MEETING TO DISCUSS LICENSING STATUS OF BLOOD PRODUCTS AT BPL ELSTREE
MONDAY 28 JULY 1986, ROOM 1533 MT

PRESENT
Mr Hagger (Chair)
Mr Betts
Mr Chugg
Mr Cox
Dr Isaccs
Mr Middleton
Mr Nilsson
Dr Rotblat
Miss Simkins
Mr Fowler (note)

1. Mr Hagger said that he had called this meeting at short notice following a request for advice from Dr Harris (DCMO) earlier that morning. He wanted to advise Ministers about the current situation concerning the screening for HIV of donors who supplied the raw material used by BPL Elstree in the manufacture of blood products, particularly Factor VIII. BPL Elstree, a special health authority, had informed the Department earlier in the year that all their blood products were derived from screened donors, but in the last week it had been learnt that this was not the case. BPL claimed however that their method of heat treatment of the product was more effective than that used by any other manufacturer. Dr Harris was considering whether to advise Ministers to declare that in future products from Elstree would be subject to the requirements of the Medicines Act, including the need to apply for clinical trial certificates and product licences but not Manufacturers licences.

2. As a special health authority it was considered that BPL probably benefitted from Crown Immunity; this, however, would have to be confirmed. BPL had not applied for product licences for any of its products. Nor did it hold any manufacturing licences. In view of the licence requirements placed on commercial manufacturers of blood products Mr Hagger wanted to consider what would be the practicalities of placing a similar requirement on BPL to obtain product licences, and what would be the implications of this for the work of the Division. Dr Harris had said he would like to advise Ministers to announce that the Medicines Act provisions would be applied to the BPL, with the exception of payment of fees and, for the present, the need for a manufacturer's licence.

3. Mr Nilsson commented on the legal aspects. He said that before the Minister could be advised we should obtain a clear picture of the management structure at BPL to ascertain what powers the Minister had to issue directions. He saw no reason why they shouldn't apply for product licences for those products already being distributed for use, but there would be problems in assessing applications for manufacturers' licences because the new plant being constructed could not be inspected until completion, which was not expected before 1987. He pointed out that both the standard and also other conditions would need to be carefully examined so as to ensure that there was no reference in them to a manufacturing licence. He raised the question whether fees should be waived since this would only involve the transfer of funds from one part of the Department to another. Supplies Division were known to hold some product licences, but it was not known whether they had paid application fees.

He queried whether under the terms of the NHS Acts Ministers had the power to direct that BPL's products should be licensed.

4. Dr Rotblat said that there was no scientific evidence to support BPL's claim that their heat treatment methods were more effective than those of other manufacturers. Only clinical evidence existed and this was limited to hepatitis. It was also pointed out that NIBSC are now checking batches manufactured at Elstree, but it was not known whether Elstree submitted all batches to NIBSC.

5. An important consideration derived from the fact that BPL produces about 50% of all the Factor VIII used in the UK. If they had to withdraw supplies pending licensing this could produce difficulties. Although it was thought that BPL were now producing Factor VIII and IX only from donor tested material they were reported to have a very large stock of non donor tested plasma (value £5M) which they would want to use for the manufacture of all blood products when their new plant comes on stream. It was proposed that they might be required to use this only for the manufacture of albumen and immunoglobulin where there was no risk of AIDS transmission.

6. Mr Middleton estimated that in order to bring the Elstree plant up to standard the services of one full time inspector would be required for at least three months. However, the Inspectorate would welcome the proper licensing of BPL products and thought that NIBSC would also.

7. It was pointed out that requiring licensing at Elstree could have implications for other similar bodies, for example BPL Edinburgh, and Porton Down, and for hospital pharmacies and MOD and Home Office hospitals which also have Crown Immunity. It was noted that Marilyn Duncan of STB4A had responsibility for other Crown Immunities.

8. The meeting decided that the licensing of products manufactured at BPL Elstree was desirable. However, the Division could not deal with a sudden influx of applications for all their products. It was decided to recommend that if licensing was introduced, BPL should be invited to apply first for the items of highest risk of AIDS transmission ie. Factor VIII, Factor IX, and Fibrinogen. They should be instructed not to use plasma from their large reserve stocks for these products. Licensing of the other blood products could follow as soon as practically possible. Although it would probably not be possible to grant a manufacturers licence until the new plant was operative BPL could be told before that to apply for a Licence.

9. Mr Hagger would advise Dr Harris that, while applying the conditions of the Medicines Act to products produced by BPL would not present insummountable problems, careful planning would be needed. Medicines Division would need to be involved at an early stage in such planning. Such a development would have a resource cost the size of which could not be determined without more information. In drawing up plans, careful considerations would have to be given as to what would happen if an application from BPL for a currently distributed product failed to satisfy the licensing authority on, for example, safety grounds.