Appendix 46
Dr. A. Scott  
Medical Director  
National Drugs Advisory Board  
Charles Lucas House  
63-64 Adelaide Road  
Dublin 2.

Dear Dr. Scott,

The Blood Transfusion Service Board (BTSB) is drafting its application to manufacture Human Factor IX Concentrate as an established drug.

This product has been prepared and used with complete success since 1972, the BTSB currently supplying 65% of the Country's needs of 1,200,000 I.U. per annum.

The reason for the continuing importation of some commercial concentrate is solely that it is packaged in a form convenient for home therapy. In order to obviate the need for such imports, the BTSB has, for some time, been evaluating a package which would include commercially manufactured Distilled Water for Injection, together with a syringe and transfer and injection needles, and a slight modification to the drying procedure of the vial of BTSB Factor IX Concentrate.

It is understood that these modifications might lead to the newly packaged product having to be considered as a new drug for product application purposes. In view of the undoubted benefits of attaining 100% home production, both for economic reasons and because of the concern over transmissible diseases, it would be contrary to the State's interests to delay implementation of the new packaging pending extended evaluation.

I trust, therefore, that the National Drugs Advisory Board will consider the proposed improvements as a natural upgrading of the present product presentation, and that the BTSB may submit its Product Application accordingly.

Yours sincerely,

[Signature]

J.P. O'Riordan

NATIONAL DRUGS ADVISORY BOARD

WORLD HEALTH ORGANISATION, NATIONAL BLOOD GROUP REFERENCE LABORATORY
Appendix 47
2493

AS/RP


Dr. J. P. O'Riordan,
The Blood Transfusion Service Board,
Pelican House,
P.O. Box 97,
40 Measpil Road,
Dublin 4.

Dear Dr. O'Riordan,

Thank you for your letter of 6th June 1984.

If I understand you correctly you will have two presentations of Factor IX concentrate available for a short period of time. The 'new' presentation will comprise a diluent vial and syringe and needles as well as the vial of Factor IX. The only significant factor requiring evaluation would appear to be the modification to the drying procedure.

It seems to me that the simplest way of proceeding would be to make an application for the two presentations at the same time, including a description of the modified process, forwarding also details of the syringe and needles and Water for Injection.

The two can be examined and completed together.

I hope you find this acceptable.

Yours sincerely,

[Signature]

A. I. Scott, M.D., F.R.C.P., F.R.C.P.I., Medical Director.
A Chaira

I am directed by the Minister for Health to refer to your letters of 1st February and 10th April, 1980 and to inform you that this Department has no objection to the proposals set out in Paras. (1) to (5) of the Policy Document on the Purchase of Concentrated Products enclosed with your letter of 1st February subject to the following comments.

It is noted that under Para. 3 the evaluation of all available products would be done in consultation with the National Drugs Advisory Board. It is presumed that the evaluation will be carried out in such a way as to avoid any overlap of responsibility with the National Drugs Advisory Board. In regard to Para. 4 it is considered that it would be more appropriate for the National Haemophilia Co-Ordinating Committee to make its recommendations to health boards rather than to the Department of Health concerning the products to be recommended each year.

The proposal that the Department should request the Blood Transfusion Service Board to begin the production of a more Concentrated form of Factor VIII has been considered. If the Board considers that it is necessary to produce a more concentrated form of Factor VIII than the present form, it is empowered under Article 4 of its Establishment Order to do so. However, in view of the general economic circumstances at present the Department should be informed of the additional resources which would be needed to undertake this work, the costs involved and how your board would propose to meet them.

Mise le meas

[Signature]

general Hospital Services Division

EK
23 JUN 1981

Dr. J. P. O’Riordan
Chairman
National Haemophilia Service
Co-Ordinating Committee
40 Mespil Road
Dublin 4

A Chara

Factor VIII Concentrate Requirements

I am directed by the Minister for Health to refer to your letter (JPOR/BOD) of 9 July, 1981 and attached report concerning above.

In order to have this matter examined, it would be appreciated if you would indicate whether the Blood Transfusion Service Board has considered the report and accepted its findings and, if so, what additional resources would be needed to implement them and how the Board would propose to meet the costs involved.

In this connection, your attention is drawn to the Department’s letter of 25 June, 1980.

Mise le meas

P. O. Beallachín
AN BORD SEIRBHÍSE FUILAÍSTRIÚCHÁIN
THE BLOOD TRANSFUSION SERVICE BOARD

Professor I.J. Temperley
Medical Director
National Haemophilia Treatment Centre
St. James's Hospital
P.O. Box 580
Dublin 8.

Dear Professor,

I wish to acknowledge receipt of your letter of 17 December 1984 and to advise that the question of heat treatment of all products for the treatment of Haemophiliacs is being given urgent attention by the Board.

As soon as it has been agreed by the Department of Health that contract fractionation from 'native' plasma be undertaken, those concerned with the treatment of haemophilia will be fully involved in the formulation of the proposals relating to such contract fractionation.

Yours sincerely,

J.P. O'Riordan

p.c. Dr. P. Cotter, Regional Hospital, Cork.
     Dr. S.M. Basheer, Regional Hospital, Limerick.
     Dr. J.H. Walsh, Department of Health.