Reference 1C

Mr Williams — I agree, but the proposal at paragraph 7 will require fuller consideration. GRO-C 7/9/79

MEDICINES ACT INSPECTION: BLOOD PRODUCTS LABORATORY - ELSTREE

1. The Department's Inspection Action Group have considered a detailed report of two recent visits by the Medicines Act Inspectorate to the NHS Blood Products Laboratory at Elstree. The Report (attached) reveals that the production, control and other arrangements at the Laboratory fall so short of the standards required of commercial establishments that had the laboratory not enjoyed Crown privilege the Group would have felt bound to recommend immediate suspension of activities. Had that been the case a formal Ministerial decision would have been required whether, despite the failure to meet Medicines Act requirements, there were nevertheless unique grounds of essential patient need which justified approval of unlicensed production.

2. The Group concluded that although a grave situation exists production should not be suspended provided certain imperative steps are taken immediately and at the same time arrangements are put in hand for the introduction of other essential improvements at the earliest possible point in time.

3. In reaching this decision the Group was strongly influenced by the following considerations:-

a) the NHS is heavily dependant on the Laboratory's blood products;

b) existing production is understood to be barely adequate and a break in production is likely to interfere with essential supplies to patients;

c) alternative supplies of all materials are not available;

d) there is no guarantee that such alternative supplies of some products as are available are safer than those produced by the Laboratory, and,

e) the Group were not aware of any weight of established evidence that the Laboratory's products had caused harm to patients: this is of very dubious comfort however, as we were advised that blood transfusions commonly cause side effects and it is unlikely that investigation would be pursued as to the precise cause.

4. The Group's recommendations are attached and, subject to your agreement, should be communicated formally without delay to Mr Dutton, HS2A in his capacity as Secretary to the BPL Joint Management Committee. Mr Harley has a copy of the Inspectors' Report and already has been in touch with the Laboratory about the nature and cost etc of improvements. I have mentioned to him the general burden of the Group's recommendations (which did not surprise him). He has already informed Private Office that he will be making a submission to Ministers on the whole problem. The Board's JMC meets on 12 September and it would be helpful if the formal recommendations were available for the meeting.

5. You may find if helpful if I make some brief general comments on matters touched upon at the Group meeting.

6. The recent visits arose in the normal course of our Inspectors' programme of action (ie there was no special hazard or urgent reason for the visits) but they were brought forward somewhat because of the Laboratory's plans to increase production. These plans were referred to as "Stop-Gap Proposals". This terminology caused me some confusion on first reading the Inspectors' Report: it has nothing directly to do with the Group's recommendations except that certain aspects of the proposals intended for increased production are seen as essential to continued production at present level.

7. The Elstree Laboratory is the largest of three similar establishments; the other two are at Oxford and at Liberton (Scotland) and as neither has been officially inspected we have no reason to suppose that their arrangements are any better than those at Elestree. Although Elstree is linked to the North West Thames RHA it is centrally financed and it is for our Finance Division in collaboration with HS2 to consider the financial implication of the essential improvement and to consider the overall implications of the Group's recommendations

8. From the Inspector's Report it is quite clear tha what started as a small research-orientated laboratory has expanded over time into a full scale production unit without proper recognition that its essential purpose had changed and called for a complete reappraisal of its organisation and procedures, the need for senior personnel experienced in production methods etc is a particular instance. I understand that very few, if any, of the present staff have industrial experience The prospects of filling the necessary new posts that have been recommended are very gloomy. The Laboratory is under complement, is not sited in an attractive area and will be competing at NHS salaries with industry in recruitment.

9. Although I hesitate to mention it the need for urgent action in the Department's best overall interests suggests that we should be prepared to think in terms of the secondment of, say, one of our Medicines Inspectorate to get things going. This would create an awkward precedent but in my view could be justified. Much will depend on the reaction of the BPL Board of Management and the Director. We understand that the Director is not hostile to the Inspectors' Report and will not be surprised by the proposed recommendations. I should point out however that I understand that the recently retired former Director, Sir William Maycock, was generally satisfied with the procedures and safe-guards operated in the Laboratory when taken together with the dedication of the staff involved.

10. It will be for the BPL via HS2 to say how and when the recommended improvements are introduced but I see formidable practical difficulties particularly in relation to staffing and it may be that Ministers would wish to offer expert assistance. (Mr Baker is consider this possibility.)

11. Finally, an early decision will have to be taken on the need to inspect both Oxford and Liberton Laboratories.

GRO-C

J B BROWN

GRO-C

7 September 1979

PS A separate matter touched upon at the Group meeting yesterday was serious doubts about the adequacy of the measures intended to ensure staff safety (as opposed to product safety) within the terms of the Health & Safety at Work Act *

* eg risk of hepatitis.

CODE 18-77

Reference.....

Distribution: Mr Beard
Dr Griffin (OR)
Dr Holgate
Dr Jones
Miss Duncan
Mr Baker
Mr Chambers
Mr Firstbrook