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**SUMMARY REPORT OF THE 19th MEETING OF THE SCIENTIFIC
COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES**

**Held on 18 January 2002 in Brussels
Adopted on 17 June 2002**

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List of participants

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MEMBERS

Dr. W.H. De Jong
Dr. R. Dobbelaer
Dr. A. Gatti
Prof. O. Goëau-Brissonniere
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
Dr. P. Vannier
Prof. D.F. Williams

APOLOGIES

Prof. P. Gustin

COMMISSION

Dr. A. Sanabria (DG SANCO/C)
Mr. D. Bouis (DG ENTR/F/4)
Mr. H. Stamm (JRC)
MR. F. Fernández-Zincke (DG SANCO/G)

EXTERNAL EXPERTS

Dr. K. Jones
Dr. M.Nübling

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 and also the representative from the EMEA.

Apologies for absence were received from Prof. P. Gustin.

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 1 October 2001
4. Election of a new Vice-Chairman of the Committee
5. Discussion and possible opinion on a draft document 'Safety of Human-Derived Products and Medical Devices With Regard to TSE's'
6. Feed-back by the Chairman on subjects discussed in the SSC which are of interest to the Committee
7. Feed-back by members of the Committee having attended working group meetings of other Scientific Committees
8. Discussion on the questions made by DG "Enterprise" concerning PVC
9. Dates for Plenary Meetings in 2002
10. Discussion on future work of the Committee
11. Miscellaneous

3. Adoption of the draft minutes of the meeting of 1st October 2001

The draft minutes of the plenary meeting of 1st October 2001 were adopted as figuring in the Document SANCO/SCMPMD/2001/0007_Final.

4. Election of a new Vice-Chairman of the Committee

Taking into account that Prof. P. Preziosi had resigned, the Committee was obliged to elect a new Vice-Chairman.

Dr. W.H. De Jong was proposed by several members of the Committee as candidate for the post of Vice-Chairman. Dr. De Jong accepted to become a candidate.

By unanimity Dr De Jong was elected Vice-chairman 2.

5. Discussion and possible opinion on a draft document 'Safety of Human-Derived Products and Medical Devices With Regard to TSE's'

The rapporteur, Prof. Löwer, explained the document in detail.

A long discussion took place and several members proposed modifications on different items.

Prof. Löwer redrafted several points of the report in order to take the Committee's observations into account.

The Committee adopted the report and opinion as in document SANCO/SCMPMD/2002/0001 Final, which contains the modifications agreed by the Committee.

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

Prof. Löwer informed the Committee 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, catgut, harmonisation of the risk assessment and evaluation of the geographical risk.

7. Feed-back by members of the Committee having attended working group meetings of other Scientific Committees.

Prof. Paoletti reported on the progress made by the WG of the SSC on “Harmonisation of the risk assessment”.

He added that he could draft the part concerning the harmonisation of the risk assessment on metabolic diseases.

8. Discussion on the questions made by DG “Enterprise” concerning PVC

Several members felt that the amount of work to draft a report and give an opinion would be substantial taking into account the sensitivity of the subject and the difficulties already encountered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE).

The SCMPMD can take advantage of the paper review and the opinion given by the CSTEE, although it would be necessary to concentrate on certain specific aspects of the use of PVC in medicinal products not included in the work of the CSTEE.

The Committee agreed to create a Working Group formed by:

Dr. W.H. De Jong, Prof. Dr. H.W.J. Marquardt, Dr. A.H. Pettersen, Dr. M.K. Paunio, Dr. E. Rodriguez Farré, Dr. A. Gatti and Prof. D.F. Williams as Chairman.

9. Dates for Plenary Meetings in 2002

The following dates were adopted:

1 March 2002
17 June 2002
26 September 2002
2 December 2002

10. Discussion on future work of the Committee

Several members of the Committee requested a meeting with DG ENTERPRISE and Directorate G of DG SANCO to be organised on the occasion of a future plenary in order to discuss future work .

Two subjects were mentioned by Dr Rodriguez Farré and Prof. O. Goëau-Brissonniere concerning “Herbal Medicines and their interaction with classical medicinal products” and safety of certain medical devices such vascular implants.

Another major subject mentioned was the guidelines to define the borderline between certain medical devices and medicinal products.

11. Miscellaneous.

No other matters.