BLOOD PRODUCTS LABORATORY

National Blood Transfusion Service

Director:
R.S. LANE, MD MRCP MRCPath.

Telephone : GRO-C

Dagger Lane,
Elstree,
Borehamwood,
Herts WD6 3BX.

24 July 1985

To: Haemophilia Directors, England & Wales.
Regional Transfusion Directors, England & Wales

INFORMATION SHEET: JULY 1985

DRIED FACTOR VIII CONCENTRATE:- HIGH PURITY, HEAT-TREATED

As reported in the Information Sheet (May 1985), a new Factor VIII concentrate (type 8Y) is now replacing the intermediate specific activity products HLH and 8CRVH. General issue will begin from September 1st 1985.

This high purity product, containing a nominal 250 iu per vial has been dry heated at 80°C for 72 hours to reduce the risk of infection by viral agents, although further assurance is sought over freedom from risk of viral transmission.

Solubility is much improved over HLH and 8CRVH; the vial containing less than 25 g/l total protein (expected range 6 - 14 g/l) in a reconstitution volume of 10 ml. A more detailed product information sheet is enclosed with this circular.

Safety and efficacy trials of the 8Y concentrate are already proceeding at several Haemophilia Centres. As of 1st July 1985, eight patients receiving fourteen infusions of three batches of concentrate have shown dose responses in the range 1.1 - 2.9, and a mean half-clearance time of 10 hours, entirely consistent with experience of unheated concentrates.

Clinical trials at six Haemophilia Centres are in progress to gain evidence of reduction or elimination of viral transmission, and several patients have safely passed the point at which first evidence of NANBH virus transmission would normally occur with unheated Factor VIII.

In accordance with the regulatory requirements, the product should be issued by clinicians on a named patient basis until a product licence has been granted: a product licence application will be lodged with The Medicines Division in the Autumn.

Factor 8Y will be issued through Regional Blood Transfusion Centres, unless special provisions exist by agreement for product to be sent direct to the Haemophilia Centre. Allocations to the BTS will observe the Pro Rata requirements for distributions agreed between BPL and the BTS except for 8Y required to fulfil the special needs of clinical trials to provide information for product licence application.

It is recognised that, until the new production unit at Elstree is completed, output of 8Y will meet about one third of current demand for concentrate and for this reason, attempts have been made to define those patients likely to benefit most from the security inherent in 8Y.

2149

15-289

Therefore, Haemophilia Centre Directors are being asked to compile lists of their patients considered 'at risk' and most Centres have complied. It is the considered view at BPL that, where possible, liaison between the Haemophilia Services and the BTS should aim at directing Factor 8Y to these patients, using the existing framework of distribution and supply.

Haemophilia patients who are HTLV III Ab negative and have no history of hepatitis are being identified as suitable persons to comply with clinical trial requirements. This treatment group is under separate discussion between the Trial Centres and BPL. For your information, a trial protocol is attached.

For any further information, please contact:

Product Services Department
01-953-6191 Extn. GRO-C

F8/7/85

15-270