

Coordination group for Mutual recognition and Decentralised procedures (veterinary)

RULES OF PROCEDURE

Article 31 of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products¹, as amended by Directive 2004/28/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 veterinary 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 31 paragraph 3 of Directive 2001/82/EC, the coordination group shall draw up its own 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 human or animal health or to the environment and make every effort to resolve issues to avoid referral to the Committee for Medicinal Products for Veterinary Use (CVMP) for arbitration.

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, as provided for in legislation, shall support worksharing between Member States where appropriate

The Coordination group for Mutual recognition and Decentralised procedures for veterinary medicinal products, CMDv,

Having regard to:

Directive 2001/82/EC laying down Community procedures for the authorisation of veterinary medicinal products for animal use in the framework of mutual recognition and decentralised procedure,

Commission Regulation (EC) N° 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

¹ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (Official Journal L 311, 28.11.2001, p. 1-66)

² Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (Official Journal L 136, 30.04.2004, p. 58-84)

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)

Has adopted the following rules of procedure:

COMPOSITION

ARTICLE 1

1. The members of the CMDv shall be appointed by the Member States of the European Economic Area (EEA), one per Member State, for a term of three years, which may be renewed. A Chairperson shall be elected as mentioned in Article 3.
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.
3. When a member of the CMDv is not able to attend, a substitute may attend in his/her place and represent the nominated member. The competent authority of the member shall advise the secretariat in writing of the name of the substitute prior to the meeting concerned.

ARTICLE 1B (ROLE OF MEMBERS)

1. CMDv members are committed to actively contribute to the efficient conduct of the business of the CMDv: to take on a fair share of the work load, to respect agreed deadlines, to prepare agenda issues before each meeting, to take part in regulatory and scientific discussions.
2. In the interest of the efficient functioning of the group, CMDv members shall ensure there is a relevant process in place within their national competent authority to input to and receive feedback from their hierarchy on CMDv matters and Heads of Medicines Agencies (HMA) meetings.
3. CMDv members are responsible for ensuring that feedback is given on the conclusions of the discussions in the CMDv 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 CMDh, CVMP including working parties, Pharmaceutical Committee, Standing Committee, and Notice to Applicants working group.

GUARANTEES OF INDEPENDENCE

ARTICLE 2

1. The membership of the CMDv 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 CMDv, their substitutes and 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, substitutes 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 provisions 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 of the European Medicines Agency are applicable to members of the CMDv, substitutes and experts participating in the activities of the CMDv and its working groups.
4. The discussion within the CMDv may raise potential conflict of interests for a participant. In such a case 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 CMDv shall be elected by and from amongst its members for a term of three years. Members from the EEA-European Free Trade association (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 CMDv meeting at which the election is to take place.

The Vice-Chairperson shall be appointed from among the members of CMDv 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 CMDv 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 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 may appoint a new member to replace the Chairperson as a member of the CMDv (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. When sponsoring candidatures for the role of chairperson, each Authority should consider identifying a substitute to participate as member in case the candidate is elected as chairperson

ARTICLE 4 (ROLE OF CHAIRPERSON AND VICE-CHAIRPERSON)

1. The Chairperson will be responsible for the efficient conduct of the business of the CMDv.

The Chairperson has, in particular, the following responsibilities in collaboration with the Vice-Chairperson:

- i. to liaise regularly with the European Medicines Agency secretariat to plan the work of the CMDv;
- ii. to monitor and promote compliance with the rules of procedure together with the European Medicines Agency secretariat ;
- iii. to convene meetings of the CMDv;
- iv. to ensure that any potential conflict of interests is declared before any particular item is discussed by the CMDv;
- 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 CMDv;
- x. to represent CMDv interests and convey CMDv views whenever participating to other meetings in the role of CMDv Chairperson;
- xi. to liaise with the HMA management group and the European Commission.

2. In the exceptional event that the Member State, which appointed the member who has been elected Chairperson, chooses not to appoint a new member due to lack of an appropriate replacement, the Chairperson may represent the views of his/her Member State and the Chairperson retains his or her vote. In such a scenario, in any debate, the Chairperson shall clearly declare when he/she is expressing views on behalf of his/her Member State. The Chairperson or any member of the group can request that the Vice-Chairperson take over the role of Chair for that part of the agenda and this is decided by simple majority of the members.

3. The Vice-Chairperson will replace the Chairperson of the CMDv in his/her absence and support the Chairperson. The CMDv may give more detailed instructions of the duties of the Vice-Chairperson.

4. 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 CMDv or the members of the CMDv may avail themselves of the services of 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 CMDv cannot adequately cover a specific field of expertise, the CMDv itself may request the contribution of further experts.

3. For the smooth and efficient functioning of MRP and DCP, (see article 9), involved CMDv members should take the necessary arrangements to provide for participation of relevant experts to product discussion. This should be achieved either by direct participation at the European Medicines Agency or by alternative communication tools (e.g. teleconference, vitero conference)

MEETINGS

ARTICLE 6 (DATES AND AGENDA)

1. The CMDv 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 circulates a draft agenda together with all relating documents in consultation with the Chairperson.
4. The working language of the CMDv is English.

ARTICLE 7 (PARTICIPATION AT MEETINGS)

1. All agreements to be adopted by the CMDv shall be reached when at least two thirds of the total numbers of CMDv EU-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 European Medicines Agency, members of the European Medicines Agency secretariat, and representatives of the Commission, may take part in all meetings of the CMDv and its working groups.

AGREEMENTS

ARTICLE 8 (GENERAL PROVISIONS)

1. Each CMDv EU-member shall have one vote.
2. Whenever possible, agreements on guidelines, SOPs, recommendations (including classification of unforeseen variations), procedural or regulatory practices or position statements of the CMDv shall be adopted by consensus. In the absence of consensus they are deemed to be adopted if supported by an absolute majority of the EU-members of the CMDv.
3. The agreement adopted shall, where necessary, and if deemed possible at national level, be concluded in a formal binding decision by the regulatory authorities of the representatives of the CMDv (see also Article 1).
4. Any divergent positions by any EU-member of CMDv shall be mentioned in the agreements of the CMDv 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 CMDv EU-members, the discussion is deemed inconclusive and hence the group can not publish any (external or internal) statement.
If a consensus is not reached, the HMA could be involved if deemed necessary.
6. The members from the EEA-EFTA States can not vote but their positions shall be recorded separately.

7. Advice formulated by the CMDv should be referred to the HMA 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, concern policy or have a considerable national impact.

ARTICLE 9 (AGREEMENTS CONCERNING APPLICATIONS FOR MARKETING AUTHORISATIONS, ARTICLES 33(1), 33(4) of Directive 2001/82/EC AND APPLICATIONS FOR VARIATIONS, ARTICLE 13 OF COMMISSION REGULATION 1234/2008)

Agreements are to be reached by consensus among all 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 36, 37 and 38.

In the absence of consensus, EFTA Member States may request EMA 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 10

Requests for advice submitted by company representatives or by one or more EEA Member States shall be dealt with in accordance with a defined procedure to be adopted by CMDv including the criteria for acceptance of such a request. Requests for scientific advice on product specific matters should be referred to the European Medicines Agency or the national competent authorities.

WRITTEN PROCEDURE

ARTICLE 11

1. Between two meetings of the CMDv, the European Medicines Agency secretariat can submit draft agreements to the CMDv 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 CMDv or the implementation of measures adopted earlier by the CMDv.
3. A full report on the outcome of the written procedure should be made at the following meeting of the CMDv.
4. Draft agreements are addressed to members of the CMDv, 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 CMDv.

HEARINGS

ARTICLE 12

1. Any request for a hearing during a procedure 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 CMDv in advance in accordance with the defined procedure.

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

WORKING GROUPS

ARTICLE 13

1. When necessary, the CMDv may decide to create ad-hoc temporary working groups (defined as "working groups"). Such working groups should not duplicate the work of working parties already established by the European Medicines Agency or its Committees.
2. Members of a working group and its chairperson will be appointed by the CMDv. They should preferably be members of the CMDv 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 CMDv as a member or a chairperson of a working group.
3. The CMDv shall adopt the mandate and objectives of each working group and the duration of their activity.
4. Participation in working groups will be limited to one delegate per EEA Member State, either a member of the CMDv or another expert. When required by the agenda, additional experts might however participate in the meeting.
5. The Chairperson must ensure that any potential conflict of interest is declared before the particular item is discussed by the working group.
6. The written minutes will be circulated to all CMDv members as soon as possible and no later than the next scheduled working group meeting.
7. Reports are presented at the following CMDv meeting by the Chairperson. The Chairperson may delegate this task to another member of the working group.
8. In agreement with the CMDv, oral presentations by companies or other interested parties can be made during working group meetings.
9. Joint human-veterinary working groups could be envisaged if needed.

CONTACTS WITH REPRESENTATIVE ORGANISATIONS / OTHER PARTIES

ARTICLE 14

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

ARTICLE 14 B

1. CMDv should promote contacts with other parties involved in the regulation of medicinal products (e.g. HMA, CMDh, CVMP and its working parties, European Commission).
2. A regular information exchange should be maintained with HMA and CVMP, also through participation of the CMDv Chairperson at HMA and CVMP meetings.
3. CMDv should promote interactions with CMDh 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 15

1. The Heads of Medicines Agencies may propose that the CMDv invites representatives of international organisations with interests in the harmonisation of regulations applicable to veterinary medicinal products as observers at the CMDv and working groups' 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.

EUROPEAN MEDICINES AGENCY SECRETARIAT

ARTICLE 16

Under the authority of the Executive Director, the European Medicines Agency shall provide assistance to the CMDv and its working groups with a view to the performance of its duties as defined by Article 31(1) of Directive 2001/82/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 record and archive regulatory and scientific agreements in a way agreed by CMDv, to set up and maintain a database for all 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 CMDv member and/or CMDv expert(s) in the preparation of the texts of the agreements, and of any other texts related to the role of the CMDv;
- To produce the minutes for each plenary meeting and to store the final agreed version accessible for the CMDv members;
- To prepare where relevant, taking into account the proposed agenda, a list of positions taken on similar issues;
- To assist the Chairperson in the preparation of the work plan and annual reports;
- To assist the Chairperson in monitoring compliance with the time periods laid down by legislation in relation to referrals to the CMDv;
- To handle declarations of interests and confidentiality undertakings and to advise the Chairperson on potential conflicts of interests;
- Facilitate the necessary contacts between the CMDv and the person responsible for the placing of a product on the market;
- Prepare statistics related to the mutual recognition and decentralised procedures in a way agreed by CMDv;
- Provide support from regulatory/legal staff with experience in the mutual recognition and decentralised procedures;
- To assist the Vice-Chair with the dedicated duties.

GENERAL PROVISIONS

ARTICLE 17

The members of the CMDv 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 EU-members of the CMDv.

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.