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DHSS

With the Compliments of

Department of Health and Social Security

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Your reference
Our reference

Brigadier R F Blackburn
Assistant Surgeon General (Medical Supply)
First Avenue House
High Holborn
LONDON
WC1V 6HE

9 September 1988

Dear Brigadier Blackburn

RE: HUMAN ALBUMIN FOR STRATEGIC RESERVE

I met with Lt. Col. Thomas at the Army Blood Supply Depot on 5 September regarding the above and he suggested that the next step was to approach you.

The attached paper explains the background to the issue. Briefly, the Blood Products Laboratory at Elstree are storing a large amount of frozen human plasma which was collected from donors before a test for HIV infection had been developed. An expert committee have advised DHSS that albumin made from this plasma would be perfectly safe to use because the pasteurisation process would inactivate any HIV present. However Health Ministers have previously given undertakings that all blood products used in the NHS are made from HIV tested plasma. We are reluctant to advise Ministers to withdraw this undertaking. The alternatives before us are therefore to discard the plasma or offer to process it for MOD strategic reserves. The value of albumin which could be made from the plasma is around £6m at world market prices.

I understand from Lt. Col. Thomas that he has already let you know that he is in agreement with the view of the expert committee that the albumin would be perfectly safe to use. A view which I understand is shared by the Director of Army Pathology Col. Robson and the Army Pharmacist Graham North.

The Army strategic requirement based on the most recent estimates from the Dep. Med Surg BAOR would appear to broadly coincide with the amount of albumin which could be made from plasma held in England and Scotland. As you may know, the Blood Products Laboratory have recently moved into a new production unit and intend to stop production in their old building. We therefore have a unique opportunity to continue production of NHS albumin in

the new building whilst processing albumin for a strategic reserve in the old facility. To seize this opportunity we will need to reach a decision in principle on the plasma stockpile within the next month or two. I would therefore welcome your view on whether MOD would be willing to purchase albumin from this source. DHSS through the NHS has already incurred expenses estimated at £1.5m in harvesting the plasma. The cost of processing through to bottled albumin would be an additional £600,000 giving a total cost of £2.1m.

I am not empowered to discuss the costs of the small amount of Scottish plasma but for your guidance it is likely to be similar to English costs giving a total cost of £2.35m. We would hope that you will agree that it would be reasonable to reimburse us for these costs.

I would be happy to provide any further particulars which you might need and apologise for the narrow time frame which the impending closure of the old laboratory forces upon us.

I look forward to hearing from you.

Yours sincerely

GRO-C

Dr R J Moore
Health Service Division

cc: Col. D Robson DA (Path)
Lt. Col. M Thomas

PROVISION TO MOD OF ALBUMIN TO BE MADE FROM STOCKS OF HUMAN PLASMA COLLECTED BEFORE THE INTRODUCTION OF SCREENING FOR HIV ANTIBODIES

Summary

1. 176 tonnes of frozen human plasma collected before testing of blood donations for HIV started in October 1985 is stockpiled at the Blood Products Laboratory (BPL) at Elstree. An expert group have advised that the plasma may be safely used to produce certain blood products such as albumin where the manufacturing procedure has been shown to inactivate HIV and other viruses. It has been suggested that albumin made from this plasma could be used by MOD to establish or maintain a strategic stockpile.

Background

2. Blood plasma is sent by Regional Transfusion Centres to BPL at Elstree. The plasma is processed into a range of blood products including Factor VIII for haemophiliacs, albumin for burns victims and immunoglobulins which increase resistance to infections. Regions agreed in 1983 to the build-up of a stockpile of frozen plasma at Elstree in anticipation of the opening of the new BPL with its threefold increase in manufacturing capacity.

3. Screening of all blood donations for HIV antibodies started in October 1985. Plasma stockpiled before that date is therefore unscreened and is at present held in quarantine. Current production is from screened donations only.

4. In a Parliamentary reply on 29 July 1986 a junior Minister of Health, Baroness Trumpington, explained that all blood products used in the NHS were made from HIV screened donations.

5. The Committee on Safety of Medicines (CSM) now insists all licensed albumin products are made from screened donations. Products from BPL are currently outside the licensing system.

6. Unscreened plasma is not needed to maintain production at BPL or to maintain output to the NHS. The planned build-up of the plasma supply by Regions should be sufficient, but any suggestions this plasma is not be used might have a detrimental effect on donations.

Size and Value of Plasma Stockpile

7. The stockpile of unscreened plasma at Elstree consists of about 176 tonnes (the product of roughly three quarters of a million blood donations). The value of albumin alone which could be made from this plasma is around £6m.

A much smaller stock of around 20 tonnes is held in Scotland by the Plasma Fractionation Centre.

8. About one quarter of this plasma was given by regular donors who have since given further donations which have been screened and found satisfactory. This plasma which can be identified is referred to as 'retrospectively validated'.

Advice of Expert Group

9. A group of experts was convened by DHSS to consider whether blood products could safely be made from the unscreened plasma (Annex A lists the experts and summarises their views). The different types of blood product undergo different processing treatments, the experts advice is therefore particular to the product and may be summarised as follows:

a) Retrospectively validated plasma may be considered as effectively tested as that tested immediately after donation. It is therefore as safe as normally tested plasma and can be used to make all blood products.

b) During manufacture, albumin is given a pasteurisation heat treatment which inactivates all viruses. There have never been any cases worldwise of viral infection associated with treatment with correctly pasteurised albumin. In the view of the experts, unscreened plasma can safely be used to make albumin.

The CSM have not been challenged over their current insistence on use of screened plasma.

Scottish Interest

10. The Scottish equivalent to BPL, the Protein Fractionation Centre, has stocks of untested plasma products at different stages of the production cycle. SHHD too have sought expert advice. Their experts went considerably further than the English group and agreed that partially processed products and finished stocks of immunoglobulins could also be safely used.

Considerations for Use

11. DHSS officials accept the expert view that medically and technically unscreened plasma can safely be used to make albumin.

Presentationally however there is concern that NHS patients would be worried that they were being put at risk from AIDS for reasons of economy. It has therefore been suggested that the plasma could be processed to form a strategic reserve for use in case of war. This would, from a DHSS perspective provide a valuable service to MOD, avoid wasting the valuable resource which the plasma represents, and avoid political repercussions over the use of products from untested plasma on NHS patients. Even were product licensing to be introducted for other BPL products, strategic war reserves would be exempt, thus avoiding conflict with the CSM.

12. The advantage to be gained by MOD would be a considerable reduction in the cost of their strategic stockpile although DOH would expect to be reimbursed for the cost of collecting and processing the plasma.

Way Forward

13. MOD are asked to agree whether in principle they are interested in albumin from this source. Assuming they are interested they are further asked to define the quantities and timescale of their requirement. Unlike other strategic reserves, the NHS would not buy back unused product nearing the end of its shelf-life. The BPL intend to stop production in their old facility shortly but would keep it open to process the stockpiled plasma if needed. This unique opportunity demands an early decision.

14. MOD, DHSS and SHHD will need to agree the way in which the Health Departments should be reimbursed.

ANNEX A

Expert Committee

Professor J Collee	Chairman Biological sub-committee of CSM
Dr H Gunson	Consultant Adviser in Blood Transfusion
Dr P Kernoff	Director, Haemophilia Reference Centre, Royal Free Hospital
Dr R Lane	Director, Blood Products Laboratory
Dr P Mortimer	Director, Virus Reference Laboratory PHLS
Dr R Perry	Director, Plasma Fractionation Centre
Dr G Schild	Director, NIBSC
Dr D Thomas	NIBSC
Dr J Smith	Director PHLS
Dr D Tyrell	MRC
Professor A Zuckerman	London School of Hygiene & Tropical Medicine
Dr E Harris - Chairman	DHSS

The above group met on 16 January 1987 and on 15 June 1987. Their consensus views are summarised below:-

1. All the epidemiological evidence throughout the world indicated that albumin was a safe product when processed correctly and has not been associated with the transmission of any infection. It was agreed that prior to 1982 when blood products were first linked to HIV transmission it had to be assumed that substantial amounts of contaminated plasma had been tractionated. There was no evidence of HIV transmission from that material through the use of albumin. This applied particularly to Japan who had used up to 40% of the USA output of albumin. Japan was only now just seeing its first cases of HIV infection. As in western nations these were being found in the high risk groups.

It was agreed by those present that the process of preparation of albumin (heating to 60^{o}C for 10 hours) produced a safe product.

2. Retrospective Assessment of Single Pack FFP Untested for HIV Antibody at Source

The group confirmed the view that provided good manufacturing practices were enforced, fresh frozen plasma from donors who subsequently had given blood which had tested negatively could be regarded as safe.

3. Use of Time Expired Plasma (TEP) and Residual Fresh Frozen Plasma (FFP)

It was agreed that following on the decision on the safety of processed albumin above, it would be acceptable to use the 120 tons of TEP and approx 15 tons of 'residual' FFP to make albumin. This decision was subject to the satisfactory resolution of GMP arrangements as discussed below.

4. Good Manufacturing Practice

It was agreed that GMP procedures required for the processing of the untested plasma to albumin should be discussed with the Medicines Inspectorate and resolved to their satisfaction.

It should be emphasised that the discussion of the risks and benefits of using the residual 15 tonnes of FFP and 120 tonnes of TEP plasma stockpile was related solely to the production of albumin. The use of it for the production of immunoglobulins was not considered as it was not proposed for this stockpile.