Central Management Committee

Rules of Procedure

The following Rules of Procedure of the Central Management Committee have been approved by the medical device Competent Authorities.

Central Management Committee and Central Management Committee Board

Article 1 – Mandate of the Central Management Committee

The Competent Authorities within the medical devices sector have agreed to establish a Central Management Committee (CMC) to improve the effectiveness of the regulatory system and ensure the appropriateness, effectiveness and continued development of the regulatory system (see Terms of Reference at Annex A).

The function of the CMC is fundamentally different to the Competent Authority meetings (CAMD). The CMC is focussed on finding practical solutions to problems or emerging issues identified in other forums (such as the CAMD) and obtaining Member State agreement to a consistent implementation on a voluntary basis whenever possible. If applicable and more appropriate, the CMC may request the European Commission to adopt legally binding measures in accordance with the applicable directive; such request may be accompanied by proposed drafts for such measures. The CAMD is primarily focussed on sharing information between Member States, identifying problems requiring resolution or emerging issues/trends that Member States or the regulatory system itself will need to address and it directs the work of the working groups set up by the CAMD.

Article 2 – CMC members

The CMC will consist of one member per Member State of the European Economic Area (EEA) and European Free Trade Association (EFTA), nominated by the Member State/Competent Authority. For each member a deputy shall be nominated by the Member State/Competent Authority. National delegations will normally consist of one person, but may exceed this number with the agreement of the chair, in case competences are divided over different centralised National Competent Authorities.

Candidate Member States and Turkey may contribute with one representative each, with observer status.

Ideally, and in principle, each member and representative should have the seniority and authority necessary to commit its Member State/Competent Authority to specific actions in respect of CMC decisions, and would normally also be a member of the statutory regulatory committee set out in the Directives.

The cooperation with the European Commission will be assured through the participation of one representative of the medical device sector of the European Commission, with no voting rights.

Article 3 – Chair/co-chair of the CMC

The chair and co-chair of the CMC shall be elected from and by the CMC members on the basis of the majority of votes cast. Tenure will be for a period of 2 years (3 years for the first one). Each Member State has one vote.

Article 4 - CMC Board

To assist the CMC, a CMC-Board elected by CMC members from within its ranks shall be created.

Article 5 – Composition of the CMC-Board

The CMC-Board shall consist of the chair and co-chair of the CMC plus four members, elected by and from the CMC membership. Normally, members of the CMC-Board will be elected for a period of 2 years (3 years for the first one).In addition to the four elected members, the CMC member for the Member State that holds the EU Presidency is an automatic member of the CMC-Board, starting from ~~at~~ the CMC-Board meeting prior to the CMC/CAMD meeting preceding the term of its EU Presidency and ending at the CMC/CAMD meeting superseding the term of its EU Presidency (if not already one of the elected members).

Members of the CMC-Board shall be responsible for specified tasks, with clear assignment given by the chair of the CMC.

Members of the CMC-Board shall have sufficient commitment and resources to fulfil their tasks.

Article 6 – Tasks of the CMC-Board

The CMC-Board shall facilitate and support the work of the CMC by ensuring co-ordination, consistency and continuity of the work and activities of CMC and providing the collective memory of CMC.

The CMC-Board will play a pivotal role in liaising with existing working groups or with small *ad hoc* groups established by the CMC, in co-ordinating the activities of specialist

working groups, in facilitating access to scientific and technical expertise and relevant collaborations, and in selecting issues to the CMC for decision.

To this end the CMC-Board shall undertake, in particular, the following tasks:

- give executive and administrative support to the CMC,
- be the central contact point for issues to be brought to the CMC,
- be responsible for communication within the CMC and to external interested parties (e.g. website),
- organise consultations for concerned stakeholder to obtain comments and proposals on drafted CMC decisions
- provide collective memory by keeping updated records of agendas, minutes and decisions for the CMC,
- assist the EU Presidency in CMC matters,
- liaising with the working groups,
- preparation of the agenda and dossiers submitted for voting at CMC meetings,
- report to the CMC, and
- other appropriate tasks agreed by the CMC.

As a general rule, the CMC-Board shall use videoconferences or similar electronic means of communication on a regular basis to perform its tasks.
By written request, members may submit items to be included in the agenda. The proposer is obliged to present the background of the proposal and what is the anticipated action.

Article 7 – Voting system of the CMC

Each Member State has one vote.

CMC-decisions can be taken, if two-thirds of eligible votes are cast.

In addition to a member's own vote each member may receive as a maximum votes from two members by proxy. The proxy shall be notified to the Chair in writing at the latest at the beginning of the meeting.

The chair shall once elected have no vote. When the chair is elected, the chair's Member State shall appoint a new voting member.

With the exception set out in the next paragraph, CMC-decisions shall be adopted by majority of two-thirds of the votes, if consensus is not possible.

The need for adoption of legally binding measures may be identified by the CMC. The adoption of legally binding measures follows the rules as established by the Treaty and the directives, i.e. implementing measures are adopted by the Commission after it has seized the Regulatory Committee established by Article 6 of Directive 90/385/EEC in accordance with the procedure specified by the relevant directive. In such cases, the view of the Competent Authorities, including measures requested, shall be presented in writing to the European Commission.
With the agreement of the chair, such requests may be prepared by the CMC-Board which shall be submitted for voting at CMC meetings. As the voting of these specific requests

anticipates on the voting through the formal regulatory committee procedure set out in the relevant Directives, the same voting procedure as used in the regulatory committee will be applied. The decision on the submission of the request to the Commission lies with the Competent Authorities.

If necessary, decisions can be adopted by written procedure. The above provisions on votes apply also to adoption by written procedure.

Article 8 – Meetings

The CMC should meet quarterly.

Meetings are convened by the chair who decides the date of the meeting. However, it is recommended that the meeting takes place

- Twice a year immediately before or after the CAMD meeting.
- At least 2 supplementary meetings a year. The meeting dates to be chosen in a practical way, preferably in connection with the meeting of the Medical Devices Expert Group, to minimise the costs of such meetings.

The schedule for the meetings should, so far as possible be spread evenly throughout the year.

An agenda, accompanied by all relevant papers, should be submitted to the members of the CMC at least two weeks prior to each meeting.

In addition to standard CMC membership, experts may attend the meetings at the discretion of the chair and in agreement with CMC-Board.

Article 9 – Minutes of meetings

Minutes of each meeting shall include a summary record of the proceedings and the decisions adopted.

Article 10 – Review of the CMC

The operation of the CMC and its continued need will be reviewed by the CMC and CAMD after a period of 2 years from its creation.

Article 11 – Expenses of the members

All costs associated with the participation in the CMC and CMC-Board shall be borne by the national Competent Authority of the member.

Annex A

Central Management Committee

Terms of Reference

The task of the Central Management Committee (CMC) is to improve and protect public health by:
(1) improving the effectiveness of the medical devices regulatory regime, primarily by achieving greater consistency in the interpretation and implementation of its provisions by means of voluntary agreements or contribution to the preparation of legally binding measures (to be adopted in accordance with the applicable directive) and encouraging compliance by all Member States.
(2) ensuring the continued appropriateness and development of the regulatory regime by maintaining an overview of its effectiveness and relevance in respect of technological and other developments.

Working Principles:

In order to allow fast decision making by the CMC, issues brought to the level of the CMC will normally have already been discussed thoroughly in existing working groups, at the meeting of Competent Authorities (CAMD), or in small *ad hoc* groups, set up with the chair's agreement.

To allow the CMC to be a tool to improve decision making and co-ordination in the medical device sector, matters referred to the CMC will be ready for resolution.

The CMC will be supported by an elected CMC-Board composed of members of the CMC. The CMC-Board will play a pivotal role in liaising with working groups or small ad hoc groups, in co-ordinating the activities of specialist working groups, in facilitating access to scientific and technical expertise and relevant collaborations, and in selecting issues ready to bring to the level of the CMC.

In view of transparency to the public and to other stakeholders the CMC may consult and try to reach consensus with concerned stakeholders with regard to its decisions, statements or projects.

The output of the CMC may be consensus statements based on majority view, voluntary agreements, requests and proposed drafts to the European Commission regarding implementing measures to be adopted by the Commission in accordance with the relevant Directives, in order to obtain a more harmonised regulatory approach among Member States.

The CMC may advise on regulatory changes needed to anticipate and re-act to changing circumstances, technological and regulatory development, or pan-EU action in response to key safety issues (pandemics, safeguards, vigilance).