File - CB4A

Reference .....

MGH 25/3.

Mr Harris

Parliamentary

PQ 3056

A suggested reply is attached. Background notes and supplementary questions are provided under the following headings.

Flag A - The New Blood Products Laboratory + Supplementaries

Flag B - Safety of Blood Products + Supplementaries

Flag C - The Plasma Supply + Supplementaries

Flag D - Self-Sufficiency in Blood + Supplementaries

Flag E - Previous Question on the Unscreened Plasma stockpile.

GRO-C

R J MOORE
HS1A
A403A AFH
EXT GRO-C

25th March 1987

CODE 18-78

PQ3056
Hans no
Col. No

The Baroness Masham of Ilton- To ask Her Majesty's Government why there is a delay in implementing development of the National Blood Products Laboratory Scheme.

SUGGESTED REPLY

In 1981 approval in principle was given for the construction of a new Blood Products Laboratory (BPL) at Elstree.Construction began in May 1983.

To enable the building to be completed earlier than traditional methods would allow,a "fast track" design and build contract was adopted.When an innovative unit like the laboratory is built under this method, it is extremely difficult to forecast the completion date accurately at the outset.At that time our working assumption was that the new BPL would be completed at the end of 1985 or early 1986.There is no single identifiable reason for the building taking longer than expected other than the complexity of the design being greater than anticipated.

The building will still have been completed 2 or 3 years earlier than traditional contracting methods would have allowed.

However,I am now pleased to say that the building will be officially opened at the end of April.After commissioning,limited production will begin later this year. Self-sufficiency will follow.

THE NEW BLOOD PRODUCTS LABORATORY (BPL)

Background Note

1. The BPL processes plasma collected from blood donors in England and Wales to make a variety of blood products. Primarily these are a) coagulation factors such as Factor VIII used by haemophiliacs to make their blood clot b) albumin for burns victims and c) immunoglobulins which increase resistance to certain diseases.

2. The new BPL will process 450,000 litres of plasma to make England and Wales self sufficient in these products. Their value to the NHS has been estimated at £60m.

3. When approved for the new laboratory was given, it was recognised that early completion would give financial benefits since our dependence on imported blood products would stop. A 'fast track' design and build contract was therefore used. There is inevitably less precision on cost and time in such a contract since designing and building proceed together. The original estimates of £21.1m cost and completion in late 1985/early 1986 have been exceeded.

4. Present estimates are £60m cost and completion by May this year. The Duchess of Gloucester will open the laboratory on 29th April.

5. A complex plant cannot go into full production at once. It is estimated that it will take 18 months to reach full production ie during 1989.

Supplementary Questions

Q. What was the original estimated cost of the new Blood Products Laboratory?

A. The original working assumption was £21.1m.

Q. What is the accepted cost of the new blood products laboratory?

A. The laboratory has been fully funded throughout and it is anticipated that the final cost will near £60m.

Q. What has the cost of the new blood products laboratory increased?

A. The complexity of the plant has also involved increased costs. The Government has ensured that this project has been fully funded to achieve the earliest completion date.

Q. What products will the new Blood Products Laboratory make?

A. The main products will be coagulation factors such as Factor VIII for haemophiliacs; albumin for burns victims and immunoglobulins which increase peoples resistence to certain diseases.

Q. What will be the value of these products to the NHS?

A. It has been estimated that the new BPL will be able to make products worth up to £60m for the NHS.

Q. Will the new laboratory be able to sell its products outside the NHS?

A. Not all the constituents of the human plasma are needed by patients to th same extent. Rather than waste those constituents which are surplus to NHS requirements, they will be processed into products which will be sold commercially. Money arising in this way will benefit the NHS.

Q. When will we be able to stop depending on imported Factor 8?

A. It is not possible for a complex pharmaceutical plant to reach full production immediately but it is expected that after commissioning, limited production will begin later this year. On current predictions, substantial supplies of Factor VIII will be available during 1988 potentially reaching 75% of present requirements. Self sufficiency should follow in 1989.

SAFETY OF BLOOD PRODUCTS

Background Note

We became aware in 1982 that haemophiliacs in the USA were contracting AIDS. Although the mechanism of infection was not known, it was presumed that it had been transmitted through use of blood products, such as Factor 8. Blood plasma from many donorsis pooled to make Factor 8. One infected donation will contaminate a whole batch.

Heat treatment techniques were developed to inactivate the AIDS virus in the USA. Heat treated Factor 8 from the USA was available for clinicians to prescribe on a named patient basis to patients in the UK from the end of 1984.

From April 1985 heat treated Factor 8 was produced by the Blood Products Laboratory at Elstree.

At present around 70% of Factor 8 is imported. All Factor 8 is now made from screened donations and is heat treated.

Before heat treated Factor 8 was generally available many haemophiliacs had been infected. Present figures show that of 2941 haemophiliacs tested 937 (32%) have been found to have antibodies to the AIDS virus. Some have already developed AIDS, others can be expected to do so.

There is no evidence to suggest that haemophiliacs are now at risk of AIDS since no instances of infection have been associated with the licensed heat-treated commercial Factor VIII products imported.

Supplementary Questions

Q. What has been done to ensure the safety of Factor 8?

A. All Factor 8 used in the UK is now made from screened donations and given a heat treatment.

Q. Is Factor 8 for haemophiliacs safe?

A. The Government has done everything possible to supply the safest blood products available in the light of medical knowledge at that time. The introduction of donor screening and heat treatment has significantly increased the safety of Factor 8. There is no evidence that heat treatment products currently available have transmitted the AIDS virus.

Q. What is being done to help those haemophiliacs with AIDS?

A. To help those who were previously infected the Government has so far provided £60,000 to each of the Haemophilia Reference Centres in England and Wales so that they can provide a counselling service. A further allocation of £44,000 has been made to each Centre for the coming year (87/88).

Q. Will haemophiliacs who get AIDS from blood products be compensated by the Government?

A. We all feel the greatest sympathy for those haemophiliacs who have suffered this grave misfortune. However, there has never been a general State scheme to compensate those who suffer the unavoidable adverse effects which can arise from some medical procedures. Compensation is awarded by the Courts in cases where negligence has been proved.

THE PLASMA SUPPLY

Background Note

1. The Blood Products Laboratory (BPL) manufactures its product range by processing human plasma. (Plasma is the liquid part of blood which is left after the red and while cells have been removed). The plasma can be safely stored deep-frozen for many years.

2. Plasma is collected from blood donors by the National Blood Transfusion Service and sent to the BPL at Elstree. Regions were set targets to increase their collection so that there would be sufficient plasma for the new BPL.

Most Regions are currently in line with their targets and it is expected that enough plasma for the new BPL will be available.

3. A stockpile of plasma has deliberately been built up at the BPL (Elstree) so that it will be available for processing once the new laboratory is completed later this year. However, screening of all blood donations for antibodies to the AIDS virus (HIV) started in October 1985. Consequently plasma in storage dated before then has not been tested. For various reasons it cannot be tested at this late stage.

4. Parliamentary questions have been asked about the disposal of this stockpile. The questions and brief are appended at Flag E .

5. A committee of experts was asked to advise on the extent to which the unscreened stockpile may be safely used. Their recommendations form the basis for a submission at present being prepared for Ministers' consideration.

Supplementary Questions:

Q. Will there be sufficient blood/plasma for the new laboratory to process?

A. Regions have been building up their collection of blood and plasma from donors for several years according to set targets. It is anticipated that the targets for self-sufficiency will be met.

Q. Will the stockpile of intested plasma be used?

A. My Department has held a meeting at which national experts were asked to advise on the extent to which the stock-pile may be safely used. Their recommendations are under consideration.

There is sufficient tested plasma in storage to ensure that there will not be a shortage when the new laboratory starts production.

## SELF SUFFICIENCY IN BLOOD

### Background Note

There is a frequent misconception that the Blood Products Laboratory process blood or that blood is imported. In fact the BPL only process plasma which is the liquid part of blood which is left after the red and white cells have been removed. Neither blood nor plasma are imported.

Supplementary Questions

Q. Do we import blood from America?

A. No. We have been self sufficient in whole blood for many years. This is supplied by the National Blood Transfusion Service to both NHS and non-NHS hospitals in the UK.

Q. Is the amount of the blood supply threatened by AIDS?

A. Blood donors know that there is no risk of catching AIDS by giving blood. They are continuing to give generously for others and we are grateful to them.

Monday 9 March 1987
Written answer

Appendix of Hansard vol col.

QUESTION :

T 7/3 PQ 3067

The oral Question from cover please

124 **Mrs Renée Short** (Wolverhampton North East): To ask the Secretary of State for Social W Services, how much blood plasma, collected before screening for HIV antibodies of blood donations was introduced, is currently stockpiled in England and Wales; whether there are any plans to test such plasma for HIV; and what plans there are for the disposal of plasma which cannot be used.

MS E— C—

~~SUGGESTED REPLY~~

A stock-pile of frozen plasma has been deliberately built -up at the Blood Products Laboratory, Elstree in preparation for the increased requirement of the new laboratory. Of this stockpile, 176 tonnes has been quarantined and consists of plasma given before testing for antibodies to HIV started in October 1985.

It is not possible to ~~directly~~ test this plasma for HIV by direct methods However it is likely that in some cases indirect methods will be able to show whether some plasma is safe to use.

A committee of experts has recently been asked to advise on the extent to which the stock-pile may be safely used and their recommendations are under consideration.

There is sufficient tested plasma in storage to ensure that there will not be a shortage when the new laboratory opens.

cc PS(H)

Plasma Stockpile at the Blood Products Laboratory

Background

1. A stockpile of plasma has deliberately been built up at the BPL (Elstree) so that it will be available for processing once the new laboratory is completed later this year.

2. There are two types of plasma in storage(1) Fresh Frozen Plasma (FFP) which is specially collected from blood donations to be made into blood products such as Factor VIII and(2) Time expired plasma (TEP) which is salvaged from blood which was not used within its shelf life and which would otherwise have been wasted. It is used for making albumin.

3. Screening of all blood donations for antibodies to the AIDS virus (HIV) started in October 1985. Consequently plasma in storage dated before then has not been tested. For various reasons it cannot be tested at this late stage.

Size of the 'unscreened' stockpile

4. There is 50 tonnes of FFP from unscreened donations in stock and 126 tonnes of unscreened TEP.

Disposal of the stockpile

5. The Department held a meeting on 16th January 1987 at which national experts were asked for their views on the disposal of the stockpile. Their recommendations are still under consideration. All details of the utilisation have not yet been decided but the following points have so far emerged:

5.1 None of the FFP will be used to make Factor VIII at BPL unless it can be definitely attributed to a regular donor who has had a donation tested and shown to be negative for HIV antibody since the donation in the stockpile was collected. It

is anticipated that about 30 to 35 tonnes will be able to be attributed and will therefore be useable.

5.2 It is unlikely that any of the TEP will be used to make albumin by BPL. It is likely that it will be thrown away (126 tonnes). Options which have been suggested for selling overseas are likely to be difficult to present. If it is unsafe to use the TEP in the UK it can be argued it would be unethical to sell it abroad.

6. There is sufficient tested plasma in storage to ensure that there will not be a shortage when the new laboratory opens.

7. The committee of experts appreciated the difficulty of the decision and the potential value of the stock-pile (£8.8m would be the international spot market price for screened plasma). However everyone was agreed that the continued safety of the blood products made by BPL must remain the overriding consideration.

8. Recommendations for the disposal of the stockpile will be submitted to Ministers in the next few weeks once all considerations have been completed.

3 March 1987

R J MOORE
HS1A