

**TWELTH MEETING OF THE ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF
BLOOD AND TISSUES FOR TRANSPLANTATION**

8 July 1997 at 12.30 pm,
Cathedral Room, Richmond House, 79 Whitehall, London SW1

AGENDA

1. Chairman's introduction and welcome.

- 1a. In addition to MSBT members, you will want to welcome Professor Thomas. Although the Hepatitis C lookback is not being discussed this time, he has been invited to attend the first part of the meeting so he can take part in the discussion of GBV-C/HGV, for which he provided the paper.
- 1b. Dr Bourdillon is attending the meeting to speak to the paper on the tissue banking review.
- 1c. Dr Thatcher will be representing the MCA, in Dr Rotblat's absence abroad.
- 1d. Dr Adrian Mairs is taking over from Dr Mock as the observer from DHSS Northern Ireland.
- 1e. Dr Bill Smith takes over from Dr Hall as the Welsh Office observer.
- 1f. You may want to mention that, as part of the latest round of internal reorganisation within DH, the MSBT Secretariat, together with other work on blood, will in future be located within the Health Services Division of DH - located at Wellington House in Waterloo Road. Alan Doran, who has already taken over responsibility at branch head level, can be introduced. Other appointments have yet to be made. Members will be notified when roles in the Secretariat have been confirmed, but in the meantime should continue to contact existing members of the Secretariat (currently still located in Eileen House) as necessary.
- 1g. You may like to apologise to members for any inconvenience caused by the later start for today's meeting, because of the meeting you had to attend this morning. (As members were notified earlier, it seemed better to stick to a date most people could make, than to try to find a fresh date.)
- 1h. An addition to the agenda is needed in respect of tissue banking - paper MSBT 12/2 which has already been circulated refers. This will probably be dealt with after item 7 - CJD - and before "any other business".
- 1i. Members may be concerned about the implications for MSBT of the change in government. We understand that although MSBT has no statutory basis, it will continue its work currently. New Ministers may want to review its role in due course, particularly in the light of their plans for devolution, but it seems unlikely to be among their initial priorities.

2. Apologies for absence.

- 2a. No apologies for absence have been received, besides those covered by para 1 above where alternative representatives are attending.

3. Minutes of the eleventh MSBT meeting - 25 March 1997. Paper MSBT 11/8.

- 3a. No comments have been received by the Secretariat in advance of the meeting, but you will want to give members an opportunity for comment at the

eting itself.

4. GBV-C/HGV (para 4 of minutes last meeting)

4a. Paper MSBT 12/2 sets out proposals for studies into GBV-C/HGV from Professor Thomas, Professor McMaster and others, as agreed at the last meeting (para 4.15 of minutes). (It was proposed then that Mr Forsythe and Dr Gorst should also be involved in drawing up the proposals, but it is not clear that this in fact happened.)

4b. Professor Thomas and Professor McMaster may want to speak to their paper.

4c. As indicated in the note covering the paper, it is intended to ask members to raise at the meeting only any major points requiring discussion. Other comments can be made in writing after the meeting.

4d. As mentioned in the covering note, you may wish to discuss handling at the briefing meeting with officials. Eg would it would be appropriate to ask for comments to be addressed to Professor Thomas, and to expect him and those working with him to take these into account and then submit the proposals to the Department of Health's research division ?

4e. If it is decided to ask Professor Thomas to take forward action in this way, he may want to suggest a closing date for any comments from MSBT members.

5. Introduction of gene amplification techniques. Paper MSBT 11/5

5a. A working group of officials met on 19 May. We hope to have been able to issue paper MSBT 12/5 a few days before the MSBT meeting, or if necessary to table it on the day of the meeting. We have first given the Scottish Office, the SNBTS, and the NBA a chance to comments on a draft version (NBA and SNBTS comments have been requested by 3 July).

5b. You may want to ask Dr Rejman to introduce the paper, which he prepared following the working group meeting, showing the arguments for and against the various options considered. The covering note invites members to say whether they agree that option (iv) - the BTS making up mini-pools which are then tested by the fractionators - is the best option currently, with the aim of moving to individual testing of donations as soon as practicable.

5c. The MCA had been asked to give an oral report on the proposals coming from CPMP. But as a copy of the latest paper from the Biotechnology Working Party of CPMP is being circulated as the Annex to paper MSBT 12/5 there may be little else they want to say. (Dr Rothlat will be attending a Working Party meeting, at the same time as MSBT is meeting. Dr Thatcher will be able to advise MSBT as required.)

**6. CJD: blood and blood products (para 7 of minutes of last meeting).
Paper MSBT 12/1**

6a. The Secretariat circulated several pieces of material about CJD and about dura mater on 24 April, following the last meeting.

6b. Dr Robinson may wish to speak to her paper MSBT 12/1 suggesting criteria aimed at excluding some dura mater recipients from giving blood. That paper was produced following discussion at the last MSBT meeting of whether

operating such an exclusion was practicable (para 7.26 of minutes).
Members will wish to comment on the proposals. The final paragraph of the covering note raises the question of deferral in the case of the use of dura mater grafts for tympanoplasty, in view of the possible effects on donor numbers.

6c. Dr Robinson has been asked to come prepared to report also on any other significant developments in relation to CJD and blood/blood products.

7. HIV transmission by blood : oral report

7a. Dr Robinson has been asked to be ready to give a brief oral report on the recent 3 cases of infection with HIV through blood given during a donor's window period. Other members may have comments or questions.

Tissue banking - addition to agenda (X) Paper MSBT 12/2

Xa. Dr Bourdillon's paper MSBT 12/2 reported some progress in addressing tissue banking and attached the draft of a submission to Ministers recommending legislation to regulate tissue banking - **to be treated as confidential**. The Appendix to the submission describes the issues in more detail and proposes a framework for regulating tissue banking, based on that of the FDA. Dr Bourdillon may wish to introduce the paper.

Xb. HSD envisage that, assuming Ministers agree to the recommendation to initiate legislation, MSBT will have the opportunity to comment during the formal consultation period. However they would welcome any immediate comments at the meeting - which you suggested should be restricted to the proposed overall approach

9. Any Other Business.

Paper MSBT 12/4: progress reports

9a. Paper MSBT 12/4 contained a progress reports on developments in the Council of Europe in relation to blood transfusion. (Apart from this, and the item on tissue banking taken as a separate agenda item, officials had no other material to offer for the meeting.)

9b. You may want to ask if members have any comments.

HTLV

9c. Mr Doran has been asked to be ready to provide an oral update on progress with the HTLV submission.

Any other matters

9d. You may want to ask if members wish to raise other subjects under AOB.

9e. Members have already been notified that the next meeting will be on Monday 27 October, at the usual time of 11 am.