

**Central Management Committee
5th Meeting
Notes**



PROTECTING PUBLIC HEALTH TOGETHER

**Draft Notes of the 5th CMC Meeting
held in Denmark, 14th March 2012**

1. Welcome and introduction

The chair welcomed the CMC-members in a conference room of Hotel Scandic in Copenhagen and thanked the Danish colleagues for organizing this meeting. He introduced Tracey Murray as a new member of the CMC on behalf of the United Kingdom. Tracey Murray will succeed Steve Owen who has left the CMC because of his retirement. The chair also introduced Heikki Matlar from Finland who has succeeded Hannu Seitsonen. From Belgium a new colleague, Vanessa Biname, was presented.

2. Approval of the agenda

Additional agenda point: due to the departure of Steve Owen, a new candidate for the CMC-board needs to be selected.

3. Acceptance minutes of the 4th CMC meeting

The minutes of the last meeting of the 26th of October 2011 were agreed and will be published on the CMC website.

4. Development of a CMC-procedure for a 'public consultation' of some CMC decisions

There was a discussion about the flow chart of the CMC standard process which was presented by the chair. It was suggested that a stakeholder's consultation could be preferable to a more general public consultation. It was arranged that Joanna Kilkowska will take care of the adaptation of the proposal.

5. Decisions on

a. NWI 7 Declaration of conformity (PL)

A draft decision on this NWI was presented. After discussions in COEN and NBOG the Polish lead official presented a draft summarising the different discussions. In the CMC there was a general discussion on the purpose of the declaration of conformity and the need mentioning specific dates on the certificates.

It was decided that:

- CMC members can provide within 2 weeks additional comments to the lead official
- the proposal will be slightly reworded in way to move from "CMC decided" to "CMC agreed"
- after that there will be a MDEG stakeholder's consultation.

b. NWI 8 Readability of instructions of use (AU)

The CMC decision: “Statement on improvement of Readability of Instructions for Use (IFU)” and the Draft letter to industry associations and NB-MED were presented and discussed. All MS agreed with the CMC-statement, which will be published on the CMC website.

c. NWI 5 NB Designation process (IRL)

IRL gave a short presentation on this work item. The principles, the challenges, comments and next steps were discussed. Peter Bischoff (COM) takes the view that it is a good document, but he also had some comments on this work item. After discussion it was concluded that this model should be used as a pilot within the framework of Commissioner Dalli’s joint action plan on re-auditing Notified Bodies in 2013..It was discussed if there is a need and additional value to have an consultation on this NWI.

It was decided that IRL will revise the text of the proposed decision and NWI in the context of the discussions in the CMC and received comments. After finalization the CMC shall come to a decision by a written procedure.

d. NWI 12 Database Helsinki summary reports

The CMC decision about this work item was presented. After discussion all the MS were in favor of the proposed decision that the Polish CA will set up and maintain a database of those summaries to which other CAs will get access.

e. NWI 13 Procedure for multilateral issues

Comments on the presented document: Procedure of multilateral issues (part 1): coordination of vigilance activities

- There was principle support for the proposal
- Concerns were raised with regards to necessary resources and if the project is too ambitious.
- Good and effective technical facilities have been considered as important and essential.

It was decided that project has to be further developed and brought in to the official format of a CMC NWI. The new Lead official is Denmark

In parallel the chair will ask his German colleagues to develop a more detailed technical solution.

6. Need of CMC – Measures in the context of the action plan provided by Commissioner Dalli

CMC members agreed that the implementation of the measures proposed by Commissioner Dalli requires a harmonized and coordinated approach. The CMC as a body dealing with harmonized interpretation and implementation of the regulation could provide substantial value to these processes.

In particular finalized, ongoing and other potential new CMC projects, like **Specific designation criteria for NB, Making the NBOG Peer Review System mandatory, NB designation process, Guidance on unannounced audits or sample taking by NB** are and could become a good basis for implementing the proposed measures.

It was decided that the discussion about the Action plan and the interaction, coordination between MS and the COM should take place at the CAMD on the 15th March 2012.

7. Progress reports on NWI

a. NWI 6 Content of NB Certificates

ES reported still being working on the consultation questions to be sent to the members of NBOG. The chair suggested that the CMC Board could intervene or support in this project. CH indicated that there are currently no more appropriate resources available to co-lead this NWI.

PT was appointed as a new co-lead official.

b. NWI 9 Period of Grace

SE indicated that despite the fact that there has been made some progress, the context of this NWI was changed by COEN. Instead of providing a common understanding on an appropriate "period of grace", COEN will provide this together with a more general guidance covering a number of different aspects of market surveillance.

This project has been given by COEN to a small subgroup under the convener-ship of FI. Therefore SE proposed that the lead-official of this NWI would be taken by FI. FI will consider this seriously.

8. Update "List of external consultations"

9. Proposal of a new NWI "Future role of the CMC"

- preparation of a NWI
- preparation of a CMC-decision to be discussed

Agenda items 8 and 9 could not be discussed due to lack of time and will be postponed to another meeting.

10. CMC decision 3:

a. Report on EUCOMED-CMC-COEN-COM meeting

SE reported on this meeting that was arranged the 13th December 2011. At the meeting it was agreed that CMC/COEN was going to develop a guide for the implementation of the decision and that EUCOMED would prepare a set of questions to be answered by CMC.

After discussion it was decided that the draft of the COEN guidance should be sent to the industry and Notified Bodies representatives organized in the MDEG to provide comments and proposals for amendments to the CMC. The COEN and if necessary CMC will assess the comments and finalize the guide.

Before starting the stakeholder consultation CMC members had the possibility to provide amendments or comments to the guide within 2 weeks after the meeting.

Election of a new CMC Board member

A request for candidates for the CMC Board for the replacement of Steve Owen was made. It had been indicated at the start of the meeting that it would be preferable to be included in the CMC Board through Presidency half a year before the Presidency starts.

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DK reported that due to their current experiences with organizing, CMC, CAMD and Presidency an earlier involvement into the work of the CMC Board seems to be necessary. It was therefore suggested to include IE as a member in the CMC Board starting on July 1st. The CMC-board shall develop a proposal to modify the Rules of Procedure accordingly.

11. Next meeting

The next meeting will be in Cyprus on the 17th July 2012.

The Chair thanked the Danish MS for hosting the meeting.