

MANDATE OF THE JOINT CMDH/CMDV WORKING PARTY ON VARIATION REGULATION

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1. Background and information

The Working Party on Variation Regulation is a joint subgroup of the CMDh and CMDv that was established in 2008 in order to facilitate the implementation of the revised variation legislation. After the new legislation entered into force, the WP remained the most appropriate forum to discuss harmonised processing for variations to MA obtained via MRP/DCP and, since August 2012, also to MA obtained via purely national procedures.

2. Mandate and objectives

The mandate of the Working Party on Variation Regulation is established to provide recommendations to the CMDh and CMDv on matters regarding the processing on variations, including the tasks below:

- Prepare proposals for updated CMD guidance and documents to the revised Variation Regulation;
- Give input to EC proposals, e.g. for future update of Guidelines and application form;
- Reach a common interpretation of the revised Variation Regulation in order to ensure a consistent approach with regards to variation procedures;
- Discuss common topics with the EMA such as recommendations on classification of unforeseen variations and work sharing.

3. Composition and rules of participation

The Working Party is composed of Member States' representatives.

As foreseen in the CMDh Rules of Procedure, observers from non-EEA Regulatory bodies or international institutions may participate with the agreement of the CMDh and CMDv provided confidentiality rules are in place.

Members of the Working Party are expected to participate actively in the work and to attend the meetings and teleconferences regularly.

Meeting documentation will be distributed to the Working Party members. The Chairperson of the Working Party in liaison with the secretariat will ensure that the membership list is up to date.

4. Meeting frequency

The Working Party meets at the Agency in the margin of the CMDh meeting according to an agreed frequency. When necessary, a remote meeting can be organised between two face to face meetings.

The frequency of the meetings is reviewed twice a year in the CMDh plenary meeting when the CMDh agrees on the 6-monthly CMDh meeting schedule.

In addition, the Chairperson can request a change in the meeting frequency at any time. The request will have to be endorsed by the CMDh.

5. Duration of activity

Temporary Working Parties/Working Groups are constituted for the period of time needed to complete tasks committed by the CMDh. The continuity of the Working Party should be confirmed by the Chairperson of the Working Party at least once a year when the CMDh discuss the 6-monthly meeting schedule or at the time of the adoption of the annual Work Plan (when relevant).

6. Rules of procedure

6.1 Election of the Chairperson

The Chairperson of the Working Party, if not a CMDh member or alternate, should be able to report from the activities of the Working Party at the CMDh plenary meetings. The Chairperson can delegate the reporting as appropriate.

The Chairperson is elected at the CMDh by majority of the Member States + one (the quorum should be reached).

There is no limitation in the number of terms.

The vice chairperson may be elected, preferably by CMDv (or CMDh, if no CMDv vice chair is elected) by majority of the Member States + one (the quorum should be reached) for a term of 2 years.

There is no limitation in the number of terms.

6.2. Organisation of meetings and reporting arrangements

The Working Party will meet regularly at the Agency. Members who wish to participate remotely must inform the Secretariat in advance and provide the necessary contact details to the Secretariat.

The draft agenda for every meeting should be circulated before the meeting, together with the relating documents.

The agenda, meeting documents and minutes of the Working Party should be circulated to the CMDh and CMDv.

The Chairperson should regularly report (or delegate the reporting, as appropriate) on the activities of the WP, at the CMDh plenary. Working party participants of the CMDv will report at the CMDv plenary.

The mandate for the WP should be agreed by the CMDh and CMDv.

Any recommendation from the Working Party should be transmitted to the CMDh and CMDv plenary for agreement/adoption.

6.3. Guarantees of independence

Guarantees of independence as described in the CMDh and CMDv Rules of Procedure apply to members of the CMDh and CMDv WPs/WGs.

When restrictions apply to a member regarding his/her participation to a meeting due to conflicts of interest, he/she must inform the Secretariat in advance.

All attendees of WPs meetings shall declare at the beginning of each meeting any specific interest, which could be considered to be prejudicial to their independence with respect to the points of the agenda.

6.4. Code of conduct

Members of the WPs/WGs and all other attendees to their meetings shall abide by the principles set out in the Agency Code of Conduct.

7. EMA secretariat

Under the authority of the Executive Director, the Agency secretariat shall provide technical, scientific and administrative support to the WPs/WGs. The secretariat of this WP will be provided by the CMDh Secretariat (C-CS-SCS).