

**Central Management Committee
6th Meeting
Notes**



PROTECTING PUBLIC HEALTH TOGETHER

**Draft Notes of the 6th CMC Meeting
held in Cyprus, 17th July 2012**

1. Welcome

The chair welcomed the CMC-members in a conference room of the Golden Bay Hotel in Larnaca and thanked the colleagues from Cyprus for organizing this meeting. He noted that the current enormous workload of the members of the CMC is making the operation of the CMC difficult. Despite these difficulties the CMC has been very successful during the last period and has proved to be able to improve its work.

He introduced some new colleagues:

From Liechtenstein: Christina Zimmer; from Norway: Sissel Dyrnes; from Sweden: Helena Dzojic (deputy) and from Germany: Lucia Voegeli-Wagner .

2. Approval of the agenda

Additional agenda point to point 12: 12a1: Database of Helsinki summary reports (NWI 12).

3. Acceptance minutes of the 5th CMC meeting

The minutes of the last meeting of the 14th March 2012 were agreed and will be published on the CMC website.

4. Changes of the rules of procedure and/or terms of reference

All MS agreed with the proposed changes in art. 5, 6 and the annex of the Rules of Procedure of the CMC. The changes are indented to allow the coming EU - presidencies a better and earlier involvement into the CMC work e.g. to be able e.g. to prepare meetings of the CMC.

5. Election of a new CMC Board member

For the free position of CMC Board member no candidates have been nominated. The chair suggested that in case that at the next CMC Meeting there would be no candidate the CMC Board would make a proposal for a new candidate.

6. New procedure: short CMC report to MDEG

During discussions around decision nr. 3 the COM had required that CMC decisions should be confirmed/approved by MDEG. After discussions it was decided that due to the different function, tasks and structure of the CMC the request was rejected. But as a matter of improving transparency of the CMC it was decided to offer to the COM that the CMC will provide short progress reports to regular MDEG meetings.

7. Outcome of the stakeholder consultation on COEN Guide

“Decision no. 3”

The chair noted that the CMC had received several comments from industry, NB's and the COM to this decision. On the basis of the several comments the CMC Board has proposed to slightly modify the wording of decision no. 3.

BE presented a proposal for modification.

After discussion it was decided that a small working group would provide a sentence in a note to be added during the lunch break. After the presentation of the modification 26 MS voted in favour of the reworded Decision No.3. There was 1 abstention.

In the light of the received comments COEN will finish the COEN Guideline on the implementation of Decision No.3. There was a discussion about changing the date for enforcing decision No. 3. Due to the fact that the date was chosen by COEN the majority of the CMC felts that this discussion must be held in COEN and that the CMC can't change this date.

The CMC is aware that future decisions require from the CMC a proper handling of the aspect of enforcement and implementation of the decision.

8. Outcome of public consultation on content of declaration of conformity

PL has received many comments on this NWI. A procedure to evaluate the comments has been prepared. A new draft of this NWI will be established in 2 weeks. For the declaration of conformity the minimum will be a paper to be used as a tool of common understanding during the negotiations at the council.

9. Outcome of the written procedure on “Revised designation process for Notified Bodies”

NWI no. 5 was agreed by written voting procedure (Votes Cast: 27; Pro: 22 Against: 4, Abstention: 1).

It will be published on the website.

10. Acceptance of proposal of 3 NWI 's Proposals related to Commissioners Dalli Action Plan

Proposal for a measure on proper designation and monitoring of Notified Bodies (NWI 16).

After discussing this item, it was accepted by all MS.

Lead official: IE

Pilot program NB 2013 (NWI 15).

This work item was also accepted by the MS.

Lead officials: CH, UK, IE

Definition of key elements of market surveillance (NWI 14).

After a short discussion the work item was accepted by the MSS.

Lead officials: SE, PT

11. Assessment of the functioning of the CMC

PL noted that the CMC will provide an activity report to the CAMD. The CAMD will create an assessment team and a questionnaire will be sent out to the authorities.

The MS were asked for their cooperation to complete this report by giving suggestions for items or writing chapters.

The chair mentioned that the CMC is intended to provide this report at the next CMC meeting in October 2012.

12. Progress reports NWI

a1 Helsinki Database

PL noted that some formal problems with the access to the database have been noted.

Due to the fact that some inquiries are classified as confidential, the Polish authorities are faced with the problem to get formal allowance from the CAs to enable them to share the information on classification/borderline issues.

It was clarified that the database access will be limited to the CA's. The CA's will get access codes and must take care of the codes.

After discussion it was decided that all CA's will receive a letter from the Polish CA with regard to the described problem, which requires a short answer from the CA .

a. Procedure of multilateral issues, vigilance + vision of stage 2 (NWI 13)

DK noted that in parallel to the NWI of the CMC, the COM was accepting the old wish of the MDEG vigilance group to held regular telephone conferences. First telephone conferences have been performed and were productive. The content and structure of the regular telephone conferences is under development and can be brought in line with the NWI.

The COM is considering the possibility to offer also to COEN the possibility to organize regular telephone conferences.

Having in mind the goal described in the NWI, the CMC decided to keep tracking and support the current developments initiated by the COM.

b. Content of certificates (NWI 6)

ES and PT reported that the inquiry activities will be done in September 2012. ES and PT have been confirmed as lead officials.

c. Specific designation criteria for NB (NWI 4)

IE reported that a subgroup of the CMC and NBOG have discussed the work item.

The final draft of this work item will be provided in October 2012.

d. Period of Grace (NWI 9)

This work item will be discussed during the next CMC meeting.

e. Effective classification/borderline resolution procedure (NWI 11)

UK reported that due to lack of time this work item will be postponed to the next CMC meeting.

13. Update List of external consultations

The List of external consultations has been put on the CMC website.

14. Next meeting

The next CMC meeting will probably be in October 2012 in Brussels.

The chair thanked the Cypriot MS for hosting this meeting

