

1. Welcome Opening

The chair thanked the Belgian Competent Authority (CA) for hosting the 1st CMC meeting and reminded CMC members of their common mission to prepare and make decision. This will require strong and serious commitments from CMC members and the CA.

2. Presentation of the result of the first CMC-Board meeting

The outputs of the CMC-Board (and Prague-Uppsala Group (PUG)), meeting on the 11th -12th November 2010 were presented and after discussion the CMC agreed that:

a. Basic principles :

A paper describing the CMC's basic working principles should be prepared and placed on the website. Amongst other items these would make clear that:

- CMC is a decision making body not a debating society;
- Work items can be referred to the CMC for resolution from CMC members, CAMD, WGs, MSs, or others (e.g. NB-Med).
- Work items should be allocated to a specific CMC-member –"lead official" accountable to the CMC for delivery according to preset timetable.
- All work items should have a work plan produced, including a timetable for delivery
- CMC-papers should be archived in a systematic way
- MSs are expected to honour agreements reached. Where it is not possible to do so this should be clearly signalled by the MS in advance.
- A written procedure should be produced to facilitate the efficient processing of papers and the decision making outside of formal meetings.
- CMC Chair/Vice-Chair are responsible for managing CMC-meetings;
- CMC Chair/Vice-Chair (assisted by the Board) will provide each CAMD-meeting with a progress report of its activities.

b. Standard CMC process

The standard process for dealing with CMC work should involve the following:
Internal/External application - →CMC-Board Assessment→rejection or transmission to CMC→1st CMC-reading→(if necessary) lead official will ensure that a proposal for a final decision will be developed within the specific timeframe and scope→ CMC-Board Assessment→ 2nd CMC reading/decision(if necessary) → CMC-Board publication, implementation and follow up etc.

c. Tools for communication and co-operation between CMC-Board and CMC members and others

First drafts of templates for CMC work were presented and proposals for improvement invited. There was consensus that final agreed templates should be available on the CMC website. Templates may be subject to further changes on the basis of actual experience of their use.

d. General principles on transparency, website

The first draft of the CMC website was presented. The address: www.cmc-md.eu .
There was consensus that CMC work should in principle be very transparent.

e. Proposal on the demarcation CAMD- CMC

A submitted paper on the demarcation between the CMC and CAMD was discussed and accepted, subject to one minor amendment on the last sentence which should now read:

" The Competent Authorities have delegated specific powers and responsibilities to the CMC which has a complementary status to the CAMD".

3. CMC Logo and Slogan

The CMC agreed to hold a competition for a CMC logo and slogan to be decided at the 2nd CMC meeting in February 2011.

4. Brainstorming session on potential New Work Items Proposals (NWIP) for the CMC

The CMC brainstormed potential New Items. The results will be refined by the CMC Board into a list of items it recommends the CMC take forward. For the next CMC meeting it was agreed that following NWIs should be on the agenda of the CMC

1. **Borderlines and Classification** –lead official UK
2. **Notified Bodies – (mandatory application of Best Practice Guidance)**
– lead official IRL
3. **Labeling: Manufacturers address** -lead official BE
4. **Acute Major issues (PIP Breast implants, partial withdrawal of the designation of the NB EMKI,)**
-lead officials FR , DE
5. **Give NBOG the task to specify the criteria for designation**
-lead official IRL
6. **Design a new designation procedure for notified Bodies**
-lead official to be appointed by the CMC-Board

5. Next meeting etc.

23rd February 2011, Hungary

Signature

**Chair of the CMC
Dr. Matthias Neumann**