AMENDED LINE TO TAKE

C/R

ALL PRESS OFFICERS

RECALL OF BLOOD PRODUCTS

Background

Bio Products Laboratory, which is the commercial, processing part of the National Blood Authority, recently tried a newly developed test on a pool of plasma, which had already been used to make blood products. This Polymerase chain reaction (PCR) test showed the presence of the Hepatitis C virus. This means that testing for Hep C at the point of blood donation failed in one or more cases. The subsequent pool (from 20,000 donations) was used to make Factor VIII (for haemophiliacs) and Albumin (for hospital use eg. burns cases).

BPL and NBA confirmed that the products had gone through the standard viral inactivation process (solvent/detergent) which meant that any viruses present would be neutralized and the products would be safe for use.

However, [NOT FOR USE] the Department felt that a recall was necessary in the interests of public confidence, especially as there were ample alternative supplies available. BPL is therefore recalling three batches of albumin and one batch of Factor VIII from hospitals, haemophilia clinics, GPs and haemophiliacs' fridges.

This raises questions of the testing procedure for blood donations, the wisdom of testing a pool retrospectively, the likelihood of infection (all for NBA) and the safety of human-derived Factor VIII rather than the artificially made recombinant Factor VIII (more for DoH). Journalists may well tack today's story on to the fact that recombinant (synthetic) Factor VIII, more expensive in the first place that the human-derived, is being VAT taxed. Scotland, unhelpfully, made an extra £1million available help pay for recombinant supplies.

Sue Cunningham, press officer at the NBA (01923 212121), has issued the attached statement and will put up the NBA's Medical Director, Dr Angela Robinson, for any bids.

The DoH's involvement will be kept to a minimum as far as possible.

LINE TO TAKE

"This is a matter for the National Blood Authority and Bio Products Laboratory. The Department fully supports this recall in the interests of maintaining public confidence and avoiding any unnecessary anxiety for patients."

[MORE]

IF PRESSED

"The Department understands that Bio Products Laboratory is recalling certain blood products, following the discovery of the presence of the Hepatitis C antibody in a pool of plasma. Independent experts confirm that the Factor VIII and albumin made from this plasma are safe for use because of the standard viral inactivation procedure carried out during manufacture. However, some people may still be concerned about their use,and as alternative supplies exist, it is sensible to withdraw these products with that concern in mind. The Department fully supports the recall, which will serve to reassure people and maintain public confidence in our blood products."

RECOMBINANT FACTOR VIII AND VAT

"Products derived solely from human plasma continue to be used for the majority of patients, and have a good safety record. Recombinant Factor VIII is not wholly artificial and free from risk as it contains human albumin, which is used as a stabiliser.

"Questions of VAT are for Customs and Excise. C&E ruled last year that recombinant Factor VIII and other recombinant pharmaceutical products do not qualify for statutory relief from VAT because they are neither human blood nor derived from human blood. The human albumin used is present as a stabiliser, not as the active ingredient."

SCOTLAND

"Unlike the NBA, the Scottish National Blood Transfusion Service supplies plasma-derived Factor VIII free of charge to the NHS. Therefore, the additional cost to Scottish haemophilia centres using the recombinant product is much greater than in England, where centres are already paying for plasma-based products, It is to assist with the costs involved in the acquisition of recombinant Factor VIII, which is only available from commercial sources, that Scottish Ministers have made £1 million avaialble in the current year.

"There are no plans to introduce funding along the lines of Scotland. Decisions on what treatment should be given are for the clinical judgement of the doctors concerned, in the light of available resources and the needs of the individual patients."

Official: Christine Corrigan CA-OPU 396 22714

Laurence Knight
19.8.96

Q&A Briefing - Blood Products Recall

WHAT HAS BEEN DOH'S ROLE IN ALL THIS - HAVE MINISTERS BEEN CONSULTED?

[DN - This could be tricky as NBA are likely to want the DOH role specified more precisely. Need to specify MCA's role/involvement?]
The National Blood Authority - which is a Special Health Authority responsible for BPL - has functions delegated by the Secretary of State and is accountable to him for the discharge of those responsilities. BPL accordingly notified the Department when the positive test result was first received and Ministers have been consulted.

IN THE LIGHT OF THIS SCARE, WHY DOESN'T THE DEPARTMENT FUND THE MUCH SAFER RECOMBINANT FVIII?

The products are not being withdrawn on safety grounds. Products derived solely from human plasma have a good safety record. The Department of Health does not allocate money to support specific treatments for particular patient groups. Decisions on what treatment should be given to patients are for the clinical judgement of the doctors concerned, in the light of available resources and the needs of the individual patients.

WHAT HAS HAPPENED TO THE HAEMOPHILIA SOCIETY'S COMPENSATION CLAIM? DOES THIS AFFECT IT? ISN'T THIS ANOTHER EXAMPLE OF THE RISK HAEMOPHILIAC'S ARE EXPOSED TO?

The Haemophilia Society have written to John Horam with their detailed proposals for financial help for those who have contracted hepatitus C through NHS treatment. The Minister is carefully considering those proposals and hopes to be in a position to reply shortly. The Minister will take all relevant factors into account when reaching his decision; however, we are not aware of any new cases of hepatitus C tranmission when adequate viral inactivation of blood products has been carried out.

IF ALBUMIN HAS NEVER TRANSMITTED THESE VIRUSES, WHY RECALL IT? DOESN'T THIS CREATE PANIC?

There will undoubtedly be some patients who, regardless of any assurances given about the safety of these products, will remain concerned about their use. Rather than risk causing unneccessary anxiety to those patients and to their doctors, and to maintain full public confidence in the plasma-derived products in use, it was felt that it would be appropriate to withdraw the products in question.

Additional Q&A Briefing - Blood Products Recall

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