MEDICINES INSPECTORATE/SNBTS ACTIVITIES:

CURRENT UNRESOLVED PROBLEMS

January 1984

JDC/CSA/1/84/3

SNBTS Directors would wish to remind PSG members of what they believe to be the current general SHS policy with regard to Good Manufacturing Practice as it affects the SNBTS. It is assumed by Directors that whilst there is no legal requirement for SNBTS establishments to hold Manufacturing and Product Licences, every effort should be made to develop a scenario in which the legal position is ignored. Thus SNBTS establishments should evolve practices which would enable them to secure both Manufacturing and Product Licences.

At the present time there are 4 areas, with reference to the operational interface between the Agency and Medicines Division, which are of concern to SNBTS Directors and which require exploration. These can be summarised as follows:-

(a) RTC General Response to Medicines Division Inspectors

The SNBTS Directors regret that there has so far been no response from Medicines Division to this document, which had the approval of the BTS Sub-Committee and was forwarded to Medicines Division on the 2nd June, 1983. As a consequence the Agency has not been advised with regard to an Inspection Policy (as requested, p. 1 of General Response), has not been briefed on the formal position with regard to requirement for licences (Manufacturing and Product) following expiry in June 1981 (p. 1/2, General Response) and has not received the requested comment on its proposed specifications for blood processing accommodation (p. 3/4 and Appendix II, General Response).

(b) I A G Reports (RTCs)

The SNBTS Directors were disappointed by the quality of these Reports. There was a significant lack of detail and in the absence of both a clearly defined Inspection Policy and comment on the proposals for Blood Processing Areas the Directors and their staff remain uncertain as to the overall commitment of Medicines Division to GMP within the SNBTS.

(c) Proposed Revision of "Red Book" (Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Associated Sterile Fluids)

The Agency has received a request for advice from Medicines Division as to whether there is a need to revise the "Red Book" and, if so, what might be its scope.

The SNBTS Directors have considered this matter and take the view that there is a pressing need for revision, that this would best be done by a small group, chaired by Mr D Haythornthwaite (DHSS Medicines Division) with NBTS and SNBTS representation. In considering the advice requested with regard to the scope of the revised version the SNBTS Directors believe it should cover those aspects as delineated in the Appendix and would propose that the Agency transmits these views to Medicines Division.

APPENDIX

SNBTS PROPOSAL FOR THE SCOPE OF REVISED VERSION OF "STANDARDS FOR THE COLLECTION AND PROCESSING OF BLOOD AND BLOOD COMPONENTS AND THE MANUFACTURE OF ASSOCIATED STERILE FLUIDS"

GENERAL COMMENTS

The revised version would include some general comments on the following aspects of good manufacturing practice:-

1. Accommodation.
2. Documentation.
3. Quality Assurance (with the provision of detailed information for blood components in an Annex).
4. Staffing levels, line management and training.
5. Services supplied.
6. Maintenance of equipment.
7. Transport.
8. Data tracking with particular reference to actioning adverse reactions to blood and blood components.

SPECIFIC AREAS

1. Donor Recruitment/Sessional Organisation

Particular reference in this area should be directed towards the screening out of high risk blood donors, production of high quality blood donations and provision of data bases for adverse reaction actioning.

2. Transportation/Blood Holding (including Quarantine) Procedures

Particular attention would be directed towards physical damage, temperature control, duration of holding procedures and quarantine facilities.

3. Donation Testing (Blood grouping, Syphilis and Hepatitis testing)

Particular attention would be directed towards validation of existing technology, data handling and donation clearance systems.

4. Donation Processing

The foundations for this area are already covered in the existing edition. An update and extension is required.

5. Blood Bank

Particular attention should be directed towards temperature control, relevant aspects of stock control and special storage needs (platelet concentrates). There will be a requirement to include an identical commitment from Hospital Blood Banks.

6. Blood/Component Issue and Transport Facilities

Particular attention will be required to be directed towards those aspects related to safety of transfusion practice.