NOT FOR PUBLICATION **ACVSB 2/10**

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

MINUTES OF THE 2nd MEETING ON 22 May 1989

PRESENT

Dr E L Harris - (Chairman)

Members	Dr R Mitchell	Professor A Zuckerman
	Dr P Mortimer	Dr R Tedder
	Dr R Lane	Dr R Perry
	Dr P Minor	Dr E Tuddenham
Secretariat	Dr A Rejman	
	Mr J Canavan	
Observers	Dr H Pickles	Dr A McIntyre
	Dr F Rotblat	Dr H Flett
	Dr J Purves	Dr A George

APOLOGIES FOR ABSENCE

1. Apologies for absence were received from Dr Gunson and Dr Summerfield.

CONFIDENTIALITY

2. The Chairman reiterated the confidentiality of the Committees proceedings.

MINUTES OF THE MEETING OF 4 APRIL 1989

3. The minutes of the last meeting were agreed subject to the following amendments:-

para 27. To read: "The view was expressed that while some fractionation steps were known to reduce the level of infectious virus, a specific virus inactivation step was mandatory for product safety: such steps should be validated to establish efficacy."

para 28. To read: "On the available evidence at the present time there was no justification for routine screening ....etc."

MATTERS ARISING FROM THE MINUTES

4. There had been a report in the New England Journal of Medicine on 4 May 1989 about the risk of blood borne transmission

WTD/ 1280

of HTLV1. The Secretariat would obtain full details of the reference and circulate to members.

HTLV1 (ACVSB 2/2)

5. Members considered the proposal by the National Directorate to survey 100,000 donors. The choice of screening test would be difficult as this was a developing science. A test for HTLVI and II was not yet available but screening for HTLVI prevalence could be undertaken now. Selective testing would generate fewer false positives, if acceptable to RTDs as a sampling method. Reference Labs should be designated. Members advised against counselling donors found positive on initial screening as results must be confirmed to be accepted as truly positive. This should be a look-see exercise.

6. The Chairman considered a sub-group should examine these issues before 100,000 donors were screened. An evaluation of the test kits would be one of the considerations. Members commended the Fuji kit as worthy of consideration.

Human Growth Hormone (ACVSB 2/1)

7. The CMO for England had put recommendations to Health Ministers, and had written to Professor Preece to ask if he would extend his study. His findings would be reported. The Chairman said it may also be necessary to follow-up recipients of genetically engineered GH which was posing problems.

EC DIRECTIVES ON BLOOD PRODUCTS (ACVSB 2/3)

8. Members considered the suggested amendment to classify blood as a medicinal product, was impractical but it was expected to be rejected by the Commission itself. Dr Purves would keep members informed of progress on the framework Directives that Dr Schild's group was considering.

OVERVIEW OF HEPATITIS

9. The Secretariat sought advice on a range of hepatitis issues including the follow-up of jaundiced blood recipients.

10. Some plasma forwarded to BPL had been negative to markers but infectious. Members advised that a study at Central Middlesex Hospital had shown the incidence of post-transfusion hepatitis to be 1%. The general incidence might be underestimated as GP jaundice reporting was poor.

HEPATITIS B (ACVSB 2/5)

11. Members considered screening for Hepatitis B in the NBTS to be adequate.

12. Professor Zuckerman advised that the defined hepatitis high-risk areas in the proposed UKBTS/NIBSC guidelines should be

revised from the "Far East" definition which was imprecise. Greenland, Alaska, Romania, Bulgaria and other countries should also be added. The NBTS would consider its guidance aided by Dr Follett's paper on anti-core when available.

13. Members also advised that the NBTS should re-consider its acceptance as blood donors of those who had had jaundice 12 months ago; anti HBc testing was recommended before acceptance.

14. Excluding plasma which is anti HBc positive might be counter-productive for the fractionators.

15. Dr Gunson is editing the UKBTS/NIBSC guidelines and it was agreed that members would pass comments directly to him, copying to Dr Rejman.

NON A - NON B (ACVSB 2/6, 2/7)

16. Professor Zuckerman pointed out a typographical error on page 6, para 2 of ACVSB 2/6; anti HBc instead of anti HBc.

17. Members advised that although colleagues in the US considered only one virus caused NANB, there may be two or more. The Chiron test was estimated to pick up approximately 50% only and there was a need for caution. There had been enormous progress and once the sequence was published it would be possible to test without recourse to Chiron.

18. The Council of Europe had issued a questionnaire to determine which nations undertook surrogate testing; Dr Gunson would update this.

19. Plasma fractionators were considering funding ALT testing once the scientific basis was established. This would be necessary if excess products were to be sold to Europe.

20. It was agreed NANB testing should not be introduced into the NBTS prior to the results of the UKBTS NANB trial; anti HBc testing was not without problems. The Chairman considered that PHLS may need to be involved in the follow-up.

21. The Department would keep the issue of testing under review. The use of Chiron or surrogate testing would be influenced by Chiron data once released; MRC might be asked to consider. Members regarded the matter to be a priority.

ANY OTHER BUSINESS

22. None.

DATE OF NEXT MEETING

23. The next meeting would be on 3 July 1989 in Room 67 Hannibal House, Elephant and Castle, London at 10.30am.