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SUMMARY REPORT OF THE 17th MEETING OF THE SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES

Held on 28 May 2001 in Brussels
Adopted on 1st. October 2001

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List of participants

MEMBERS

Dr. W.H. De Jong
Dr. A. Gatti
Prof. O. Goëau-Brissonniere
Prof. P. Gustin
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. P. Preziosi
Dr. P. Vannier

COMMISSION

Dr. A. Sanabria (DG SANCO)
Mr. G. Fracchia (DG SANCO)
Mr. H. Stamm

EMEA
Dr. J. Purves

1. Welcome, apologies and declarations of interest.

Prof. Dr. Löwer welcomed the members of the Committee and the representatives of the Commission attending the meeting as well the representative from the EMEA.

Mr G. Fracchia informed the Committee that he had been nominated to a new post within the Commission's Directorate General for Administration and therefore this would be the last Scientific Committee on Medicinal Products and Medical Devices meeting he would attend. He thanked the members of the Committee for the help he had received during the years he had working with the Committee.

Dr Löwer thanked Mr Fracchia for the effort he had devoted to the Committee and wished his every success in his new post.

Apologies for absence were received from Dr. R. Dobbelaer, Dr. Ph. Vannier and Prof. P. Preziosi.

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 26 February 2001

4. Activity Program of JRC: presentation by Mr H. Stamm

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

6. Feed-back by members of the Committee having attended working group meetings of other Scientific Committees
   a) Genetically modified cotton (Prof. Williams)
   b) Harmonisation of risk assessment (Prof. Paoletti)

7. Information on the 'Blood and vCJD' working group

8. Discussion and possible opinion on a draft 'State of Art Report on Tissue Engineering'

9. Discussion and possible opinion on a draft 'State of Art Report on Xenotransplantation'

10. 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/2001/0001_Final.

4. Activity Program of JRC: presentation by Mr H. Stamm.

Dr. Stamm presented the work performed at the Institute for Health and Consumer Protection (IHCP), which is one of the eight institutes of the Joint Research Centre of the European Commission.

He gave an overview of the objectives and the activities of the Institute in support of the Commission's policies on health and consumer protection.

The institute's role in the following areas was described:
(i) food safety and food quality, including genetically modified organisms,
(ii) toxicology and chemical substances,
(iii) validation of biomedical testing methods (ECVAM)
(iv) support to pharmaceutical regulation, and
(v) biomedical materials and systems.

Dr. Stamm expressed the interest of the IHCP to support the scientific committee with its scientific competence and research facilities in the above-mentioned areas, especially regarding issues related to the safe application and reliability of medical devices.

The Chairman thanked Dr. Stamm for his presentation.

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

Prof. Dr Löwer informed the Committee that since the last plenary meeting of the SCMPMD, several meetings of the Scientific Steering Committee (SSC) had taken place.

He said that discussion concentrated mainly on subjects concerning BSE such as geographical risk classification of certain third countries, and the risk of tallow and its derivatives.

Another subject discussed in the SSC was Risk Evaluation Harmonisation.

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

a) Genetically modified cotton (Prof. Williams)

Prof Williams informed the Committee that this matter is not easy to deal with because in his bibliographic research no data were found.

He said that it is important to take the physical properties into consideration as well as the possible toxicity, the allergies that it could provoke when used as a tampon, and the possibility of undesirable effects with the utilisation of this type of cotton.

Nevertheless if it is true that there is no proof of danger related to the use of this type of cotton, it is still a very sensitive matter and it is necessary to be prudent.

Prof. Dr Löwer requested Prof. Williams to send the conclusions to the WG of the SSC in order to incorporate them in their report.

b) Harmonisation of risk assessment (Prof. Paoletti)

Prof. Paoletti informed the meeting that the Scientific Steering Committee WG on this subject will meet in June, and distributed a document.

7. Information on the 'Blood and vCJD' working group

Prof Lower informed the Committee that at its next plenary meeting the Scientific Steering Committee will discuss the safety of human-derived products and medical devices with regard to TSE's. This subject will be tabled at the request of Directorate G of the Health and Consumer Protection Directorate General.

The question will not only relate to blood but will include other problems such as possible methods of decontamination of surgical instruments. Therefore a new working group must be created to deal with this subject.

He also spoke about the task of the group that is working in Germany on the same subject.

Certain members spoke about the problems of the decontamination of prions from instruments used in dentistry.

Finally Dr Paunio presented a document on "Plasma Derived Medicinal Products and Pool Size" which will be submitted to the Working Group.

8. Discussion and possible opinion on a draft "State of Art Report on Tissue Engineering"

Prof. Williams presented a 2nd. draft report on this subject to the Committee, adding that the final draft will be available for the next plenary meeting.

He requested observations on the report, which could be sent to him by E-mail before the next meeting of the Working Group, emphasising the fact that this is a subject of global importance.

Several members made observations on the document and Prof Williams promised to include them in a new version of the document, which will be discussed by the working group.

9. Discussion and possible opinion on a draft "State of Art Report on Xenotransplantation"

Dr De Jong circulated a draft report, informing the Committee that a further meeting of the Working Group would be necessary in order to revise the document and finalise it before the next plenary meeting.

He emphasised the hazards of the retrovirus and other unknown animal pathogen agents which could emerge in the practice of xenotransplantation and said that it will be necessary to request certain supplementary sanitary conditions on the farms providing animals for xenotransplants.

Several members asked if it is possible to vaccinate the recipients of the xenotransplants against certain animal viruses.

Certain members noted that the hazards would be greater in situations where a combination of viruses might be present and have an effect on a recipient who is immunosuppressed to prevent rejection of the xenotransplant tissue.

10. Miscellaneous.

- Prof. Gatti reported on the results of on-going studies in his laboratory concerning possible health risk relating to the consumption or application of certain products that contain non-biodegradable components such as silicates.

  The Committee concluded that, in the absence of clinical studies, if was not possible to establish a cause-effect relationship.

  Nevertheless, the Committee would remain vigilant.

- Dr. Rodriguez Farré requested that the transparencies he presented at the last plenary meeting be distributed to the other members of the Committee. He also distributed a note on the problem of "Herbal medicine".

- The next Plenary Meeting of the Committee will be 1 October instead of 3 September.