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SUMMARY REPORT OF THE 23rd MEETING OF THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Held on 19 June 2003 in Brussels
Adopted on 16 October 2003

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List of participants

MEMBERS

Dr. W.H. De Jong
Dr. A. Gatti
Prof. Dr. J. Löwer
Prof. I. Lucena
Dr. M. Madsen
Prof. Dr. H.W.J. Marquardt
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

EXTERNAL EXPERTS

Mrs. G. Silvester (EMEA)

COMMISSION

Dr. A. Sanabria Tienza (DG SANCO/C2)

1. WELCOME, APOLOGIES AND 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.

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.

2. ADOPTION OF THE AGENDA

The agenda was adopted as follows:

1. Welcoming address, apologies for absence, declarations of interest
2. Adoption of the draft agenda
3. Adoption of the draft minutes of the 22nd SCMPMD plenary meeting.
4. Feed-back by the Chairman on subjects discussed in the SSC which are of interest to the Committee
5. Feed-back by members of the Committee having attended working group meetings of other Scientific Committees
6. Feed-back from the relevant services of the Commission on the follow up to the opinions adopted previously by the SCMPMD.
7. 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 organd used for transplantation in the European Community": for discussion
   - "Potential transmission of blood-borne diseases through natural rubber latex medical devices": for discussion
8. New requests for opinion
9. Miscellaneous

3. ADOPTION OF THE DRAFT MINUTES OF THE 22ND SCMPMD PLENARY MEETING.

The draft minutes of the 22nd SCMPMD plenary meeting, held on 13 February 2003, were adopted as figuring in the Document SANCO/SCMPMD/2003/0009_Final.

(http://europa.eu.int/comm/food/fs/sc/scmp/out46_en.pdf)

4. FEED-BACK BY THE CHAIRMAN ON SUBJECTS DISCUSSED IN THE SSC WHICH ARE OF INTEREST TO THE COMMITTEE.

The chairman informed the meeting that the Scientific Steering Committee had already finished its mandate and had held its last meeting.

Prof. Löwer reported on several items that were discussed at the Scientific Steering Committee (SSC) during its last meeting.

He reported mainly on "Evaluation Risk Harmonisation", "Geographical Risk", "Laboratory Tests" for "BSE".

Concerning "Risk Harmonisation", Prof. Paoletti informed the Committee that the European Society on Toxicology has already discussed the document.

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

Dr. Pettersen informed the Committee that he had attended several meetings of the Working Group on "Fluoride" of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, in which the consequences were discussed of the use of this element in children under the age of 6 years.

Several members asked Dr. Pettersen if the multiple expositions (water, toothpaste, chewing-gum with added fluor, etc) to fluor in order to prevent fluorosis had been taken into account.

Dr. Pettersen affirmed that several sources of exposition to fluor had been taken into account.

Dr. Pettersen and Prof. Puig reported on the Joint Working Group on "Alternative non-animal Testing" of the Scientific Committee on Toxicity, Ecotoxicity and the Environment.

6. FEED-BACK FROM THE RELEVANT SERVICES OF THE COMMISSION ON THE FOLLOW UP TO THE OPINIONS ADOPTED PREVIOUSLY BY THE SCMPMD.

Given the fact that the Committee has not adopted any opinions recently, this point was postponed to a future meeting.

7. 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.***

Prof. Lower said that the Group would meet on 7 July in order to discuss the working method and the distribution of tasks. He expects that during this meeting all the main points of the report and the opinion can be established.

Mrs Silvester of the EMEA informed the Committee on the work already done by the Agency on this subject with respect to plasma derived products and said that at the end of July the EMEA could have a position on it.

Prof. Lower requested that Mrs Silvester be invited to the meeting of the group.

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

Dr. De Jong reported that the group had met twice already, and that industry had already responded to certain questions submitted by the Working Group.

The greatest difficulty is to respond to the question whether latex is safe in preventing the transmission of the prions, because no scientific literature is available. But he said that in any case no transmission had so far been reported other than that caused by an accidental cut or puncture in the glove.

He also reported that two other meetings are scheduled in order to finalise a draft opinion and report for the next plenary meeting.

8. NEW REQUEST FOR OPINION

There were no new requests for opinion.

9. MISCELLANEOUS.

(1) Prof. Gatti explained certain points of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

(2) 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.

(3) The Committee agreed to postpone the next plenary meeting to 16th October. If necessary one other plenary could be planned for 20 November.