

STATEMENT OF DR IAIN S MACDONALD**B4**

(i) This witness statement relates to the request received by the Scottish Government Legal Directorate on 18 March 2011. As with the witness statement request in relation to topic C1, the events in question took place at a time when I was one of 2 Deputy Chief Medical Officers. The other Deputy Chief Medical officer, Dr Graham Scott, was the person who had responsibility for blood transfusion matters. Therefore, I had no direct personal involvement with the issues covered. I became Chief Medical Officer on 1 December 1985, at which point blood transfusion matters came within my overall remit.

(ii) The paragraph numbers used in this statement relate to the paragraph numbers in the Inquiry's witness statement schedule.

4. I do not know what the DHSS author of the paper DHF.002.5897 meant by the statement "We would therefore be in a strong position to make decisions about the need to buy from one of the five US pharmaceutical companies." I do not know whether it was intended that the commercial tests for the USA would only be brought into the UK in the event that the Middlesex/Wellcome test proved unsatisfactory for UK requirements. I imagine that there would have been an array of different views as to the desirability of buying commercial tests between the various people involved in the implementation of HIV testing.

5. I do not know whether the Advisory Committee on the National Blood Transfusion Service was the first forum in which the introduction of donor screening for HTLVIII was discussed. I suspect it would have been discussed before the first meeting of this committee on 27 November 1984, although this was possibly the first time that a formal meeting had been convened specifically to discuss the introduction of testing. Several expert committees were considering various aspects of the HIV problem. Coordination of the work of these committees was dealt with by DHSS. SHHD tended to send an observer.

The way in which the government's health interests were distributed in the ministerial and departmental arrangements had a bearing on how significant policy issues such as those arising from the emergence of HIV/AIDS were determined. In departmental terms a major role fell to DHSS, but the Scottish, Welsh, and Northern Ireland Offices (sometimes described as territorial departments) each had a health department within their arrangements in Edinburgh, Cardiff, and Belfast.

It was expected that DHSS, as a Whitehall department, would take the lead and that they and the 'territorial departments' would then implement a common policy, subject only to a modest degree of adaptation by the latter departments if required by local circumstances.

Staffing implications followed from this. DHSS had significantly larger numbers of both administrative and medical staff who could give their attention to health matters than SHHD. Consequently individual members of staff in DHSS could handle in greater depth a smaller number of issues than their opposite numbers in SHHD who had to spread their attention more widely.

8. I do not know when the discussions referred to in the paper of January 1985 (DHF.001.9036) took place, nor who was involved. The assessments would have been necessary because we would need to know what we were buying. The Government would have been criticised had we not carried out an assessment of the available tests. I don't know the scale on which the assessments were intended to be carried out. Those charged with carrying out the assessments would employ their judgement as to the scale required to enable them to offer an opinion.

9. I do not know whether it is correct that the assessment was to be carried out solely on the commercial products from the USA and was not to include the Middlesex Hospital/Chester Beatty Institute RIA. If anyone in the Scottish Home and Health Department did know the answer to this, it would be based on second hand information obtained from DHSS.

10. January 1985 seems to be the point at which SHHD were beginning to get involved. I cannot explain why the English Ministers were not told about the evaluation programme at this stage. I do not imagine that the Scottish Ministers

would have been involved about the evaluation prior to this, but they were told thereafter. I did not attend the proposed meeting between DHSS and SHHD. I do not know whether this took place, nor what was discussed if it did happen.

As the implications of the HIV/AIDS situation emerged more fully it became clear that this was going to be a very difficult issue for Ministers. Although the wider implications soon became clear to doctors in various medical fields, the public perception, diligently presented by the media, was that this was a dreadful problem created by homosexual males and by injecting drug misusers. I am aware from discussion at meetings of the four CMOs that from the early months of 1985 until well into 1986 the CMO at DHSS had difficulties because of the absence of a political 'steer' from Ministers. Nevertheless, he had to press from time to time for necessary decisions to be taken. When the full extent of the HIV/AIDS situation among injecting drug misusers in Edinburgh became clear in the latter months of 1985 a similar situation arose in Scotland.

11. I do not know who the parties referred in the memo (DHF.001.9097) were, nor do I know the background to the memo. I do not know where the idea for the DHSS evaluation programme came from however it was completely normal practice to evaluate new tests prior to introduction. I would have expected this to happen. I do not know which manufacturers were intended to be subjected to the evaluation programme, who was intended to carry out the evaluation or how much involvement SNBTS/NBTS/SHHD had regarding the evaluation programme and the question of whether one was necessary. This was an area where DHSS would be heading for central contracts and therefore they would have taken the lead. SHHD would simply follow the DHSS lead and take advantage of the central contracts which DHSS had managed to negotiate.

13. I am not surprised that it was decided that the Middlesex Hospital and Wellcome tests had to be evaluated in the same way. If commercial tests were being submitted to evaluation, the "home" test would need to be evaluated in the same way to make sure that they were as least as good as the commercial tests.

15. I cannot explain the discrepancy between documents DHF.001.9105 and DHF.001.9143, however I note from later documents referred to that Middlesex Hospital was developing its own test and therefore may have had a conflicting interest. I do not know what was decided.

17. I do not know whether EAGA members were aware that the decision to carry out the evaluation had already been made and that letters had been sent to all manufacturers. I would have expected DHSS to have been proactive in relation to this matter. EAGA as an entity would not have had the budget to instigate their own evaluation. DHSS would have known that an evaluation would be required and therefore there would seem to be no point in waiting until EAGA issued a recommendation to that effect. While there might have been questions about who ought to carry out the evaluation and the exact form of the evaluation, there can be no doubt that EAGA would have supported the principle.

19. I do not know what was meant by the DHSS author of DHF.001.9175 when they said "I think we would regard the commercialisation of the BTS test as quite separate from the evaluation programme that we are setting up". To my mind this shows that DHSS were proceeding to set up an evaluation process while keeping Wellcome's interests in mind; I think this was fair.

21. I have no knowledge of the "secret meeting" referred to. I do not know if it took place or, if it did, when it took place or who was in attendance.

22. It makes perfectly good sense not to have run the evaluation exercise in parallel with the introduction of testing. As a general proposition, it is not appropriate to introduce testing until there is some form of confirmatory testing available. To give false positive results to the donors would have been highly undesirable.

23. I do not know which DHSS personnel might have been involved with the introduction of HTLVIII screening. I suspect that the person who may have known would have been the late Dr Bell.

24. I have some sympathy for SNBTS in wishing to do things on their own account without waiting for NBTS; as the smaller system, I can imagine that it may have been frustrating to have to wait for NBTS, which in turn would have had to wait for DHSS.

26. I have no knowledge as to whether SNBTS abandoned its own evaluations to await the DHSS evaluations, whether this decision was made by SNBTS or SHHD or what discussions took place between SNBTS and SHHD regarding this matter.

27. It would appear that, despite initially wishing to proceed without waiting for NBTS, SNBTS eventually decided not to introduce testing until this could be achieved on a national basis. With regard to an issue such as HIV testing, where there is media interest and a concerned patient group, it would be very easy for one system to embarrass the other by doing different things. The suspicion would be that one system was right and one was wrong, or at least that one would be better than the other. It should also be borne in mind that at the relevant time SHHD and DHSS were simply 2 different Departments of the same Government.

29. I recall that the blood transfusion services were desperately worried, for two reasons, about the possibility of homosexual men turning up in large numbers to be tested. The first was a real concern that false negative results may be returned, meaning that infected donations may have slipped through. The second was that donor sessions might be inundated and overwhelmed. It should also be borne in mind that supplies of the test would have been limited initially.

31. HTLVIII screening was introduced in October, some months after the first stage evaluation was completed, because there was a need for a second stage evaluation. This took place "in the field", in two English centres. There was also a need for health boards to put in place alternative testing facilities. The health boards were responsible for arranging alternative testing. There was also a requirement to ensure sufficient funding for the testing was in place, although this was an area where it was clear that funding could not have been allowed to be a barrier to

progress being made.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated.....17 August 2011.....