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DATE: 20/1/96

PAGES: 21 **including this one**

MESSAGE: AS ATTACHED.

Dr Rejman CA OPU2 — 19.1.96
Dr Troy RD
Dr Purves MCA
Dr Doyle CHD
Dr Nicholas HCD

From : Ann Towner CA OPU2
Date : 11 January 1996
Copy : Mr Pudlo CA OPU2
Mr Levy CA OPU2
Mr Nash CA OPU2

MINUTES OF THE MSBT MEETING HELD ON 8 JANUARY 1996

1. I attach a draft note of the above meeting. This includes in paras 1,2, 6 (mins 4.7-4.13, 4.18-4.20 and 11.1-11.2) 9, 11 and 12 material drafted by Leonard Levy.

2. I would be grateful for your suggestions for any amendments to the draft - where possible without further lengthening. This is largely unfamiliar and highly technical territory for administrators like us, so we look to the experts to check that we have got it right.

3. Could comments, or confirmation that you are content with the draft, please reach me Friday 19 January. I will then put the revised version to Dr Metters for his agreement, before the minutes are circulated (relevant parts only to Hep C working group members).

Ann Towner
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Room 313 EH
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CONFIDENTIAL TO COMMITTEE MEMBERS MSBT 7/6
NOT FOR PUBLICATION

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF BLOOD AND TISSUES FOR TRANSPLANTATION (MSBT)

MINUTES OF THE MEETING HELD ON 8 JANUARY 1996

Chairman :	Dr J S Metters
Members present :	Dr D W Gorst Dr D B L McClelland Dr P Mortimer Dr R J Perry Dr E A Robinson Dr T Snape Dr R E Warren Professor J D Williams Professor A Zuckerman
Also present	Professor H Thomas (Items 1-4 and 6 [minutes 11.1-11.2] only)
Observers :	Mrs J Dhell Dr P Doyle Dr J Ludlow Dr G Mock Dr I H Nicholas Dr J Purves Mr J S Sloggem Dr J Toy (Items 1-4 and 6 [minutes 11.1-11.2] only)
Secretariat :	Dr A S M Rejman Miss A Towner Mr L Levy

1. Chairman's Introduction and Welcome

The Chairman welcomed Professor Thomas and Dr Toy (Mrs Griffin's successor), who had been invited to the first part of the meeting for the discussion on matters which related to the Working Party on the Hepatitis C Look-back.

2. Apologies for Absence

Apologies were received from Dr Cant, Dr Keel, Miss Lord, Professor McMaster, and also from Dr Gillon and Dr Westmoreland who had been invited to attend the discussion about the Hepatitis C Look-back Working Party's work.

3. Minutes of the 5th Hepatitis C look back working party - 13 October 1995

Dr Gillon had written suggesting two amendments to the minutes :

para 6.3 : delete "infected" and substitute "positive by PCR"

para 7.5 : amend first sentence to read "The Chairman agreed that consistency was needed - RIBA indeterminates shown to be PCR positive had been included in all cases in Scotland but only some 2/3rds in England."

The minutes were agreed, subject to these amendments.

4. Hepatitis C look back programme

4.1 Dr Rejman provided a table summarising progress as at December 1995, and gave new figures received from Scotland that morning. Although there was a fair amount of work left to do, he thought that the original estimate of some 3,000 people who were still alive being identified as Hepatitis C positive would probably prove about right. Officials would be making a submission to Ministers, but sought the benefit of MSBT's views first.

4.2 Dr Robinson said the NBA had some later figures to pass on. She agreed that the difference between the numbers followed up and numbers counselled and tested could include some who refused testing, as well as cases where action was outstanding.

3 Dr Ludlow said that because of the scattered population the exercise was being done in 2 stages in Wales; first tracing, then counselling. The picture on tracing hospitals records remained dismal despite the help of an NBA secondee. Dr Mock said that in Northern Ireland they suspected a problem in tracing records in the bigger hospitals, while the fact that the deputy director of the transfusion service was herself doing all the counselling could be causing delays. Dr Mock undertook to investigate why Northern Ireland figures showed a much higher average of donations per donor than for the other countries.

4.4 The Chairman mentioned increasing press enquiries suggesting that the exercise was going slowly and asking why Ministers was were not taking action. One option was to abandon the lookback and offer Hepatitis C tests to anyone who had been transfused. Members were not in favour of this as the lookback exercise was expected to produce important information about Hepatitis C. The alternative to simply letting the exercise run on as it was, was action to try and speed up completion. But simply sending out messages from the centre seemed unlikely to produce action in the field.

4.5 Hospital records, and counselling, for which there was shortage of suitably trained staff, were identified as key bottlenecks. The Chairman emphasised the initial agreement that counselling must be done well; patients must not be misinformed. Dr Robinson said that counselling was being done effectively by transfusion staff, but they faced a heavy load because GPs were often unable or unwilling to undertake that role. Dr Rejman mentioned that for the CJD/NvH lookback counsellors trained in other fields had been used after being taught the necessary facts about CJD.

4.6 Suggestions for relieving the bottleneck at the hospital records stage included :

- establishing a task force

- representatives of the blood service visiting or phoning hospitals where there were particular problems,

- approaches to medical directors, before looking at the records (along similar lines to the approach taken by the Leukaemia Research Fund)

- using nurses with special experience in this field, eg epidemiological research, or the infection control nurses in post in most hospitals.

4.7 The Chairman asked whether some short delay in completing the exercise could adversely effect patient health. Professor Thomas and Professor Zuckerman thought that about 7 years would the earliest time at which cirrhosis might develop; 20-30 years was more ~~normal~~ common. It was thought that the exercise would produce important results which must not be jeopardis~~ing~~ed by any undue haste. On the other hand, there was a risk of the exercise grinding to a halt if no new action was taken to ensure early completion.

4.8 Professor Thomas pointed out that after identification through the look back exercise patients still had go through further stages of the NHS system, eg biopsy and treatment. This meant pressure at purchaser level - in his area only one purchaser was currently funding interferon treatment, despite the advance warning given of the demand the lookback exercise might generate. The suggestion of direct referral to liver units for testing and counselling might be feasible, but would still leave bottlenecks at the biopsy stage (about 40% of cases).

4.9 The Chairman agreed that the NHS could only deal with patients at a certain pace; this was an important point to make to Ministers. ~~But officials proposed to offer Ministers the option of action to tackle the problem at the medical records stage, possibly through the use of infection nurses. It could be helpful to be able to demonstrate that we had a~~

least facilitated entry to the system, and getting to that stage would also enable us to see the size of the problem. But officials would also make clear that if that problem was dealt with there could be problems at later stages such as counselling and testing, hepatology, biopsy, and treatment. (Members had suggested that these other problems might later be dealt with sequentially, if necessary.) The Chairman had in mind to circulate the options to MSBT and working group members, before the submission, relating to the whole of the UK, went forward.

4.10 The Chairman asked that National Blood Services make contact with hospitals before April (a year after the issue of the CMO letter) enquiring about progress, and asking for estimates of when tracing might be completed. This approach might be better done personally by phone or visit than by standard letter.

4.11 Dr Rejman reported on recent discussions at the Leukaemia Steering Committee, the umbrella group of the MRC adult and child steering groups. Of 180 patients tested 13(7%) were found to be Hepatitis C positive, 9 of whom were also PCR positive. The highest proportion were bone marrow transplant recipients, who had the high usage of blood products. The Steering group had agreed that it was not unreasonable for multiple blood transfusion recipients to be tested for Hepatitis C on request. Before coming to any conclusion about whether all children who had blood transfusions should have such tests, they wanted to await the outcome of the Hepatitis C look back exercise. MSBT members were asked whether they were content with this approach.

4.12 Members thought the 7% figure might be quite high, depending on the dates to which it related. Dr Rejman offered to send copies of the data to those who were interested, but confirmed that none had been transfused since 1991.

4.13 The Chairman summarised MSBT's members views as being that they were content with the Leukaemia Steering Committee's

tance. There was no attempt to limit clinicians' freedom to offer a test if they felt it appropriate.

4.14 Dr Mortimer wondered whether younger age-groups might be targeted, but was unsure how the lookback could accommodate these. The Chairman saw this as added reason for making an effort to complete the lookback exercise and identify those affected. Consideration could then be given to whether any group should be given priority.

4.15 Dr Troy said DH was awaiting the amended protocol on research promised by Julia Heppenstall. He had also received two spontaneous proposals - one for a sero-prevalence study in relation to child health and the other for a cohort study of women. The research division were finalising their summaries of the recommended proposals and hoped to advertise to the research community very soon.

4.16 Exceptionally the MRC had agreed to the setting up of a trial development group to look at treatment with interferon, prior to the agreement of funding. It was intended to study the effects of treatment with RBE in addition to interferon, and to see if a way could be found of identifying early on in the treatment programme the 75% who would not respond to a course of treatment with interferon. As interferon was now licensed, the agreement of the various purchasers involved would need to be obtained.

4.17 Dr Gorst asked about the earlier intention to study the efficacy of, and to improve, counselling. Dr Troy would agreed to consider this, although as it had not been highlighted as a priority area, no budget had currently been allocated for this.

4.18 Dr Robinson reported that the data base was being set up for the national archive. But she was unsure about the Data Protection Act implication of requests of information, in cases where there was no patient consent.

4.19 Members suggested that PHLS had a fairly well established procedure for dealing with such questions which Dr Robinson might be able to draw on, while local ethics committees could help on appropriate questions (a national ethics committee was in the process of being set up). Annonymisation of data could avoid problems under the DP Act. In some cases consent could be obtained retrospectively, eg those where contact was made with the hepatology unit.

4.20 Dr McClelland said that in Scotland PHLS had established systems for exchanging information with other organisations. Information about these arrangements might prove helpful in the present case.

4.21 Mention was made of the need for co-ordination, to avoid duplication of tests.

ACTION

- Officials to prepare submission to Ministers, including possible recommendations for speeding up completion of the exercise, after consulting MSBT/working group members (paragraph 4.9)

- All National Blood Services to obtain estimates from hospitals of likely timescales for completion of tracing of medical records (paragraph 4.0.)

-Dr Mock to investigate high proportion of donations per donor in Northern Ireland suggested by their entries in the tables (paragraph 4.3)

5. Minutes of the sixth MSBT meeting - 13 October 1995 (paper MSBT 6/9)

Following comments from Dr Cant, it was proposed that the following be substituted for paragraph 12 of the minutes :

" Dr Cant mentioned two child deaths following bone marrow transplantation where there had been a failure of graft and children suffered marrow aplasia for several weeks. Both developed an erythematous skin rash and pneumonitis, and died from pneumonitis. Both had receive multiple infusions of blood products. Analysis of skin and lung at post mortem was strongly positive for HHV6 by PCR testing. There had been other reports of HHV6 related death in immuno-deficient children who had received multiple infusions of white blood cells. Thus HHV6 infection transmitted by blood products was a potential worry in patients undergoing bone marrow transplantation. Dr Cant's unit used white cell filters when giving blood products to bone marrow transplant patients, to reduce the risk of HHV6 and CMV infection, although they always used CMV negative blood so the risk of this latter infection was small. "

6. Matters arising from the MSBT minutes, not dealt with as separate items:-

- minute 4.1 - 4.4 : arrangements for reporting transfusion events

6.1 Dr McClelland introduced the paper tabled at the meeting. Most of the documents were those prepared by Dr Williamson for the last meeting of the steering group for the proposed system for reporting hazards of transfusion. The initial report form was designed to be very simple to complete; this would be followed up by a more detailed form related to the specific circumstances of the case. It was explained that the form did not contain much detail in the case of infection, as this was covered by the PHLS system and attention was drawn in the form to the need for such events to be reported by that route.

6.2 A committee would oversee the new system, with a small executive responsible for day to day operations. It was hoped

to persuade Julia Heppenstall to serve on the steering group, which had no microbiologists on it at present. Wales had been involved in the working group, and information was being provided to Northern Ireland who it was hoped would also use the system.

6.3 No start date had been agreed, but it was hoped that the system would become operational in April 1996, provided funding could be obtained. Approaches to DH had been unsuccessful, but Dr McClelland and Dr Robinson were exploring ways of obtaining funding from the transfusion services.

6.4 Members welcomed the proposals and felt the system would be valuable.

6.5 The Chairman pointed out that it would not be possible for the Department to provide protection against sub-poena's, as suggested in para 7 of the paper. This had only been possible exceptionally for the inquiry into ~~cot~~ maternal deaths. The Chairman asked that any further comments from members be sent to Dr McClelland.

ACTION - Members to send any comments to Dr McClelland.

- minute 4.7 - 4.13: blood safety leaflet

6.6 The Chairman commended the leaflet. Dr Robinson said it would be officially launched on 1 February, and should be treated as confidential until then.

- minute 4.17 : optimal use of FFP

6.7 After the last meeting Dr Rejman had advised Ministers that MSBT had not seen any need for any change in the stance they had previously recommended. No response had been received yet.

6.8 Dr Rejman had commented on Dr Robinson's first draft of

aterial for CMO Update. Dr Robinson said she had now responded, and hoped the material could go in the next Update.

- minute 4.18 - 4.20: tissue banking review

6.9 Dr Doyle confirmed that Ministers have agreed to take the review's recommendations forward. He explained that there were two main issues; one was safety, the other was the constitution of a supervisory accredited body to ensure quality. He said that a consultation about the latter would take place shortly.

- minute 7.1 - 7.6 : guidance on the safety of transplantation of human tissues and organs

6.10 Dr Rejman thanked members for their final comments on the draft guidance. Ministers had now agreed to its issue. Arrangements were being made for printing, in a booklet format which should last. Issue as health service guidelines meant that there would be no expiry date. Besides being sent to health authorities and trusts and to consultants in relevant specialisms, the material would also go to the Royal Colleges and others with an interest, eg related patient interest groups. Mention of publication in CMO Update was planned, and it was hoped that the Colleges might mention this in their own newsletters.

6.11 The Chairman mentioned the draft guidelines of the Council of Europe Select Committee of Experts on the Organisational Aspects of co-operation in Organ Transplantation, on serological screening methods for the most relevant microbiological diseases of organ and tissues donors (paper MSBT 7/4). He drew attention to footnote 2 on page 3 suggesting testing for ~~positive HBs antibodies, ruling out the use of tissues from donors who tested negative, and recommending use of their organs only in urgent cases~~. The Chairman asked if members felt that this note should be reflected in our own proposed guidance.

6.12 It was pointed out that this material was far more likely to be relevant other parts of Europe, where eg Eastern European organs might be offered, or where donor history was not always obtained. Dr Doyle thought including the footnote might be useful to draw attention to the potential problems, should use of suspect material be necessary as a fall-back strategy. Dr Zuckerman also favoured inclusion, despite the problems this would cause for the health advisory group, as the material was scientifically accurate.

6.13 Other members were concerned that including the note might conflict with our intention to keep practice on organs closely in line with that on blood. The Chairman said that had the material been included he would have wanted parts deleted and other parts softened. However, he concluded that the committee's view was that the material should not be included; our material already made it clear that it was only guidance only and was not definitive.

- <u>minute 8.1 - 8.3 : guidance on the collection, storage and infusion of bone marrow and stem cell</u>

6.14 Dr Rejman had received a number of comments following discussion at the last meeting. It was therefore planned that the sub-group meet again on 24 January. Their agreed version of the material would then be sent, at the same time, to members of the MSBT and to professional bodies on a limited consultation, giving about 6 weeks for comment. The Chairman stressed the need to get the guidance out soon.

- <u>minute 11.1 - 11.2 - new hepatitis viruses</u>

6.15 Dr Mortimer said that very little information had been published since the last meeting, although there will be a paper in Science shortly. He said that hepatitis G and hepatitis GB-C appeared to be the same agent, which affected about 1-2% of the donor population in the United States. The

agent is believed to give rise to chronic infection, but there is no serological test for it yet, and it appeared similar to hepatitis C.

6.16 Professor Zuckerman then presented some more details about current knowledge of hepatitis G. A significant proportion of infected individuals had a normal ALT. Epidemiological risk factors were similar to those for hepatitis B and hepatitis C. Some patients developed cirrhosis, although overall the infection is clinically mild. The antibody tests appeared unreliable, and much of the work had been done using PCR.

6.17 Professor Thomas said that the Science paper will confirm that the virus can be transmitted through transfusion and is infectious. He added that it responds to Interferon, but there is a high relapse rate.

6.18 Dr Rejman quoted a German study of commercial plasma pools, which showed a 7-40% positivity to GBC, in the 6 January Lancet.

6.19 The Committee agreed with the Chairman that further data should be presented to the next meeting.

ACTION - Dr Rejman to co-ordinate a paper for the next meeting, with contributions from Dr Mortimer, Professor Zuckerman and Professor Thomas.

7. CJD and blood transfusion

7. 1 Dr Purves said that CPMP had twice during 1994 discussed the issue of recall of blood products from pools where contaminated donors were implicated. At the first, the French had wanted ~~a lot of groups excluded~~. They subsequently recognised this would mean losing a large proportion of their product supply (perhaps 60-70%). Experts on CJD attended the second meeting, which concluded that even if there was an

nfected donation in a pool there was insufficient reason to withdraw the product from the market.

7.2 Following the recall of products ~~by the FDA~~, CPMP looked at the issue again in 1995, and again decided against withdrawal. Dr Purves confirmed that all Members States now shared this view. There was no positive proof of infection by this means, and uncertainty about what products could be considered safe if any were withdrawn.

7.3 It was thought that political considerations, and the possibility of legal action, had been determining factors when countries had decided to withdraw products. In America and Canada large amounts of products were taken of the market. Dr Perry thought that when decisions were taken the industry had been unable to estimate the likely extent of product withdrawals.

7.4 Dr Purves was anxious that decisions should be taken on a purely scientific basis, and saw a need to keep a close eye on what other Member States were doing. Steps had been taken to involve manufacturers associations in decisions in the Europe.

7.5 Dr Perry explained that EPFA had been developing a line, but this had been overtaken by CPMP's work. The EAPPI line (paper circulated in October 1995) resulted in dual standards. In America, products from potentially infected pools were withdrawn while in Europe the guidance was permissive. Theoretically that could mean products rejected in America being accepted in Europe, but Dr Purves confirmed that CPMP had included a statement that such products should not be used in Europe.

7.6 The Chairman mentioned letters received from relatives of those with CJD asking if potentially infected products were withdrawn from the supply. They were being told that was not in accordance with CPMP guidelines. Some writers were also

asking if UK experts were agreed on this approach. Dr Snape clarified existing practice :- while products from infected pools were not being withdrawn, infected donations were being excluded from plasma for fractionation.

7.7 Dr Rejman warned that the Guardian planned an article on the subject. The Chairman underlined the sensitivity of the issue from both a political and a scientific standpoint. The CPMP line was helpful and the UK did not want to disturb this. And while Canada was doing a full lookback exercise, the MSBT had agreed at an earlier meeting that the UK should not do so.

8. Virological Screening of UK blood donations - HTLV I/II and HHV 6

8.1 The Chairman thought papers MSBT 7/1 and 7/5 complemented each other well. Although MSBT had previously concentrated on considering testing for HTLV I, other matters such as parvovirus were also coming forward. MSBT now needed to take a look at where it was going on screening generally.

8.2 Introducing paper MSBT 7/6, Dr McClelland said he was seeking initial reactions from the committee before progressing, if requested, to more detailed work. The broad options outlined in the paper were :

- testing, either generally or of specific groups (3(i) of the paper should perhaps refer to testing of first time donors as well as to universal testing)

- doing something to the product ~~to increase~~ to reduce the risk of infection

- reducing the number of donors whose blood goes into each patient.

8.3 Tables 1 and 2 (based on data from Edinburgh) showed that a high proportion of children under 1 received transfusions, and on average each were transfused quite a number of times. Special treatment of that group was therefore suggested in paragraph 4. These children were mainly in special care baby units, with their own blood banks, in fact most were premature babies under 1 month old. Blood from a particular donor, who had tested negative over perhaps 2 or 3 years, might be divided into a number of paediatric size packs which would then be dedicated for use for a particular child. It was not thought that this would significantly increase wastage.

8.4 While it was hard to prove the benefits of this approach, the theoretical arguments were good. But early introduction would involve quite a lot of work, and probably additional cost. Other concerns were whether it might generate unreasonable demand, and whether we could justify special treatment of this group alone.

8.5 Members welcomed the paper. Dr Warren wondered whether a cut-off at age 1 as distinct from say age 5 was right when the higher figure would increase coverage significantly. Dr McClelland was ready to consider the higher figure, although he and Dr Robinson had some reservations as the special paediatric blood banks would not be used for the older children.

8.6 Dr Rejman reminded the committee that for HHV-6 testing was not a viable option, as ~~no supplies left~~. Dr Mortimer confirmed that there was no data for HHV-6, ~~although~~ filtration should eliminate most infection,

8.7 The Chairman summarised that members thought it worth pursuing the idea of a cut-off at 1 month or 1 year. Dr McClelland and Dr Robinson agreed to develop the logistics of the case further for consideration at the next meeting, with help from Dr Rejman as required. The Chairman thought the duty of care to these young children might be adequate defence against arguments that we were introducing a two tier system.

It was suggested that it might also be helpful to obtain the views of the wider range of medical experts represented on the Standing Medical Advisory Committee.

8.8 The Chairman asked whether members disagreed with the recommendation for screening for HTLV-I contained in the final paragraphs of the BMJ article circulated as part of paper MSBT 7/1. He confirmed that sound tests were available. Dr Robinson said that SAACTI would be considering aspects such as lack of viability and costs at their meeting next month. It was agreed therefore to defer discussion by the MSBT until the next meeting.

ACTION - Dr McClelland and Dr Robinson to develop a more detailed paper for the next meeting.

9. Screening for HIV-1 Antigen

9.1 Dr Rejman introduced Paper MSBT 7/3, which had been circulated before the meeting, and invited members' views on whether HIV-1 antigen screening should be introduced in the UK. He added that it had been recommended by the FDA, but there had been no support from the CPMP, because the low incidence of HIV in the population and particularly blood donors meant that the slight shortening of the "window period" was likely to identify very few additional infected donors.

9.2 The Chairman summarised the consensus of the Committee, which was to agree that HIV-1 antigen screening did not represent a significant improvement over antibody screening and donor deferral.

10. Other EU activities relevant to the committee - viral inactivation of intra-muscular immunoglobulins

10.1 Dr Purves introduced paper MSBT 7/2 outlining the background to CPMP's decision that additional valid viral

inactivation steps should be applied to intramuscular immunoglobulins, with nucleic acid amplification tests for HCV RNA where such steps were not in place. MSBT members had expressed concern about the CPMP position at the last meeting.

10.2 Dr Purves explained that the German plan in 1994 had required action by manufacturers within 6 months. However CPMP had adopted a strategy of developing regulations in the light of discussions with manufacturers associations. They also sought information on methods of viral inactivation, eg why was the Cohn fractionation method apparently produced safe intramuscular, but not intravenous, immunoglobulins.

10.3 The problem had been compounded by the FDA decision on PCR testing for Hepatitis C for intravenous as well as intramuscular immunoglobulins. The UK view was that the adequacy of PCR testing needed to be proved before it was introduced. The UK wanted to look at ways of introducing additional viral inactivation steps in conjunction with manufacturers.

10.4 Paragraph 2.6 of the paper recognised that viral inactivation methods must not adversely affect overall safety.

10.5 Dr Purves clarified that the penultimate sentence of paragraph 3.2 (page 5) referred to discussions with the commercial sector so that they were not surprised by the requirements.

10.6 Dr Purves drew attention to CPMP's conclusions and recommendations (page 12). The first point introduced reality into the timescale for the exercise, while the reference to "valid" viral inactivation steps was useful to flag up questions about whether particular processes, including those adopted by the FDA, were so validated. The fact that the third point said that testing was "requested" made it clear that this was not mandatory. There was thought to be room for the UK to interpret this pragmatically. CSM had considered the question of use of products from positive pools, and wanted to

consider supply problems individually as they arose.

10.7 While there had been years of successful use of the Kohn method, batch by batch, for viral inactivation of intramuscular immunoglobulins, data was needed to demonstrate that systems were valid. There was a need to ensure that sufficient account was taken of other changes, for example changes to batches, and of new viruses. There were also questions about light exposure methods. Dr Mortimer said he was not convinced they were safer.

10.8 Dr Snape had anticipated that a requirement for testing would be introduced in July. He was generally content with the position outlined in the paper. However he felt that so as not to compromise safety use should not be made of immunoglobulins from pools later found to be infected, as without individual PCR screening ~~their~~ seemed no protection against infection. Dr Perry was concerned about justifying use of a "second class" product if this was released to meet supply problems, and more generally about the injection of the immunoglobulins into healthy women, if there was any doubt at all doubt about their safety. Dr Purves saw these concerns as underlining the need and for test methods to be fully validated, working closely with manufacturers, and for taking as long-term a view as possible.

10.9 Dr Snape pointed out that what manufacturers were in practice saying and doing has a major impact. If most carried out HCV PCR screening and publicised this, it would effectively become necessary for their competitors to do this too.

10.11 The Chairman referred to paragraph 3.1 on page 5 which pointed to the good safety record of intramuscular immunoglobulins, but asked if batches be released if they were later found to be PCR positive ? Dr Purves said that the product was believed to be safe but stressed the need to

continue to co-operate with manufacturers to ensure that it remained so. Many new tools for doing so had been gained over the last few years. A better forum for debate and taking sound decisions had been created, with networking in Europe, the CPMP Biotechnology Working Party and the involvement of manufacturers. There was also the opportunity for MSBT to have an influence on outcomes.

10.12 The Chairman concluded that the UK was in a better position now than if Germany had been allowed to have their way, and had not been forced into the early and unjustifiable introduction of tests. Manufacturers and regulators working together paved the way for better results. We had achieved as good an outcome as we could have hoped for given the need to come to an agreement with our European partners. The fact that we were applying such an agreed European approach was a good defence should our approach be questioned.

11. Any Other Business

The Committee agreed to Dr Rejman's proposal that parvovirus B19 should be on the agenda for the next meeting.

12. Date of next meeting

The next meeting would be held in May or early June, on a date to be arranged.

ACTION - Secretariat to arrange next meeting