

EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Doc.SANCO/SCMPMD/2001/0007 Final

SUMMARY REPORT OF THE 18th MEETING OF THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Held on 1st.October 2001 in Brussels Adopted on 18 January 2002

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List of participants

MEMBERS

Dr. W.H. De Jong Dr. A. Gatti Prof. O. Goëau-Brissonniere Prof. I. Lucena Prof. Dr. H.W.J. Marquardt Prof. R. Paoletti Dr. M.K. Paunio Dr. A.H. Pettersen Prof. M. Puig Dr. E. Rodriguez Farré Prof. D.F. Williams

<u>APOLOGIES</u>

Dr. R. Dobbelaer Prof. P. Gustin Prof. Dr. J. Löwer Dr. M. Madsen Prof. P. Preziosi Dr. M. Thomsen Dr. P. Vannier

COMMISSION

<u>EMEA</u>

Dr. A. Sanabria (DG SANCO)

Dr. J. Purves

1. Welcome, apologies and declarations of interest.

Prof. D.F. Williams chaired the meeting and informed the Committee that Prof. Dr. J. Löwer was unable to come and chair the meeting.

He welcomed the members of the Committee and the representatives of the Commission attending the meeting and also the representative from the EMEA.

Apologies for absence were received from Dr. R. Dobbelaer, Prof. P. Gustin, Prof. Dr. Löwer, Dr. M. Madsen, Prof. P. Preziosi, Dr. M.Thomsen and Dr. 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 28 May 2001.
- 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. Information on the 'Safety of Human-Derived Products and Medical Devices With Regard to TSE's" working group.
- 7. Discussion and possible opinion on a draft 'State of Art Report on Tissue Engineering'.
- 8. Discussion and possible opinion on a draft 'State of Art Report on Xenotransplantation'.
- 9. Miscellaneous.

3. Adoption of the draft minutes of the meeting of 26 February 2001

The draft minutes of the plenary meeting of 26 February 2001 were adopted as figuring in the Document SANCO/SCMPMD/2001/0005_Final.

4. Feed-back by the Chairman on subjects discussed in the SSC which are of interest to the Committee.

Not relevant matter to report.

5. <u>Feed-back by members of the Committee having attended working group</u> <u>meetings of other Scientific Committees.</u>

Not relevant matter to report.

6. <u>Information on the 'Safety of Human-Derived Products and Medical Devices</u> <u>With Regard to TSE's'' working group.</u>

The group will met in September in order to prepare a document and a draft of opinion in response to the questions put on the table by the Directorate G of the Health and Consumer Directorate-General.

The draft document should be presented to the "TSE "ad hoc" Scientific Steering Committee group" and the plenary of the SSC for comments.

Finally the draft opinion and document could be submitted to the Scientific Committee on Medicinal Products and Medical Devices at the end of the year or in January, for discussion and adoption.

7. <u>Discussion and possible opinion on a draft 'State of Art Report on Tissue</u> <u>Engineering'.</u>

The rapporteur, Prof. D. F. Williams, explained the report.

After a long discussion, certain modifications, as requested by several members of the Committee, were taken into account in the report and the opinion .

Finally the report and opinion were adopted as figures in document SANCO/SCMPMD/2001/0006 Final.

8. <u>Discussion and possible opinion on a draft 'State of Art Report on</u> <u>Xenotransplantation'.</u>

The rapporteur, Dr. W.H. De Jong, explained the rapport and the respective opinion.

A productive discussion on the subject took place and the members of the Committee proposed several modifications to the report and to the opinion.

The modified report and opinion figures in document SANCO/SCMPMD/2001/0002 Final as adopted by the Committee.

9. Miscellaneous.

Several members of the Committee suggested that the Committee could consider certain topical subjects such as:

- "Stem cells".
- "Herbal Medicines" and their interaction with classical medicinal products.
- Safety of medicinal products in the treatment the chronic diseases in elderly patients.
- Safety of certain medical devices.

The members asked to discuss these and other possible subjects which could affect human health at a future meeting.