N4M20111026

Central Management Committee
4th Meeting
Notes

PROTECTING PUBLIC HEALTH TOGETHER

Draft Notes of the 4th CMC Meeting held in Poland, 26th October 2011

1. Welcome and introduction

The CMC Chair welcomed the CMC-members in a conference room of the Qubus Hotel in Krakow and thanked the Polish colleagues for organizing this meeting. He introduced Ed Jansen as a new member of the CMC on behalf of the Netherlands. Ed Jansen will succeed Sabina Hoekstra who has left the CMC to take up a new position in industry. The Chair expressed his appreciation for Sabina's great support and for the preparation of this meeting. The Chair introduced Ms. Els Schakel from the Ministry of Health, Welfare and Sport in the Netherlands, who has been assigned to provide administrative support to the work of the CMC. The Chair thanked the Dutch ministry for making this possible.

2. Approval of the third CMC meeting minutes

The minutes of the last meeting of the 7th of June 2011 were agreed and will be published on the CMC website.

3. Organizational issues

a. Contact points of the CMC in case of external requests for contact, for issues or questions that are not limited to a specific Member State.

The CMC members agreed that the CMC chair and vice chair are the primary contact point for external requests to the CMC.
Answers to external questions of general nature will be developed by the CMC Board and signed by the CMC Chair or vice chair. All CMC members will receive a copy of these communications.
If an answer requires a common view the CMC the answer will be developed by the CMC.

b. The members were asked to check their data on the membership list. It was agreed that Els Schakel will update the membership list.

c. Dates of next CMC-meetings
The next CMC meeting will be in Denmark on the 14th March 2012.
The next CMC Board meeting is foreseen at the end of January or the beginning of February 2012.

4. Election of CMC Vice-chair / CMC Board member

Due to the resignation of the vice chair the CMC went over to the election of a new vice-chair. One candidate was nominated for the post of vice chair: Joanna Kilkowska (PL). She was elected unanimous.

As Joanna Kilkowska was already a board member, it was necessary to elect a new CMC board member from the existing members of the CMC.

For the position of CMC Board member there was one candidate Stelios Christofides (CY). He was elected unanimous.

5. Short explanation on closed Work Items

a. WI 1 Borderline and classification cases (UK)
This item is closed.
The decisions taken were transferred to the B&C WG. The B&C WG has adopted the decisions without comment and included them in the Manual of decisions. Thereafter the decisions were informed to the public. This work item indicates the need to have a critical review of the currently established procedures and mechanism within the MDEG Borderline and Classification group. The CMC has established a NWI covering this task. A progress report on this will be given under TOP 8.g.

b. WI 8 Readability of instructions of use (AT)

This work item is considered to be closed.
The CMC agreed that future regulation require stronger requirements to improve the readability of the instructions for use (IFU). This request was taken on board on the Council Conclusions on innovation in the medical device sector (2011/C 202/03). This issue is also on the "wish-list" of the CAMD "Recast Mirror" Group.
The CMC indicates the need that this NWI should be documented as a CMC Decision. It was agreed that this decision shall be made publicly available via the CMC-website and communicated to NBOG and the relevant European industry associations.

6. Follow up on decisions in the implementation phase

a. WI 3 Labelling manufacturers address (BE)
After the decision the CMC Chair and vice chair were confronted with a number of requests from industry, Notified Bodies and standard bodies to provide clarifications on the consequences of this decision. In particular the statement from COEN (which was asked by the CMC to take care for a harmonized implementation of the decision), that CAs will start the enforcement of the decision in September 2012 was of great concerns.

In providing answer to these requests the CMC Chair and vice chair sent specific letters to CEN asking for initiating the necessary changes of relevant standards which are not in compliance with the CMC decision. CEN agreed and is considering the necessary activities. To provide answer to the concerns of the industry, there will be a meeting with representation from industry, the chairs of the CMC and of COEN and representation from the European Commission. The outcome of this meeting will be reported back to the next CMC meeting.

The discussion in the CMC on this issue led to the following results.

- The CMC will stick to its decision. Special cases where a specific manufacturer encounters serious problems to make the necessary changes in time shall be assessed by the CA on a case by case basis.
- To provide more transparency and clarity on CMC decisions, the CMC will develop and integrate into the decision making process a public consultation procedure where potentially concerned stakeholder could provide comments and proposals on drafted CMC decisions. The CMC Board should make a corresponding proposal for such a procedure to the next CMC meeting.
- Future decision will include the investigation and discussion by the CMC on the most efficient way to implement the decision.
- Whenever possible the aspect of implementation should be considered by the CMC and should also be part of the final CMC decision

7. Future role and status of the CMC

The Chair gave a presentation on the future role and status of the CMC. According to several informal statements and communications from the European Commissions services it is obvious that a CMC -like committee as a committee of MS/CA will not be part of the official proposal of the European Commission.
It must be assumed that the European Commission envisages to create an Expert Group/Committee served by or being part of EMA or JRC assisting the European Commission to develop implementing legal measures or delegated acts.
A harmonized interpretation and implementation of the regulation by CAs as it is intended to be achieved by the CMC can not be reached with an advising expert committee. The Commission preferred Expert Group/Committee will not be a solution of our (CA) problems. The creation of an (additional) advisory expert group would only make sense if the European Commission has the intention to take over a broad number of additional responsibilities from the MS, which is unlikely to be accepted by the Council.
Therefore the CMC should develop its own model for getting a legal status in the future medical devices legislation. A coordinating committee of CAs as described in article 27 of the 2001/83/EC directive on human medicinal products could be an inspiration for the CMC model. The future (CMC) committee should get some responsibilities, like: designation, monitoring of NBs, establishment of a European market surveillance program and achieving harmonized interpretation and implementation of the regulation.

After discussion it was noted that:

- Achieving a legal status for the CMC is the first priority of the CMC, if the CMC will be legally accepted it will be a plus.
- In the event that the future legislation doesn't offer a legal status for the CMC or a CMC like committee it is necessary to investigate the possibilities of a closer cooperation of the CAMD/CMC with HMA in order to allow the CAMD/CMC to continue the work started by the CMC.

It was decided that the CMC Board should prepare a NWI on "The future status of the CMC".

8. Follow up on open work items

a. NWI 2 Best practice guide NB's (IRL)

This work item is closed.
This work item should be implemented in February 2012. NBOG will be asked about experiences with the CMC decision.

b. NWI 4 Give NBOG task specify criteria designation (IRL)

An update of this work item was presented by IRL.
There will be a discussion with the CMC-NBOG subgroup (CH, DE, IRL, NO and UK)
It will be discussed at the NBOG meeting in November2011. A draft for a CMC decision should be ready for the next CMC meeting.

c. NWI 5 Design a new designation procedure NB's (IRL)

An update of this work item was presented by IRL.
The next steps will be to discuss and seek agreement at discussion within NBOG and at a specific meeting with DAs not being represented in NBOG. In December 2011 there could be a written procedure.

d. NWI 6 Clarify the content of NB certificates (CH/ES)

The discussions about this work item are ongoing between COEN and NBOG. There is already a delay of 6 month. It was planned to conduct a survey into this item. A discussion arose about the formulation of the survey, which caused the delay. The CMC chair mentioned that the lead officials should indicate the need for support from the CMC if necessary. It is the purpose of the CMC to reach decision in an efficient way and not to wait until there is a unanimous agreement amongst all experts

e. NWI 7 Clarify the content of declarations of conformity (PL)

COEN was of the view that the NWI also requires input from NBOG. This work item has not been discussed at NBOG yet. After consultation with NBOG a CMC decision should be in principle available on the next CMC meeting.
The CMC suggested that COEN should also consider ways for implementing the decision in an appropriate efficient way.

g. NWI 11 Effective classification/borderline resolution procedure (UK)

Too many issues have been delayed at the MDEG B&C WG. The development of a quicker procedure is advisable. The MDEG B&C WG is already developing new procedures. Depending on the progress made in this group a final report on the NWI could be possibly provided to the next CMC meeting.

Work items 9, 10, 12 and 13 could not be discussed due to lack of time.

10. Closing

The Chair thanked the colleagues from the Polish CA for hosting the meeting.