To: Parents of Children with Haemophilia & Patients with Haemophilia

From: UK Haemophilia Centre Doctors Organisation

13th June 2001

Re: Shortage of Recombinant Factor VIII

As you will know by now, problems in the manufacture of Kogenate and Helixate have caused Bayer to release very little of these brands of factor VIII since late last year. It now seems likely that reliable regular supplies of these products will not resume until early next year. This effectively reduces the World's supply of recombinant factor VIII by about 50%. To avoid running out of recombinant factor VIII altogether it has, therefore, been necessary to take many patients off recombinant factor VIII and to re-establish them on high purity plasma derived factor VIII treatment.

The UK Haemophilia Centre Doctors Organisation (UKHCDO), in partnership with the Haemophilia Society and the Department of Health have drawn up guidelines for the use of recombinant factor VIII for the duration of the this supply crisis. These guidelines give advice on the reduction in the use of recombinant and give priority to the use of recombinant factor VIII for children rather than adults. Accordingly, it is our current recommendation that all patients over the age of 16 years should be changed to plasma derived factor VIII until supplies improve. Supplies are so short in some centres that many children over the age of 10 years have been taken off recombinant factor VIII to conserve supplies. UKHCDO are co-ordinating a scheme to re-allocate recombinant factor VIII to children's centres to prevent small children and children who have only ever been treated with recombinant factor VIII from having to change to plasma derived products.

I would emphasise that none of these production problems affect the safety ofHelixate and Kogenate. Furthermore, the high purity plasma derived factor VIII concentrates that we are using as an alternative are also completely safe as far as it is possible to determine.

Our information is that supplies of recombinant factor VIII will gradually improve from August but will probably not normalise until the New Year. This should enable us to put patients back onto recombinant factor VIII in stages, starting with the youngest children, so that we hope everyone who had been treated with recombinant factor VIII will be back on this product by the end of the year. The current guideline, a copy of which is attached, will be reviewed as supplies improve. We will continue to work closely with the Haemophilia Society and the Department of Health to minimise any problems that this severe shortage may cause.

Dr CRM Hay
Acting Chairman - UK Haemophilia Centre Doctors Organisation

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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.

15/5/01