Snape Terry

From: Snape Terry
To: Cunningham Sue
Cc: Nickolds Sheila; Williamson Sue; Jenkins Stephen
Subject: Amersham recall
Date: Wednesday, 19 November, 1997 13:03PM

Several enquirers this morning asked Linda for a faxed statement in respect of the original BPL recall. I am reluctant to distribute copies of the original recall notice/news statements. They all include refernce to "a new CPMP position on nv-CJD" and we now know that there is no such thing - MCA were a little anticipatory in that respect. I don't want to cause problems with EMEA by continuing to send out an incorrect statement.

I attach a very simple draft note, which sets out the key issues raised in questions so far. I believe this will fit the bill. I am required to get this cleared by MCA (it was faxed to Nigel Goulding at 12:15, but I don't expect an answer before 15:00). Would you mind casting an eye over it please?

<<File Attachment: CJD97022.DOC>>

[Sheila: will you please make sure that Linda sees this, but doesn't send out the copy before it's approved?]

[Sue W: will you please ask Angela to cast an eye over the draft when she's back - particularly my reference to the ethical committee view? It's in there because some Amersham customers are asking whether patients or treating physicians should be told.]

CJD 97022-DOC

Draft statement in respect of the basis for recall of BPL Zenalb, used to prepare Nycomed Amersham "Amerscan Pulmonate II"

1. Bio Products Laboratory (a part of the National Blood Authority, NBA) withdrew a batch of Human Albumin Solution (Zenalb) on 4 November 1997. The recall was a precautionary measure, undertaken under MCA instruction, based on receipt of information that one of the blood donors whose plasma was used to manufacture the albumin had developed new variant Creutzfeldt-Jakob disease (nv-CJD).
2. There is no evidence that Creutzfeldt-Jakob disease (CJD) of any kind has ever been transmitted by blood or blood products. Because nv-CJD is different from classical CJD, it is possible that this history of freedom from infection may not be predictive for nv-CJD. Against this background, recall of the affected batch of albumin was therefore considered to be a sensible precaution.
3. The batch of albumin in question was used by Nycomed Amersham in the manufacture of those batches of Amerscan Pulmonate II, and it is this association that lead to the MCA request that Nycomed Amersham recall those batches.
4. There is presently no diagnostic test for CJD infection (any type); there is no prophylaxis against, or treatment for, CJD infection; the incubation period for the disease is variable and long. The ethical committee advising on CJD surveillance in the UK has indicated that there is no basis for advice to patients previously treated with plasma products derived from an affected donor.