Tuesday 19 December 2000
Written Answer

PQ320 /2000/2001
Han Ref: Vol
Col

Cousins, Jim (Lab Newcastle Upon Tyne Central):

Mr Jim Cousins (Newcastle upon Tyne Central): To ask the Secretary of State for Health, if it is his policy that user-patients should be informed if the Bio Products Laboratory withdraws blood products on the basis of past donation information relating to CJD protection requirements. (143857).

SUGGESTED REPLY

The Department ~~of Health~~'s current guidance, based on the advice from ethical experts, is that clinicians should not tell patients if they have received such products. This is because:

- the risk that vCJD might be transmitted in this way is low;
- there is no diagnostic test for vCJD
- even if a test was available, there is no treatment.

The guidance goes on to state that:

"In deciding whether or not to inform a particular patient, the benefit/harm balance for their individual situation must be carefully considered. In communicating with patients who have received implicated products, it is therefore for individual clinicians to decide whether to follow this general ethical advice."

The Department is continuously reviewing this advice to ensure that it is line with current scientific information and ethical thinking.

Hold to discuss with Lord Hunt has confirmed that this is the line. Pat Troop.

Now agreed.

Background **PQ320**

This PQ stems from the issue surrounding a blood donor who gave plasma during 1996 and has since been found to have variant CJD. A submission was sent to PS(L) on Friday 15th December. This is one of 3 PQs on haemophilia and blood products and so it is likely that the organisation Haemophilia North (based in Newcastle) have been lobbying Jim Cousins MP. This organisation is not part of the Haemophilia Society.

The Plasma was fractionated into several batches of different blood products and supplied to customers in the UK and overseas. All products are now passed their expiry date. Albumin made from plasma from this donor was also supplied to four UK companies for various uses, including as an excipient in oral polio vaccine supplied to the Republic of Ireland. The Irish Health Department has now established that four batches of this implicated vaccine have been used extensively in the Republic up to the Summer of this year when it was withdrawn on finding that it contained fetal calf serum of UK origin (as was the case in the UK). The Irish are very concerned about the impact news of this will have on their vaccination programme, and we are liasing with Irish officials to ensure that they are fully informed of action being taken in the UK.

Irish Ministers held a press conference on 19 December in order to provide public reassurance and keep the issue under control. Irish GPs have been provided with Q&A to respond to concerned parents whose children were included in the polio vaccination programme.

BPL stopped using plasma from UK donors in 1998 and all their products are now made from US plasma. In 1998 a programme of recovery and replacement was carried out by BPL in order to remove, wherever possible, any remaining products made from UK plasma from hospital shelves.

Action taken by BPL

BPL has written to the major distributors of BPL products and to hospital chief executives and clinicians to inform them of the incident, listing the batches of implicated product supplied. They have written similarly to their overseas customers. This is not a recall, however, as the products are all past their expiry date and should, in any case, have been caught by the recovery and replacement exercise in 1998 (following the ban on the use of UK plasma). NBA have set up a special customer service line to deal with enquiries from hospitals and clinicians.

We will follow-up BPL's letter to overseas customers with information to the relevant UK embassies.

Informing Patients

In 1998, after two recalls of blood products containing plasma from vCJD donors, the Department issued advice to NHS Trusts addressing the issue of whether patients who had received these products should be told. This advice, which still stands, was that these patients should not be told because:

- the risk that vCJD might be transmitted in this way is low;
- there is no diagnostic test for vCJD
- even if a test was available, there is no treatment.

The guidance goes on to state that:

"In deciding whether or not to inform a particular patient, the benefit/harm balance for their individual situation must be carefully considered. In communicating with patients who have received implicated products, it is therefore for individual clinicians to decide whether to follow this general ethical advice."

It should be noted: This advice is now out of step with the view that has been taken on incidents involving vCJD-implicated surgical instruments, where patients will be given the opportunity to decide where or not they wish to be told. We had planned to refer this issue to the next scheduled meeting of the vCJD Incidents Panel on 22 February, but are now working on arranging a special meeting of the Panel in mid January.