REDEVELOPMENT OF BLOOD PRODUCTS LABORATORY, ELSTREE

1. This note sets out the circumstances surrounding the escalating cost of the re-development project at the Blood Products Laboratory (BPL), Elstree, in response to the points raised by MS(H) in his minute of 25 September to Sir Kenneth Stowe. The project was originally approved at £21.1m (November 1981 prices), but CBLA are now asking for £35.3m (June 1984 prices) plus £3.45m for extra buildings. The elements of project control are described first: then the case for proceeding, the options available and the financial implications are examined.

Project Control - (A) Responsibilities within DHSS

2. HS, as the policy division and budget holder for CBLA, was responsible for taking the project proposal to the stage of approval by Ministers, having obtained professional advice from Med SFB & Finance Division, Economic Advisers Office and Works Group. Works Group then assumed responsibility for monitoring and control of the project during its construction stage.

3. When this fast-track design and build project was put in the hands of the newly formed Central Blood Laboratories Authority (CBLA) at the end of 1982, Works Group proposed particularly close control and suggested that a member of the Group should be on the CBLA's Project Committee. The then PS(H), Mr Finsberg, opposed direct participation because he wished the CBLA to be fully accountable for the project. Works Group interpreted this as an indication that they should "stand-back" from the project, and have monitored it less closely than would have been the case had direct participation not been an issue.

4. In April 1983, Works Group wrote to the CBLA transmitting in unequivocal terms a cost limit of £21.1m approved by Ministers, subject only to revaluation in line with inflation as approved by the Department. The letter asked CBLA for quarterly reports on current expenditure and also forecasts of projected expenditure. These reports were not made regularly. The first in August 1983 suggested increases of some £2.4 million in project costs not attributable to inflation. Works Group, Finance and HS Divisions had talks with CBLA continuing to October 1983 on the need to design within the approved sum and the details needed in quarterly reports but the matter was not resolved. In February 1984, Works Group reminded CBLA that its next report was considerably overdue. This was received at the end of March 1984 and indicated further escalation. The absence of regular reporting was also noticed by Audit Branch in that month. The estimated final cost of £35.3 million did not emerge until the end of May 1984. The nature and extent of the project escalation which involved an additional £3.5m for works not included in the original proposal (making a total cost of £38.8m) were only identified by the Department in subsequent discussions.

Project Control - (B) Responsibility of CBLA

5. The CBLA were given project responsibility with a cash limit of £21.1 million but evidently never regarded this as a realistic cash ceiling; they did not however formally challenge it. The CBLA saw project completion on time as the prime objective, given the employment of a fast-track design and build system. The CBLA accepted their Project Team's assertion that the project costs would be "at risk", ie not finally determined, for the first 10-12 months from May 1983, until the detailed design work had been substantially completed and firm tenders had been obtained. Members of the Authority were given no more information by their Project Team than was sent to the Department. The Project Team did not report to the Authority details

of design developments and their cost implications it agreed with the contractor. The situation was one in which the CBLA were taking and implementing design decisions, apparently assuming that they could subsequently seek approval and increased funding retrospectively from the Department; the absolute nature of the cost limit was ignored since the CBLA would apparently have regarded it as incompatible with a fast-track project.

Project Control (C) Future arrangements

6. The CBLA has now appointed its Deputy Chairman to lead the project team, with the specific task of ensuring that there is no further escalation in costs. The Authority intends to be kept better informed through his regular reporting. With the project passing out of the design phase, the scope for changes and variations is in any case much reduced, and for the Department, Works Group will continue its monitoring by insisting upon regular financial reports and following up if they do not arrive.

Case for proceeding

7. The case for continuing with this project remains a strong one; the Annex to this note sets out the arguments for self-sufficiency, and the economic case for savings in NHS expenditure on commercial products. DCF calculations on the new cost basis (£38.8m) continue to show a strongly positive return, on the assumption that there will be a ready market for products surplus to NHS requirements.

Options

8. The options (i) to abandon the scheme or (ii) to redesign to the original limit revalued to £25.3m have been examined again and have been discarded for the reasons set out in the submission to Ministers on 21 September. Abandonment would waste £11 million already spent, and put at risk a further £12 million committed expenditure on the project; it would also cost the NHS £12 million p.a. in savings they could expect to make from self-sufficiency. Redesign to £25.3 million would be impracticable since some £23 million has already been spent or committed on the current design. The option (iii) to agree to CBLA's request for £38.8m, whilst admittedly producing the end result desired for the NHS, imposes no element of financial discipline on CBLA, nor does it convey Ministerial disapproval for having allowed this huge escalation to occur without consulting DHSS at a much earlier stage. A further option (iv) to approve expenditure to £35.3m (on the basis that that is all the money the Department chooses to make available) would not directly prejudice the main production building but would force the CBLA to seek alternative solutions to its proposed extra buildings for warehousing and quality control. Such an option would also make the CBLA reconsider its arrangements for forecasting future requirements, and would emphasise the need for more timely application to the Department for funding.

Financing

9. The CBLA, as a special health authority complementing the National Blood Transfusion Service, is financed from Section A (HCHS) of the HPSS Vote; the CFS part of this Vote is inappropriate and in any case is fully committed. This project was originally funded by pre-emption upon the HAs' programme. The extra cost, or part of it, might be met either by an increased pre-emption ("top-slicing") or by reducing the call on HCHS capital by other central projects. MS(H) and Finance Branch consider that further "top-slicing" of the HCHS capital would be unacceptable because of other constraints (a submission on bids for central funding from HA resources has now been put forward by FA). If increased funding for the BPL project is to be found without

seriously reducing the HCHS capital programme, this can in practice be achieved only by abandoning or privately financing the CAMR Fermentation Pilot Plant; even on this basis there will be problems in 1985-86.

SELF-SUFFICIENCY IN BLOOD AND BLOOD PRODUCTS IN THE UK

1. The case for self-sufficiency in blood and blood products which is expected to be attained when the newly built Blood Products Laboratory is processing 450 tonnes of plasma has not substantially changed since Ministers agreed it in 1981.

2. In the first place Ministers are committed to the WHO recommendation that member states should be self-sufficient. It is ethically unacceptable for developed countries to rely on blood products obtained from people in less well developed countries who may suffer from inadequate nutrition. Both these and donors elsewhere are paid for their donations and for that reason may fail to reveal adverse circumstances which would normally render their donations clinically unacceptable.

3. The case of AIDS is apposite in illustrating this dilemma. There is no test at present to screen donors for evidence of infectivity. Groups at high risk of AIDS in the USA are known to be drug abusers who need funds to support their addiction. There is evidence in both the US and the UK that Factor VIII produced in the USA has transmitted AIDS to haemophiliacs. It cannot be guaranteed that AIDS-infected volunteer donors in the UK can be excluded from giving blood, but most volunteers from high-risk groups would be likely to observe the request not to donate. Only one UK donor, whose earlier donations were used in blood product manufacture, is now known to be suffering from AIDS.

4. It should be noted that AIDS is not the only transmissable agent; hepatitis is still an important infectious hazard for recipients of blood and blood products and again emphasises the advantages of a population of volunteer donors.

5. Between 50-60 per cent of the Factor VIII required to maintain the 4,500 haemophiliacs in the UK has to be imported as BPL are currently only able to manufacture sufficient for 40 per cent of them. The cost of commercial Factor VIII is held down in the UK because of the availability of the UK product. A much higher price is charged by commerical interests in West Germany for instance. However if there is a move to market commercial heat treated Factor VIII, (as there may be if research confirms the hypothesis that the AIDS agent is heat labile) then the costs of imported Factor VIII will probably escalate in the UK.

6. The economic argument for becoming self-sufficient in blood products is a convincing one in that a cost benefit analysis showed in 1980 that for the expenditure of £25 million, the outlay would be paid back in terms of replacement of imported commercial products within 3 years of opening the new unit. The same argument holds for an expenditure of £35 million, with reduced running costs - the break-even period is again 3 years of commencing production.

7. Ministers will be aware that Factor VIII, the most significant blood product, has been produced in the laboratory by genetic engineering methods. As far as any prediction can be authoritative in this highly complex and commercially secretive field, it is considered that it will take up to five years at least for this product to be available on a commercial scale. Even then its cost may be high compared to that obtained from human plasma. This possible development has been borne in mind and the plans for BPL are sufficiently flexible to allow the refining of such products from genetically engineering source material when available in the future.