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5 February 1996

Copies to: (list attached)

## **INTERIM REPORT ON THE HEPATITIS C LOOK-BACK EXERCISE**

### **Introduction**

1. This submission is for information to update Ministers one year after the scheme was announced. No action is required, although Minister may wish to meet with officials to discuss this report.

### **Background**

2. In December 1994, the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) recommended to Ministers the introduction of a Look-Back of those blood transfusion recipients infected with Hepatitis C prior to the introduction of Hepatitis C screening in September 1991. More details are given in Annex A. The MSBT felt there was a duty of care to those infected as a result of NHS treatment.

3. Two factors determined the recommendation at that time:

- (i) the feasibility of a Look-Back had been demonstrated by a study in Scotland
- (ii) Interferon, a drug which is useful for some patients infected with Hepatitis C, became licensed in the UK.

4. Ministers agreed to the submission from MSBT dated 15 December 1994, and on 11 January an inspired PQ announced this. To coincide with this announcement a press release was distributed and a press conference was held. An EPINET message was sent to GPs and all hospital consultants and a freephone helpline was set up.

5. Ministers also agreed that a Working Party should be set up under my chairmanship to draw up guidance on procedures for undertaking Look-Back, protocols for counselling and options for treatment, together with any other action which should be taken to satisfy the NHS's duty of care. This might include, for example, recommending additional research.

### **Response to the Announcement**

6. There were over 12,000 calls to the helpline. BBC Panorama broadcast a programme on 16 January "Bad Blood" which was critical. Some anxiety was generated by this and by parts of the media, but overall the response was not too negative. There were individual problems re whose duty it was to provide testing and counselling etc.

### **Meetings of the Working Party prior to Launch of Look-Back**

7. The membership of the Working Party is at Annex B.

8. To plan the Look-Back, meetings of the Working Party were held on 20 January, 24 February and 14 March. At these meetings documents were drafted for use during the Look-Back including a CMO Letter, appended at Annex C, which spelt out how the process would work and guidance for non-specialist medical practitioners. The CMO letter was issued on 3 April 1995 and was accompanied by an HSG (Annex D), PQ and press notices. The Look-Back phase officially went live although in some parts of the UK, notably Scotland, a lot of the work had already been started.

### **Results so far**

9. Further meetings of the Working Party were held on 25 May and 13 October. The most up-to-date figures available are given in Annex E which show 1727 donors positive for Hepatitis C who had given blood prior to 1991. 9048 donations have been identified and 2808 recipients have been identified by hospitals of whom 1631 have already died, of unrelated causes. These figures suggest that the original estimate of identifying approximately 3000 recipients who are alive was realistic.

### **Reasons for slow progress**

10. Members of the MSBT considered why the exercise was taking longer than originally envisaged. They identified two particular bottlenecks, one was tracing medical records for recipients identified in the hospital blood banks and, secondly, a shortage of counsellors available to see patients prior to and post testing.

11. The MSBT accepted that if both of these areas of difficulty were overcome, it was likely that the hepatology services for specialist assessment and, where appropriate, commencement of treatment would probably not be able to cope.

### Alternate Ways Forward

12. The MSBT felt that there were several options available. These are detailed in Annex F. Overall MSBT's view was that central exhortation to speed up the process was unlikely to achieve much. They were strongly against abandoning the planned Look-Back. It was felt that communications between the BTS and hospitals where there were particular problems was the best way forward, supplemented by the offer of assistance to overcome the bottlenecks in tracing hospital records and a shortage of suitably trained counsellors.

13. The Committee felt that a delay in identification that might be extended for the rest of 1996 would not disadvantage patients as the evidence was of a 20-30 year time frame for significant liver damage to occur.

14. Officials agree with MSBT's view, but if Ministers wish to expedite the Look-Back programme, some or all of the actions proposed in Annex F could be introduced.

### Other Related Matters

#### Research

15. The Working Party considered aspects of the Look-Back which should be used for research into the medical history of Hepatitis C as well as transmission routes and disease management and treatment. The Working Party had some draft proposals and suggested the setting up of a database. Other research projects are to be prioritised following on from this.

#### Testing/Counselling

16. There were difficulties with some GPs, who did not wish to be involved in additional work, and there were some criticisms of the Blood Transfusion Services.

#### Referral to Specialists and position of treatment

17. A number of letters were received by DH asking for ring fencing for treatment of Hepatitis C. After consulting Mr Sackville, then PS(H), officials used the following response *"despite the very substantial real increases in funding, which the Government has allocated to the NHS, the resources of the NHS are finite. It is for doctors and managers to make local decisions as to what forms of treatment and what drugs are to be made available to patients based on the needs of the local population.*

*There are inevitably and rightly rising expectations of what the NHS should provide as developments in medical science continue to make new treatments available. We are keen to respond and funding is sufficient to allow new treatments to be introduced. However, decisions on whether individual patients are likely to benefit from particular drugs are for the clinical judgement of the doctors concerned".* In most instances it would appear recipients are being referred to appropriate specialists.

#### **Further follow-up reports**

18. Further follow-up on the Look-Back exercise will be carried out by the MSBT. The few members of the Working Party who are not members of MSBT have been invited to attend for this item at the subsequent meetings of the MSBT.

19. A further report will be made to Ministers in approximately 6-9 months, depending upon the rate of further progress with the Look-Back exercise.

#### **Summary**

20. The Look-Back so far has been slower in achieving its objectives than had been predicted. The Blood Transfusion Services are being encouraged to work better and faster on this project. The MSBT considered possible ways to overcome bottlenecks in respect of hospital patient records and counselling. Possible ways to expedite the programme were identified (see Annex F). Ministers are asked to note the results so far in paragraph 9, and PS(H) may wish for a meeting with officials to discuss progress.

GRO-C

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