Background

1. This is one of five PQs from Lord Clement-Jones on the safety of Fresh Frozen Plasma and Transfusion Related Lung Injury. He has raised 20 other PQs on this issue over the last few months which have all been very similar in their content.

2. We think it is very likely that the reason he has asked questions on FFP is that he and a number of 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 (SD FFP).- paras 12 to14 below

3. The PQ refers to a letter published in "Vox Sanguinis" a publication produced by the International Society of Blood Transfusion. The letter supports the use of SDFFP. One of the authors of the letter is employed by Abacus International which is a strategic healthcare marketing company, "Octapharma Ltd" are listed as a clients.

Fresh Frozen Plasma (FFP)

4. 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.

Transfusion related acute lung injury (TRALI)

5. Occasionally, FFP causes a rare condition called `transfusion related acute lung injury (TRALI). This can happen if the donor plasma contains antibodies that can react against the patient's white blood cells. Red cells and platelets can also cause a reaction. Donors generally produce these antibodies after pregnancy or transfusion.

Action on TRALI by the National Blood Service

6. TRALI is high on the NBS Blood and Tissue Safety Assurance Group list of priorities and funding is available to the NBS to aid production of FFP and the plasma used to suspend pooled platelets, from male untransfused donors. Funding is also available to select untransfused male donors for virally inactivated FFP (using methylene blue viral inactivation method) from the United States for children born after 1 January 1996 (DH announcement August 2002).

Current Position

7. NBS have recently advised us that the NBS Board have recommended to DH that the contract for the supply of US single unit FFP for neonates and children born after 1 January 1996 has been awarded to Blood Systems Incorporated (BSI). BSI cannot however guarantee to source all plasma from untransfused male donors but there are overriding quality benefits (single quality system, single labelling and direct control of supplying centres) which provide added assurance with regard to the supply.

8. The contract will run for 3 years and the annual costs tendered by BSI is £498,593. DH has accepted the Board's recommendation and we are waiting for notification that BSI has

accepted the contract. It is planned that the imported FFP will come on stream later this year.

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

9. 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.

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

10. 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.

11. Following further discussion at MSBT, Ministers agreed and made an announcement 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). The imported FFP would be virally inactivated using Methylene Blue treatment.

Octapharma

12. 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.

13. 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.

14. Octapharma have mounted a 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.