(68)

NOTE OF A MEETING HELD ON 27 NOVEMBER 1979 IN ROOM 114 FINSBURY SQUARE HOUSE TO DISCUSS MATTERS RELATING TO THE BLOOD PRODUCTS LABORATORY ELSTREE

Present Mr R N Williams (in the Chair)
Mr J B Brown
Dr J P Griffin
Mr B K Chambers
Dr J A Holgate
Mr J Flint
Mr G E J Firstbrook
Mr R N Davidson (Secretary)

1. The purpose of the meeting was to consider

a. Mr Harley's minute of 29 October to Mr Firstbrook reporting interim remedial measures for the deficiencies in premises, facilities, processes and documentation found on inspection of the BPL Elstree;

b. the draft submission to Ministers prepared by HS Division in this connection.

2. The following comments were made on the measures reported in paragraph 3 of Mr Harley's minute

3(i) Production of freeze-dried plasma should have ceased already. Our information is that this activity was continuing.

3(ii) It is not possible to comment on this item in the absence of details.

3(iii) The installation of the new freeze-drier etc is a worthwhile improvement although it does not go far enough to meet the recommendations of Medicines Division. The quality of air supply did not meet required standards for a permanent installation. Recognising the high cost of a satisfactory installation, the slight improvements in the quality of air resulting from other proposed changes in the freeze drying area may be acceptable in the meantime. The possibility of installing a larger fan to increase the number of air changes should be explored. The provision of a changing facility was welcomed. This had been planned following a suggestion by Mr Flint.

3(iv) Details of the programme of staff training and by whom it would be carried out are required. It is hoped that staff would be seconded to industry to gain experience in good pharmaceutical manufacturing practice.

3(v) This is noted and welcomed.

3(vi) It is essential that standardised documentation be prepared for operations in the existing facility. Revised documentation will be

required for the fully upgraded facilities.

3(vii) While Dr E Bidwell may be excellent for the analytical control aspect of quality assurance it is very doubtful whether she has the experience of a person responsible for total quality assurance in large-scale manufacture of sterile products. Therefore we are not in a position to comment objectively on the value of the proposal. So far as it goes it is acceptable but we are looking for the appointment of an expert in the field of quality assurance.

3(viii) The appointment of Dr Smith as Dr Ellis's successor seems entirely appropriate. However he is unlikely to have the expertise in pharmaceutica manufacture expected of a director of production. Biopharmaceutical experience with a firm such as Evans, Wellcome or Pfizer is a pre-requisite of such an appointment, with a commensurate salary.

3. Referring to paragraph 4 of Mr Harley's minute, the meeting would not accept that the suggested improvements went a considerable way towards improving g.m.p at the laboratory. It was essential that further measures should be taken in the short term to provide minimum safeguards in the production of preparations. It is understood that the "Stop-Gap" proposals have been dropped: alternative proposals are required therefore. In the appendix* to these minutes are set out essential short-term requirements for the next five years.

* being prepared.

4. The following comments were made on the draft submission

General

Any discussion of and submission on this problem must take into account the premises and facilities of Blood Transfusion Centres and arrangements between them and the BPL for the pooling of blood, and the raw material for the manufacturing processes of the latter. It would be meaningless to upgrade the BPL if the supply of blood were of sub-standard quality. The premises and facilities of some Centres are such that the risk of microbially contaminated blood is high. Remedial measures have already been initiated in a few Centres at not inconsiderable cost. (Liverpool Centre has spent about £300,000 to upgrade the premises and facilities). The pooling of blood in 5 litre bags increases the risk of microbial contamination and Centres using such bags would need to be upgraded to reduce the risk. Single-pack collection and processing by BPL would considerably reduce the need for Centres to be upgraded to ensure the integrity of blood supplied but the BPL would, in consequence, need specially designed equipment, machinery and premises. However the adoption of single-pack

collection and processing would mean that smaller facilities, and thus savings, would be needed by the BPL for other processes.

During 1980 Blood Transfusion Centres are to be formally inspected.

(a) Summary It was agreed that five years was realistic.

(b) Para 1 line 3. Insert "Oxford" after PFL to ensure that there is no confusion with Liberton.

(c) Para 3. The purpose of the "Stop-gap" proposals was to reduce dependence on overseas supplies. As these have been dropped, it follows that supplies will still be needed from overseas, and may increase at an increased cost, unless an alternative to "Stop-gap" is adopted.

(d) Para 4 (line 9) "there are numerous precedents" is not correct. There have been cases where the cessation of manufacture would have stopped supply of medicinal products essential for the treatment of serious cases with possible disastrous consequences. It would be more accurate to say "there are some precedents" or "there have been cases of a similar nature". However the standards applied on inspection have always been the same. Substitute "Medicines Division" for "Inspectors" in line 8.

(e) Para 6 The hazard aspect has not been correctly represented. Blood products are administered to seriously ill patients. It is not improbable that any adverse effects are attributed to the patient's condition and not to the product administered. It has been said that adverse reactions are almost expected in patients to whom blood products are given. The paragraph should make it clear that the products are inherently hazardous.

(f) Para 7 Mr Flint queried whether the contents of the report were "widely known". Some members of the public had seen the report (those on the Committee for the BPL and some officers of the N W Thames RHA). Mr Flint said that if the report was to be seen by the public generally the form of some items would need to be changed (eg tropical blood was a term which could be misunderstood by the layman). Mr Flint had already considered what changes were necessary.

(g) Para 8 (line 4) It was felt that "for an indefinite period" might be replaced by "for other than a short period (not exceeding five years)". The two references to "Inspectors" should be altered to "Medicines Division".

(i) Para 9 (line 4) It was felt some rephrasing was necessary ie "(3) work has started on some short-term measures for which money is immediately available".

(j) It was suggested that the short-term measures proposed by HS might be mentioned in the submission (before that part dealing with longer term options) and included as an appendix.

(k) Para 10 It was thought that ministers should be asked plainly whether they wished to obtain blood products from commercial concerns or via the NHS and that they be advised of what was required to be built if they decided in favour of the latter. In paragraph 10 of the report, no reference had been made to the Plasma Fractionation Centre at Oxford. It would perhaps save misunderstanding if it were pointed out that the facilities there were not at present of an acceptable standard.

(l) Para 10 (f) The PFC at Liberton is due to be inspected in the week commencing 10/12/79. It would be preferable to say in line 5 that conditions there are not yet known but that an inspection is imminent. It is suggested that the last line should read "need to be reviewed in the light of the Medicines Inspector's report".

(m) It is important to point out that the BPL at Elstree cannot operate separately from the NHS as it receives its supplies from the NHS. Related to the question of finance, it should be borne in mind that the sources of supply (the Regional Blood Transfusion Centres) need to be upgraded. The problem could be approached in a variety of ways but all involved finance. It would be important to include the need for this finance in any costing exercise for the provision of blood products. Another consideration was that whatever option was chosen there would be a need for a transfer of staff between commercial concerns and the NHS.

(n) Para 14 It should be emphasized that it is essential to have cross-fertilization of experience between the industry and BPL otherwise the staff of BPL would soon become out of date with pharmaceutical development.

(o) Para 16 There would not be sufficient production required to involve two commercial firms. If only one firm was involved, a monopoly would exist and this would be most undesirable.

(p) Para 18 It is suggested that sub-paragraph (v) become sub-paragraph (i) since everything flows from this policy. In relation to sub-paragraph (i), it is felt that an early announcement of the intention to ensure supplies of blood is essential in order to boost staff morale at the Blood Products Laboratory. No mention is made in the paper about low staff morale. Reference to staff morale is in the report (page 40) and it is felt that some reference should be made to it in the submission.

SUMMARY

5. It was agreed that Mr Brown would contact Mr Harley by telephone and state that it was Medicines Division's intention to send to HS Division:

(a) comments on the remedial action detailed in Mr Harley's minute of 29 October plus details of areas where further action was considered necessary

(b) comments on the draft submission to Ministers. HS Division would be invited to amend their paper to take account of the MD comments, MD would include them in a separate paper. It was hoped that it would be necessary to refer only lone paper to Ministers.