N.B. Since the next meeting will not take place for over a year Directors are asked to address any comments or queries to the Chairman now.

MINUTES OF THE MEETING OF THE DIRECTORS OF THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE AND HAEMOPHILIA DIRECTORS HELD IN ST ANDREW'S HOUSE ON MONDAY, 9 FEBRUARY 1987

Present:
Dr J M Forrester (Chairman)
Dr B Bennett
Dr C A Ludlam
Dr D B L McClelland
Dr E W A Brookes
Dr J D Cash
Dr R J Perry
Dr P Foster
Dr I M Hann
Professor R H Girdwood
Dr G A McDonald
Dr E Mayne
Dr C D Forbes
Dr S Urbaniak
Dr F E Boulton
Dr T Taylor

In Attendance:
Mr D Macniven (for item 3 only)
Mr G M Thomson
Mr R Angus (Secretary)

Introductions

The Chairman introduced Mr Macniven, Mr Thomson and Mr Angus to the members of the Committee.

1. Apologies for Absence

Apologies for absence were received from Dr Heppleston, Dr M McClelland, Dr Mitchell and Dr Dawson.

2. Minutes of Meeting held on 5 March 1986

Minutes of the last meeting were noted.

3. Compensation for participants in clinical trials

Mr Macniven informed the meeting that he had fully recognised the reluctance of Haemophilia Directors to perform clinical trials of the new PFC preparation of factor VIII until assurances could be provided about compensation in the unlikely event that harm might befal the patients. The Department had consulted with Treasury, and he was able to report that a scheme similar to that already in force for the production of Anti-D would operate in the new factor VIII trials. Any claims would be considered by a 3 man panel and the ABPI guidelines would apply. He noted that the guidelines do not provide for consideration of compensation unless damage is substantial.

A lengthy discussion followed in which the following points emerged:

a. The new agreement would only apply to the initial trials of the new factor VIII, but the Department continue to pursue the interests of participants in trials of PFC products generally, and the Agenda for next year's meeting will include this item. Meantime proposals for compensation schemes to cover trials for further products may be made to the Department. In particular, Mr Macniven agreed to investigate the position in relation to "named patient" administration of products, which follows initial trials.

b. There have been no claims under the existing schemes and thus no precedents to indicate the amounts likely to be awarded.

c. No one under the age of consent should take part in the trials.

d. The newly secured compensation scheme does not apply to administration for therapeutic purposes.

e. All volunteers should sign a document agreeing to take part in the trials. However, this does not in itself protect doctors from legal action.

f. Volunteers should inform their insurance company, although there had been no problems with insurance companies in the past.

g. Professor Girdwood asked whether or not the Ethics committee could be sued and Mr Macniven advised that the Department was investigating this complex question.

h. The role of product licences in relation to compensation is not clear at present, and will be on next year's Agenda.

Dr Ludlam thanked Dr Forrester and Mr Macniven, on behalf of those present, for their efforts in arranging the scheme.

4. Report from SNBTS

Dr Cash introduced the report which had been precirculated, and expressed his thanks to the SNBTS Directors and especially Dr Perry for their assistance in providing information. He particularly emphasised the following points:

a. The input of fresh frozen plasma to PFC has fallen, for the first time in many years. Dr Urbaniak reported concern in Aberdeen at a 5% annual decline in the number of donors during the past 2 years.

b. There has been a fall in the use of factor VIII in Scotland during 1986, and on a population basis overall use is less in Scotland than in England and Wales.

c. Plans are now well advanced for the introduction of a new factor VIII which is of higher purity and higher yielding. Further batches manufactured since January 1987 have been dry heated at 80^{o}C for 72 hours to inactivate virus including HIV, and thus should be safer in this respect than ever before. Dr Perry exhibited the product to those present and reviewed the relevant studies of virus inactivation. Dr Hann welcomed the new product and hoped for a smaller vial to use in children. Dr Ludlam wished success to PFC's efforts to make a purer product still, and he and Dr Forbes agreed to accept the new product for trial.

c. Suspicion existed in Northern Ireland that one batch of heat-treated Factor IX lacked efficacy when given to patients with inhibitors. Dr Mayne however doubted whether any lack could be linked to a single batch.

e. SNBTS contemplate a new product: activated Factor IX. It would remove the existing need to purchase a commercial equivalent, but its testing would present difficulties.

Dr Perry amplified Dr Cash's report and pointed out the increase in the use of factor IX during 1986. Dr Hann welcomed the increase if it represented satisfactory replacement for FEIBA, but its actual destination is unclear.

Dr Perry noted that Scotland's use of Four Factor Concentrate is small: in the order of 250 vials per year. Four Factor Concentrate cannot be heat treated, but is obtained from screened donors. Members were invited to consider whether it might be best to purchase any future needs from commercial sources, especially since it would be superseded by the introduction of heat treated factor VII. PFC was advised to cease production of Four Factor Concentrate. Dr Perry mentioned that clinical trials of factor VII would be ready to begin either in Autumn or towards the end of the year.

In answer to a question, Dr McClelland informed the members that approximately 1 in 50,000 blood donations was found to be HIV positive.

5. Current target for factor VIII production

The members agreed to postpone consideration of this item until the next meeting, since current usage is far short of target, and the new product offers a markedly higher yield.

6. Z8 product

Dr Perry reported that production of the current product was being run down and it was planned that the Z8 product would be available in 500 u vials as well as in smaller quantities. He informed the members that the PFC could produce 190iu plasma of the current product from each litre of plasma, but 300 iu of the Z8 product. The PFC has a potential output of 18 million units per year if the supply of plasma stays constant.

7. Non-A, Non-B Hepatitis screening

Dr Forrester reported the results of the recent Transfusion Associated Hepatitis Working Party meeting. In the USA between 5% and 25% of transfusions lead to the recipient contracting Non-A, Non-B Hepatitis. In the UK the figure is approximately 2.5% and in Scotland, during the last decade, there have only been 1 to 5 cases per annum. Non-A, Non-B Hepatitis would appear to be relatively benign, despite some risk of cirrhosis of the liver in the long term, unless the recipient is pregnant when the effects can be very serious. In the USA screening by the combination of a liver function test and assay of Hepatitis B core (not surface) antibody removes between 30% to 40% of cases for the loss of 1% of donations. In the UK it is proposed to set up a study based on 4 centres, one of which will be in Scotland. The purpose of the study will be to discover:-

a. The number of donations affected

b. What does a positive test mean about the donor?

c. The effect of giving blood positive on this screening

d. The cost of screening.

Dr Cash noted that question b. was of an academic nature, so that its resolution might lead to delay in the introduction of screening; meantime commercial products, if derived from screened plasma, might enjoy an advantage over SNBTS products derived from unscreened plasma. But Haemophilia Directors advised that they would not resort to commercial products for this reason.

The cost of screening in Scotland would be approximately £750,000 per year. Dr Perry expected improved heat treatment to do more to abolish transmission of non-A, non-B Hepatitis than screening could, and Dr Ludlam considered that Scottish Factor VIII was already safer than before in this respect.

8. Any Other Business

None.

9. Date of next meeting

It was agreed that the next meeting would take place on Thursday, 5 May 1988 at the Protein Fractionation Centre, Liberton at 11.00 am and would include a short tour of the centre.

4 March 1987