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DEPARTMENT OF HEALTH 98/182 Wednesday 13th May 1998

COMMITTEE ON SAFETY OF MEDICINESCOMPLETES REVIEW OF BLOOD PRODUCTS

The Committee on Safety of Medicines (CSM) has completed its review of the sourcing of blood products, as announced on 26 February 1998.

A number of precautionary measures to protect patients against the theoretical risk of contracting new variant CJD were announced at that time, including permission if necessary for the importation of plasma for manufacture, and a CSM review of the use of UK-sourced plasma, a component of blood used in the manufacture of a variety of blood products.

The CSM has reviewed all products individually and has advised that manufactured blood products should not be sourced from UK plasma for the present time (advice attached). The Secretary of State for Health has accepted this advice.

The reasons for moving to non-UK sourced plasma for the time being are that, although there is currently no evidence that nvCJD can be transmitted by blood, there is nevertheless a theoretical risk. Currently there is no test that can be applied to donors to detect the presence of the prion associated with nvCJD.

It is possible that manufacturing processes used to produce blood products may destroy the agent thought to cause nvCJD infections. However, no test is available to confirm this.

As a precautionary measure, therefore, the Government is allowing the NHS's Bio Products Laboratory and the Scottish National Blood Transfusion Service's Protein Fractionation Centre to import plasma from outside the UK until such time as a test is developed to screen for the possibility of infection, or it is proven that nvCJD cannot be transmitted through blood products, or that it can be proven that the manufacturing process destroys any infective agent.

Only when quality inspectors are assured that the stringent safety standards applied to the new sources of plasma are equivalent to those currently available in the UK will plasma be imported.

Professor Michael Rawlins, Chairman of the CSM, said: "No new evidence has been reported indicating that nvCJD can be trannsmitted via blood products. However, while the risk remains only hypothetical, it cannot be fully discounted.

"The NHS Bio Products Laboratory and the SNBTS' Protein Fractionation Centre have been advised to take steps to source products from plasma derived from outside the UK, while giving due regard to the supply of vital products to patients. This will not happen overnight, as suitable collection centres abroad will have to be identified and inspected by the UK authorities. After this, the plants manufacturing the products will have to be cleaned before overseas plasma can be used for manufacture. The CSM recognises that all this will take some months.

"Some of the less common products such as antibodies used to treat and prevent rare diseases may take longer to replace, but these are often life-saving products and doctors should continue to use them in the short term.

('s important to note that the use of blood for transfusion, platelets and fresh frozen plasma is not affected by this advice. These products are produced from single donations and patients would not be exposed to the same large number of donors as when the manufactured products are used."

"There is absolutely no question of any risk to blood donors of contracting nvCJD. With the NHS treating more patients than ever before, blood stocks need urgent replenishment. It is vital that blood donors support the NHS and continue their life-saving work."

NOTES FOR EDITORS

1. Details of the precautionary measures announced on February 26 are contained in Press Notice 98/076.

COMMITTEE ON SAFETY OF MEDICINES: TSE/nvCJD - RECOMMENDATIONS OF THE COMMITTEE ON SAFETY OF MEDICINES AT A MEETING HELD ON 30 APRIL 1998

1. The group considered that manufactured blood products should not be sourced from UK plasma. Although it was accepted that some parts of the manufacturing process for blood products may separate prion proteins, the present state of the art means that these processes cannot be validated. Therefore the theoretical risk that nvCJD could be transmitted by blood products cannot be discounted.

2. BPL and PFC should move to sourcing products from plasma derived from outside the UK in a time frame to be agreed with the CSM and giving regard to the effects on the supply of all products, but especially of vital but less readily obtainable products such as some rare and life saving specific immunoglobulins. The latter may have to stay on the market for a longer period of time if replacement products could not easily be found. BPL and PFC should be asked to give a date by which non UK products could be made available. In the future when a test is available to identify the agent of ncCKD in blood donors or when a validated inactivation process is developed it is hoped that there will be a return to the use of UK donor plasma.

3. In the interim period clinicians who do not wish to use products derived from UK plasma have a choice of licensed products from other source plasma to replace all the commonly used products.

4. A date after which no products from UK plasma could be released for use should be agreed. It is not intended that products should be recalled. The group recognised that a period of several months would be required to establish satisfactory sources of plasma, to clean equipment and to produce products from the new source plasma.

5. The group advised that all CTXs for blood products derived from UK donors should be suspended.

6. The group also asked that the BPL and PFC should be encouraged to undertake research into validating processes for the identification and removal of nvCJD agents in source plasma, so that the use of UK plasma may be re-established safely in the future.

7. The group suggested that there was a need for clinicians to be educated in minimising the use of blood products where alternative treatments were available, for example the use of steroids in children with ITP and the use of Hepatitis A vaccine for travellers. The CSM was asked to consider how to take this forward.

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