Copy of letter sent to all Haemophilia Centres

Our Ref.:PI8HT/01

24th January, 1985

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Dear &NAME&

Supplies of Heated Factor VIII Concentrates

I am writing to advise you of the progress made in the development, by the Blood Products Laboratory, of heated factor VIII concentrates, and to invite you to make written requests to BPL for stocks of heated factor VIII concentrate for use in the treatment of named patients.

Heated Factor VIII Concentrates : anticipating our original estimate of April for the availability of a heated factor VIII concentrate, limited supplies of a heated intermediate purity concentrate will be available early in February. This concentrate, which is a dry-heated variant of the NHS concentrate previously supplied to you, will be the product generally available for the next three to four months, the amounts available being 50-60% of what would otherwise have been supplied as unheated concentrate.

A direct consequence of heating this preparation in the dry-state is a reduced unitage of factor VIII per vial - approximately 185 iu factor VIII per vial; additionally solubility of the product is marginally impaired, although resolution should be achieved within 10 minutes if the vials of dried concentrate and Water for Injections are pre-warmed to about 30°C.

From April onwards, an improved higher purity concentrate, designed specifically with anti-viral treatment in mind, will be introduced, initially in limited quantity. This concentrate, coded 8Y, will completely supercede the intermediate purity product, and it is anticipated that all issues of factor VIII will be in this form by June 1985. In addition to improved specific activity (and a consequent improvement in solubility), it is anticipated that this product will tolerate sufficiently extreme conditions for viral inactivation as to address the problem of inactivation of hepatitis viruses as well as inactivation of HTLV-III.

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Arrangements for Supply of Heated Concentrates : these products are not presently covered by a product licence so that certain restrictions on issue are necessary. Additionally, in the case of the new 8Y preparation in particular, it is important that Blood Products Laboratory recover maximum information on all aspects of safety and effectiveness in clinical use, in order to support a product licence application for this preparation.

Issues of these preparations will be made direct to haemophilia centres in response to a specific request for heated concentrate to treat named patients. The attached protocol distinguishes three categories of patient follow-up, one of which will be appropriate to any patient treated. Please indicate in your request for supply the following information on each patient :-

i. category (1 to 3 in the context of the protocol);

ii. anticipated requirement of concentrate based on treatment history.

BPL will not be able to supply the total national requirement for heated concentrate in the short term, but supplies will be distributed between haemophilia centres as equitably as possible. You should understand that regular return of the data appropriate to each category of follow-up is a condition for continued supply. I am sure you will appreciate the need to secure information for product licensing at the earliest possible opportunity, permitting us to issue heated concentrate more freely.

The initial request for supply, and all subsequent correspondence on this matter, should be addressed for my attention at BPL.

Yours sincerely,

T. J. SNAPE
Head of Quality Control
jg

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