18/6/01 – Photocopy given to MPW for ? action in your absence.

Hill Frank Secretary (RQ3) BCH

From: Hill Frank (RQ3) BCH
Sent: 18 June 2001 11:28
To: Mann Pat
Subject: FW: Management of National Supplies of Recombinant Factor VIII

From: Bradshaw Chris (RQ3) BCH
Sent: Monday, June 18, 2001 11:27:57 AM
To: Kelly Deirdre (RQ3) BCH; Hill Frank (RQ3) BCH; Williams Mike (RQ3) BCH; Williams Charles (RQ3) BCH; Bown Chris (RQ3) BCH
Subject: FW: Management of National Supplies of Recombinant Factor VIII
Auto forwarded by a Rule

for action

-----Original Message-----
From: p=NHS NATIONAL INT;a=NHS;c=GB;dda:RFC-822=Email-Addresses(a)doh.gsi.gov.uk;
Sent: 18 June 2001 12:44
To: p=NHS NATIONAL INT;a=NHS;c=GB;dda:RFC-822=Email-Addresses(a)doh.gsi.gov.uk;
Subject: From the Department of Health: Management of National Supplies of Recombinant Factor VIII

Dear Chief Executive,

This e-mail is intended for the Medical Director of your organisation.
Please could you forward it to the relevant person.

To: Medical Director

We currently do not have all of your contact details, please send your full details - including your name, organisation, full postal address (including postcode), 'phone & fax numbers and e-mail address - to email-addresses@doh.gsi.gov.uk or fax 020 7972 1609

To: All Medical Directors of Health Authorities (England)
All Medical Directors of NHS Trusts (England)

copy: Regional Directors of Public Health

15 June 2001

Dear Colleague

MANAGEMENT OF NATIONAL SUPPLIES OF RECOMBINANT FACTOR VIII

Issue

1. My letter of 4 May explained that supplies of recombinant Factor VIII would be severely reduced for at least the remainder of 2001 following the suspended release of Kogenate and Helixate. I also stressed the importance of managing supplies corporately across the NHS. That position remains materially unchanged.

2. This letter makes the provision of information to support the management of supplies of recombinant Factor VIII a legal requirement.

Action Required

3. Many Haemophilia Centres are already experiencing severe shortages of product. It is therefore vital that we manage the distribution of available supplies across the NHS to ensure that, as far as possible, recombinant clotting factors continue to be provided to patients in the

priority groups identified by UKHCDO. Updated UKHCDO guidance is enclosed at Annex A below.

4. In order to manage the situation effectively, we have agreed with UKHCDO that each Haemophilia Centre should provide fortnightly information on stocks and usage of recombinant Factor VIII. This data, together with information from manufacturers on supply, will be co-ordinated by the Purchasing and Supplies Agency (PASA). PASA will then be able to advise Centres on redistribution of product to meet patient need. A standard form for Centres to complete is attached in the Excel file at Annex B.

5. This arrangement can only work if all Haemophilia Centres participate. Previous requests for information from UKHCDO have met with a generally good response with some Centres providing excellent information, others nothing. We are therefore requiring Centres to provide the information at Annex B under the terms of paragraph 8 of Schedule 2 paragraph of the NHS & Community Care Act 1990. I would be grateful if you would ensure that Haemophilia Centre Directors are aware of this requirement.

6. We will continue to keep these arrangements under close review with UKHCDO and PASA and modify them as necessary. I will also alert you to any significant changes in the supply position or to our arrangements for managing the situation. Meanwhile, any comments or questions about these arrangements should go to Charles Lister on 020 7972 4316. <mailto:charles.lister@doh.gsi.gov.uk>).

By E-Mail
SHEILA ADAM
Health Services Director
Department of Health

ANNEX A

Revised Advice from the UKHCDO Advisory Committee on Managing the Shortfall in Recombinant Factor VIII.

The UKHCDO Advisory Committee met on 15/5/01 to discuss the current shortage of recombinant factor VIII and revised the guidelines for dealing with this shortage as follows. It is clear that there is no shortage of plasma-derived factor VIII (pdVIII), and the use of these products does not have to be restricted at this time. Measures for optimal use, to conserve stocks of recombinant factor VIII, are as follows:-

1. Haemophilia Centre Staff should review infusion practices (i.e. rVIII units/dose) being used by individual patients with a goal of potential reduction in dosage if possible.

2. Those patients for whom there is insufficient recombinant factor VIII for treatment should be switched to plasma-derived VIII (use UKHCDO Therapeutic Guideline for selection of product). Priority for recombinant factor VIII (rVIII) should be given to individuals who have always been treated with these products and to PUPS.

3. Patients over the age of 16 years currently treated with rVIII should be changed to pdVIII until an improvement in supply permits them to change back to rVIII. Consideration should be given to changing children currently treated with recombinant, but previously treated with pdVIII, back to pdVIII until supplies improve.

4. Treatment centre staff should consider increasing the interval between doses on an individual basis and using individual dose of 25 units/kg for children on long-term prophylaxis with rVIII. Such modifications to prophylaxis must be accompanied by advice on sporting and life style activities.

5. Non-urgent surgery with rVIII should be postponed with immediate effect.

6. Starting patients on immune tolerance with rVIII should be postponed. Immune tolerance may start using high-purity pdVIII. Immune tolerance currently in progress should continue without dose-alteration, but using pd VIII rather than rVIII.

7. Patients currently using pdVIII should not be switched to rVIII until the shortage is over and patients previously treated with rVIII have changed back to those products.

8. Product usage in all patients should be decreased by considering the greater use of continuous infusion for surgery and serious haemorrhage.

9. Patients using plasma-derived factor VIII may be treated as before the shortage, using these products.

(See attached file: Annex B.xls)

Please reply to Email-Addresses Mailbox (email-addresses@doh.gsi.gov.uk) <mailto:email-addresses@doh.gsi.gov.uk> if there are any changes in

Excel 2.x Chart

your Email details.