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Jgw.lmm 2.16T · 17th July 1978

Dr John D Cash
Regional Director
Edinburgh and South-East Scotland
Blood Transfusion Service
Royal Infirmary
EDINBURGH
EH1 3DE

Dear John

FACTOR VIII DEFICIENT PLASMA AS ASSAY SUBSTRATE

The continuing problem of obtaining sufficient supply of factor VIII substrate continues to exercise concern. Despite the stalwart assistance of some of our colleagues the supply is still limited and spasmodic and I gather that your laboratory is also being affected by this problem. The net effect is that our production of factor VIII concentrate is beginning to become a spasmodic affair. The material enters into process smoothly and at regular intervals and comes to the stage immediately prior to issue in a smooth and even pattern. As final quality control progresses the rate of progress is dictated primarily by the supply of substrate plasma both to the PFC add to your own centre. In recent time we had delays of up to four weeks before your laboratory was able to provide confirmatory assay information such that we could release a number of batches to issue.

In order to circumvent some of these difficulties and in an attempt to keep the supply of issuable product as smooth as possible the PFC has now embarked on a programme to purchase suitable substrate plasma from commercial sources. This, as you might expect, is going to have a very substantial effect on our budget during the coming months since charges for suitable material are close to £2.50 per ml. As you are also aware, we have attempted to use the various substitute materials which have been developed but find that they/

they are not truly suitable for assay of clinical materials.

I feel that the time has now come when I should warn you and our colleagues that supplies of human factor VIII concentrate (product licence number 3473/0007) from the Protein Fractionation Centre are likely to be uncertain. This may mean that, at any given time, it may be impossible to provide issuable material from the Centre. In reaching this stage of progress I am acutely aware that several of our haemophilia treatment centre directors have made a major effort to secure adequate supplies of substrate and that in some cases these efforts have resulted in disproportionate supply. One would like to think that some attempt should be made to safeguard supplies of factor VIII concentrate for those haemophiliac patients who, at some personal disadvantage, have answered our cry for help. In the meantime I have issued instructions designed to arrest, postpone or cancel our development programmes at PFC which are aimed at increasing or improving the yield or quality of factor VIII concentrates. I have done this with some reluctance but we have now reached such a backlog of samples for assay that the length of storage makes the information which we are likely to obtain almost certainly of no value.

With kind regards

Yours sincerely

JOHN G WATT
Scientific Director

c.c. Regional Transfusion Directors
Dr A E Bell - SHHD