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31st December 1995

DEPARTMENT OF HAEMATOLOGY

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Mr D J Palmer
The Scottish Office
Department of Health
NHS Management Executive
St Andrew's House
EDINBURGH
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Dear Mr Palmer

REQUIREMENT FOR RECOMBINANT FACTOR VIII

Thank you for your letter of 23rd October which was considered at a meeting of Haemophilia Directors on the 23rd November.

We confirm our previous view that the patients who should receive the recombinant product first should be previously untransfused patients (PUP's), children and HCV or parvovirus negative individuals. We have taken this position because there are still reports appearing of HCV seroconversions (Shopnick et al, Lancet 1995, 2 645 and Evensen et al, Eur J Microbiol Infect Dis 1995, 14, 631). There is also accumulating evidence for the undesirability of parvovirus infection for which no plasma derived concentrate is of proven safety. It is for this reason that a recent SNBTS position paper to SACTTI recommends the use of recombinant concentrate in parvovirus negative haemophiliacs.

The proposals that we have put forward concerning the groups to be treated are very similar to policies that have been developed at major large Haemophilia Centres in England where considerable amounts of recombinant concentrate are currently being used particularly in children.

There has been much concern in Scotland about the additional demands for factor VIII that might arise as children are put on prophylactic therapy. At our recent meeting it became clear that the majority of children are currently receiving such treatment, in keeping with the UK Haemophilia Centre Directors Organisation recommendations. Thus there will not be any further surge in demand, as a result of a group of patients currently receiving on demand being changed to prophylaxis, as was previously anticipated.

All Haemophilia Directors have scrutinised their patient and transfusion records in considerable detail and our estimates for recombinant factor VIII at each Haemophilia Centre is as follows:

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	Units for first year (x million)
Aberdeen	0.650
Dundee	0.300
Edinburgh	1.050
Glasgow	1.700
Inverness	0.200
Total	**3.900**

It would be possible to break down the use further by Health Board but this would not be easy because some of our patients attend more than one Haemophilia Centre, e.g. students and those working away from home.

This total is approximately 30% of the total factor VIII used in Scotland at present. Initially approximately 80% of the recombinant product would be used in children. We would anticipate that the need for recombinant concentrate will rise rapidly after this such that we should plan for virtually all patients to receive it within the next 2-4 years. You will appreciate that there is considerable pressure already for it but this will escalate shortly after it is introduced. We will have the very difficult situation where some members in a family may be on recombinant concentrate while others will still be on plasma derived product. I am sure you will appreciate the difficulties this is likely to produce for us.

We welcome the recent Management Executive "A Guide to Consent to Examination, Investigation, Treatment or Operation". The guidance is very much in line with the recent UKHCDO recommendations that we should receive written consent from patients and parents for the use of coagulation factor concentrates. This we are therefore planning to implement in the near future. A concern has been raised as to what we should do if a patient, or parent, refuses to give consent for a plasma derived product.

We are very mindful that the move to recombinant factor VIII will put an additional strain on the NHS finances and we spent a considerable period in our meeting considering how we could most appropriately arrange its introduction. Our concern is that if funding is left to purchasers our current arrangements whereby coagulation factor concentrates are made available on a national basis to provide a uniform level of treatment might be jeopardised. This may apply particularly to smaller Health Boards where the fluctuations in consumption between years may be large. It is likely that total fundholding GP's might also have some difficulty. We are therefore very keen to see an agreement whereby Haemophilia Directors can negotiate on a national basis with manufacturers for the purchase and distribution of recombinant factor VIII. Such an arrangement is also likely to enable purchase at a more favourable price than if it is done at a local level. Not only is a mechanism required for the initial year's purchases but there needs to be agreement about the arrangements for succeeding years.

You will know that we have had a National Audit scheme for haemophilia in place for Scotland and Northern Ireland for the past 4 years. This has been so acclaimed as successfully maintaining and enhancing the haemophilia service that it has now been emulated by a similar scheme in England and Wales. If difficulties arise in the provision of appropriate factor VIII concentrates because of different intentions and abilities of Purchasers to fund the service for people with haemophilia it will cast serious doubt on the value of our audit arrangements as we shall have difficulty maintaining a uniform level of care. We hope that the ME would not wish to see the validity of the audit process undermined, particularly when it is held in such high regard in the UK.

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We are keen to see national arrangements agreed in the near future to prevent fragmentation of the present supply arrangements and of well co-ordinated arrangements for the provision of haemophilia care in Scotland under the terms MEL (1994) 29.

Yours sincerely

Christopher A Ludlam and Gordon D O Lowe
Co-Chairman, Haemophilia Directors for Scotland and Northern Ireland

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