

**1st MEETING OF THE
HOMEOPATHIC MEDICINAL PRODUCT WORKING GROUP
APRIL 20-21-22, 2005
AMSTERDAM, THE NETHERLANDS**

Draft Agenda

Wednesday,	20-04-2005,	15:00 – 17:00	HEARING
Thursday,	21-04-2005,	9:00 – 16:00	MEETING
Friday,	22-04-2005,	9:00 – 14:00	MEETING

Wednesday, 20-04-2005

Hearing with interested parties (Homeopathic/Antroposophic Industry-, Prescribers- and Patients organizations).

Organizations which have confirmed their participation:

- AESGP, European Self-medication Industry
- British Association of Homoeopathic Manufacturers
- CIPH, Comité International des Pharmaciens Homeopathes
- ECHAMP, European Coalition on Homeop./Antroposophic Medicinal Products
- European Committee for Homeopathy
- European Council for Classical Homeopathy
- European Federation of Patients Association for Antroposophical Medicine
- International Association of Antrophosophical Pharmacists
- International Federation of Antroposophical Medical Associations
- Neprofarm, Dutch Self-medication Association

Thursday, 21-04-2005

1. Welcome

2. Domestic

- a. Adoption of agenda

- a. Adoption of revised Minutes of the Rome Meeting May 2004

- b. Adoption of draft Minutes of the Dublin Meeting November 2004

- c. Report to HMA Meeting Reykjavik February 2005

3. Pharmacopoeia Issues

- a. Report on the EDQM Conference on Homeopathy and Pharmacopoeia Strasbourg, February, 15-16, 2005. For conference lectures see <http://www.edqm.org> (conference archives:2005).

- b. Pharmacopoeia items

4. Mutual Recognition

- a. Cooperation with the MR Coordination Group

- b. Discussion on the comparison of a national registration followed by MRP versus a decentralised procedure

- c. Discussion on the Guideline on the definition of Potential Health Risk

- d. Development of a template for a MRP assessment report

5. Discussion concerning the Hearing, held on 20-04-2005

6. Safety Assessment

- a. WG on safety assessment: Report of the meeting January, 21 2005, Brussels
- b. Safety assessment: A case study
- c. Module 4
- d. Safety of ethanol in oral drops

7. Discussion on nosodes

8. Mutual Recognition and the use of the CTS

9. Reports from related meetings

Friday, 22-04-2005

10. Introduction of Braille on the packaging material

11. Quality aspects

- a. Guidance document CTD, regarding Part 1 and Module 3
- b. Good Agricultural Practice: Development of a Guidance document

12. WHO program on Homeopathics

13. Homeo MPWG – current and future developments

- a. Publications already published on the HMA website and procedure for release
 - Homeo MPWG Mandate
 - Draft Guidance document 'Points to Consider on Safety of Homeopathic Medicinal Products for human and veterinary Use from Biological Origin'
 - Other documents to be published in the near future

- a. Rules of procedures

- b. Information from the Heads of Medicines Agencies Management Group (HMA-MG)

- c. Actions to be taken (table of decisions)

- d. Any other business

- e. Looking forward to next meeting