DRAFT POLICY FOR THE ISSUE OF BLOOD PRODUCTS FROM PROTEIN FRACTIONATION CENTRE

1.0 INTRODUCTION

In the light of continuing public, media and parliamentary interest in the impact of AIDS on the safety of blood transfusion and the safety of blood products, it is essential that the PFC and SNBTS has, in place, an agreed policy relating to the manufacture and issue of blood products. Such a policy will be constrained by a number of factors.

(a) Current state of scientific knowledge.

(b) Plasma supply situation (existing strategic plasma stocks).

(c) Product supply situation (status of existing product stocks).

(d) Regulatory policies from DHSS licensing division (licenced products only).

(e) Operational impact and feasibility of options in respect of National Self-Sufficiency.

(f) Political preferences - promulgated by SHHD but as yet undefined.

(g) Policy (? adopted) by DHSS/BPL - see attached letter from Dr Snape and associated Parliamentary questions and answers.

Presented below is a summary of the present position within PFC and an outline policy for formal consideration by SHHD/SNBTS.

2.0 PLASMA STOCKS

2.1 Fresh Plasma (Normal)

The PFC has operated a policy of entering only accredited plasma into process since January 1, 1986 which led to an expectation that all FVIII and FIX issues from PFC would be derived from such plasma from August 1986. Recent and detailed examination of plasma input records have indicated that despite vigorous attempts to exclude untested plasma from process during the past 12 months occasional plasma pools have been 'contaminated' with untested plasma. The proportion of untested donations in these pools is very low (<5%) and attempts are now being made to retrospectively accredit these donors. It is anticipated that the level of untested plasma in such pools can in this way, be reduced to <1%.

Policy

All fresh plasma (normal) entering process after January 1 1987 has been from tested donations. All normal plasma in stock is accredited.

2.2 Outdated and Cryosupernatant Plasma (Plasma Stockpile)

This plasma is used solely for the manufacture of albumin products which are considered to be rendered safe by pasteurisation at 60°/IU. Approximately 30% of this stockpile (7,000 kg) is tested plasma. Approximately 14,000 kg was collected and received before testing began in October '85.

Albumin product has been manufactured from untested plasma pools during 1986 and is now part of the National Stock.

Policy

Outdated and cryosupernatant plasma from untested donations will be used but only for the manufacture of albumin products which are subject to terminal wet pasteurisation.

2.3 Hyperimmune Plasma (and Intermediate Pastes and Powders)

There exist substantial and essential stocks of intermediate pastes and powders derived from untested plasma.

The raw plasma stock position is as follows:

Plasma Type	Hep B	Tetanus	Zoster	Anti-D	Rabies	Rubella	Measles	CMV
% Tested	100%	30%	0%	50%	100%	100%	100%	70%

Policy

All existing stocks of hyperimmune plasma, intermediate powder and pastes will be processed to finished product and issued.

NB. Strenuous efforts will be made to test existing stocks of untested plasma. Some untested plasma may be salvaged by retrospective accreditation of donors.

3.0 PRODUCT STOCKS

3.1 Intravenous IgG (Normal)

All PFC stocks are derived from tested plasma.

Policy

All IV IgG (Normal) Issued After March 1, 1987 from PFC has been from tested plasma.

3.2 Intravenous IgG (CMV, Measles and Tetanus)

All existing stocks are derived from untested plasma. These stocks are

fairly substantial.

Policy

Existing stocks (all of which are derived from untested plasma) will be issued until exhausted.

3.3 Intramuscular IgG (Normal)

All existing PFC stocks are derived from tested plasma.

Policy

All IM IgG (N) issued from PFC has been manufactured from tested plasma after March 1, 1987. IgG (For Use With Measles Vaccine) is now derived exclusively from tested donations.

3.4 Intramuscular IgG (Specific)

All existing stocks of product are derived from untested donations as are intermediate materials (pastes and powders).

With the exception of Zoster, there exists, at PFC, stocks of tested plasma.

Policy

All existing stocks of specific immunoglobulin products (which are derived from untested donations) will continue to be issued until exhausted.

All stocks of plasma and intermediate materials will be processed to finished product and issued.

3.5 Factor VIII

All existing stocks of FVIII at PFC are derived from tested plasma. There are residual stocks of FVIII from plasma pools described in 2.1.

Policy

As from January 1, 1987, all FVIII issued from PFC has been derived from screened donors.

3.6 Factor IX

All existing PFC stocks are derived from tested plasma.

Policy

From March 1, 1987, all FIX issued from PFC has been derived from screened donors.

3.7 Albumin Products (SPPS and Human Albumin)

There exist substantial stocks of product derived from untested donations and there are significant stocks of non-tested outdated plasma awaiting processing. This plasma is required to maintain self-sufficiency in albumin products.

Policy

PFC will issue all albumin products including those batches derived from non-tested plasma.

3.8 PPSB (Four Factor FIX Preparation)

This product has been discontinued.

4.0 CRITERIA FOR RELEASE OF PRODUCTS ASSOCIATED WITH POTENTIALLY INFECTIVE DONATIONS

An SOP (2nd revision) describing the action required following receipt and processing of infective donations is appended.

R J PERRY
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