

SCIENTIFIC AND TECHNICAL COMMITTEE FOR THE CENTRAL BLOOD LABORATORIES

H/823/RH05/3

Implications for the National Blood Transfusion Service of an adverse report on the Blood Products Laboratory at Elstree by the Inspectors of Medicines Division.

001 B

Memorandum by the Chairman

1796

1 A very serious situation has arisen within the NBTS following visits to the Blood Products Laboratory at Elstree by Inspectors of Medicines Division. One conclusion from their report epitomises the position: "If this were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level" (Conclusion 7, Document A).

2 The implications of the above conclusions are alarming. The NHS depends heavily on plasma fractions processed at Elstree but a fatal reaction in a patient, following transfusion of this material, would now place the Director of the Laboratory in an extremely difficult situation, and the DHSS itself could be found culpable.

Remedial action of two kinds is needed:

- (a) money is required immediately to upgrade the existing facilities;
- (b) a completely new plant must be planned and built with the greatest urgency.

If the above two steps are taken there will be a reasonable defence against any possible accidents which may occur until the new plant is in operation.

3 The Committee has in fact been emphasising the need for new plant for some time. The Inspectors' report simply increases the urgency of this requirement.

The present plant is not only far below modern standards but is also far too small so that, for example, it is producing less than half the country's need for antihaemophilic globulin, the rest being purchased from commercial sources at a present estimated cost of well over £4 million a year (Document C).

Construction of a new plant can be strongly justified on economic grounds. Calculations indicate that if a new plant were built there would be a rapid and growing return on the investment with all the capital expenditure paid back in the first 15 months of full-scale operation (Document B, page 4).

4 The Committee has considered the alternative of abandoning production at Elstree and thus leaving the NHS with no alternative but to buy all plasma and plasma fractions from commercial sources. They reject this alternative for the following reasons:

- (a) at present, the NHS benefits from almost 2,000,000 units of blood a year given free of charge by volunteer donors. Plasma from almost half of this blood is fractionated at Elstree. The cost to the NHS of obtaining an equivalent amount of plasma from paid donors would be at least £5 million per annum.
- (b) although some donors would doubtless continue to give their blood even if it were processed commercially, other donors might not be happy to realise that the same plant was processing plasma from paid donors and selling the latter material for a high price.
- (c) plasma from some paid donors is known to be more likely to transmit disease (particularly hepatitis) than is plasma from volunteer donors.
- (d) the availability of products from BPL must tend to impose price-limits on commercial blood products purchased by the NHS.

5 In summary, the closure of BPL would have the gravest implications for the NBTS. Not only would closure greatly increase the cost to the NHS of obtaining plasma and plasma fractions, but it could also lead to a diminution in the number of volunteer blood donors which in turn would create serious shortages in hospitals and to the need to recruit paid blood donors. For a country which has pioneered a transfusion service based on voluntary donation, a service which has been admired and copied all over the world, this would be a tragic and most retrograde step.