Council of Europe
Conseil de l'Europe

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EUROPEAN HEALTH COMMITTEE (CDSP)

39th meeting

Strasbourg, 25-27 June 1996

MEETING REPORT OF THE

COMMITTEE OF EXPERTS ON BLOOD TRANSFUSION AND IMMUNOHAEMATOLOGY (SP-HM)

(Strasbourg, 22-24 April 1996)

1. Opening of the meeting

Professor van Aken opened the meeting, excusing Prof. Leikola for having been unable to attend the meeting from the very beginning.

The Secretariat informed the SPHM that Ms Tholomier had left the Health and Social Policy Division to go to work in the European Department for the Quality of Medicines. Dr Mierzewski assumed the activities of the blood sector until a new administrator could be appointed, presumably in the autumn. The experts instructed the Secretariat to pass a notice of thanks to Ms Tholomier for the excellent work she did as a secretary of the SPHM.

2. Election of the Chairman and members of the Bureau

The current members of the Bureau were re-elected, with the exception of Prof. van Aken who resigned and left the Bureau for professional reasons. The experts thanked prof. van Aken for his stewardship which made SPHM a major actor on the European blood policy scene. Dr Jean-Claude Faber (Luxembourg) was elected Chairman of the Bureau. Dr Christian Desaint (France), Prof. Halina Seyfried (Poland) and Prof. Hele Everaus (Estonia) were elected as additional members of the Bureau, in the eventuality that the Bureau is expanded to 10 members (See Appendix I, list of participants).

3. Adoption of the draft agenda

The agenda was adopted (see Appendix II), with an additional point 7.2 "Recent developments in Germany" and point 12.1.1. "Developments in the European Pharmacopoeia Group 6B". These modifications were taken into account in this report

4. Decisions of the CDSP

The Secretariat informed experts that about the CDSP at its November 1995 meeting, had proposed new methods of work, particularly for adopting the appendix to the "Recommendation on the preparation, use and quality assurance of blood components".

The CDSP had agreed that in the absence of any written objections from the member states to the text by a certain date, it would be considered adopted; the text would otherwise be submitted for adoption at the following CDSP meeting. In the year the SP-HM does not meet, the appendix to Rec. R (95) 15 should be adopted by correspondence.

5. Working methods

The Secretariat introduced document CDSP (96) 11 on the methods of work of the SP-HM. He explained that this document would be submitted to the CDSP in June for approval The document proposed, inter alia, that Bureau membership be extended to 10, elected by a method ensuring an equitable representation of the member States, that its current power and competence be confirmed and that the SP-HM continue to meet every two years. The document also made proposals for dealing with urgency. A proposal was made to include automatically the past president of the Bureau. In general, a balance between geographic equilibrium and personal professional experience should be maintained.

The **Committee** approved a document on working methods and transmitted it to the CDSP for approval (CDSP (96) 11)

I. PROGRAMME OF WORK

A. EUROPEAN POLICIES : ETHICAL, LEGAL, AND ORGANISATIONAL ASPECTS

6. Voluntary and non-remunerated blood donation : monitoring of practices and developments in member States

The issue would be dealt with after receiving replies to the questionnaire on the 1995 data for the non Community member State of the Council of Europe

7. Responsibility of health authorities concerning blood transfusion

7.1. Draft recommendation : "Documentation and records keeping to guarantee the traceability of blood and blood products especially in hospitals"

At its 36th meeting the CDSP, on a proposal of the SP-HM, entrusted the SP-HM Bureau with the preparation of guidelines on documentation and record keeping to ensure the traceability of blood and blood products.

Dr Rejman (UK) prepared a draft Recommendation, dealing with traceability step by step through every single stage, in order to prevent the loss of identification of donors and patients. This enables finding patients and donors when something goes wrong to prevent further contamination. The proper level of generalisation allows to follow the procedures described in this draft despite that the blood transfusion systems differ very much between member states.

The recommendation, a timely exercise in haemovigilance, should be used together with the Guide, regulating closer the mutual relations donor-recipient. Pharmacovigilance is now compulsory according to EU pharmaceutical legislation; the preamble to the draft Recommendation refers to the relevant Directives. In the discussion amendments were proposed on the documentation of lots of the albumins (suggestion that the manufacturer should be informed about any irregularities and himself should inform those using the particular lot of albumins). The interest of the patient prevails over the administrative inconveniences.

The **Committee** approved the draft recommendation, as set out in Appendix III to this report.

7.2 Recent developments in Germany.

The German expert presented the work of a Working Group on Blood (Arbeitskreis Blut), the role of the Paul Ehrlich Institute as a German FDA and the activities of the Robert Koch Institute in the field of epidemiology. The group issues a consensus document every 2 month, containing quasi-binding recommendations. A substantial backlog of problems

developed. In the opinion of the Working Group the two major threats to the self-sufficiency are: an indiscriminate use and a big, often inappropriate demand. In Germany the autologous blood donation is gaining momentum, driven by the anaesthesiologists.

8. Task Force on blood transfusion and plasma fractionation : restructuration in Central and Eastern Europe

8.1 Report of one year activities : Missions in the Slovak Republic and Estonia

Prof. Politis presented the document SP-HM (96) 13/Revised on the "Task Force on Blood Transfusion". She reminded that the mission of the Task Force is to review comprehensively a national blood policy and to advise on global strategic issues, not on particular projects or programmes. This approach must be confronted with real situations, where governments already have decided about their priorities in blood policy (e.g. plasma fractionation). Different conditions prevailing in different member states call for flexible approaches, taking into consideration changing priorities, culture and economic situation.

The results of the missions are confidential, available only to the government in question. The Task Force proved to be a timely response to the needs and demands of the new member states. In certain cases the Task Force decided not to send missions to a country to avoid duplicating projects by other international organisations. The main lesson learned is that this sort of activity is a two-way learning process: how to understand better needs of a country and how to optimally absorb the technical advice.

Concerning Estonia, the mission successfully performed the assessment of the blood transfusion services and made proposals to the Ministry of Health. According to the representative of Estonia and members of the mission, the results of the mission might become a turning point in reforming the blood services in this country. The perfect cooperation with the national authorities and the pivotal role of prof. Everaus was emphasised. Concerning the Slovak Republic, the terms of reference for a second mission, drafted by the Task Force should be revised in the light of the experience after the first mission..

The **Committee**

- expressed its appreciation for the work done and stressed the need to continue it,
- took note that Prof. Leikola would prepare a report of the first mission to Estonia.

8.2 Information on the expert visits and the Task Force meetings

The Committee was informed of a possible second mission to the Slovak Republic, on the basis of modified terms of reference. The Slovak government will establish the most suitable time for that. The next meeting of the Task Force is planned in September 1996. A preliminary request for assistance was made by the delegate from Lithuania, recently confirmed by the Lithuanian Minister of Health.

The Task Force will study this request of Lithuania and the follow up to be given to

a first mission organised in the Slovak Republic.

B. EUROPEAN SELF SUFFICIENCY

9. Cooperation of the Council of Europe with other organisations

9.1 Report of the European Commission

The Representative of the European Commission apologised for absence. No written report was available.

9.2 Activities of the Council of Europe and relations with the European Commission and the WHO

The Secretariat presented document SP-HM (96) 3 on "Blood transfusion activities at the Council of Europe and relations with the European Commission, the WHO and the International Federation of Red Cross and Red Crescent Societies", regarded as a draft for a cooperation plan. He explained that the purpose of the document was, inter alia, to inform new member states on the activities of the SP-HM, to take stock of the work carried out to date and to set out the future orientation of activities.
The Committee suggested that it was vital to define a frame "European Policy" on blood policy which would be agreed by the four organisations, particularly in view of the developments in the European Union after establishing the "Blood Self-sufficiency Group".

The SP-HM discussed the relevance of such a policy and how to approach the problem of co-operating with the other organisations, how to set out which subjects should be dealt with by each organisation and which fields left to the responsibility of national authorities, how to define the activities that could be carried out jointly and those activities that could be complementary An inventory could be made of the important issues of common interest and the working relationship between the secretariats should be strengthened. A starting point for improving the existing liaisons should become a mutual exchange of plans and work programmes, early enough to make appropriate adjustments.

The Secretariat suggested that as a practical first step a preliminary draft should be prepared on the basic principles of a blood transfusion policy in Europe. This would be intended for discussion by the SP-HM together with the representatives of the EC and the WHO and as a basis for a coherent planning of activities.

. The **Committee**

- agreed with the general orientation described in doc. SP-HM (96) 3

- agreed to invite Mrs F. Delaney to the next SP-HM Bureau meeting,

- asked the Secretary to the SP-HM, to pay a working visit to Luxembourg, and to draft a letter to the European Commission, proposing a meeting in Luxembourg in connection with a meeting of the Blood Self-Sufficiency Group of the European Commission. This letter would be subject to approval by the SP-HM Bureau,

- thanked Dr Faber for offering to prepare a framework document for cooperation with the European Commission and WHO.

10. Follow up to CE recommendations and EEC directives

10.1 Report of the Group of specialists on the clinical use of blood products (SP-S-EC)

It was recalled that the rationale for drafting this report was to contribute to the objective of European self-sufficiency with a better use of blood products. To this end the role of demand and consumption patterns had to be reviewed.

This document was originally intended as a clinical guideline for clinical practice, but expanded into a comprehensive handbook with policy and political implications. It would be very difficult, if not impossible to reach consensus between 40 different member states with widely differing health systems and medical practices. Moreover, the confusion might arise where the document covers areas described also in the Guide. To keep the Guide as a transparent and authoritative reference on Council of Europe blood policy the SP-HM decided not to publish the report as a Council of Europe publication.

The SP-HM instructed the Bureau to send a letter to the authors, thanking them for the considerable effort, appreciating the results and explaining the reasons for the SP-HM decision. The authors will be asked instead to provide a summary, comprising the general principles and the health policy aspects of the report, especially the relation to the self-sufficiency issue. This would be published on the responsibility of the authors. The body of the report will be available to the member states and other interested parties, which could make the best use of the technical content in a way they want.

11. Collection and use of human blood and plasma in Europe

11.1 Self-sufficiency in the European Union (F. Delaney)

Madame Delaney apologised for absence. She was not able to present a written contribution to the topic.

11.2 Questionnaire (of the European Commission) on the 1995 data for the non Community members States of the Council of Europe

The discussion was postponed until after receipt of more replies to the questionnaire on the 1995 data for the non Community members States of the Council of Europe. Dr Rejman was asked to analyze the replies to the questionnaire. This document should be published by the end of 1997.

C. PROMOTION OF SAFETY and QUALITY OF TRANSFUSION

12. Quality assurance (SP-R-GS)

12.1 Recommendation on the preparation, use and quality assurance of blood components

The Secretariat submitted doc CDSP (96) 20 containing the revised version of the appendix to the Recommendation on the preparation, use and quality assurance of blood components.

Due to the substantial amendments carried out by the SP-R-GS and the short lapse of time available for the Secretariat to prepare the revised version, the document was distributed late and the French version was not available yet.

The Secretariat would circulate the amended text of the Recommendation by 30 April 1996. The members of the SP-HM were requested to send their amendments by 30 May 1996.

12.1.1 Developments in the European Pharmacopoeia Group 6B

The Secretariat reported on developments in the Group 6B of the Pharmacopoeia which was working on a monograph on fractionation. The monograph referred to the criteria of donor selection contained in Recommendation (95) 15, to the exclusion of the definition of voluntary donors, and the frequency of donations.

Experts contended that the excluded criteria were ethical issues with implications on the quality of blood. They felt they should be reinserted in the monograph.

After discussion the SP-HM instructed the Secretariat

- to draft a letter to the Chairman of the European Pharmacopoeia Commission, asking that the extracts of the Recommendation on the preparation, use and quality assurance of blood components which had been omitted should be reinserted in the monograph on fractionation;

- to circulate the draft letter to all SP-HM and CDSP members for their approval, prior to signature by the Chairman of the SP-HM.

12.2 Approval of the revised version of the annex of the appendix to the above Recommendation

See under item 12.1.

13. Prevention of transfusion transmitted diseases

Prof. Morell presented the document SP-HM (96) 9, for which was commended by the Committee. In the discussion the following points were mentioned:

- the German Working Group on Blood recommends testing by the PCR as mandatory

- the FDA examines the problem of blood derivatives contaminated with plasma from the Creutzfeld Jacob disease (CJD) donors and the role of the B-24 antigen testing in closing the window period in HIV infection (by 6-7 days, 50 mln $ cost to detect 5-6 persons)

- in the UK the pooled immunoglobulins are tested for HB-C and by the PCR. The Biotechnology Working Party, recently established, instructed the use of PCR

- the Polish expert suggested adding LAT as a marker of liver pathologies

- PCR is yet poorly standardised and gives inconsistent results, especially when it is applied on a broader basis.

The **Committee**

- thanked Prof. Morell for his doc. SP-HM (96) 9,

- proposed a number of amendments,

- invited Prof. Morell to prepare a revised version of the text and to add a bibliography.

14. Autologous transfusion

The UK expert informed about developments in this area, including a case of HB-B transmission to the autologous bone marrow donor (bag leakage). An anonymised system of reporting is being developed. She suggested that an appropriate chapter on autologous transfusion might be added to the Guide.

Other experts reported that the informed consent principle is to be observed, that every unit should be mandatory tested (the infected ones being destroyed) or that testing should be done before collecting the blood.

The Committee decided that this subject would be retained on the agenda.

D. IMPACT OF NEW DEVELOPMENTS (molecular biology area)

15. Impact of recombinant Factor VIII

More information would be available after receiving replies to the questionnaire on the 1995 data for the non Community members States of the Council of Europe.

16. Oxygen carrying substances

16.1 Statement on haemoglobin solution prepared from human blood

The Secretariat recalled that rationale for this study was the lack of information about the clinical indications and potential demand for blood for this purpose. The ethical implications called the Council of Europe to take a clear position on this new category of products and the use of blood as raw material for their preparation

BAXTER, the leading company in this field, was invited for a hearing on the subject in order to obtain fuller information.

Prof. Leikola had prepared a document together with the Secretariat of the CDBI.

In the ensuing discussion it was pointed out that selling surpluses of blood to commercial vendors should not be a driving force to over-collecting of blood; the economic principles should follow the non-for-profit one. There was here a potential for conflict of interest between different missions of the blood centres. An informed consent in writing should be required for permission to process blood commercially. Experts noted that clinical indications were not yet developed adequately and the criteria for use of the product should be defined precisely. The issue of import/export of the products also needed to be examined.

The **Committee**:

- approved a draft statement with the amendments introduced by prof. Leikola after the discussion, which is submitted to the CDSP for adoption (Appendix IV)

- authorised the Secretariat to transmit the statement to industry.

E. TRAINING

17. 1995 Course in Helsinki : Optimal Use of resources and Management of blood transfusion centres

The Secretariat conveyed its thanks to Prof. Leikola for the excellent organisation of the course. All Eastern and Central European countries were represented and participated quite actively in the discussion.

Prof. Leikola recalled that many of the students at the Course in Helsinki 21 years ago were now members of this Committee.

Following the success of the course, the SP-HM members insisted on the need to continue such courses.

18. CNED - Council of Europe Course on blood transfusion in collaboration with the Centre National d'Enseignement à Distance.

The Secretariat informed the SP-HM that the next edition of this distance learning course was uncertain. The interest in it had diminished considerably and the quality of teaching material should be improved to be in accordance with the standards of the Council of Europe as it bears its name.

F. SERVICE ACTIVITIES

19. Technical protocol: n° 26

The Secretariat reminded the SP-HM that the Committee of Ministers would adopt the Protocol to Agreement 26 once the Council of Ministers of the European Union approved it. To that purpose the revised protocol had been sent to the European Commission. Approval was delayed due to consultation with the European Medicine Agency in London and the final elaboration of a European Union blood strategy which was still in process.

The **Secretariat** confirmed the intention to have the Recommendation on the preparation, use and quality assurance of blood components as technical protocol to Agreement No.26.

20. European Bank of frozen blood of rare groups

Prof. van Aken would provide a financial report to the Secretariat, as requested by the CDSP. He mentioned difficulties in recruiting donors for the sickle-cell disease recipients.

G. COORDINATED RESEARCH

21. Activities of blood banks related to bone marrow transplantations

Dr Kroczek informed the SP-HM that replies to the questionnaire on the activities of blood banks, the HLA testing and the quality issues have been received from several member states. Study visits had been finished and the study reports collected.

The final report, based on the answers to the questionnaire will present a general overview of the current situation in Europe and to what extent the blood banks are actually involved in bone marrow transplantation. The report will also present the future developments for the blood services in bone marrow transplantation, collection and processing of stem cells and cord blood.

22. Proposals for a subject for 1997/1998

The issue of "Viral inactivation of labile blood components" was chosen as a subject for the 1997/1998 or 1998/1999 coordinated research. Prof. Morell agreed to be study director. Study visits were deemed essential for this project. The issue would be discussed by the CDSP in 1997 in the context of the preparation of the 1998 programme.

II. OTHER BUSINESS

- Experts were invited to send the written versions of their interventions to the Secretariat by 15 May 1996.

- The proposal to open a SP-HM page (possibly as a part of the Council of Europe one) in the World Wide Web of the Internet was widely supported. The Finnish delegate offered technical support and programming assistance

- Safety of blood donors was proposed as one of the main issues to be tackled in the near future by the SP-HM.

H. APPROVAL OF THE TERMS OF REFERENCE OF THE SP-HM FOR 1997/1998

Draft terms of reference for 1997/1998 were approved and submitted to the CDSP for adoption (APPEDIX V).

I. PUBLICATION

The publication on the "Activities of the Council of Europe in blood transfusion" by Prof. Genetet, was fairly advanced, and the French version should be ready in the next couple of months.

J. REPORT OF CEC, WHO, ISBT, IFRCRC

The representative of the IFRCRC and the SP-HM agreed to exchange documents for comments and critical review. The representative of the American FDA gave a detailed report of their activities, suggesting closer cooperation and mutual exchange of information.

K. DATE and PLACE OF THE NEXT SP-HM MEETING

The next meeting of the SP-HM would take place in mid-May 1998 in Strasbourg. The SP-HM instructed the Secretariat to hold the meeting of the SP-R-GS in mid-February each year.

APPENDIX I

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APPENDIX II

DRAFT AGENDA

1. Opening of the meeting (Prof. Leikola)

2. Election of the Chairman and members of the Bureau

3. Adoption of the draft agenda

4. Decision of the CE bodies (CDSP) (Secretariat)

5. Working methods (Secretariat)

I. PROGRAMME OF WORK

A. EUROPEAN POLICIES : ETHICAL, LEGAL, AND ORGANISATIONAL ASPECTS

6. Voluntary and non remunerated blood donation : monitoring of practices and developments in member states (Secretariat)

7. Responsibility of health authorities concerning blood transfusion

   7.1. Draft recommendation : "Documentation and records keeping to guarantee the traceability of blood and blood products (Dr Rejman)

8. Task Force on restructuring of blood transfusion and plasma fractionation in Eastern and Central Europe

   8.1 Report of one year activities : Missions in the Slovak Republic and Estonia (Dr C. Politis)

   8.2 Information on the experts visits and the Task Force meetings (Secretariat)

B. EUROPEAN SELF SUFFICIENCY

9. Cooperation of the Council of Europe with other organisations

   9.1 Report of the European Commission (F. Delaney)

   9.2 Activities of the Council of Europe and relations with the European Commission and the WHO (Secretariat)

10. Follow up to CE recommendations and EEC directives

    10.1 Report of the Group of specialists on the clinical use of blood products (SP-S-EC) (Dr Sörensen)

11. Collection and use of human blood and plasma in Europe

    11.1 Self-sufficiency in the European Union (F. Delaney)

11.2 Questionnaire on the 1995 data for the non Community members States of the Council of Europe (Secretariat)

11.2.1 Comments of all members (Round Table)

11.2.2 Proposal for a consultant

C. PROMOTION OF SAFETY and QUALITY OF TRANSFUSION

12. Quality assurance (SP-R-GS)

12.1 Recommendation on the preparation, use and quality assurance of blood components (Secretariat)

12.2 Approval of the revised version of the annexe of the appendix to the above Recommendation (Dr Sörensen)

13. Prevention of transfusion transmitted diseases (Round Table)

14. Autologous transfusion (Prof. A. Robinson)

D. IMPACT OF NEW DEVELOPMENTS (molecular biology area)

15. Impact of recombinant Factor VIII (Prof. Van Aken)

16. Oxygen carrying substances

16.1 Statement on haemoglobine solution prepared from human blood (Prof. Leikola)

16.2 Other substances

E. TRAINING

17. 1995 Course in Helsinki : Optimal Use of resources and Management of blood transfusion centres (Prof. J. Leikola)

18. CNED (Secretariat)

F. SERVICE ACTIVITIES

19. Technical protocol : n° 26 (Secretariat, European Commission)

20. European Bank of frozen blood of rare groups (Prof. Van Aken)

G. COORDINATED RESEARCH

21. Activities of blood banks related to bone marrow transplantations (Dr. R. Kroczek)

22. Proposals for a subject for 1997/1998 (Round Table)

II. OTHER BUSINESS

H. APPROVAL OF THE TERMS OF REFERENCE OF THE SP-HM FOR 1997/1998

I. PUBLICATIONS :

"Activities of the Council of Europe in blood transfusion" by Prof. Genetet

J. REPORT OF CEC; WHO; ISBT; IFRCRC

K. DATE and PLACE OF THE NEXT SP-HM MEETING