MCH 15/7.

Mr Harris
Mr Langsdon

The attached submission alerts PS(L) to the possibility of press criticism concerning the manufacture of Factor VIII Y for haemophiliacs by the Blood Products Laboratory, Elstree from plasma which has not been screened for the AIDS virus.

GRO-C

DR R MOORE
HSl
Room GRO-C
HANH

15 July 1986

cc: Mr S Heppell
Mr J Cashman
Dr A Smithies
Mr T Murray
Mr D Hagger

15 JUL 1986

10/67

SUBMISSION TO MINISTERS: FACTOR VIII MANUFACTURE AT THE BLOOD PRODUCTS LABORATORY, ELSTREE

Summary

PS(L) will wish to be alerted to the likelihood of criticism of the Department for allowing the Blood Products Laboratory (BPL) at Elstree to make, until June 1986, Factor VIII Y from plasma which has not been screened for the AIDS virus. Although there is no concern over product safety, officials were misinformed by the Central Blood Laboratories Authority regarding this practice. PS(L) is asked to agree the line to take.

Background

1. Factor VIII is the blood clotting agent used by haemophiliacs. It is made from plasma from blood donors. About one third of the haemophiliacs in E & W now carry the AIDS virus. They were infected in the past before heat treated Factor VIII was available (April 1985).

Factor VIII may now be made safe from the AIDS virus by an adequate heat treatment process during manufacture.

Less than half the E & W requirement for Factor VIII is made by BPL; the rest is imported from commercial sources.

Commercial Factor VIII

2. Medicines Division have insisted that commercial Factor VIII imported since at least January 1986 must be both heat treated and made from screened plasma, ie the donors must have been tested for antibodies to the AIDS virus and found free. This is because Medicines Division were not satisfied that the heat treatment process used by some commercial manufacturers could destroy the AIDS virus.

Their view is now supported by evidence that some commercial Factor VIII from unscreened plasma has probably transmitted the AIDS virus to two haemophiliacs (one in the UK).

3. As a consequence of this evidence, the American manufacturer of the Factor VIII has written to all Haemophilia Centre Directors in the UK asking for any remaining batches of 'unscreened' Factor VIII to be returned. Medicines Division consider it unlikely that these old stocks are still held.

BPL Factor VIII Y

4. These events have focussed attention on heat treated Factor VIII made by BPL. This is called Factor VIII Y. The heat treatment given to Factor VIII Y by BPL is both for a longer time and at a higher temperature than that used by any of the commercial processes. Studies with Factor VIII Y have shown that there is no evidence of transmission of the AIDS virus to haemophiliacs using it. The BPL product may therefore be considered safe whether made from screened or unscreened donations.

5. All blood donors in the UK have been screened for antibodies to the AIDS virus since October 1985. However BPL have a buffer stock of plasma and have been using old stocks of unscreened plasma

to make Factor VIII Y. They have been confident that the heat treatment would make the product safe.

Since early June 1986 for operational reasons unconnected with the safety of Factor VIII, BPL have stopped using this unscreened plasma. All Factor VIII Y is therefore now made from screened plasma.

6. Officials were aware of the presentational problems presented by requiring commercial Factor VIII to be made from screened donations whilst not applying the same restrictions to BPL. In February this year officials were informed by the Central Blood Laboratories Authority (CBLA) that from January 1986 all Factor VIII had been made from screened donations. This information was incorrect. Had officials been correctly informed of the use of unscreened plasma it is likely that BPL would have been required to use screened material to bring them into line with commercial manufacturers. However this would have been for presentational reasons rather than product safety.

7. All briefs, POs and PQs on this topic from the Health Services Division have been checked to see whether they have included the incorrect information. Only one PO(H) case has been identified (Appendix 1).

It is suggested that the offending paragraph is not explicit and could be explained as unhappy drafting if necessary. Information put out by PMC (AIDS Unit) is at present being checked. If it is accurate, then it may not be necessary for the fact that the Department was misinformed to become public knowledge.

8. Haemophilia Centre Directors and their patients may express concern at the delay by BPL in using screened donations. Commercial manufacturers of Factor VIII may protest that BPL has relied on Crown Immunity to protect its actions.

Suggested Line to Take

9. On the principle of making Factor VIII Y from unscreened plasma we can support the line that the heat treatment used by BPL is better than that used in commercial processes. The BPL product is therefore safe whether made from screened or unscreened plasma.

10. If we are directly asked whether we knew that unscreened plasma was being used or if it transpires that DHSS have used the incorrect information publicly there is no point in dissembling. We must state that we were misinformed.

11. If pressed we can say that had we been correctly informed we would have required BPL to use screened plasma to bring them into line with commercial manufacturers. This would not have been on the grounds of safety but to support our wish that BPL should be seen to be a leader in the field.

Decision Required

12. PS(L) is asked to approve the suggested line.