6 MAR 1992 12/17

Mr Davey
A/U

From: Mr J Canavan
HC(A)4B
505 Eileen House
Ext GRO-C

Date: 5 March 1992

cc: Dr Rejman HC(M)2
Mr Thompson A/U
Dr Exon A/U
Miss Johnson-Laird
A/U

High Purity Factor VIII

Thank you for your minute of 24 February.

I understand that the Haemophilia Centre Directors are reconsidering their guidelines for treatment with Factor VIII but that it may be some months before any new guidance is issued.

Apparently there are some treaters who do not wish to move away from BPL's Factor 8Y in view of its record of safety and efficacy. The guidance therefore may not be quite along the lines suggested by the Royal Free, although it seems likely that high purity Factor VIII will be more strongly recommended than in the past.

The suggestion of central funding is news to me and I would be interested to know how the Royal Free gained that impression. We have no intention of providing special funding and I am not aware of any moves elsewhere in the Department. Any such move would simply open the flood gates to claims for special funding for a number of high cost pharmaceuticals. High purity Factor VIII prices are already falling through competition and perhaps customer resistance to prices.

Alan - I'm confused.
Aren't all Directors
definitely recommending
(H.P.) F VIII for all HIV Infected

GRO-C

J CANAVAN

Linda.

Haemophiliacs etc.

Could you draft a letter. Needs to be cleared i) DT 2) Lilly+

also Caravan etc. Letter to go to Co-ordinators / ROBs.

Needs to be along lines of:

* Haemophilia Cake Donation recognising Heat Treated Factor VIII

in HIV+ + also others.

* Costs are not built into allocation of AIDS money + it is

not a legitimate call thereon. AIDS money not a windfall to pay for unexpected pressures elsewhere.

* Regions expected to meet from reserves ~~money~~ for blood products. ~~But~~

~~but for~~ (Advice from Caravan needed)

Peter E will have Haemophiliacs Demand.

DRAFT REVISED 11/11/92

POH9/1694/4419

JOHN MARSHALL ESQ MP

Thank you for your letter of 6 October about funding for high purity Factor VIII for the treatment of HIV infected haemophiliacs, in response to Dr Lewis' letter to Haemophilia Directors of 19 August.

The Department of Health is not in any way advocating the denial of treatment to haemophiliacs with HIV infection.

Earlier this year the UK Haemophilia Centre Directors Committee issued consensus recommendations to clinicians on the choice of therapeutic products for the treatment of haemophilia. These recommendations are not Department of Health guidance. The recommendations were for the replacement of intermediate purity Factor VIII (IP) with high purity Factor VIII (HP) in the treatment of haemophiliacs who have tested positive for HIV antibodies and for transition from IP to HP with appropriate surveillance of safety and efficacy for other patients. This product is currently more expensive than the intermediate product. Concern still exists among some clinicians about the relative advantages of HP. The decision about which product to prescribe for particular patients is one for individual clinicians to make, within locally agreed priorities and within the resources.

Because it is currently more expensive than IP, any increased usage of HP Factor VIII would, of course, have resource implications for health authorities. This is true of many of

the advances which the medical profession is continually developing and seeking to implement. The Government would expect regions to finance the introduction of HP Factor VIII from the growth money for the health service secured within the public expenditure process.

Regions are best placed to make decisions on how fast any particular medical advance should be introduced. The Department of Health does not and would not wish to get involved in detailed decisions on the application of resources for individual treatment. This could only be done in any case, by some central funding initiative which could be funded only by top-slicing health authorities allocations. Earmarking money in this way for medical advances is considered inappropriate by the Department and has never been intended for the introduction of HP Factor VIII.

Nor is it appropriate to use earmarked AIDS funds for this purpose. Traditional methods of allocating funds to the National Health Service could not take account of the uneven incidence of HIV infection and AIDS which has placed the overwhelming financial burden on the four Thames regions. Earmarking of AIDS money was accordingly introduced in response to this new infectious disease, with no cure or vaccine, to ensure that adequate services were developed and essential prevention programmes initiated to contain the epidemic. Funding this new product, high purity Factor VIII, which is essentially for the treatment of haemophilia, is therefore not regarded as an appropriate use of these AIDS

funds.

To clarify the position the Department of Health wrote to Directors of Haemophilia Centres stating that the resources set aside specifically for the development of HIV/AIDS services should therefore not be used to fund HP Factor VIII.

I understand that there are some instances where AIDS funds have been used to fund the high purity product for HIV positive haemophiliacs. If in individual cases the abrupt withdrawal of funding would have a detrimental effect on treatment we accept that it may be necessary to allow time to make the transition to other funding sources.

TO PO 30/10/92 GEB 15
HIM 1

POH9/1694/4419

JOHN MARSHALL ESQ MP

Thank you for your letter of 6 October about funding for high purity Factor VIII for the treatment of HIV infected haemophiliacs, in response to Dr Lewis' letter to Haemophilia Directors of 19 August.

Perhaps if I explain the background to the letter it will be clear that the Department is not in any way advocating the denial of treatment to haemophiliacs with HIV infection, as has been implied.

Earlier this year the UK Haemophilia Centre Directors Committee issued consensus recommendations to clinicians, on the choice of therapeutic products for the treatment of haemophilia. The recommendations were for the replacement of intermediate purity Factor VIII (IP) with high purity Factor VIII (HP) in the treatment of haemophiliacs who have tested positive for HIV antibodies and for transition from IP to HP with appropriate surveillance of safety and efficacy for other patients. These recommendations are <u>not</u> Department of Health guidance. This product is currently more expensive than the intermediate product. Concern still exists among some clinicians about the relative advantages of HP, but the decision about which product to prescribe for particular patients is one for individual clinicians to make.

Because it is currently more expensive than IP, any increased

usage of HP Factor VIII would of course have resource implications for health authorities. This is however equally true of many of the advances which the medical profession is continually developing and seeking to implement. As such we would expect regions to finance the introduction of HP Factor VIII from the growth money for the health service secured within the public expenditure process.

Regions are best placed to make decisions on how fast any particular medical advance should be introduced and the Department does not and would not wish to get involved in detailed decisions on the application of resources for individual treatment. This could only be done in any case by some central funding initiative which could be funded only by top-slicing health authorities allocations. Earmarking money in this way for medical advances is considered inappropriate by the Department and has never been intended for the introduction of high purity Factor VIII.

It follows that if it is inappropriate to earmark topsliced NHS money to fund medical advances, it is even more inappropriate to use earmarked AIDS funds for this purpose, particularly when, as in this case, the new product is for the treatment of haemophilia rather than specifically for HIV/AIDS related illnesses.

To clarify the position the Department wrote to Directors of Haemophilia Centres stating that the resources set aside specifically for the development of HIV/AIDS services should

therefore not be used to fund HP Factor VIII.

We understand that there are some instances where AIDS funds have been used to fund the high purity product for HIV positive haemophiliacs. If in individual cases the abrupt withdrawal of funding would have a detrimental affect on treatment we accept that it may be necessary to allow time to make the transition to other funding sources.

I hope this is helpful.