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Dr H H Gunson
National Director
National Blood Transfusion Service
The National Directorate
Gateway House
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Manchester M60 7LP

8 March 1989

Dear Harold

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD

The United Kingdom Health Ministers have agreed to set up an expert advisory committee on the virological safety of blood. They believe it is of the utmost importance that the UK Blood Transfusion Services act in unison on this subject, and with the benefit of the best advice available.

I am writing to ask if you would agree to serve on the Committee. The Terms of Reference are:

> "To advise the Health Departments of the UK on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing."

We anticipate that the new Committee will need to meet quarterly, and the first meeting is planned for Tuesday 4 April at 10.30 am in Room 87, Hannibal House, Elephant and Castle, London SE1.

I hope you will be able to assist us by agreeing to serve on this Committee.

Yours sincerely

GRO-C

E L HARRIS
Deputy Chief Medical Officer

c.c. Mr Canavan → Dr Reyman
Dr Pickles

I've sent similar letters to all on the attached list. Dr Harris decided not to enclose the membership list.

09 MAR 1989
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Yvonne de S. 7/3/89.

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD


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April '89

IN – CONFIDENCE

[ACVSB1]

# ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD
# 1ST MEETING

## AGENDA

| | | |
|---|---|---|
| 1. | Introductions | |
| 2. | Terms of reference of this and related committees | ACVSB1/1 |
| 3. | Overview of foreseeable problems and plan of work | ACVSB1/2 |
| 4. | EC Directives on Blood Products | ACVSB1/3 |
| 5. | HTLV1 | ACVSB1/4 |
| 6. | Human growth hormone recipients | ACVSB1/5 |
| 7. | A.O.B. | |
| 8. | Date of next meeting | |

April '89

ACVSB1/1

## TERMS OF REFERENCE

1. Committee on the Virological Safety of Blood (ACVSB)

"To advise the Health Departments of the UK on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing".

Note remit is UK-wide. Our concern is matters of major policy, not the detailed implementation of policy. The intention is that any proposed changes in requirements or practices of one of the main groups (transfusion service, fractionators, regulators) that has major implications for the others are brought to this group first for discussion. Whilst our specific remit is with blood donors, our advice will also be made available to those within the Department who have policy responsibility for tissue and organ donors. Where the advice is clearly not relevant to these other donors, it would be helpful if this could be indicated in the discussions.

## TERMS OF REFERENCE OF RELATED GROUPS

2. Committee on Safety of Medicines (CSM) and the Biologicals Subcommittee

Gives advice to the Licensing Authority on the quality, safety and efficacy of medicinal products. The Licensing Authority covers the entire UK. The Medicines Act prohibits consideration of cost, need or supply. Whole blood and cellular components are not considered medicinal products.

3. National Transfusion Directorate and advisory groups

Implements the national strategy for the transfusion service and coordinates the activities of the BTS and the CBLA. England and Wales only, although frequent consultation with Scotland. Concerned with safety and welfare of donors, supply of safe fresh blood and blood components for patients as well as plasma for fractionators; subject to resource constraints.

4. UK Advisory Committee on transfusion transmitted diseases

This new UK group will be considering many of the same issues as the present committee, but only from a transfusion viewpoint.

5. NBTS/NIBSC liaison group

Formed between the NBTS/SNBTS and NIBSC to formulate (scientific) guidelines for the standardisation and safety of blood and blood products. The liaison group would be the appropriate forum for considering the detailed implementation of recommendations arising from the ACVSB.

6. NBTS/CBLA liaison group

A new group to discuss problems such as plasma supply and quality.Covers England and Wales only.

7. Expert Advisory Group on AIDS (EAGA)

Advises the Chief Medical Officers on matters relating to HIV infection. UK wide. Has given advice in the past on HIV1 and HIV2 testing for the transfusion service and will continue to do so if appropriate, but feeding through the Committee on the Virological Safety of Blood.

8. Advisory Group on Hepatitis

This group "provides medical advice to the Chief Medical Officers of the Health Departments on all aspects of communicable hepatitis" and has the appropriate expertise for detailed consideration of the technical aspects of screening donors and plasma for various forms of hepatitis, leaving the advisory committee on the virological safety of blood to consider the wider policy issues.

9. Microbiology Advisory Committee (MAC)

Advises the Department of Health (England) on disinfection and sterilisation applicable in and appropriate to the Health Service, and gives guidance on microbiological aspects of equipment etc. This committee should not overlap with the present committee.

IN - CONFIDENCE

April '89

ACVSB1/2

## OVERVIEW OF PROBLEMS FOR THIS COMMITTEE

1. The EC Directives on Blood Products could have a major impact on the UK. Products now made under Crown Privilege will have to be licensed. Blood will have to be harvested from donors selected according to the Directives and certain tests for virological conditions may be mandatory.

   This committee must ensure that consultation takes place so that the UK representative at the EC is adequately briefed on all the relevant interests, and in the event of conflict the final decision should lie with this advisory committee. Thus each meeting of this committee is to be briefed on the current position.

2. AIDS viruses (HIV1 and HIV2)

   The transfusion service, having taken note of the views of EAGA, attempts to select donors at low risk of HIV infection. This advisory committee may be considered to have a locus here only should there be disputes, say between the fractionators and the NBTS, on these exclusion criteria. In this age of litigation it is important, however, that common standards are operated throughout the UK, unless justified on clear epidemiological grounds. At present in England, slightly different exclusion categories are used by different transfusion services and we would look to the National Director to achieve rationalisation.

   Items to be brought to this committee in due course will include (a) a revised version of the "high risk" groups as advised by EAGA, amended for example in the light of increasing evidence of high prevalence heterosexual spread in some countries outside Africa, (b) consideration of if and when HIV2 screening should become routine.

3. HTLV1

   In view of recent action by the FDA, this problem needs urgent attention so a considered UK line can be given. This is an agenda item for this meeting - see paper ACVSB1/5.

4. Non A Non B

   The issue of surrogate or direct testing for Non A Non B hepatitis is also of some urgency. It is suggested this could be a major item for the next meeting, even though a final decision may have to await UK research currently in progress.

5. CJD

Another area where the FDA have pronounced and the UK may appear lagging behind is in the identification and exclusion as donors of human growth hormone recipients. This is an agenda item for this meeting - see paper ACVSB1/6.

6. Other

Depending on the views of members, there could be other items to be brought before this committee, for example in relation to agreed markers of hepatitis B infection, wider aspects of selection of hepatitis low-risk individuals or the place of CMV screening.

CHAIRMAN'S BRIEF

ADVISORY COMMITTEE ON THE VIROLOGICAL SAFETY OF BLOOD
MEETING 4 APRIL 1989 - 10.30 HRS: ROOM 65 HANNIBAL HOUSE

Domestic Arrangements

1. A morning only meeting is envisaged. Consequently we have not arranged a working lunch.

Introductions

2. There will be name plates and the list of members, secretariat and observers was circulated with the Committee members. However you may wish to go round the table and allow members to introduce themselves. In addition you could mention that Dr Tedder has agreed to serve since the membership was circulated; and that Drs Mitchell, Minor and Tuddenham will also be members but unfortunately could not attend this first meeting.

Terms of Reference (ACVSB1/1)

3. It would be worthwhile in introducing this paper to remind members of the terms of reference set out in paragraph 1 of ACVSB1/1. Their attention could also be drawn to following points:-

- remit is UK wide and Committee will formally report to the CMOs;

- committee is concerned with major policy and not detailed implementation;

- other groups with interests in this field will bring to the committee any proposals which impact on the others;

- committee is specifically concerned with blood donors. However advice will be made available to others in the Department with responsibility for tissue and organ donors. Members should indicate in their discussions if their advice is not relevant to these other donors.

4. Should also make the point that the intention in drawing up the membership has been to embrace representatives of all parties at producer and user levels as well as expert advisers.

5. It would then be appropriate to invite [ DHP ] to provide some background to the Committee.

Overview of Problems and Plan of Work (ACVSB1/2)

6. You may wish to introduce this paper. The main point to be made is that the issues which seem to require early attention are the EC Directive on Blood Products, HTLV1 and CJD and that these are ~~currently~~ papers to be discussed at this meeting. The issues of AIDS viruses and Non A Non B hepatitis are to be considered at future meetings.

7. We would not wish to have the Committee discuss the merits of the proposed programme at this stage. However it could be mentioned that they will have the opportunity to suggest items for future meetings.

EC Directive on Blood Products (ACVSB1/3)

8. Mr J Canavan will introduce this and one paper setting out how the consultation might be conducted. The ~~paper~~ cabinet has been tabled at the meeting.

9. Following this introduction, Dr Purves could be invited to comment as Medicines Division has been in the lead in this matter.

10. It would then be worthwhile seeking Dr Gurson's comments. He will be particularly concerned that the BTS should have the opportunity to comment on the technical specifications which will give effect to the framework Directive. Dr Lane may also express the same concerns about consultation with BPL interests.

11. At the end of the discussion you may wish to assure the Committee that their interest in this field has been made known to Medicines Division and that they will be consulted about the development of the technical specifications. Also at each meeting there will be a progress report.

HTLVI (ACVSB1/4)

12. Dr Regman will introduce this paper focussing on the conclusions and draft recommendations.

13. Afterwards Dr Gunson should be invited to comment and ~~give~~ report the views expressed by his Advisory Committee on Transfusion Transmitted Diseases. This Committee considered the subject at its meeting on 24 February 1989.

14. Dr Mortimer could then be asked if he has any further information on the figures he supplied for the annex to this paper. He may also wish to say what progress has been made with Mrs Janet Mortimer's application for research funding as mentioned in paragraph 7(1)(b) lof the paper.

15. Following the general discussion you will wish to focus the Committees attention on the draft recommendations and take them point by point through paragraphs

12.1) to establish whether it is agreed as drafted or how it should be
12.2) amended. In relation to 12.3 it should be pointed out that if
12.3) Departmental funding was required, the usual protocols would have to
12.4) be submitted for consideration.

You will also wish to establish if there are any additional recommendations that the Committee considers appropriate.

16. You could then propose that the recommendations will be circulated to members (including those not present) with the minutes by mid April to confirm they are in the format members would like. Comments would be asked for by mid May. If any major disagreements were expressed by those who had not attended this meeting, the issue would be discussed again at the next Committee meeting. Otherwise the recommendations will go forward to the CMOs for their consideration.

## Human Growth Hormone Recipients (ACVSB1/5)

17. Dr Pickles will introduce this paper.

18. After the discussion you will wish to go through the draft recommendations at paragraph 7 to determine the Committee's view on their appropriateness. Recommendations 7(1)(2) and (3) can be treated as a group and 7(4) and 7(5) can be considered separately.

19. The intention would be to circulate members with the agreed recommendations in the same timescale as for HTLV (paragraph 16 above). If there were no major objections these would also be forwarded to the CMOs.

## Any Other Business

20. This opportunity could be taken to ~~and~~ ask members if they are content with the way it has been proposed that the Committee should function or if they have suggestions for improving it.

21. Members should also be reminded to submit any topics for future meetings either at this meeting or by writing to the Secretariat, ~~if they wish to do so.~~

## Date of Next Meeting

22. This is expected to be about 3 months hence, subject to members availability.

Background Note

Historically the Blood Transfusion Services have adopted new screening procedures in an ad hoc fashion in response to advances in clinical knowledge. In some cases the advice of specially constituted expert groups have been sought as with Hepatitis and AIDS.

Concern to maintain the safety of the blood supply has been heightened by greater public and clinical awareness of the potential for viral contamination and the developments in product liability legislation. Decisions on testing for particular viruses involve a range of disciplines. Clinical and scientific expertise must be balanced by expertise representing the practicality and cost/benefit of testing. Other interested parties in this field such as the Committee for the Safety of Medicines, the Central Blood Laboratories Authority and the Blood Transfusion Services do not have the remit nor the expertise to take this broader approach. Hence the need for this new Advisory Committee on which all the interests are represented but which can also take an overview.

~~JOHN CANAVAN~~
~~Room A403A~~
~~AFH~~
~~Ext~~ GRO-C

24/SMD