ANNEX B

BACKGROUND BRIEFING

The Central Blood Laboratories Authority (CBLA)

12. The Authority was established in December 1982 to manage the 3 Central Blood Laboratories; the Blood Products Laboratory (BPL); the Blood Group Reference Laboratory (BGRL) and the Plasma Fractionation Laboratory (PFL) which are both at Oxford.

The Blood Products Laboratory (BPL)

13. BPL is essentially a pharmaceutical factory, employing some 200 staff which receives plasma from Regional Transfusion Centres and fractionates it into various products - notably Factors VIII and IX for the treatment of haemophiliacs, protein solutions for the treatment of burns etc, and normal and specific immunoglobulins for protection against various infections.

Upgrading

14. A £2.5 m upgrading programme has recently been completed to enable the Laboratory to meet modern pharmaceutical standards and to increase production.

Redevelopment

work has started

15. Ministers are committed to making the NHS self-sufficient in blood products and to this end have authorised a 3 year redevelopment programme at BPL at a cost of £24 m. When completed - the target date is December 1985 - the Laboratory will be of a size capable of meeting the demands in England and Wales for blood products.

16. Sections of the existing Laboratory will be utilised in the new facility for Quality Control, Research and Development and Engineering Services.

Plasma Supply

17. Regional Transfusion Centres generate about 150,000 kg of fresh frozen plasma per year, this is rising steadily. RHAs have been consulted about their willingness and ability to produce 400,000 kg by the mid-80s (the capacity of the new Laboratory). Without exception, RHAs supported in principle the move to self-sufficiency and accepted the economics of producing more plasma to reduce expenditure on imported commercial blood products (at present estimated to cost the NHS around £12 m a year). Several, however, doubted their own ability to reach Regional self-sufficiency targets without substantial extra investment in plasma collecting facilities and were not prepared, at the time, to commit themselves to the necessary additional expenditure.

18. As PS(L) knows Secretary of State recently announced the introduction of handling charges for blood and blood derivatives supplied to private hospitals and undertook to ask RHAs to ensure that the income (estimated at £1.5 m per year) is used to increase the supply of plasma to BPL.

19. The introduction of a pro-rata system of product distribution in proportion to the quality and quantity of plasma supplied per Region has already had a significant beneficial effect on plasma supply.

Increasing Health Authorities Awareness

20. The CBLA are in the middle of an educational programme aimed at convincing Regional Transfusion Directors, Treasurers and Administrators of the benefits of increased plasma production.

21. A recent review of stock control and record keeping procedures in Regional Transfusion Centres and hospital blood banks indicated, particularly in hospitals, a lack of awareness of the value of blood products. Guidance has now been prepared, by DHSS, in the form of a draft health circular which asks HAs to examine closely their usage and control of blood and blood products. When consulted about the terms of the guidance the majority of HAs raised objections to the proposals on the grounds of resource implications (Ministers' views will shortly be sought in the light of HAs comments).

Factor VIII Production

22. (Factor VIII is a clotting agent essential to the treatment of many haemophiliacs.) In 1981 35.5 Million international units of imported FVIII were used in this country. In 1981-82 22 million units were manufactured by BPL. Regional Transfusion Centres manufactured a further 1-10 m.i.u. in the form of cryoprecipitate.

It is estimated that by the mid-1980s around 100 m.i.u. will be required.

AIDS (Acquired Immune Deficiency Syndrome)

23. PS(L) is aware of the concern surrounding the possible transmission of AIDS in imported blood products and the related pressure on the Government to ensure that financial constraints do not slow the drive towards self-sufficiency.

Genetic engineering

24. It is likely that genetically-engineered blood products are a decade or more away. However, in reaching the decision to redevelop BLP, full consideration was given to the possibility that a breakthrough may be made at any time. Even were this to be the case, safety and efficacy testing prior to licensing of this type of product would take at least 5 years during which time it has been calculated that the new factory would pay for itself in terms of import substitutions.

Collaboration with industry

25. The Authority is under obligation to establish links with industry which will present opportunities of mutual benefit to both public and private sectors.

26. The Blood Group Reference Laboratory is collaborating with Celltech (a company established by the BTG and city institutions) in the development and introduction to the market of monoclonal reagents while a contract is under negotiation with the Wellcome Foundation for a joint (with BPL) development of diagnostic tests for hepatitis.