THE SCOTTISH OFFICE

Department of Health

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To:
Name: CHRIS CORRIGAN
Address: DH (HSD 1)
Fax: GRO-C

From:
Name: MIKE PALMER
NHS Management Executive
Trust Directorate
Provider Policy Development Division
Room
St Andrew's House
EDINBURGH
EH1 3DG
Phone:
GTN: GRO-C
Fax:

CHRIS:

I ATTACH DRAFT SPEAKING NOTE FOR TOMORROW'S DEBATE, WHICH WENT UP TO MINISTER LAST NIGHT. AM I RIGHT IN PARAGRAPH 9 OF THE COVERING SUBMISSION TO SAY THAT YOU ARE ASKING HA TO FIND THE RECOMBINANT MONEY FROM WITHIN EXISTING BUDGETS?

ANY COMMENTS WELCOME (BY 4.00 PM TODAY IF POSS.)

GRO-C 3/3

PS/Mr Galbraith

Copy to:

PS/SoS	*
PS/US of S	*
PS/DoH	
CMO	
Dr Woods	
Mr Aldridge	
Dr Keel	
Mr D Palmer	
Mr Harvey	*
Mr Welsh (HR)	*
Mr McCroskie, InD	
Ms Alexander	

* = w/o attachment

ADJOURNMENT DEBATE, 4 MARCH 1998, ON PROVISION OF RECOMBINANT FACTOR VIII IN TAYSIDE

Purpose

1. To clear with the Minister draft speaking notes for the forthcoming adjournment debate tabled by Roseanna Cunningham MP on the provision of synthetic Factor VIII in Tayside.

Timing

2. **Immediate.** The debate has been tabled for 10.00 pm on Wednesday 4 March. A briefing meeting is scheduled for 4.30 pm tomorrow.

Background

3. Roseanna Cunningham, MP for Perth, has tabled an adjournment debate for Wednesday evening with the following title: 'Availabilty of Synthetic Factor VIII in Tayside Health Board Region.'

4. The provision to all Scottish Haemophilia A patients of synthetic - or recombinant - Factor VIII clotting factors has been a wish among haemophilia lobby groups and clinicians for over two years now. The recent concern over the possible transmission of nvCJD through blood products has now raised the profile and urgency of these concerns significantly - the recombinant product is not derived from human plasma and therefore is not prone to the viral or prion-spread diseases to which plasma-derived Factor VIII may be susceptible.

5. In 1996 the Department made available central funding to pump-prime the take-up of recombinant Factor VIII by the NHSiS, starting with priority groups such as children and previously untreated patients. The recombinant product is a commercial drug rather than a blood product produced free by SNBTS, and its purchase has therefore represented a totally new charge on Health Boards' budgets.

6. Funding for recombinant Factor VIII has since been devolved to Health Boards and become part of their general allocations. Last year a consortium of Health Boards and haemophilia clinicians was established to deliver a measured and equitable transition during the rest of the decade to recombinant Factor VIII across Scotland. Some 72% of Scottish patients are now treated with recombinant products.

7. However recent concerns about the possibility of transmission of nvCJD through blood products has prompted the Consortium to recommend that all Health Boards should move to use of recombinant Factor VIII for all their patients within 1998/99. Lothian and Greater Glasgow have already agreed to follow this recommendation and we are hopeful that the other Boards will have also done so by the time of the debate on Wednesday, allowing the Minister to announce that Scotland will be 100% recombinant in Factor VIII within the next year.

8. It is important to note that no extra central funds are being made available to move to this position, which is being done on the initiative of the Health Boards themselves. However it is also noteworthy that this move will have taken place through a consortium-led national approach, preserving the principle of equal treatment for all patients irrespective of where they live. This avoidance of post code prescribing is an aspect which may cause difficulties for England and Wales, where the powerful haemophiliac lobby often focuses on significant regional variations.

9. In the wake of the nvCJD scare England is now instructing Health Authorities to fund children and previously untreated patients but has expressed concern at the pressure which they could receive to extend this advice to all patients if Scotland were to put out a press notice on Wednesday to herald the achievement of 100% recombinant usage north of the Border. This is an aspect which can be discussed with the Minister at the briefing meeting tomorrow, for which we will also produce appropriate Q & A briefing.

The situation on Tayside

10. We suspect that Roseanna Cunningham MP has tabled this debate following the refusal of four patients in Tayside to receive plasma-derived Factor VIII in the wake of the nvCJD concerns. The Minister can give a very strong reply on Wednesday, pointing out that Tayside has decided with immediate effect from last Friday to prescribe recombinant Factor VIII for all its patients.

11. Otherwise the draft speech seeks to inject some balance into the current debate surrounding blood products, reemphasising our message on nvCJD - which got somewhat confused in much of the media coverage - and reminding the House of

SNBTS' achievements and of the excellent safety record of plasma-derived Factor VIII, which has been rather lost in the clamour over recombinant products.

Recommendation

12. That the Minister notes, for any comments he may have, the attached draft speaking note.

GRO-C

Michael Palmer
Health Care Policy Division
Room 253A SAH
Ext GRO-C
2 March 1998

ADJOURNMENT DEBATE, 4 MARCH 1998
Roseanna Cunningham MP (Perth)

Title: Availability of synthetic Factor VIII in Tayside Health Board region

Madam Speaker

May I thank the Hon Member for Perth for bringing this important issue to the attention of the House. I recognise that it is not only a matter of great concern to the haemophiliac community in Tayside but also part of a wider concern throughout Scotland to ensure that the safest possible treatment can be given to this vulnerable group of patients.

It is a matter which Ministers in this and the previous administration have considered very extensively since recombinant Factor VIII became available as a licensed product in 1993, and of course I appreciate that interest in the provision of this drug - a product not derived from human plasma - has been heightened since last week's expert advice received by the Government about the theoretical possibility of transmission of nvCJD via blood products.

Scotland has a good story to tell on the provision of recombinant Factor VIII and I will turn to that specific issue in a moment. However before doing so I would like, in the light of any doubts raised by last week's announcement about blood products and nvCJD, to reaffirm the Government's commitment to Scotland's blood transfusion services and the excellent job they do in supplying Scotland with safe high quality blood and blood products.

The Scottish National Blood Transfusion Service - the SNBTS - has served Scotland for over 50 years and continues to be at the forefront of excellence in health care delivery and new technology in its efforts to deliver a first class service to Scotland's patients. To give an idea of the scale of the operation, last year [April 1996-April 1997] SNBTS collected over 300,000 donations from donors and supplied transfusions for some 85,000 patients across the country. It also provided blood products for some 90,000 patients in Scotland.

As you know our blood service relies entirely on the generosity and support of voluntary donors and has managed to match supply with demand by constantly improving and adapting its practices to make collection services more 'donor-friendly' and by working with hospitals and clinicians to ensure that treatments make the fullest and most optimal use of donors' blood.

I know that the SNBTS is fully committed not only to developing its service in these ways but also to ensuring that it continues to enjoy the excellent record it has earned for the safety and high quality of its blood and blood products. Its record in this area is world class - a recent review has demonstrated that over the past five years in Scotland no transfused blood or blood product has been shown to have infected the recipient with any adverse disease. This is a truly

impressive record given that 1.25 million blood donations have been collected, processed, tested and delivered to hospitals during that period.

The safety and quality of SNBTS' blood and blood products have been vastly enhanced in recent years by dramatic improvements in testing procedures and the ability to inactivate any blood-borne viruses.

New technologies continue to evolve and SNBTS is constantly developing the structure and nature of its processing and testing facilities to ensure that it is equipped to keep abreast of these changes. For example, it is currently putting in place state of the art hyper-sensitive 'PCR' testing equipment, designed to pick up the smallest traces of viral infection well before any blood or blood product reaches a patient.

This brings me to last week's announcement on blood products and nvCJD. I first want to reiterate that there is *no evidence of any risk* of transmission of nvCJD through blood products. There is no more than a hypothetical risk of transmission, a risk which the available evidence suggests would be small even if it were proved to exist. The measures taken last week were therefore purely precautionary and do not mean that our blood or blood products are unsafe.

What they do signal however is our determination to take without delay practical measures which can cut out even a hypothetical risk - it makes sense to take these actions where we can. We are also convinced that it is right to be open and honest with the public about what we are doing. We all saw with BSE what excessive secrecy and caution can lead to - this Government will not go down that road again.

However I also want to reassure Members that, contrary to what a number of media reports have suggested, the Government measures taken last week were *not* to dump UK plasma stocks, ban products and switch immediately to imports. What we *will* do is, as in the past, to follow the expert advice to the letter - the advisory Committee on Safety of Medicines will be undertaking a product-by-product risk assessment of UK-sourced blood products and will determine for each product whether it would be advisable to source plasma from outwith the UK. We will follow that advice as and when it issues and SNBTS have been instructed to make arrangements to import non-UK plasma where deemed necessary by that risk assessment.

Meanwhile SNBTS will continue to produce blood products to the extremely high standards to which it is accustomed.

This brings me to the Factor VIII blood clotting factor, which until recently could only be obtained as a plasma-derived blood product and has for many years been one of the SNBTS' staple blood products, manufactured at the Protein Fractionation Centre, its blood products plant. Factor VIII is a concentrated blood product, made from the pooled donations of many thousands of donors. The heightened risk of one infected donor spreading disease in this

way is obvious. I am sure Members will recall the horrors of the HIV infections of haemophiliacs through infected Factor VIII in the early 1980s, followed more recently by infections from Hepatitis C and Hepatitis B. These tragic cases reflect the vulnerability of this group of patients, who rely for their lives on regular treatment with these products.

But I want at this point to congratulate SNBTS on the wonderful work which its staff have done over the years to refine and improve the safety of its plasma-derived Factor VIII product, a fact which is too easily overshadowed by the terrible tragedy of those infections. The current product produced by SNBTS is (about) as safe as any plasma-derived product in the world; the record speaks for itself - no reports of HIV infection since 1984 and no reports of Hepatitis A, B or C or any other virus since the current product was introduced in 1992, with the possible exception of human parvovirus, a virus which is already endemic in the UK population and has not been shown to have adverse effects on Scottish haemophiliacs.

However despite this excellent record there is no denying that with the recent appearance of recombinant Factor VIII as a commercially produced drug - devoid of human plasma with its risk of viral infection - we finally have a product which can lay to rest for haemophiliacs their fears of infection. I know that the current theoretical risk of nvCJD transmission only adds to these fears and fuels their wish to receive the recombinant product, knowing that it can lift this burden from them.

And Scotland has not been deaf to these concerns. In 1996 the Government recognised that provision needed to be made for the NHS in Scotland to begin the transition to purchasing recombinant Factor VIII for its 330 or so haemophiliacs. In response to requests from the haemophilia community and their clinicians funding of £1.1m was provided to all Health Boards in Scotland - including Tayside - to enable them to begin this process and to provide the recombinant product for the most vulnerable groups within the haemophiliac community, such as children.

Having helped kick-start this process the Government has now asked the Health Boards to take the matter forward as part of their pursuance of health care strategies across Scotland. All funds for this treatment as for others have now been devolved and I know that the Boards have been considering long and hard the priority that should be given to this treatment against the other competing demands on their budgets. This is what the Boards are there to do and it is not for me, thankfully, to take these decisions for them. However, there is one thing I do tell them; do what is right by patients for the enhancement of patient care - I am glad to say that in my experience so far they have invariably had this overriding need in the forefront of their minds.

The Government has also helped the Boards in this particular matter by encouraging them to set up a consortium in order to ensure that this process is carried forward on an integrated, equitable and fair basis throughout the

country, with the consortium co-ordinating the provision of Factor VIII in Scotland and helping Boards to keep in step in their approach to the issue.

This consortium includes a number of Health Boards and representatives of the Haemophilia Directors - the clinicians who oversee haemophilia treatment in Scotland. Its key role is to advise on the priority which Health Boards should give to allocating from their funds provision for recombinant Factor VIII, and in so doing achieve an expansion of recombinant provision which maintains an equality of treatment for all patients across the country.

Much progress has been made already. Of Scotland's 331 treated haemophiliacs 237 - some 72% of the total number of patients - already receive recombinant Factor VIII. These use 52% of the total amount of Factor VIII used in Scotland. The remaining 48% is plasma-derived product, used by the remaining 28% of Scottish patients.

The Consortium has however also recognised the added urgency introduced by the recent concerns raised over nvCJD and I can confirm that it recently recommended to all Health Boards in Scotland that in light of these concerns the extension of recombinant treatment in Scotland should be accelerated such that all Health Boards should offer recombinant Factor VIII treatment to all their haemophiliacs within the next year. [I am pleased to announce that all Health Boards in Scotland have now agreed to this recommendation and that by April 1999 all haemophiliacs in Scotland who so wish will be treated with the recombinant product. This will ensure that all Scottish patients receive the same standard of care irrespective of where they live or which hospital they attend.]

With regard to Tayside region, in particular, I can also confirm that in response to the Consortium's recommendations Tayside Health Board have agreed to offer the recombinant product immediately to all their haemophiliacs still on plasma-derived Factor VIII [- including the constituents mentioned by the Hon Member opposite].

I hope that this allays the Hon Member's concerns and serves to demonstrate the energetic steps which the NHS in Scotland has and continues to take to ensure that all haemopiliacs in Scotland have equal access to the best and safest treatment available.