

**Central Management Committee  
2<sup>nd</sup> Meeting  
Notes**



*PROTECTING PUBLIC HEALTH TOGETHER*

**Final Draft Notes of the 2<sup>nd</sup> CMC Meeting  
held in Budapest, 23<sup>rd</sup> February 2011**

**1. Welcome Opening**

The meeting was opened by the CMC Chair. The Chair thanked the Hungarian Colleagues for their efforts and the very good preparation of the meeting.

**2. Approval of the minutes of first CMC Meeting**

The draft of the minutes of first CMC meeting was approved in principle. One CMC member provided some proposals for mainly editorial improvements. There was agreement that the editorial proposals will be considered by the finalisation of the minutes and publication of the “web-minutes”.

**3. Presentation of the result of the second CMC-Board meeting/Development of CMC-Procedures**

a. Basic Principles

The chair reported about the request from some delegations to send observers to the CMC meetings. After short discussion it was concluded that for the time being there is no need for an observer status in the CMC terms and references. The discussion will be re-opened in Autumn 2012.

b. Standard CMC-Process

The modified scheme for the CMC standard process was presented. Due to having the best clarity it was decided after discussion to establish two schemes. One scheme should deal with external proposals. The other scheme should deal with proposals identified by the CMC itself.

- c. Tools for communication and co-operation including templates and formats

The latest CMC formats were presented and accepted by the CMC having in mind that these formats/templates will be modified in light of experiences made.

- d. General principles on transparency, website, "web-minutes" of the first CMC-meeting

The draft of the "web-minutes" was accepted taking into account the proposed editorial improvements from the CMC members. The "web-minutes" should be published on the CMC website

#### **4. Logo/slogan competition**

The Jury presented the results of their assessment on the provided proposals for the CMC Logo/slogan. The Jury identified/accepted three proposals for the CMC logo and three proposals for the slogan. It was decided to have a confidential voting procedure on the slogan and on the logo. After assessment of the results of the voting procedure it was decided that the logo and the slogan proposed by colleagues from the MHRA will be the logo and slogan of the CMC



„Protecting Public Health Together“

#### **5. Prepared Decisions:**

- a. **Borderlines and Classification**

The background and goal of the prepared decisions were presented. Since the proposed decisions are dealing with issues which were already subject of comprehensive discussions/assessments of Competent Authorities there was a broad consensus in principle. Some members expressed their need to vote against the proposals or to abstain, but indicated their willingness to respect valid CMC decisions and to act in the future in line with the decision of the CMC. Due to the fact that the CMC decision could in the future require the initiation of an article 7 procedure according to Article 13 MDD it was decided that according to

article 7 of the CMC Rules and Procedures Document the voting procedure foreseen for the article 7 Committee should be applied.

Results of the voting procedures:

a. In favour: 19	Against: 1	Abstention: 2
b. In favour: 22		
c. In favour: 21	Against: 1	Abstention: 1

After the decision it was agreed that the CMC chair will send a letter to the chair of the MDEG-WG on Classification and Borderline inviting the group to take account of the CMC decision and to include the decisions into their Manual.

**b. Best Practice Guide Notified Bodies mandatory**

The proposal for the decision was presented. Some CMC members expressed their concerns with regards the proposed future status of NBOG guidelines and their concerns that the decision includes some very specific implementation measures which are not fully in line with the NBOG guidances. After discussion the chair and the lead official proposed a modified decision. It was agreed that the CMC will apply a normal voting procedure on the modified proposal.

Result of the voting procedure:

In favour: 20	Abstention: 1
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**c. Labelling: Manufacturers address**

The proposal was presented. There was great consensus between the CMC members to have a normal voting procedure.

Result of the voting procedure:

In favour: 21	Abstention: 1
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After the decision it was agreed that the CMC chair should send a letter to the Chair of COEN informing the COEN about the decision and requesting the consideration of suitable implementation measures.

**6. Acute Major issues**

**a. PIP-Case**

The experiences and the status quo in this case were presented to the CMC.

**b. EMKI-Case**

In the case of a limitation of the designation of a Hungarian Notified Body it

was presented how the concerned CAs established a harmonised approach to deal with the problem.

On the basis of the two reports the CMC discussed the need to establish special CA procedures for multilateral critical issues in the field of vigilance and market surveillance since the currently used mechanism seem to be not sufficient for such challenges.

**7. NWIP proposed by the CMC-Board for CMC consideration:**

- a. Give NBOG the task to specify the criteria for designation

**Accepted**

- b. Design a new designation procedure for Notified Bodies

Some delegation expressed their concerns that this project is outside of the scope of the CMC. The chair tried to clarify that the intention of the project is not the immediate decision on or implementation of a new designation process, but a support for the COM to consider new models for a transparent designation process which achieves the necessary harmonized high level of performance of Notified Bodies and Designating Authorities. Other members of the CMC claimed that the project should clearly include the re-designation of Notified Bodies. After discussion the Chair proposed that the lead official will revise the NWI in light of the discussion. The revised NWI will be provided to the CMC for a written procedure.

- c. Clarify the content of Notified Body certificates

**Accepted**

- d. Clarify the content of declarations of conformity

**Accepted**

- e. Improve the readability of instructions for use

**Accepted**

- f. Agree on consistent rules in respect of “periods of grace” to be allowed to manufacturers in order to allow non-conformities to be addressed or in cases of reclassification of devices

**Accepted**

- g. Coordination of external consultations

**Accepted**

**8. Next meeting**

The next meeting should take place in conjunction with the next MDEG beginning of June 2011. There was the offer of the COM to provide a half a day of the MDEG to the CMC

**9. Closing**

The vice chair thanked the CMC members for their active participation and the Hungarian Competent Authority for hosting the meeting