N3M20110607

Central Management Committee
3rd Meeting
Notes

PROTECTING PUBLIC HEALTH TOGETHER

Final Draft Notes of the 3rd CMC Meeting held in Brussels, 7th June 2011

1. Welcome
Ms. Elizabeth Kuiper, health attaché at the Dutch Permanent Representation in Brussels, welcomed the CMC-members in the conference room of the Dutch Embassy.

2. Organizational issues
The chair introduced Ms. Els Schakel from the Ministry of Health, Welfare and Sports in the Netherlands, who has been assigned to provide administrative support to the work of the CMC. The members are asked to copy her in all their CMC correspondence.

3. Approval of the agenda
COM asked that the agenda item concerning "classification and borderline" (5c and 9a) be delayed until after lunch to allow Ms. Céline Bourguignon of COM to participate. This was agreed.

4. Approval minutes of the second CMC meeting
The minutes of the last meeting of the 23rd of February 2011 were agreed and will be published on the CMC website.

5. Follow-up on decisions made
The meeting agreed a standard format in which it will publish its decisions on the website. The format would consist of: 1. decision; 2. rationale and 3. background

6. Procedural issues
a. Redraft of the format of the NWI
Various amendments in the form for the New Work Items's (NWI) were discussed and agreed. Further suggestions would be welcome..

b. Coding of CMC documents
It was agreed that CMC papers should be subject to a standard coding system to facilitate their control. Els Schakel explained the chosen system and will be responsible for the management of it.

7. Written procedures: results of voting
a. NWI 5 New designation process for NBs

A NWI making a proposal for a harmonised, transparent and consistent new system for the designation and monitoring of Notified Bodies was agreed by a written procedure (Votes Cast: 25; Pro 17; Against: 8).

The aim of this work item is to establish a proposal for a future system, which should inspire the COM while preparing the Recast of the Medical Devices Directives.
It was noted that not all Designating Authorities (DAs) are members in NBOG and would therefore not be involved into the development of this NWI. Accordingly it was decided that a small group consisting of the CMC, NBOG and the other DAs (via seperate invitation) be established to progress the NWI.

Lead official: IRL.

b. NWI 3 Decision on the address of the Authorised Representative

It was agreed by written procedure (Votes Cast: 25; Pro: 24 Against: 0,)
to accept COEN's request that the CMC guidance on the content of the manufacturer's name and address should be extended to include the Authorised Representative.

8. HMA-CAMD workshop Budapest, 27 April 2011
a. Short report (NL)

On the 27th of April, the Hungarian Presidency, in cooperation with a joint HMA-CAMD steering group, organized the first joint HMA-CAMD workshop in Budapest. The focus was on the question: "Is there a need for further cooperation between HMA and CAMD?". Three potential areas for cooperation were identified: Resources, fees and funding of device authorities, clinical investigations and combination products & borderlines. Companion diagnostics was briefly touched upon. The overall conclusion was, that better understanding of each other's legislative systems has a value of its own, and that cooperation could be further enhanced on fees/funding, market surveillance, combination products and clinical trials. The joint HMA-CAMD steering group will continue to coordinate the start of the work on the joint projects.

b. Discussion on next steps, including the follow-up in Vienna in Sept. 2011

It was agreed to explore the possibilities to reserve a date for a CAMD/HMA meeting/workshop under the Danish presidency 1st half 2012. The medical device members of the steering group will cooperate to set up a useful program for the Vienna meeting.

9. Proposals for NWI's

a. Possible improvements to the process for resolving classification and borderline issues

The MDEG Classification and Borderline Working Group is currently considering how its processes can be streamlined to enable it to reach decisions on queries quicker. After discussion it was agreed that a joint exercise with the CMC could be useful if acceptable to

the Classification and Borderline Working Group. It was therefore agreed that a suggestion of joint working would be made to the Working Group's new Chairman.

Lead Official : UK

b. Establishment of a central database of Helsinki summary reports

It was decided to create a small group to explore the possibilities of creating a database of the Helsinki summary reports.

Lead official :PL/FR.

c. Development of procedures to deal with critical multinational vigilance and market surveillance issues

There was some discussion whether the word 'critical' in the title of the work item correctly reflects the content of the work item. But the common experience was that some 'critical' multilateral issues do not fit within the existing COEN2 and NCAR mechanism and need a dedicated procedure. This work item was accepted by the CMC.

Lead official: FR.

10. Future of the CMC and the RECAST Project of the COM

The meeting discussed a "Vision Paper" that suggested that the future Medical Devices Directive should provide a legal status for the CMC comparable with the status of the "Coordination Group for Mutual Recognition and Decentralised Procedures" in the pharmasector, which is part of the HMA, but which gets administrative support by the EMA. In this context possible advantages of closer working and integration of the CAMD/CMC with the HMA were discussed.

It was noted that:

1. HMA's have a very well established network structure
2. HMA's have expressed their intention to cooperate with CAMD/CMC
3. There is already an example of a statutory committee with a legal position under the HMA: the "Coordination Group for Mutual Recognition and Decentralised Procedures".
4. Cooperation between an "Old approach" network and a "New approach" network, each with their different legal roles and background, could give problems.
5. Not all MSs MDs are under the authority of the HMA's, in some MS's these are separate.

It was agreed that there could be advantages in closer integration. However the different possibilities and methods of a closer co-operation would require an assessment of the real benefits for both sectors.

In summary there was a high level of interest for cooperation of CAMD/CMC with HMA "under their umbrella".

The steering group will continue the exploration of the cooperation. The preparation of the workshop in Vienna was supported by the CMC. Currently, the "device part" of the steering group consists of: BE, DE, IRL, NL and UK.

11. Progress/status reports

a. NWI 4 Give NBOG the task to specify the criteria for designation
This issue is on the agenda of NBOG 22nd June 2011. Furthermore NBOG organises a workshop on the peer-review process on the 21st of June 2011.

Lead official: IRL

b. NWI 5: refer to agenda item 7a

c. NWI 6 : Clarify the content of Notified Bodies certificates

This proposed NWI appears to be more complex than anticipated and needed further discussion with NBOG. An inquiry will be organised.. Depending on the outcome further steps, either within NBOG or NBOG in cooperation with the CMC, will be considered.

Lead officials: CH/ ES.

d. NWI 7 Clarify the content of declarations of conformity.

This proposed NWI is to be discussed at the NBOG meeting on the 22th of June 2011.

Lead official: PL.

e. NWI 8 Improve the readability of instructions for use.

The subject has been included in the Council conclusions on the innovation in Medical Technology of 6th June 2011. This subject will be transferred to the CAMD.
The work item is closed.

Lead official: AT.

f. NWI 9 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.

COEN is progressing this work item and is co-operating with the Classification and Borderline Working Group and NBOG. It is anticipated that a proposal will be presented for initial discussion at the CAMD in Poland.

Lead official: SE.

g. NWI 10 Coordination of external consultations.

An update of 'outstanding consultations' was presented based on the information on the website of COM. It was agreed that only consultations relevant for the MD sector would be

included and that necessary updates 'in between CMC meetings' will be communicated by e-mail.

Since no opportunity for structural access to relevant EMA/CHMP consultations is available, CMC-members were encouraged to share such consultations, if they come to their knowledge, with the lead officials.

Lead officials: AT/ NL.

12. AOB

Ms. Céline Bourguignon was shortly to leave the Commission and the CMC expressed their appreciation for her efforts and cooperation in the past few years by applause and by a small present.

13. Homework

The homework-list will be sent around.

14. Closing

The Chair thanked the Dutch Permanent Representation/Embassy for hosting the meeting.
The Vice-Chair thanked the CMC members for their active participation and the valuable contributions.

PL announced the next CMC meeting in Poland, Krakow, on 26th October 2011.