NOT FOR PUBLICATION
COMMERCIAL IN CONFIDENCE
COMMITTEE ON SAFETY OF MEDICINES

CSM/86/5th Meeting

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

CSM/BIOLS/86/ 3rd Meeting

MANUFACTURE OF BLOOD PRODUCTS FROM PLASMA DERIVED FROM UNSCREENED DONORS

The three main classes of blood products currently controlled by the National Institute for Biological Standards and Control are 1) blood clotting factor concentrates, such as Factor VIII; 2) immunoglobulins and 3) albumin (including plasma protein fraction). NIBSC now receives protocols and samples from all the licensed commercial manufacturers, and also the two U.K. manufacturers, namely BPL, Elstree and PRC, Edinburgh.

Screening of blood donors for the presence of anti-HTLV III antibodies was introduced in the United States in the spring of 1985, and in the U.K. in October 1985. The Licensing Authority, on the advice of the CSM(B), has written to all manufacturers, requesting that Factor VIII and immunoglobulins should be prepared from donors that have been screened for anti-HTLV III antibodies. In the case of immunoglobulins, the manufacturers have been given until July 1986 to meet this requirement. In the case of Factor VIII, all manufacturers are currently submitting batches that have been derived from screened donors. To the best of my knowledge, no information has so far been received, either by the Licensing Authority or at NIBSC, specifying the type of diagnostic test kit that is used in screening for anti-HTLVIII antibodies.

Samples of albumin are still being sent to NIBSC in which the product has been prepared from donors that have not been screened for anti-HTLV III antibodies. All albumin products are heated at 60° for 10 hours in the wet state, and this is believed to inactivate the viruses of HTLV III and hepatitis; no case of AIDS has been reported from recipients of albumin. The general view is that albumin is a safe product, and any contaminating viruses are inactivated by heat treatment. However, it could be argued that all blood products should now be prepared from

screened donors. On the grounds of Good Manufacturing Practice, it is preferable that plasma entering a manufacturing plant should come from screened donors, and it is an unnecessary risk to allow the same plant to use plasma derived from both screened and unscreened donors.

The Committee may wish to consider that the Licensing Authority should be advised that all blood products marketed in the U.K. should now be prepared solely from plasma whose donors have been screened for the absence of anti-HTLV III antibodies.

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COMMITTEE ON SAFETY OF MEDICINES

BIOLOGICALS SUB-COMMITTEE

Manufacture of Blood Products from Plasma Derived from Unscreened Donors

In reference to Dr Thomas's paper for CSMB May 1986 a list of currently licenced products containing human blood is appended.

Normal immunoglobulins and Factor VIII preparations are not included in the listing since they are already subject to action regarding screening of plasma for HTLVIII antibodies.

A list of products holding Product Licences of Right which are alleged to contain blood, has been submitted to the Secretariat to the CRM, for inquiry as to the source of blood used. Most of these products in fact contain animal blood.

It is noted that from September 1986 all blood products subject to FDA licencing action will be required to be manufactured from donations individually tested for HTLVIII antibodies.

MEDICAL RECOMMENDATION

1. All products listed in this paper should be prepared from plasma individually tested for HBSAg and anti HTLVIII. The companies involved should be asked to apply for variations to their licences to cover this point.

2. Details of the method of testing for HBSAg and HTLVIII should be supplied.

3. All preparations not subject to the batch release procedure should be required to comply with it.

DR F ROTBLAT

PL NUMBER	PRODUCT	COMPANY
0003/0087	Humotet human tetanus immunoglobulin	Wellcome Foundation
0022/5008	Albumin Kabi	Kabi-Vitrum
0032/0107	Atgam Injection	Upjohn
0034/0164	Aggregated albumin powder	Squibb
0055/0071 0072	Plasbumin-5 Solution Plasbumin-20 Solution	Miles/Cutter
0068/0041	3M brand Albumin microspheres 99MTC Labelling Uit	3M Health Centre
0086/0047	Factor XIII Concentrate	Hoechst UK
00116/0051 0053	Buminate 5% Human Albumin " 20% "	Travenol
0116/0142	Plasma Protein Fraction 5%	Travenol
0215/0002	Human Plasma Protein Fraction	Immuno
0215/0009	Human Albumin 20%	Immuno
0221/5011	^{125}I Human Fibrinogen	Amersham Int
0221/5060	^{125}I Human Serum Albumin	Amersham Int
0221/5063	131I Human Serum Albumin	Amersham Int
0231/0056 0057	Ambuminar-5 Injection Albuminar-20 Injection	Armour Pharmaceutical
03132/0017	Albumin Nordisk 20%	Nordisk UK
03586/0008	Pulmolite Technetium TC99M Aggregated Albumin Kit	F Nen Medical Products
05849/0005	" " "	Du Pont (UK)
	Review Products	
0770/5017	Vigour AIDS tablets	Wessex/Herbalist
0857/5017	Malt extract with Haemoglobin Syrup	Evans Medical
00904/5043	Golden Health Tablets	Kerbina/Vindor

(The source of blood for these three products is not known)