CENTRAL BLOOD LABORATORIES AUTHORITY

CENTRAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN BLOOD TRANSFUSION

Minutes of the fifth meeting of the Central Committee for Research and Development in Blood Transfusion, held on 2 April 1985 in the Board Room, The Crest.

Present:
Dr H H Gunson (Chairman)
Dr K I Gibson
Dr R S Lane
Professor L Luzzatto
Dr C Rizza
Dr D P Thomas

In Attendance:
Mr W P N Armour (CBLA)
Dr A E Bell (SHHD)
Dr A Smithies (DHSS)

1/85 Apologies for Absence

Apologies for absence were received from Professor A Bloom, Dr I A Fraser, Dr A M Holburn, and Dr D B L McClelland.

2/85 Minutes

The minutes of the meeting held on 9 November 1984 were approved as a correct record.

3/85 Matters Arising from the Minutes

3.1 Genetic Engineering and Blood Products

The Secretary reported that he had received a letter from Professor Brownlie in reply to earlier correspondence he had sent to him regarding genetic engineering and blood products. It was noted that Professor Brownlie's department at Oxford were on the verge of producing, from a genetically engineered source, an improved quality and safer viral-free Factor IX, and were keen upon a development collaboration with the CBLA on this production.

Dr Lane referred to a recent telephone conversation held with Professor Brownlie on this matter and said that the BPL would be keen to support any collaborative work of this nature. He felt that a meeting therefore should be arranged to discuss this as soon as possible.

2038

77/61

Dr Thomas stressed the need to produce a paper outlining proposals for such a collaboration and it was agreed that a meeting would be arranged with Professor Brownlie in order that a protocol could be drawn up. The Chairman of the CBLA, Dr Gunson and Dr Lane would explore avenues for co-operation with Professor Brownlie.

Dr Gibson raised a question regarding patenting of the product bearing in mind that an article had appeared in Nature on Professor Brownlie's work. It was agreed to raise the issue of patents with Professor Brownlie. In the meantime, it was agreed that Dr Smithies should also investigate matters relating to the protection of this development. This matter would be reviewed at the next meeting.

3.2 Bridge Anticoagulant Neutralising Reagent (BANA)

It was noted that Dr Nour Eldin had recently written to Dr Gunson asking about progress in relation to this matter. The Secretary confirmed that no response had yet been received from DHSS, although the recommendations of the Research Committee had been referred to them.

3.3 Clinical Trials of alpha-1 Antitrypsin

Dr Lane referred to a meeting held on 6 February with BPL's Research and Development Department and it was noted that two Consultants, one from Papworth Hospital and the other from Addenbrookes Hospital, Cambridge, had expressed an interest in the production of alpha-1 antitrypsin in connection with heart and lung transplants. It was considered that such a programme would cost approximately £12,000 and financial support was likely to be available from Papworth. It was noted that the Consultants concerned would be speaking to their colleagues on this and further information was now awaited on a possible protocol for this development work.

Dr Lane expressed his enthusiasm for the project provided the necessary financial backing from Papworth Hospital was available.

Dr Lane confirmed that the possible production of alpha-1 antitrypsin by plasma fractionation for administration to patients with hereditary AT deficiency, had not attracted financial support. A protocol for this therefore had now been put in abeyance.

77/62

3.4 Information on Haemoglobin Solution for Transfusion

Dr Gunson confirmed that he had written to Mr D Smith at Travenol, requesting further information about the development of haemoglobin solutions for transfusion. A reply was still awaited.

Dr Lane reported that he had received a proposal from the ABSD, Aldershot which involved it using haemoglobin solutions for military purposes. It was agreed that Dr Lane would circulate information about this proposal to members.

3.5 Status of Central Committee for R & D in Blood Transfusion

It was noted that there were no further developments in regard to the matter of whether or not the Committee should be regarded as a UK Committee. Discussions were continuing.

4/85 A I D S

4.1 Introduction of anti HTLV3 Testing in BTS

The Chairman confirmed that five USA companies had been asked to set up screening tests in 1984; two firms had now been licencedby FDA for the test which meant that exported tests from USA could be used in other countries.
The Chairman highlighted possible problems for the BTS as a result of the introduction of the tests, as follows: -

a) Obtaining a proper valuation with the US test on donor population would be difficult, and the UK might have to consider doing its own.

b) The implication of the test was not really known. A positive test indicated that donor had been exposed to virus but may exhibit no signs of illness. The implications regarding transmission to others or personal health could not be determined at present.

c) Whilst persons in a high risk group were currently being asked not to donate blood, some might be attracted to donor sessions simply in order to be tested, if the BTS introduced the test unilaterally.

d) If tests were not introduced simultaneously in the UK, public concern was possible if certain Regions fell behind schedule.

Dr Smithies reported that evaluation studies of the tests had been set up. A protocol for the evaluation had been sent to manufacturers and results would hopefully be received by mid-May. It was noted that the DHSS expected to publish the results of the evaluation to the NHS.

77/63

Dr Smithies reported upon the current number of AIDS cases in the UK and it was noted that the first case of a drug abuser had occurred.

The importance of evaluation of the tests was emphasised and it was agreed that an adequate confirmatory laboratory service was required, especially in view of the high incidence of false positive results.

In answer to a question raised by the Chairman about testing in the haemophiliac population in the UK, Dr Rizza and Professor Luzzatto informed the Committee of tests they had carried out in Oxford and at the Middlesex Hospital and the results of these had confirmed the importance of evaluation.

4.2 Use of Heat Treatment on Factor VIII and Factor IX Preparations

Dr Lane confirmed that BPL had been looking at heat treatment for two years, with the primary aim to inactivate non A and non B hepatitis virus. He said that hopefully, the HTLV3 virus would also be dealt with in the heat treatment programme.

It was noted that a high purity product (Factor VIIIY) had now been achieved and three trial batches sent out. Clinical trials had so far proved encouraging.

Dr Lane informed the Committee that an abridged licence for the product was to be applied for in the near future. It was expected that the new product would pass through Q.C. procedures by the beginning of June.

In regard to Factor IX, Dr Lane said that examination of both wet and dry heat treatment had taken place. A current problem was the elevation of Thrombin activity which suggested the unstableness of the product under heat treatment. The Chairman said that because of the demand for heat treatment Factor IX, imported material was on the increase.

Dr Rizza reported that he had received samples of the new high purity Factor VIII heat-treated product and had used it for administration to patients suffering from haemophilia A. The product had exhibited satisfactory in vivo response and the patients had given unsolicited information concerning the absence of side reactions. He was continuing with longer term experiments with respects to the investigation of transmission of non-A, non-B hepatitis.

77/64

5/85 Any Other Business

5.1 The composition of the Central Committee was discussed. It was agreed that it would be useful for members to receive a current membership list.

6/85 Date and Time of Next Meeting

The next meeting would be held at Elstree on Tuesday 9 July at 11.00 a.m.

77/65