UK BTS/NIBSC

WORKING GROUP ON PLASMA FRACTIONS

Minutes of 2nd meeting at NIBSC, South Mimms, London
11.00am - 4.00pm Tuesday, 24 November 1987

Present:

Dr D P Thomas	(Chairman)	NIBSC
Dr D R Bangham	(Secretary)	NIBSC
Dr T W Barrowcliffe		NIBSC
Dr B Cuthbertson		BFC Edinburgh
Dr J K Smith		BPL Elstree
Dr T J Snape		BPL Elstree
Dr R Thorpe		NIBSC

Precirculated papers included:

- Minutes of 2nd meeting of 17 June 1987 (PF.WG.87/2).
- Photocopies of WHO document 'Collection, Fractionation, Quality Control and use of blood and blood products, 1981', with proposed draft amendments of 'Requirements'.
- List of International and British Standards for substances in haemostasis.
- Copies of relevant monographs from BP Addendum 1986 (pp 517-518).
- Agenda.

Tabled:

- Draft specification for viral inactivation during the freeze drying and heating of clotting factor, concentrates manufactured in the UK. B Cuthbertson.

1 Minutes of 1st meeting were accepted. (Coded PF.WG.87/1).

2 General

Liaison: At the 2nd meeting of the BTS/NIBSC Liaison Group it was recommended that members of each Working Group should be allocated to liaise with other relevant Working Groups. A Director of an RTC is needed to liaise with the WG on Blood Components for specifications of the quality of the types of bulk plasma sent to Plasma Fractionation Centres (PFC). Dr Thomas agreed to write to Dr Wagstaff requesting him to nominate an RTC Director to join this WG.

Liability: as stated in a paper dated September 1987 'Product Liability Considerations for the Blood Transfusion Service' by R A Moore (DHSS), where any damage is caused by a defect in a product, the producer shall be liable for damage. If the producer cannot be identified, then the supplier of the product shall be liable. The person suffering the damage has to prove that the damage was caused by the defect but does not have to prove negligence on the part of the producer. 'Liability' will come into force in the UK on 1 March 1988. The EEC Directive on Liability comes into force on 1 July 1988.

The nature of various 'control' documents and the means to effect control of 'biologicals' in the UK were extensively discussed. (See also minutes of 1st meeting of WG on Microbiology). It is proposed that the BTS/NIBSC 'guidelines' document will follow, where appropriate, the general structure and style of the WHO 'Requirements for the collection, processing and quality control of human blood and blood products'. This document, produced in 1977 (see 27th Report of WHO Expert Committee on Biological Standardization, 1978) is to be revised and updated in December 1987. The form of such WHO 'Requirements' has been developed over many years and is used for control of a wide variety of 'biological' products.

The proposed BTS/NIBSC Guidelines will, like the WHO Requirements, include 'general considerations' for each type of biological, and invoke various other general requirements such as proper documentation, national inspectors, and the control testing and batch release of products by a National Control Authority. Where general tests (eg for sterility and for pyrogens) are described in official publications, such as the British Pharmacopoeia, these documents will be referred to. Only certain specialised procedures may be spelled out in detail. Where relevant, distinction is made between those guidelines that are 'compulsory' (and must be complied with), and those that are desirable (should be complied with), or flexible, or tackled in various different ways.

Members were therefore asked to prepare their drafts in the general style of the WHO 'Requirements'.

Working Group on Microbiology has been formed, as recommended at the 2nd meeting of the BTS/NIBSC Liaison Group. It is expected that its work will consist largely of responses to requests made by other Working Groups.

3. Aspects of Control of Dried Factor VIII Concentrate were discussed, as an example of the aspects to be included in guidelines for a product. They included:

- The official name and definition
- Quality of the bulk source plasma, specifications
- Tests for HIV and Hepatitis, quarantine of plasma
- Other microbiological tests (total viable count)
- Pool size minimum/maximum, methods of taking samples for tests
- Rejection criteria
- Characteristics of the intended product eg solubility, potency limits
- Concentration procedure
- In-process monitoring
- Virus inactivation procedures and validation of tests and process
- Documentation for the product and process
- Specification of the final product eg as BP monograph
- General comments on the use of standards, assays, pass/fail confidence interval

It was agreed that the 1st draft would be prepared by BC and TS; on viral inactivation by BC and JS; comment on standards, etc, by DT and TB.

4. Aspects of Control of Albumin Solution

- Proper name and definition
- Types of bulk source material include:
  . Fresh frozen plasma (FFP), after removal of Factor VIII
  . Time expired plasma (TEP), handled differently
  . 'Recovered' plasma, 'cryosupernatant', after removal of Factor VIII and Factor IX etc
  . Recovered plasma after removal of immunoglobulins
- Criteria for rejection of individual donations
- Quarantine
- Microbiological tests on pools of source donations
- General characteristics of product;
- Outline of production/extraction process
- In-process testing/monitoring
- Virus inactivation procedures, validation of process and tests
- Documentation of process and batch
- Final product specifications
  - as BP monograph
  - additional ones: PKA test, Aluminium, caprylate, LAL test
- Stability
- Criteria for release of batch

Draft to be prepared by TS and BC
Standards and assays of F.VIII and F.IX by DT and TB

5. Factor IX

Similar style first draft for F.IX product proposed by JS.

6. These drafts will be distributed to the WG several days before the next meeting - 19 January 1988 at 10.30am at NIBSC.