From the Parliamentary Under Secretary of State for Public Health
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Ms GRO-A

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Dear GRO-A

Thank you for your letter of 25 June to Alan Milburn about the use of fresh frozen plasma in England. Dr Liam Fox has also copied me your letter dated 28 January and has asked me to respond to you direct. I will send him a copy of my reply and apologise for the delay in replying to you.

I hope that you will accept my sincere apologies that you have not received an earlier response to your letter from this Department. This is contrary to the high standards we aim for in replying to correspondence and I have asked the head of the Blood Policy Team, Charles Lister, to write to you personally with an explanation of the delay.

I was very sorry to read in your letter that you may have contracted a viral transmission through the use of NHS fresh frozen plasma. The Government considers the safety of blood and blood products used in the NHS to be of paramount importance.

In your letter you have referred to the advice issued in 1998 on blood and blood products from the Committee on Safety of Medicines (CSM) which referred to minimising the unknown risk to patients of variant CJD. It is correct that the advice was that manufactured blood products should not be sourced from UK plasma. Since 1998 the Government has acted on expert advice and sourced plasma for the manufacture of licensed blood products from the United States and Germany. However, with regard to Fresh Frozen Plasma (FFP) an unlicensed product, the Department was advised by the National Blood Service that imported plasma for FFP could not be obtained for the large number of patients who use it every year. The Spongiform Encephalopathy Advisory Committee and the expert Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) advised that UK FFP should continue to be provided but that the position should be kept under review. There is no evidence that CJD or variant CJD has ever been transmitted to patients through blood or blood products.

The safety of blood and blood products used in the NHS is of paramount importance. 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, and Syphilis before it is released to hospitals.

Department of Health

On 15 August we announced that as an added precautionary measure against the theoretical risk of variant CJD, FFP will be imported from the United States for young children and babies and will be treated with methylene blue to reduce the risk of blood borne viruses for this most vulnerable group. It should be noted that US FFP is only used in single units and not pooled. A further product, "Octoplas" which is a solvent detergent virally inactivated pooled FFP, is an option for clinicians to purchase however our expert advisory group MSBT have indicated a preference for the Department not to source pooled FFP.

It is never possible to guarantee 100% safety but the steps that have already been taken ensure that blood and blood products used in the NHS are amongst the safest in the world and MSBT constantly keep under review new ways to improve the safety of blood.

You may not be aware that NHS Hospitals also take part in The Serious Hazards of Transfusion (SHOT) reporting system. This was set up in 1996/97 as a vigilance system covering blood transfusion in the UK and Republic of Ireland. It is an independent inquiry now funded largely by the National Blood Services and is affiliated to the Royal College of Pathologists. It has a Steering Group representing a wide range of clinical interests. Although the SHOT report demonstrates that serious adverse events associated with blood transfusion are rare, many of them are avoidable. Improving patient safety, including reducing unintended harm to patients, is a major Government priority. We will be looking to SHOT and the new National Patient Safety Agency to help us take a more comprehensive approach to improving patient safety in the NHS.

In your letter you have referred to recommendations on the use of FFP from the 7th Edition of the Council of Europe guidelines. Our understanding, and that of other members of the Council of Europe, is that this guidance refers to the practice of using FFP where virally inactive clotting factors such as Factor 8 (which is what is meant by the reference in the Recommendation to a stable product) are not available. Because of the ambiguity of the wording consideration will be given to a revision later this year.

You have raised concerns that patients are being treated with transfused blood products without informed patient consent being taken. It is vital that where possible, patients are made fully aware of the choices of treatments they are offered. On 4th July we issued new guidance to the NHS on "Better Blood Transfusion – Appropriate Use of Blood" this guidance has an objective to "Ensure patients at risk of transfusion are informed of their choices". The National Blood Service is currently preparing a patient information leaflet, "Blood Transfusion Explained – Information for Patients and Relatives" which will be available very shortly and we have asked NHS Trusts and Primary Care Trusts to ensure that written information is made available to patients on blood transfusion and alternatives by April 2003.

GRO-C

MS HAZEL BLEARS