GA-9730

european plasma fractionation association

Draft minutes of the General Assembly of the European Plasma Fractionation Association, 25 April 1997, held at the ZLB Central Laboratory of the Swiss Red Cross Blood Transfusion Service SRK, Berne, Switzerland

List of participants: see Attachment I (GA-9730.a)

1. Opening

a. Opening and welcome
After opening the meeting and welcoming the participants of the General Assembly, the President thanks Dr. Wäger and Dr. Gander for the excellent arrangements.
Dr. Wäger welcomes the participants to the General Assembly, thereby expressing his appreciation to the EPFA Board and secretariat.

b. Adoption of the agenda
The agenda is adopted without changes.
Presentations were given by respectively Dr. Wäger and Dr. Stucki from ZLB, Dr. Strengers of CLB and Paul Rogers of SNBTS.
Copies of the overheads used by the speakers are attached.
Mr. Numata of the Japanese Red Cross Fractionation Center kindly requests the members of the General Assembly to fill out a questionnaire regarding PCR testing of plasma pools for the Japanese blood centres.
After the meeting Numata will distribute the outcome of the questionnaire.

2. General Assembly

a. Minutes of the General Assembly meeting of 8 October 1996 in Amsterdam, The Netherlands (GA-9701)
The following amendment should be made:
page 7, agenda item 10 Reports by member institutes: Finland - second line "distribution and **preparations of cellular components** and 16 local ..."

b. List of actions from the GA meeting (GA-9702)
- Preparations International Plasma Quality meeting
  * It has been decided by the Executive Board to prepare the International Quality meeting in phases
- EPFA membership survey
  * There is still concern among the members regarding the confidential data of their institutes. It has been decided to collect and use non-confidential data for promotional activities.
- European Product Exchange System
  * This Working Group on Regulatory Affairs proposed to the EB to use the concept of European Economic Interest Grouping (EEIG) as a mechanism for a European Product Exchange System. This proposal is still under discussion.

- Update Beal/V.Aken report
  * This action will, similar to the plasma quality meeting be incorporated in an integrated set of EPFA actions, to be discussed by the EB.
- Contact financial auditor Ries for March 1997
  * This issue will be further discussed under agenda item 3
- 2nd draft "Position on CJD" of the Standing Committee on Quality Assurance
  * This issue will be further discussed under agenda item 7
- Brokerage day
  * Is tentatively scheduled for September 1997, but will be considered with the integrated set of EPFA actions.
- Newsletter
  * See above.

3. EPFA Finances

a. Draft financial statement EPFA 1996 (GA-9703)
Evers gives a short explanation of the surplus of 1996 and underlines that the surplus is exceptional. Gander, EPFA's treasurer agrees with the explanation.

b. Annual Auditor's Report (GA-9704)
In accordance with Article IX Section 3 of the EPFA statutes the General Assembly is requested to approve the annual auditor's report. The report is approved and the Treasurer and the auditor are discharged for the year 1996.

4. Secondment at the EPFA-secretariat

Evers reports in brief that he has invited all members to present candidates for the secondment. Only CSL - Australia had proposed a candidate, but after careful considerations this candidate was not accepted. Afterwards DRK-Springe also came forward with a candidate. Springe had indicated that it cannot financially support the secondment. It has been decided that EPFA will pay the salary. The candidate is a scientist, involved in PCR testing. Her primary task will be to provide technical/scientific expertise to the secretariat. The salary costs for 1997 will be paid with the 1996 surplus. For 1998 the membership fees will be raised as follows:

Cat I	< 50.000 l	ƒ 16.000 + 3.500
Cat II	50.000 - 150.000 l	ƒ 23.600 + 4.500
Cat III	150.000 - 300.000 l	ƒ 31.200 + 5.500
Cat IV	> 300.000 l	ƒ 38.800 + 6.500

5. Membership issues

a. Application for associate membership of Fundaçao Pro-Sange, Sao-Paulo, Brazil (GA-9705)
The General Assembly approved the associate membership of Fundaçao Pro-Sangue. Evers will inform the institute.

b. Miscellaneous
Further information is necessary for both the New York Blood Center and the National Institute of Public Health.

6. International developments

a. EMEA/CPMP/BWP
For 21 May 1997 a workshop will be jointly organised by EMEA/EPFA and EAPPI. The two main topics are "Plasma Master File" and "Nanofiltration". Each EPFA and EAPPI member institute is allowed to bring two participants to the workshop. Registration is necessary due to security measures at EMEA.

b. European Union
Van Aken reports about the recent meeting, organised by the WHO, on all aspect of CJD. Confusion was raised by an early press article and a Reuters press release, implying that experiments at NIH had shown transmission of CJD by blood transfusion. The meeting however looked at the available data and concluded that the safety of blood is not implicated, but that further studies were required. The meeting also addressed the concerns about the gelatine industry and discussed the latest information on variants.

c. Council of Europe
The text of the draft revised "Guide" has been distributed to the members for comments.

d. Other (international) developments
V.Aken recently visited the CSL plant and the Australian government. In Australia one is more interested in the regulatory developments in Europe than in the United States. Positive remarks were made about EPFA.

7. Reports from the Working Groups

Evers presents an overview of the main issues on the agenda's of the working groups (see attachments). The EB has agreed to rename the Standing Committee on Quality Assurance in Working Group on Quality Assurance.

8. Meeting of production experts

Evers gives a summary of the outcome of the recently held meeting at CLB of Production Experts (see attachments). Participants felt that the meeting was successful. CLB will be asked to submit the final report.

9. Report from the Executive Board

Van Aken gives an overview of the main items from the EB-meeting, including

- the ongoing discussion about an EPFA strategic plan
- the positive support for the introduction of ISBT 128
- the issue of EPFA liability, for which legal advice will be sought.

10. Format of future General Assemblies

V.Aken informs the General Assembly about the new structure of the Executive Board, existing of one (appointed) participant of each European member institute and a representative of the associate member institutes. In the Executive Board issues will be discussed which are necessary for the secretariat and the members. The General Assembly will become the opportunity for exchange of information. Today the start for the "new" format has been set by the presentation of 4 speakers.
Evers adds that in future the secretariat will try to organise the working groups a day before the General Assembly, so more staff of EPFA members can participate.
Walker wonders why only the Japanese Red Cross is present and no other associate member institute. Van Aken asks Numata if this new style GA is of use for the Japanese institute: Numata agrees. It is agreed that the other associate members will be questioned about the new format of the General Assembly.

11. Reports by EPFA member institutes

Belgium
Rits reports that CAF and CLB signed a letter of intent for collaboration.

England
Walker mentions a recent case of an HIV positive donation. A copy of the press release will be distributed.

Switzerland
Gander reports that the business year 1996 was a difficult year for ZLB, marked by many inspections ordered by authorities, recalls (CJD) and technical problems leading to recalls.
In 1996 ZLB launched the sale of two new products in Switzerland:

- in February "Recombinate SRK", a recombinant factor VIII product from Baxter;
- in April "Rhophylac SRK", a product developed by ZLB for the treatment of anti-D.

1996 can also be described as the year of inspections. In total ZLB was inspected 10 times:
- 4 times by FDA
- 1 time by the Canadian Bureau of Biologics
- 4 times by BAG and IKS (Swiss Health Authorities)
- 1 time by a company

1996 was additionally the year of recalls. These had to be carried out on one hand on order of the FDA because of the known CJD situation, on the other hand because of technical problems leading to PKA in Albumin, a new situation for ZLB.

The reorganization of the Blood Transfusion Service of the Swiss Red Cross led to a new structure of this body which is now made up of 13 Regional Blood Transfusion Services which are organized in the form of foundations. The Blood Transfusion Service ZLB was relieved from its responsibility for the overall Swiss blood provision for which the 13 regional foundations are now responsible.

France
Eisenmann reports about 3 issues:
- ongoing reorganisation of the BTS's from 150 centres down to 40
- the changing responsibilities between the blood agency and medicines agency
- the recent CJD-initiated recalls

Springe
Mohr reports that most blood transfusion services introduced HCV-PCR for pool testing (100 donations).
The Paul-Ehrlich-Institute proposes to introduce PCR testing for release of red cell concentrates.
Gander asks if there are differences in the tests used by Hagen and Springe.
Mohr confirms that there are differences. In Hagen the test is a more sensitive one. Standardization is necessary.

Denmark
Kongstad reports that the Danish Haemophilia Association asked for compensation for HCV-transmission. A decision has not yet been taken. He also mentions that Immuno has won the court case in Denmark, regarding the fractionation of Danish plasma.

The Netherlands
Buunen describes the ongoing reorganisation of the BTS's and CLB. The new organisation should be set-up by 1 January 1998. Buunen also mentions the letter of intent for collaboration with CAF.

Scotland
Cuthbertson reports that McIntosh has left the institute and his successor is Angus McMillan Douglas. SNBTS assists Slovenia with plasma fractionation. Plans are underway for PCR testing in mini pools.

Finland
Virkajärvi reports that in contrast with other countries there is no reorganisation going on in Finland.

Japan
Numata reports about (1) the storage system of source plasma. The plasma sent from the blood centers is identified by the match of both FD and the plasma's serial number. At present it takes about 1 month to use the plasma as source materials after the plasma arrives at the Plasma Fractionation Center. But to cope with post donation information, they are planning to change the storage period from one month to three to six months.
(2) Coping with past donation information. At present, a procedure manual at the Japanese Red Cross has been under way. Viruses concerned are HIV, HBV and HCV. The information consists of the report from blood donors, seroconversion of donors, adverse reactions from the transfusion, and the cases not covered by screening (HAV and CJD). At present this has been under a trial period. In any case, PCR testing has been carried out in the donors' retain sample and decides the treatment of plasma products. Retaining donor samples were introduced last September.
(3) PCR testing. Manufacturers perform PCR testing on final products. should the product be positive, it will not be acceptable in society. Therefore, it cannot be put on the market. However, the government has not accepted this PCR testing as donor screening. Also there is no set standard among the manufacturers.
(4) Viral inactivation of FFP. SD treated FFP has not been studied at the Japanese Red Cross. Methylene blue treatment is now at the stage of research.

12. Miscellaneous

- Plasma pool size.
  . It is proposed to have this item discussed by the WGQA and the production experts.
- Collaborative activities with third parties
  . EMEA workshop will be held on 21 May 1997 in London
- NAT workshop
  . The workshop will be held 20 June 1997 in London and is in full progress.
- RA symposium
  . Scheduled for 28-29 October 1997 in Amsterdam. The 4th EPFA/EAPPI Regulatory Affairs Symposium will focus on "Mutual Recognition and Harmonization".

13. Dates and venues of forthcoming General Assemblies

The President invites the representatives of the (associate) member institutes to host the next General Assembly, that is scheduled for April/May 1998.

14. Closure

Van Aken thanks all participants and in particular ZLB for its hospitality.