EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

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SUMMARY REPORT OF THE 21st MEETING OF THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Held on 26 September 2002 in Brussels
Adopted on 13 February 2003

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List of participants

MEMBERS

Dr. W.H. De Jong
Dr. A. Gatti
Prof. O. Goëau-Brissonniere
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. P. Gustin
Prof. I. Lucena
Prof. Dr. H.W.J. Marquardt
Dr. P. Vannier

EXTERNAL EXPERTS

COMMISSION

Mr. A. Lacerda de Queiroz (DG ENTR/G/4)
Ms. K. Howes (DG ENTR/G/4)
MR. M. Walsh (DG SANCO/C/2)
Dr. A. Sanabria Tienza (DG SANCO/C2)
Mr. H. Stamm (JRC)
Mr. S. Schreck (DG SANCO)

1. WELCOME, APOLOGIES AND DECLARATIONS OF INTEREST.

Prof. Dr. J. Löwer chaired the meeting.

He welcomed the members of the Committee and the representatives of the Commission attending the meeting.

Apologies for absence were received from Dr. Dobbelaer, Prof. P. Gustin, Prof. I. Lucena, Prof. Dr. H.W.J. Marquardt and Dr. P. Vannier.

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

2. ADOPTION OF THE AGENDA

The agenda was adopted as follows:

1. Welcome, apologies and declarations of interest
2. Adoption of the draft agenda
3. Adoption of the draft minutes of the meeting of 17 June 2002.
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. Discussion and possible opinion on an Report on PVC in medical devices for infants
7. Discussion on an Report on "Methods of Sterilisation of Surgical Instruments"
8. Discussion on a possible update of the opinion on "The Effects of Xylitol and Other Polyols on Caries Development"
9. Presentation of possible scientific subjects which could be submitted to the Committee by Directorate G of DG Health & Consumer Protection (DG SANCO) and DG Enterprise (DG ENTR) in the areas of:
   - Public Health
   - Medical Devices
10. Presentation of possible scientific subjects which could be submitted to the Committee by the Joint Research Centre (JRC) in the area of:
    - Public health
11. Miscellaneous

3. ADOPTION OF THE DRAFT MINUTES OF THE MEETING OF 17 JUNE 2002

The draft minutes of the plenary meeting of 17 June 2002 were adopted as figuring in the Document SANCO/SCMPMD/2002/0003_Final
(http://europa.eu.int/comm/food/fs/sc/scmp/out42_en.pdf).

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

Prof. Löwer reported on several items that were discussed in the Scientific Steering Committee (SSC).

The main items of interest to the Scientific Committee on Medicinal Products and Medical Devices were BSE, Mycotoxins, Risk Harmonisation, Antimicrobials and Vaccination of children.

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

Prof. Paoletti reported that the WG of the SSC on "Harmonisation of risk assessment" has met once since the last plenary meeting of the SCMPMD.

He promised to send the draft report of this group to all members when he received it.

He also spoke on possible co-operation with other Scientific Committees that dealt with alternative methods which could provide the same level of information as that obtained in experiments using animals.

At the request of several members, Dr. Stamm from Joint Research Centre (JCR) will send to all members of the Committee information on the European Centre for the Validation of Alternative Methods (ECVAM) integrated in the JCR.

6. DISCUSSION AND POSSIBLE OPINION ON AN REPORT ON PVC IN MEDICAL DEVICES FOR INFANTS

The Rapporteur of the Working Group made a presentation of the document containing the draft report.

An animated discussion took place with observations from several members of the Committee.

The opinion and report were adopted with several modifications and figures in the Document SANCO/SCMPMD/2002/0010_Final
(http://europa.eu.int/comm/food/fs/sc/scmp/out43_en.pdf).

The representative from DG Enterprise, Mr. A. Lacerda, thanked the Committee for the opinion and said that they will send it to the members of their expert group for information.

He said also that if it is necessary to put other scientific questions on the subject they would come again to the Committee to request their opinion.

7. DISCUSSION ON AN REPORT ON "METHODS OF STERILISATION OF SURGICAL INSTRUMENTS"

The Chairman declared that this point would be discussed at a future meeting.

8. DISCUSSION ON A POSSIBLE UPDATE OF THE OPINION ON "THE EFFECTS OF XYLITOL AND OTHER POLYOLS ON CARIES DEVELOPMENT"

The rapporteur explained the document in detail.

After discussion, the Committee adopted an opinion as figures in document SANCO/SCMPMD/2002/0003_Final.
(http://europa.eu.int/comm/food/fs/sc/scmp/out44_en.pdf)

9. PRESENTATION OF POSSIBLE SCIENTIFIC SUBJECTS WHICH COULD BE SUBMITTED TO THE COMMITTEE BY DIRECTORATE G OF DG HEALTH & CONSUMER PROTECTION (DG SANCO) AND DG ENTERPRISE (DG ENTR) IN THE AREAS OF:

- **Public Health**
- **Medical Devices**

Public health

Mr Schreck, the representative from Directorate G of DG Health & Consumer Protection spoke on the Directive concerning "Blood" and on "TSE's Geographical Risk".

He also informed the meeting that certain new questions from his Directorate will be sent to the Committee in the near future.

Medical Devices

The representative from DG Enterprise, Mr Lacerda, reported on the system of classification of different medical devices, on the modification of the Directive on Medical Devices, on the clinical evaluation of medical devices, on the role of the Notified Bodies, on the possibility to creating a Consultative Committee for Medical Devices and on Interaction between the Directives concerning "Medical Devices" and "Biocides".

The Committee thanked Mr Lacerda for the information and requested that the Scientific Committee on Medicinal Products and Medical Devices be consulted on all scientific subjects on medical devices.

Certain members insisted that the SCMPMD could help DG Enterprise and the Notified Bodies in certain subject areas such as of Guidelines on Innovation Materials.

10. PRESENTATION OF POSSIBLE SCIENTIFIC SUBJECTS WHICH COULD BE SUBMITTED TO THE COMMITTEE BY THE JOINT RESEARCH CENTRE (JRC) IN THE AREA OF:

Public health

The representative from the JCR (Ispra), Mr. H. Stamm, presented the JCR Research Activities on the area of Health, comprising mainly of the Multi-Annual Workprogramme for 2003-2006.

He stated that one of the core areas of this Programme is that related to Food, Chemical Products and Health. The priorities in this area are the safety and quality of food and feed, biotechnology, the safety of chemicals, the technologies for health applications and the risk assessment in support of EU policies.

He reported that subjects which could be of interest to the Scientific Committee on Medicinal Products and Medical Devices are included in the Technologies for Health Applications. These are Medical devices and health technologies (MEDTECH), European Network on Nuclear Medicine (EMIR), Biotechnology developments and human health, Reference systems for in vitro diagnosis and health, Analytical chemistry for clinical applications, Alpha-immunotherapy and cell toxicity and Development and exploitation of neutron capture therapy.

Several members requested clarification on certain subjects such as the research on BSE/TSE, and methods of financing the programme among others.

Mr. H. Stamm clarified the above-mentioned subjects and explained other matters.

The Chairman thanked Mr. Stamm for the information and requested the secretariat to attach a copy of the slides shown by the representative from JCR to the minutes.

11. MISCELLANEOUS.

Mr M. Walsh informed the Committee on the future functioning of the European Food Safety Authority (EFSA) and that of the 3 Scientific Committees which will not be integrated into the EFSA.

The Chairman presented a document on the possible future activities of the Committee and requested Prof. Williams, Prof. Goëau-Brissonnier, Dr. De Jong and Dr. Pettersen to revise it and make the necessary changes in order to discuss it again at a future plenary. He also invited all members to send to Professor Williams any ideas, which might contribute to improve the document.

No other matters.