PQ11311

Background

1. This is one of 6 PQs from Lord Clement-Jones. We think it is very likely that the reason he has asked these questions is that he and a number of other MPs have been approached by a company called "Octapharma Ltd" who are a Swiss research and development based company who specialise in blood products. Octapharma produce Octoplas a pooled solvent detergent treated fresh frozen plasma (FFP).

Fresh Frozen Plasma (FFP)

2. Plasma is the fluid in which the red and white cells and platelets are suspended and carried around the body. This fluid is separated from donated blood units by centrifugation and frozen. FFP contains clotting factors, antibodies, albumin and minerals. It is an unlicensed product. It is used for patients with blood clotting problems, supporting some ICU patients, for premature babies, babies and children having heart surgery, liver transplants and after major accidents and injuries.

DH Press Release 15th August 2002 "National Blood Service making further improvements to blood safety"

3. On 15 August 2002 PS(PH) announced that the NBS would be importing FFP from the United States for new born babies and children born after 1.1.96 as an added precaution against the theoretical risk of vCJD transmission. The FFP would be in single units rather than pooled and would be sourced from unpaid donors. There would be further treatment to reduce the risk of transmission of viruses by Methylene Blue viral inactivation.

4. There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. Clinicians must consider the balance between the real risks to patients of not giving their patients blood and the theoretical risk of transmitting vCJD through blood and blood products.

5. For patients outside the above age group UK FFP will continue to be used. Every reasonable step has been taken to minimise any risks during blood transfusion. The current high levels of safety are achieved by screening out potential high risk donors and then further testing every unit of donated blood for the presence of infections such as HIV, Hepatitis B, Hepatitis C before it is released to hospitals.

6. FFP is produced by the UK blood services using plasma from UK donors which has been leucodepleted to remove the white cells (which evidence suggests may carry the greatest risk of transmitting variant CJD). Each unit of FFP is also made from plasma from a single blood donor.

Background on FFP and Advisory Committee on Microbiological Safety of Blood and Tissue for Transplantation (MSBT)

7. MSBT has been discussing the issue of the use of FFP following the Committee on Safety of Medicines recommendation that UK sourced plasma should no longer be used in view of

possible risks of transmission of vCJD. Earlier work on leucodepletion of blood (removing the white cells) and processing blood from imported plasma should reduce the unknown risks from vCJD to the million or so patients transfused every year with blood and blood products.

8. In 1998, the Department was advised by the National Blood Service (NBS) that imported plasma for FFP could not be obtained for the 100,000 to 150,000 patients every year who require this blood component. The Spongiform Encephalopathy Advisory Committee (SEAC) and MSBT advised that UK FFP should continue to be provided but that the NBS should keep the position under review. In June 2000, MSBT commissioned a risk assessment of FFP and vCJD in conjunction with a further international search for possible alternatives to UK FFP.

9. In April 2001 MSBT advised that a switch to using US FFP was desirable (subject to obtaining safe and sustainable supplies) based on a vCJD risk assessment. The risk assessment showed that, in a primary epidemic of 10,000 cases of vCJD, switching to US FFP could reduce cases of vCJD secondary transmission by up to 85 a year. The NBS established that some supplies of US plasma for FFP could be imported.

10. Following further discussion at MSBT meetings in October 2001, January 2002 and June 2002, Ministers agreed in August 2002 that NBS would import FFP from the US for neonates and children born after 1.1.96 (children born after 1995 will not have been exposed to BSE through the foodchain) and that it would be virally inactivated using Methylene Blue treatment.

Octapharma

11.Octapharma see the NBS as a competitor, and one using unfair competition practices to favour their own FFP. There are differences in the way the 2 products are made although they are essentially the same. However, Octapharma argue that their product is safer.

12. Octoplas is licensed under the Medicines Act 1968, is a pooled product made from US plasma and is virally inactivated using solvent detergent treatment. The NBS FFP is classed as a blood component and is not, therefore, subject to licensing. The currently available product is non-pooled made from UK plasma and not subject to viral inactivation.

13. Octapharma is mounting separate legal challenges against the NBS around the costing basis their FFP and the purchasing practices of NHS Trusts. Most hospitals purchase NBS FFP over Octoplas, almost certainly because of the cost. Octoplas is for sale in the UK at between £40-50 for 200ml unit. In comparison NBS FFP is under £20.

14. Octapharma have written to PS(PH) requesting a meeting to discuss these issues.