responsible for ensuring that feedback is given on the conclusions of the discussions in the CMDh within their national competent authority and shall liaise, as appropriate, on issues of mutual relevance with their national members of other relevant groups including the CMDv, CHMP including its working parties, and national members in non-EMA structures as Pharmaceutical Committee and Standing Committee.
3. CMDh members shall ensure there is a relevant process in place within their national competent authority to input to and receive feedback from HMA meetings on CMDh matters.

PARTICIPATION OF EXPERTS

ARTICLE 6

1. When necessary, the CMDh or the members of the CMDh may avail themselves of the services of other experts, see Article 2. The names of these experts shall be notified to the chairperson and the secretariat before the meeting which they are due to attend. This could be achieved either by direct participation at the European Medicines Agency or by alternative communication tools.
2. When experts accompanying members of the CMDh cannot adequately cover a specific field of expertise, the CMDh itself may request the contribution of other experts.

MEETINGS AT THE EUROPEAN MEDICINES AGENCY

ARTICLE 7(DATES AND AGENDA)

1. The CMDh shall normally meet monthly at the European Medicines Agency.
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. In this case the availability of alternative communication tools should be taken into account.
3. The draft agenda for every regular meeting shall be agreed upon in advance of the meeting. It is recommended that the European Medicines Agency secretariat shall circulate a draft agenda together with all relating documents in consultation with the chairperson.
4. The working language of the CMDh is English.

ARTICLE 8 (PARTICIPATION AT MEETINGS)

1. All agreements to be adopted by the CMDh mentioned in legislation shall be reached when at least two thirds of the EU-members are present.
2. The quorum in paragraph 1 covers all agreements except for applications for marketing authorisations, variations or referrals in mutual recognition or decentralised procedures where consensus is needed, as set out in article 10.
3. The Heads of the national agencies, the Executive Director of the European Medicines Agency, members of the European Medicines Agency secretariat, and representatives of the Commission, may take part in all meetings of the CMDh and its working parties.

AGREEMENTS

ARTICLE 9 (GENERAL PROVISIONS)

1. Each EU-member shall have one vote. The EFTA-states shall not participate in the voting.
2. Whenever possible, agreements on the list of products for harmonisation, guidelines, standard operation procedures, recommendations, procedural or regulatory practices or position papers or question & answers documents of the CMDh shall be adopted by consensus. In the absence of consensus they are deemed to be adopted if supported by a majority of the EU-members of the CMDh.
3. The agreement adopted shall, where necessary, be concluded in a formal binding decision by the regulatory authorities of the representatives of the CMDh (see also Article 1).
4. Any divergent positions by any member of CMDh including EFTA States members shall be mentioned in the agreements of the CMDh upon request of those members concerned. The position of the EFTA States shall be recorded separately. They shall state clearly the reasons on which they are based.
5. In the absence of a majority position of the CMDh, the discussion is deemed inconclusive and hence the group can not publish any (external or internal) statements.
6. Advice formulated by the CMDh should be referred to the Heads of Medicines Agencies group for endorsement and implementation in cases where consistent practices and communications are

considered to be in the interests of the Union. HMA should also be consulted in matters which are resource-related, concerns policy or have a considerable national impact.

ARTICLE 10

(AGREEMENTS CONCERNING APPLICATIONS FOR MARKETING AUTHORISATIONS, ARTICLE 29(3), (4) OF DIRECTIVE 2001/83/EC AND APPLICATIONS FOR VARIATIONS, ARTICLE 13 OF COMMISSION REGULATION (EC) 1234/2008)

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

In the absence of consensus, EFTA-Member States may request the European Medicines Agency to initiate an arbitration procedure. Such a request shall, in the first place, be addressed to the Commission which shall, where it considers that the request is of common interest, forward it to the Agency for further processing.

ADVICE

ARTICLE 11

Requests for advice submitted by applicants or Marketing Authorisation Holders or by one or more of EU-Member States or EFTA States shall be dealt with in accordance with a defined procedure to be adopted by CMDh including the criteria for acceptance of such a request. Request for scientific advice on product specific matters should be referred to the European Medicines Agency or the national competent authorities.

WRITTEN PROCEDURE

ARTICLE 12

1. Between two meetings of the CMDh, the European Medicines Agency secretariat can submit draft agreements to the CMDh after approval of the chairperson for adoption by written procedure according to an agreed timetable.
2. Such written procedures should be restricted to measures deemed urgent by the chairperson, the adoption of draft agreements previously discussed by the CMDh or the implementation of measures adopted earlier by the CMDh.
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 CMDh, who may raise objections within a specified time period, to be established in agreement with the chairperson.
5. In case of major 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 CMDh.

HEARINGS

ARTICLE 13

1. Any request for a hearing during a procedure by an applicant or a Marketing Authorisation Holder 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 CMDh in advance in accordance with the defined procedure.

The CMDh shall not express any final positions during a hearing.

WORKING PARTIES

ARTICLE 14

1. When necessary, the CMDh 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 European Medicines Agency or its Committees.
2. Members of a working party and its chairperson will be appointed by the CMDh. They should preferably be members of the CMDh but may include members of any of the European Medicines Agency Committees or its working parties. National competent authorities could also propose a non-member of CMDh as a member or a chairperson of a working party.
3. The CMDh 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 EU-Member State and EFTA State, either a member of the CMDh 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 information by the CMDh. 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 CMDh members as soon as possible and no later than the next scheduled working party meeting.
7. Reports are presented at the following CMDh meeting by the chairperson. The chairperson may delegate this task to another member of the working party.
8. In agreement with the CMDh, 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 15

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

ARTICLE 15B

CMDh should promote contacts with other parties involved in the regulation of medicinal products (e.g. H M A, CMDv, Committees within the European Medicines Agency and their working parties, European Commission).

A regular information exchange should be maintained with HMA and CHMP and its working parties.

CMDh should promote interactions with CMDv in order to address issues of common interest and harmonise positions. This should be achieved by frequent exchange of information and organisation of joint meetings.

OBSERVERS

ARTICLE 16

1. The Heads of Medicines Agencies may propose that the CMDh invite representatives of international organisations with interests in the harmonisation of regulations applicable to medicinal products as observers at the CMDh 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 18

EUROPEAN MEDICINES AGENCY SECRETARIAT

ARTICLE 17

Under the authority of the Executive Director, the European Medicines Agency shall provide assistance to the CMDh 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 Article 13 of Regulation 1234/08 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 and to store accessible letters sent to or received from the European Commission on such matters;
- to facilitate liaison with European Medicines Agency Committees/working groups and interested parties;
- to assist the responsible CMDh member and/or CMDh expert(s) in the preparation of the texts of the agreements, and of any other texts related to the role of the CMDh;

- to produce the minutes for each meeting and to store the final agreed version accessible for the CMDh members;
- to prepare for each meeting, taking into account the proposed agenda, a list of positions taken on similar issues, where relevant;
- to assist the chairperson in the preparation of the work plan and 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 CMDh;
- to facilitate the necessary contacts between the CMDh and the person responsible for the placing a product on the market;
- to prepare statistics related to the mutual recognition and decentralised procedures;
- to provide support from regulatory/legal staff with experience in the mutual recognition and decentralised procedures;
- to handle declarations of interests and confidentiality undertakings and to advise the chairperson on potential conflicts of interests;
- to assist the vice-chairperson with the dedicated duties.

GENERAL PROVISIONS

ARTICLE 18

The members of the CMDh 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 19

The decision to adopt or to amend these rules of procedure shall be taken by a majority of the EU-members of the CMDh. The EFTA-states shall not participate in the voting.

ARTICLE 20

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 CMDh in January 2010
Agreed by HMA in May 2010
Agreed by European Commission in June 2011

Date of entry into force: 1st August 2011