UK BTS/NIBSC

WORKING GROUP ON PLASMA FRACTIONS

Minutes of 6th meeting at NIBSC, South Mimms, Hertfordshire at 10.30am on Wednesday, 29 June 1988.

Present:

Dr D P Thomas	(Chairman)	NIBSC
Dr D R Bangham	(Secretary)	NIBSC
Dr T W Barrowcliffe		NIBSC
Dr B Cuthbertson		PFC, Edinburgh
Dr P Harrison	(vice Dr Snape)	PFC, Elstree
Dr K T Forman		RTC, Sheffield
Dr J K Smith		PFL, Oxford
Dr R Thorpe	(for immunoglobulins)	NIBSC
Dr A R Hubbard	(for albumin)	

Apologies from Dr T Snape.

Precirculated papers included:

- Agenda
- Minutes of 5th meeting of WG.PF (April)
- Draft introduction section on Plasma Fractions (Dr Thomas)
- 1st draft - Albumin (Dr Cuthbertson)
- 1st draft - Immunoglobulins (Dr P Harrison) 3 June
- Draft paper - Reducing the Risk of Transmitting HIV by Blood Products (Dr Thomas)
- 25 April draft - Specification for Plasma Intended for Fractionation
- 25 April draft - Factor VIII Concentrates
- 25 April draft - Factor IX Concentrates
- 25 April draft - Validation of virus inactivation procedures

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1 Minutes of 5th meeting (April) were accepted.

2 Matters Arising

2.1 - An ad hoc meeting of Dr Napier (WG Microbiology) and virologists from NIBSC had been held on 27 June 1988 to discuss the measures to avoid/remove/inactivate viruses in plasma and plasma products. Several amendments were suggested for the 25 April draft paper Validation of Virus Inactivation Procedures of the WG.PF. Dr Cuthbertson will amend accordingly and send it to members of the WG.PF, WG.M and the ad hoc meeting. Minutes of the ad hoc meeting will similarly be distributed.

2.2 - There is still no progress in the preparation of national working standards for HBsAg or for HIV because no suitable safe ampouling premises are available.

2.3 - The 1988 revised WHO document on the Requirements for blood and blood products had just been received from Geneva. It would be circulated to members of the Working Groups with the invitation to make comments - which could be sent direct to Dr Magrath in Geneva or via Dr Thomas - for consideration by the Expert Committee on Biological Standardization, in October. (The WHO paper for Requirements for Immunoglobulins has not yet been sent out from Geneva).

2.4 - The summary of the meeting on 30 March at NIBSC on removal/inactivation of viruses in blood has been distributed. A review of another meeting held on the same topic by manufacturers has recently been published. It was suggested that a paper should be prepared for the CSM Biological Sub-Committee.

2.5 - Specification of an upper limit for ALT screening cannot yet be made until there was evidence that it was useful as an indicator of hepatitis activity. (The current 3 centre trial may provide a suitable figure).

2.6 - Evidence of the value of the Chiron test for non-A non-B hepatitis is not yet available in this country. Future developments will be watched with much interest.

3 Meetings of Chairmen of Working Groups on 25.5.88

3.1 - It was suggested that the draft documents on characteristics of Factor VIII and Factor IX products should be sent for comment to Haemophilia Centres. The WG, however, recommended that this should not be done until the whole guideline/requirement document had been compiled and was also sent to RTC's at the same time.

3.2 - The two draft documents on bulk plasma (prepared for the Plasma Fractionation Laboratory and for the RTC's by Dr Harrison and Dr Cuthbertson respectively) need to be correlated so as to eliminate any incompatabilities, or possible duplication, by the two authors.

3.3 - The one document describes the qualitites of the bulk plasma collected for fractionation, the other describes the in-process control applied during fractionation. The differing purposes of these two documents should be explained in the general introduction to the document.

3.4 - The minimum potency of anti-D in plasma donations acceptable for the preparation of anti-D immunoglobulin product, is not yet agreed.

3.5 - The issue as to whether the UK BTS/NIBSC document should be suitable to apply only to the UK BTS - or whether it should also explicitly apply to manufacturer's products from abroad, is not yet resolved. Dr Wagstaff, chairman of the BTS/NIBSC Liaison Group is intending to discuss this with officials at the DHSS.

4 The Design/Characteristics of an Albumin Products
(1st draft from Dr Cuthbertson

4.1 - The paper aimed to highlight aspects not covered by the Pharmacopoeia specification of the final product.

4.2 - The limit to be set for the estimated concentration of endotoxin is uncertain: products from manufacturers abroad are consistently below 0.5 iu endotoxin/ml, those of the two UK blood product laboratories average about 2.5 iu/ml or below by the LAL gelation test. All such batches pass the BP rabbit pyrogen test.

4.3 - A note in the introduction about the type of use of the product will help to explain reasons for certain specifications.

4.4 - Various amendments will be incorporated by Dr Cuthbertson.

5 Immunoglobulins
(1st draft 3.6.88 from P Harrison)

5.1 - An introduction should comment on the wide diversity of the different specific immunoglobulins and the purposes/circumstances for which they are given, (but not in the individual detailed indications listed in this draft).

5.2 - Immunoglobulins intended for i.m. and for i.v. administration should be dealt with in separate sections.

5.3 - A section on a limit for haemagglutinins should be added.

5.4 - A comment on stability, and a test for stability should be added.

5.5 - Several other amendments will be incorporated in another draft by P Harrison.

6 The next meetings will be on Tuesday, 6 September and Wednesday, 5 October, at 10.30am at NIBSC.

Since the Liaison Group will meet on 8 September, it is expected to distribute copies of the latest drafts from all Working Groups ten days before, so please send amended papers to NIBSC before then.