NOTE FOR FILE

SEROLOGICAL PRODUCTS LIMITED

Mr Lort and I had a discussion with Mr Norman Berry (ex-Wellcome Foundation) and Dr Eibl of Immuno, concerning the proposed marketing of certain blood products in the United Kingdom. These products will all be manufactured by Immuno in Austria, and marketed by Serological Products in this country. Immuno has three new products which they are proposing to market in this country, through Serological Products Limited. These blood products are * Factor VIII concentrate, Factor IX concentrate and prothrombin complex. Dr Eibl assured me that all the blood used for preparing these blood fractions was obtained from Austria and Germany. They have about six plasmapheresis stations, where they they collect plasma weekly from a known pool of donors. All donors are tested for Australia antigen and transaminase levels at each visit. I told them that they would have to prepare full submissions for the Committee for these three products, and such submissions would be considered in the usual way. I suggested that if they have considerable clinical data following the use of these preparations, it might be worth their while to consider applying for a Product Licence in the first instance.

Mr Berry sought clarification of the workings of the Medicines Act, and the current status of Serological Products Limited TSA licences for plasma protein, albumin and fibrinogen. Mr Lort pointed out that as no applications had been made by Serological Products before the deadline, they were not entitled to any Product Licences of Right, under the Medicines Act, in respect of their TSA Licences. He explained to Mr Berry how Serological Products could set about rectifying this situation.

We left it that Serological Products would prepare formal submissions to the Committee for the new products that they wished to market in the UK. I told them that it would take at least three to four months after receiving the submissions before Product Licences could be issued. In the meantime, it would be quite in order for Immuno to supply Factor VIII concentrate if a request came to them from a doctor treating a bleeding patient. I told him that while the Licensing Authority would be prepared to authorise importation on an individual basis, we could not agree to a store of material being kept in this country on a contingency basis.

GRO-C

Dr D P Thomas
22 September 1972

Copies to: Dr Holgate
Mr Lort