Charles Lister
28/09/2000 13:05

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Subject: URGENT: BLOOD AND VARIANT CJD: PRESS RELEASE ISSUED BY OCTAPHARMA LTD

Rachel

I would be grateful for urgent advice on the following matter.

I deal with the National Blood Authority. As a precuationary measure against the theoretical risk that variant CJD might be transmissible through blood - particularly through plasma and white blood cells - the NBA now imports plasma from the US for the manufacture of fractionated blood products such as clotting factors for haemophiliacs. However, UK plasma is still used by NBA to make a non-fractionated component known as Fresh Frozen Plasma (FFP). This is mainly used as a source of clotting factors for patients with life-threatening haemorrage, liver disease/transplanation and premature infants. We investigated the possibility of importing plasma for FFP a couple of years ago but at that stage it was simply not possible to obtain the quantity of plasma needed and, since then, we have kept the position under review with our expert committees. A further risk assessment on FFP is currently in progress.

On 19 September, Octapharma (an international company specialising in plasma-derived blood products) issued a press release following the publication in the Lancet of research demonstrating that BSE can be transmitted between sheep by blood transfusion. Lord Hunt, who is aware of the press release, has asked for advice by Monday 2 October - including advice from SOL - on what action we could take against Octapharma.

The text of the press release is as follows:

"re Blood Donors - Spread of nvCJD - 100,000 British patients still receiving British plasma

The general public appear to be unaware that every year more than 390,000 units of blood plasma are collected from UK blood donors and used in patients. UK blood plasma is, in fact, still being used for blood transfusions as fresh frozen plasma (FFP) in approximately 100,000 patients in the UK.

The growing concerns as to whether the nvCJD agent is transmitted via blood can be overcome by the use of blood plasma from nvCJD-free countries.

Since 1998 virus inactivated blood transfusion plasma from nv-CJD countries has been supplied under the trademark OCTAPLAS to the UK by Octapharma Limited, Coventry.

OCTAPLAS is used by some UK hospitals concerned with the current virus safety of UK plasma. The additional benefit of Octaplas is that it is made from nvCJD-free blood plasma.

Octaplas is the most commonly used form of blood transfusion plasma in Europe where several countries use it exclusively to avoid the risk of viruses such as HIV and Hepatitis C.

Due to its major international role in the field of safe blood plasma products, Octapharma would be in a position to swiftly meet the entire demand for nvCJD-free blood plasma in the UK."

Our view is that the issue of this press statement was a totally irresponsible and unjustified action on the part of Octapharma. Furthermore they are not in a position to claim that the plasma they use is "nvCJD free", given that there is currently no test to detect the presence of vCJD in blood, and the plasma used in Octoplas is sourced from continental Europe where there are known cases of BSE and vCJD.

I would be grateful for your advice on whether there is any legal action the Department could take against Octapharma on the basis of their press release. Even if there is, my inclination at present would be to advise Lord Hunt against legal remedies on the grounds that these could backfire, especially with the BSE Inquiry report being published next month. However, I would like to tell him what the options are. I do think however that the Department should at least write to the MD of Octapharma expressing our disappointment with the way they have chosen to handle this. Lincoln Tsang at MCA has offered to help draft such a letter.

Given Lord Hunt's deadline, would it be possible to get back to me on this by close of tomorrow?

Charles