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PS/Mr Forsyth

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Director, SIO
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TESTING OF BLOOD DONATIONS - TEST FOR HEPATITIS C

1. This note is to advise the Minister about an article in today's Guardian (copy attached) which seems likely to prompt other media enquiries.

Background

2. The test referred to in the article has been added to a study for non-A, non-B hepatitis (NANB) (now referred to hepatitis C), which was already underway within the Scottish National Blood Transfusion Service and the Blood Transfusion Service in England and Wales. Ortho Diagnostic Systems Ltd had offered a number of tests free of charge for evaluation purposes. Other countries are also trying the Ortho test, but we understand that it is not in routine use in any country, and it does not have a product licence in the United States. There is no other comparable test on the market at present.

3. A pilot study has been carried out on volunteer donors in Scotland and England who agreed to have their blood screened for non-A, non-B hepatitis. The samples obtained were also tested using the Ortho hepatitis C (HPC) kits, and of those 0.5% - 1% proved positive. Those donors who proved positive are being recalled for medical assessment and further tests, to check on the consistency between the tests.

4. Only a minority of those infected with HPC display any symptoms either in the short or long term (as referred to in the 3rd paragraph of the Guardian's front page article). The statement that "6000 people last year may have received blood transfusions contaminated with hepatitis C" assumes that 1% of all donations were from donors who are infectious (ie not just carriers), and that they passed on the antigen, and not just the antibody in their donation. The emphasis placed on this by the Guardian is, therefore, unnecessarily alarmist.

5. The meeting, referred to in the article, which took place on 23 August was between Ortho and the Director of the National Blood Transfusion Service in England and Wales, Dr H Gunson: Dr R Mitchell, Director of the West of Scotland Blood Transfusion Service was also present. It was made clear that they were not representing the UK Health Departments at the meeting. This was one of several discussions with Ortho to obtain further information about the product - such as cost and other practicalities - and also to report results of the pilot study.

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Current Position

6. There is no meeting involving Chief Medical Officers planned for October, but the Health Departments' committee of experts on the virological safety of blood (which includes representatives from SHHD and the SNBTS) will be discussing the test, as an agenda item, at their next regular meeting, on 17 October.

7. The accuracy of the test has not yet been fully established, and it is felt to be essential to have confirmatory assays to eliminate the possibility of cross-reactivity with other antigens before policies for generalised screening of blood donations are implemented. The cost to the SNBTS of introducing this additional test into routine screening in Scotland is estimated to be in excess of £600k per annum.

Line to Take

8. If asked to comment it is suggested that the Minister uses the following:-

- (a) Donors should not be deterred from giving blood.
- (b) UK blood is still considered one of the safest in the world, and we continue to investigate ways of making it safer still.
- (c) The Ortho test is under review here as in other countries.
- (d) The prevalence of HPC in the population in this country has not been established, nor has the role of blood in its transmission.
- (e) The UK Health Departments, along with the UK Blood Transfusion Services, are examining all the available data before making any decision about generalised testing, and the public would be informed before any such test is routinely introduced.

9. This is a UK issue and D of H will be taking the lead but SHHD and SNBTS will be represented in any meeting and the Minister will be consulted before any decisions are taken.

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