BLOOD PRODUCTS LABORATORY
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Wd'AM/AH. Your Ref: Hl/Bl3/2D. 26th July 1977.

Mr. T.E. Dutton,
Department of Health and Social Security,
Hannibal House,
Elephant and Castle,
London SEl 6TE.

Dear Mr. Dutton,

Plasma for PFC Liberton

5L bags frozen time-expired plasma and cryoprecipitate supernatant

Set out below are details of the matters about which agreement will have to be concluded with Scotland. This information was set out before I received your letter of 21 July 1977 and, as you will see, assumes that the negotiations with Scotland, or certainly the main part of them, will be carried out between DHSS and SHHD. I look forward to discussing these proposals with you.

(1) The Blood Products Laboratory can now begin to release time-expired plasma and cryoprecipitate supernatant which are in excess of its capacity. Arrangements should be made to fractionate the excess at Protein Fractionation Centre, Liberton. The excess is expected to be about 25,000 L p.a. which would match the available capacity at PF Centre discussed at the DHSS/SHHD meeting on 11 March 1977. Efforts would be made to release a fixed amount of plasma monthly, but arrangements should be flexible.

The plasma should be fractionated to produce plasma protein fraction and possibly also, at some time in the future, normalimmunoglobulin, all of which should be returned. At present BPL has no need for the remaining fractions, which can be left in Scotland, but none should be released by PF Centre to users or their agents outside the NHS. SHHD should provide DHSS at agreed intervals (e.g. quarterly) with records of intermediate products, bulk products and finished products derived from BPL plasma and details of in-process control and other documentation (as defined in Guide to Good Manufacturing Practice 1977, pages 2-3) should be available to BPL if needed. DHSS and SHHD should decide from time to time the disposal of fractions which have been left in Scotland. It is possible that BPL may wish to receive back certain fractions from time to time.

(2) In spite of past requests, BPL has not yet been able to examine samples of plasma protein fraction prepared at PF Centre. It is essential that BPL should examine examples of Scottish PPF before an agreement is concluded with PF Centre, so that differences between the products are defined, as far as possible, before they go to users.

Frozen fresh plasma

(3) Although the target of frozen fresh plasma, set in 1975, has been reached without RTCs Manchester and Liverpool contributing their full quota, BPL will probably be able to fractionate the additional plasma these two centres are expected to produce (i.e. plasma from 46,000 donations per year). The planned capacity of BPL is 1,200 L per week. When this figure is reached, arrangements for fractionating further volumes of fresh plasma will then have to be brought into use. /Preliminary discussions could with advantage take place when arrangements for time-expired plasma are considered./

Financial and other arrangements

(4) It will be necessary to make a financial agreement with SHHD which would, presumably, be linked with the volume of plasma fractionated and take into account: (a) any fractions derived from BPL plasma and used in Scotland; (b) the primary DHSS investment in PF Centre. It is suggested that the agreement should be reviewed annually.

(5) It will also be necessary to approve the details of:-

(a) specification of product
(b) types of containers and closures
(c) labelling and packaging
(d) method of transfer of plasma from Elstree to Edinburgh
(e) distribution from Edinburgh of the finished plasma fractions prepared from BPL plasma.

(6) Plasma should be transferred to Edinburgh from BPL and not from separate transfusion centres. This will permit only RIA tested plasma to be sent to PF Centre and for RTCs to continue to receive sterility reports. Such an arrangement will avoid PF Centre having to give instructions to RTCs in England and Wales, which already are instructed by BPL; confusion will then be less likely to occur. It is essential that BPL should co-ordinate supplies of plasma prepared in England and Wales and act as the representative of NBTS in all matters concerning plasma fractionated at PF Centre.

(7) The PPF prepared should be sent to DoE Store, Bristol. PF Centre should notify BPL of each despatch and send BPL copies of documentation of each batch as defined in Good Manufacturing Practice, 1977 (see also para 5(e) above).

(8) BPL will examine samples of each batch.

Yours sincerely,

GRO-C

W. d'A. Maycock.