

Central Management Committee 3rd Meeting Agenda



PROTECTING PUBLIC HEALTH TOGETHER

Agenda of the 3rd CMC Meeting to be held in Brussels on the 7th June 2011

Place: Dutch Embassy, 4-10 Avenue Cortenbergh, 1040 Brussels, Room 7.01 (7th floor)

Time: 10:15

1. Welcome
2. Organisational issues
3. Approval of Agenda
4. Approval Minutes of the second CMC-Meeting
5. Follow-up on decisions made
 - a. Final Formats of Decisions (Matthias)
 - b. Publication on the website (Matthias)
 - c. Communication with and feedback from the MDEG WG on Classification and Borderline (Steve)
6. Procedural issues
 - a. Redraft of the format of the NWI (Anne)
 - b. Coding of CMC documents (Els, Wolfgang)
7. Written Procedures: Results of Voting
 - a. NWI 5 New Designation process for NB
 - b. NWI 3 Decision on the address of the Authorised Representative
8. HMA-CAMD workshop Budapest, 27 April 2011 (5-8 Minutes + discussion 20 min)
 - a. Short report (Sabina)
 - b. Discussion on next steps, including the follow-up in Vienna in Sept. 2011 (all)
9. Proposals for NWI's
 - a. Possible improvements to the process for resolving classification and borderline issues (Steve)
 - b. Establishment of a central database of Helsinki summary reports (Joanna)
 - c. Development of procedures to deal with critical multinational vigilance and market surveillance issues (Jean-Claude, Matthias)
10. Discussion - future of the CMC and the RECAST Project of the COM (Steve, Matthias)

11. Progress/status reports (max. 5min per NWI) (lead officials) on

- a. NWI 4 Give NBOG the task to specify the criteria for designation (Niall)
- b. NWI 5 Design a new designation procedure for Notified Bodies (Niall)
- c. NWI 6 Clarify the content of Notified Bodies certificates (Peter Struder, Carmen)
- d. NWI 7 Clarify the content of declarations of conformity (Joanna)
- e. NWI 8 Improve the readability of instructions for use (Wolfgang)
- 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 (Steve, Lars)
- g. NWI 10 Coordination of consultations (Sabina, Wolfgang)

12. AOB

13. Home work

14. Closing