

142
Important
BPL file ? / m/sb
From: Mrs G R Skinner, HSD1 of Department of Health
Subject: Dr Metters' letter to BPL
Item posted: Thu 29 Jan 98 18:33
To: Ms Christine Corrigan, HSD1 of Department of Health
Cc: Dr Michael McGovern, HSD1 of Department of Health
Mrs Mary Sandillon, HSD1 of Department of Health

David suggested I do some briefing on the Metters/Snape correspondence as you were busy with the paper.

I have taken this to mean Press briefing and attach a draft. I should say that I have not had time to read your second paper so have not been able to draw on it, but have focussed on the fact that a recall when there is suspicion but not confirmation may escalate the perception of the problem. I have said that a full paper will soon be with Ministers.

I assume BPL will act as Dr M says. I have spoken to Tom, saying that I did not know whether the letter had been faxed to Dr Snape or gone by post. Tom was unaware of it but will keep us in touch with plans, timing etc.

I will redraft if you want.

Gwen

Data file: BPL.1
File type: wordperfect
Computer: MS Windows
Updated: Thu 29 Jan 98 18:23
Length: 9k

This is to advise that there is likely to be a further recall by BPL of Factor VIII and Albumin derived from plasma from a blood donation from a person now suspected (but not confirmed) as suffering from nvCJD. Information on the timing of the recall will be provided as soon as it is available. The non-UK countries who have received products are Brazil, India and Malaysia.

This does not follow the pattern of other recalls, since the nvCJD diagnosis is suspected, but not confirmed.

The change of position arises from notification by BPL to the MCA and the Department that they had traced the issue of the products derived from the plasma from a donation given in 1997 and received by BPL in September. They were holding products not yet issued, and planned no recall whilst the nvCJD case remained unconfirmed (with immediate recall if confirmation was received). This was in line with the current publicly expressed CPMP view that as a precautionary measure it would be prudent to withdraw batches of plasma derived medicinal products from the market in the event that a donor to a plasma pool subsequently has a confirmed diagnosis of nvCJD.

However, on 27 January CPMP recommended that the recall policy be extended to include implicated products from donors strongly suspected of having nvCJD by a recognised reference centre. This new guidance will not be announced until the next CPMP meeting at the end of February, but on behalf of CMO Dr Metters has written to BPL to advise that there are substantial public health grounds for recalling a product if, as in this case, a contributing donor is suspected to have nvCJD. To delay the recall for several months while waiting for the diagnosis to be confirmed could be much criticised.

The Government has strongly emphasised its commitment to taking whatever steps are necessary to protect the public, and its adherence to the advice of national and international expert committees. The anticipation of the CPMP announcement emphasises still further the commitment to protecting, but may initially, especially when unlinked to a formal CPMP announcement, be taken as meaning that there has been a significant shift in knowledge about nvCJD with consequent alarm.

A full submission on the current position on nvCJD and blood, and likely imminent developments, will shortly be with Ministers.

Suggested line to take

Change in basis of recall

We believe that we are anticipating forthcoming advice from the European Regulatory Authority, the Committee on Proprietary Medicinal Products (CPMP). The actions being taken in respect of nvCJD are **precautionary**. The product recall where diagnosis has not yet been confirmed is one additional such measure. An extra safeguard is being put in place, but this is as a result of extra caution, not extra knowledge. We will be open about

information on nvCJD as it emerges.

Growing problem

This latest product recall does not indicate an escalating problem. The recalls happen as new cases are identified. They are all part of the same package - a thorough and prudent approach.

Implications for Bio Products Laboratory (NBA)

We export blood products which are in excess of our own national need. The income helps to offset the cost to hospitals here. Some of the products involved in recalls have been exported. We are looking at all the issues.