SUMMARY REPORT OF THE 24th MEETING OF THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Held on 16 October 2003 in Brussels
Adopted by written procedure on 27 November 2003
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List of participants

MEMBERS

Dr. W.H. De Jong
Dr. A. Gatti
Prof. Dr. J. Löwer
Dr. M. Madsen
Prof. R. Paoletti
Dr. M.K. Paunio
Dr. A.H. Pettersen
Prof. M. Puig
Dr. E. Rodriguez Farré
Dr. M. Thomsen
Prof. D.F. Williams

APOLOGIES

Dr. R. Dobbelaer
Prof. O. Goëau-Brissonniere
Prof. P. Gustin
Prof. I. Lucena
Prof. Dr. H.W.J. Marquardt

EXTERNAL EXPERTS

Dr. C. Micha Nübling

COMMISSION

Mr P. Wagstaffe (DG SANCO/C7)
Mrs M. Marini (DG SANCO/C7)
Dr. A. Sanabria Tienza (DG SANCO/C7)
1. **Welcome Address, Apologies for Absence, Declarations of Interest.**

Prof. Dr. J. Löwer chaired the meeting and welcomed the members of the Committee and the representatives of the Commission attending the meeting.

Apologies for absence were received from Dr. Dobbelaer, Prof. O. Goëau-Brissonniere, Prof. P. Gustin, Prof. I. Lucena, Prof. Dr. H.W.J Marquardt.

All members present confirmed that they had no conflict of interests to report relative to the items for discussion.

The Chairman introduced Mr P. Wagstaffe, Head of the Unit dealing with the Committee.

Mr P. Wagstaffe, Head of Unit SANCO C.2, gave information on the future of the SCMPMD. He spoke about the possible new structure, workload, call for interest and the link of the Scientific “Non Food” Committees with the EFSA.

Finally he thanked the Committee for the quality of its work during the mandate.

The chairman thanked Mr Wagstaffe for the information.

2. **Approval of the Agenda**

The agenda was adopted as follows:

1. Welcoming address, apologies for absence, declarations of interest
2. Approval of the draft agenda
3. Adoption of the draft minutes of the 23rd SCMPMD plenary meeting
4. Feedback by members of the Committee having attended working group meetings of other Scientific Committees
5. Discussion and possible adoption of a scientific opinion
   - ‘The potential impact of arthropod borne disease (including the West Nile virus) on the safety of blood used for transfusion as well as organ used for transplantation in the European Community’: *for adoption*.
   - ‘Potential transmission of blood borne diseases through natural rubber latex medical devices’: *for adoption*.
6. New requests for opinion
7. Miscellaneous
3. **ADOPTION OF THE DRAFT MINUTES OF THE 23RD SCMPMD PLENARY MEETING.**

The draft minutes of the 23rd SCMPMD plenary meeting, held on 19 June 2003, were adopted as figuring in the Document SANCO/SCMPMD/2003/0024_Final. (http://europa.eu.int/comm/food/fs/sc/scmp/out47_en.pdf).

4. **FEED-BACK BY MEMBERS OF THE COMMITTEE HAVING ATTENDED WORKING GROUP MEETINGS OF OTHER SCIENTIFIC COMMITTEES.**

E. Rodríguez-Farré reported on the content of the "Report on Setting the Scientific Frame for the Inclusion of New Quality of Life Concerns in the Risk Assessment Process" (37 pages, Appendix 7 of the "Second Report on Harmonisation of Risk Assessment Procedures") from the Scientific Steering Committee. He said that the impact of risk perception on quality of life is analyzed in the report. Consideration is also given to quality of life assessment including animal quality of life. In addition, four case studies - pesticides, BSE, EMF (electromagnetic fields) and GMOs - are examined in the Report. Discussion on the subject noted the need to define more precisely the social and psychological concepts included in the text and to relate them with the definitions of risk assessment used in the main Report on Harmonisation of Risk Assessment and its Appendices. It was understood that a revised version would be required to have a more useful Report.

Drs Pettersen and Puig reported on their participation in the ad hoc Working Group created to assess the scientific quality of the report submitted by the BUAV-ECEAE on “Action to end animal toxicity testing”, and the adequacy of the proposal for classification and labelling, and risk assessment of industrial compounds. The Working Group includes members from the CSTEE (Scientific Committee on Toxicity, Ecotoxicity and the Environment), SCCNFP (Scientific Committee on Cosmetics and Non-Food Products intended for Consumers), EFSA SC (Scientific Committee of the European Food Safety Authority) and SCMPMD (Scientific Committee on Medicinal products and Medical Devices).

The Working Group has met on two occasions, generating a draft document that, together with a copy of the BUAV report, was distributed to the members of the SCMPMD during the meeting. Due to the relevance of the topic (animal testing) and the impossibility to carefully evaluate the text distributed during the meeting, it was decided that all comments by any of the members of the SCMPMD should be mailed to Drs Pettersen and Puig before October 24th. Based on these comments a statement reflecting the opinion of the SCMPMD will be elaborated by Prof. Löwer and sent to the Chairperson of the Working Group.

All members of the SCMPMD unanimously agreed on the need to reduce the use of animals for toxicology and pharmacology testing, and at the same time to actively refine and validate legitimate non-animal testing alternatives.

Even though the BUAV report deals exclusively with toxicity testing of chemicals and industrial compounds, the members of the SCMPMD discussed the use of animals for pharmacological testing and the strict regulations existing in the different countries of the
EC. It was strongly felt that in order to speed-up the development of alternative-non animal methods, additional resources should be made available to support research in this field.

5. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

– “The potential impact of arthropod borne diseases (including the West Nile virus) on the safety of blood used for transfusion as well as organs used for transplantation in the European Community”: for discussion.

Dr. Nübling, as rapporteur, explained the document drafted by the working group on the subject.

Several members requested certain modifications, mainly on the conclusions.

It was agreed that prior to publication of the final opinion, the text incorporating the proposed amendments would be circulated once more to Committee members.


– “Potential transmission of blood-borne diseases through natural rubber latex medical devices”: for discussion

Dr. De Jong reported on the draft opinion and requested final comments from the members of the Committee.

It was agreed that prior to publication of the final opinion, the text incorporating the proposed amendments would be circulated once more to Committee members.

The opinion was adopted, with minor changes requested by several members, as figuring in the Document SANCO/SCMPMD/2003/00023_final. (http://europa.eu.int/comm/food/fs/sc/scmp/out48_en.pdf).

6. NEW REQUEST FOR OPINION

There were no new requests for opinion.

7. MISCELLANEOUS.

On behalf of the SCMPMD, Prof. Dr. J. Löwer, chairman of the Committee, thanked Dr. Sanabria, and all the secretariat of the Committee, for their help during the mandate of the Scientific Committee.