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Note: All figures quoted are based on the 7th International Standard. Future documents/minutes will contain figures calculated using the 8th International Standard.

**NOTE OF THE MEETING OF THE DIRECTORS OF THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE AND HAEMOPHILIA DIRECTORS HELD IN ST ANDREW'S HOUSE, EDINBURGH ON FRIDAY 11 MAY 1990**

Present

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| Chairman: | Dr McIntyre, SHHD |
| SNBTS: | D McIntosh, General Manager<br>Dr Stewart, Clinical Trial/Product Development Manager<br>Dr Perry, PFC<br>Dr Foster, PFC<br>Dr Galea, Aberdeen and North East<br>Dr Brookes, East |
| Haemophilia Directors: | Dr Ludlam, Royal Infirmary, Edinburgh<br>Dr Lowe, Royal Infirmary, Glasgow<br>Dr Gibson, Yorkhill, Glasgow<br>Dr Bennett, Royal Infirmary, Aberdeen |
| SNBTA: | Professor Girdwood, Chairman |
| NIBTS: | Dr McClelland, Director |
| Secretary: | R Angus, SHHD |

1. **APOLOGIES FOR ABSENCE**

Apologies for absence were received from Dr Dawson, Dr McDonald, Dr Urbaniak, Dr McClelland, Dr Whitrow, Dr Taylor, Dr Boulton, Dr Mayne, Dr Mitchell and Professor Cash.

2. **NOTE OF MEETING ON 27 JULY 1989**

The following amendments were agreed:-

2.1 delete Dr Bennet and Dr Whitrow from the list of those present;

2.2 item 3.8 should read "OAS programme had already started in the South East and was due to start in the West in April 1990";

2.3 item 3.11 delete "and less than 10% is outdated before issue"; and

2.4 item 5 delete "It was noted that Scotland had the lowest prevalence of HIV infection in Haemophiliacs in the world".

Apologies were offered for the delay in producing the note of the last meeting which was due to staff shortages within the Department.

There was a short discussion about the status of the note of the meeting and whether or not formal minutes should be taken. The Chairman

explained that although the meeting was a very valuable forum for discussion, and the Chairman and Secretary were provided by the Department, the meeting, as far as the Department was concerned, was informal.

(There was a short discussion on the future of the meeting and this is covered under item 8).

**3. SNBTS PLANNING FOR THE FUTURE PRODUCTION OF BLOOD PRODUCTS FOR THE MANAGEMENT OF PATIENTS WITH HAEMOSTATIC OR THROMBOTIC DISORDERS**

Dr Stewart introduced his paper and expressed his thanks to those who had provided the information for the report. Dr Stewart explained that the figures for 1990 were the result of extrapolating the figures for the first 9 months to the whole year.

Attention was drawn to the following points:-

3.1 Following the request at last year's meeting, cryoprecipitate had been removed from the figures.

3.2 Due to a change in the working standard, this year's report was the last one to use the 7th International Standard and future reports would use the 8th International Standard.

Fresh Plasma Procurement for Factor VIII

3.3 The actual figure for SNBTS fresh plasma procurement for Factor VIII production in 1990 was 63,800kg.

3.4 The actual figure for Factor VIII issues in 1989/90 was $7.86 \text{ iu} \times 10^6$.

3.5 Plasma "quality", apart from regional and seasonal variations, is fairly constant, and there is a project underway to improve quality.

Commercial Factor VIII Concentrates

3.6 The 1989/90 figure for commercial Factor VIII concentrates refers to usage rather than purchase as in previous years.

3.7 Concentrates produced by BPLA Elstree are treated as commercial in the report.

3.8 Glasgow's purchases of commercial Factor VIII concentrates (appendix IV) in 1989/90 were $564 \text{ iu} \times 10^3$. The increase towards the end of the year was due to surgery.

Total Factor VIII Usage

3.9 The reason for the fall in total Factor VIII usage in 1989/90 was not known but it was not due to mortality.

Future Production Targets

3.10 There were problems re-starting production after the planned shutdown in October/November 1989 but production was now back on course.

3.11 The stock at 31 March was 2.05 iu x $10^6$.

3.12 The production targets for SHS should read as follows:-

| Year Ending 31 March | iu x $10^6$ |
|---|---|
| 1990 | - |
| 1991 | 13.40 |
| 1992 | 16.44 |
| 1993 | 13.59 |
| 1994 | 14.35 |
| 1995 | 13.32 |

The SNBTS anticipates that with these levels of production it will be able to meet demand. The 1995 production target assumes a reduction of the stock following the completion of the PFC phase III/IV building programme.

3.13 Meeting these production targets would require changes in working practices at the PFC eg, introduction of shift working, and these were in hand.

Product Developments

3.14 The production trial of S8 had been completed up to freeze-drying stage and was now at the end of the heat treatment process. The results would be available shortly.

3.15 There are no plans for development of an activated Factor IX.

3.16 Reservations were expressed about the quality of Factor IX when used for treating Christmas disease and that an updated one factor product would be preferable to the current 3 factor product. In reply, it was stated that the quality issue concerned the thrombogenic risk associated with these products and that the SNBTS did have plans to develop a non-thrombognic product.

3.17 The SNBTS have plans to produce a plasma derived Factor VII for use by patients suffering from haemophilia A with inhibitors or who are over-warfarinised with Factor VIII. It is expected that a commercial synthetic Factor VII will be available shortly.

Factor IX Concentrates

3.18 Commercial purchases of activated Factor IX concentrates (Appendix VII) by Glasgow in 1989/90 were 137 iu x $10^3$.

3.19 It was agreed that anti-thrombin III statistics should be included in future. It was pointed out that anti-thrombin III was available from Oxford and it was agreed that this would be pursued by the Factor VIII working party.

PFC Supplies to Northern Ireland

3.20 There was a very low uptake of Factor VIII by Northern Ireland in the second half of 1989/90. Dr Stewart undertook to check the figure for Factor IX supplied in 1987/88.
3.21 SNBTS Factor VIII and Factor IX concentrates are to be licensed by the March 1991 deadline.

**4. SECOND ANNUAL REPORT OF THE SCOTLAND AND NORTHERN IRELAND FACTOR VIII WORKING PARTY**

Dr Ludlam introduced the second annual report of the Factor VIII working party.

During a general discussion, the following points arose:-

4.1 The presence of a Departmental representative in the working group would be welcomed. It was explained that due to staff shortages, this would not be possible at the present time.

Quantity of SNBTS Factor VIII

4.2 The minimum national reserve stock of Factor VIII should be the equivalent of 3 to 4 months usage.

Quality

4.3 Once S8 was in production the haemophilia directors would like a development programme for a product with a specific activity of 30-50 iu/mg protetin.

4.4 The general unsatisfactory standard of the Z8 product was discussed. Problems had been experienced during the year with the solubility when reconstituting and in addition Z8 did not contain sufficient von Willibrands factor for treating these patients. In defence it was countered that Z8 was a very safe product and, because of the manufacturing processes involved, higher purity products may be less safe. The SNBTS are committed to a high purity product but are interested in safety first and convenience second. Co-operation with the French to produce a high purity product was under consideration. Due to the quality problem Northern Ireland had not been taking up its full allocation.

Usage Statistics

4.5 Although very time-consuming to collect, the stats produced by Dr Stewart are extremely useful and have allowed the re-distribution of surplus Factor VIII to Glasgow/Lothian thereby saving them money.

Distribution of Factor VIII

4.6 The new distribution arrangement will involve the smaller centres requesting the amounts that they require and the remainder being shared between Glasgow and Lothian. This arrangement will be underwritten by issues from the national stock if required. Distribution should be automatic based on minimum stock levels with a back-up system in cases of emergencies. Guidelines will be

issued setting out what minimum stock level a Centre should hold against unforeseen circumstances.

Future Projected Requirement for Factor VIII Concentrate

4.7 Based on current growth rates of approximately 10% per annum, the estimate of 16 iu x $10^6$ by 1994/95 was agreed.

Surveillance of Safety of SNBTS Products

4.8 The Previously Untransfused Patient (PUP) Surveillance Study has been launched and has so far shown that heat-treated Factors VIII and IX do not appear to transmit either hepatitis or HIV.

4.9 Dr Ludlam expressed concern that without support, he would be unable to continue due to the amount of time required for the study. A request for Departmental funding for a half-time secretary for Lothian and a half-time nurse for Glasgow was made under the auspices of Medical Audit. One of the haemophilia directors questioned whether this was not a question of product safety and quality assurance and therefore for the SNBTS to fund. The urgency of finding a solution to this problem was stressed because of the need to identify babies at an early stage.

## 5. EFFECT OF WHITE PAPER ON HAEMOPHILIA CENTRES

The Department's views on the White Paper implications for co-ordinated national haemophilia policy were requested. Concern was expressed that Health Boards might decide to start treating haemophiliacs locally. It was considered that this would be detrimental to patient care and would upset the present Factor VIII distribution arrangements. The Chairman explained that the Department appreciated the important service which the Haemophilia Centres had provided and undertook to raise the matter in the Department, explaining the pros and cons and conveying the directors' concerns.

Dr Ludlam offered to produce stats from North America on centralisation if they would be of any help.

## 6. CURRENT TARGET FOR FACTOR VIII PRODUCTION

This item was covered under item 4 (see 4.7).

## 7. ANY OTHER BUSINESS

Dismay was expressed that during a radio interview on the withdrawal of a batch of Factor VIII because of possible contamination with Hepatitis B, Dr Lane, Bio Products Laboratory, Elstree had given the impression that the English product was safer than the Scottish product which could alarm users of the Scottish product.

## 8. DATE OF NEXT MEETING

The Chairman explained that due to changes of policy and practice, the Department would no longer be able to be directly involved with "informal" meetings such as the Haemophilia/BTS Directors meeting. He expressed a wish that the meetings should continue either under the

auspices' of the SNBTS or the Common Services Agency. It was hoped that it would be possible for an observer from the Department to attend.

It was agreed that the next meeting should be on Friday 10 May 1991 at 1.30pm.