May 13, 1998

COMMITTEE ON SAFETY OF MEDICINES COMPLETE REVIEW OF BLOOD PRODUCTS

The Committee on Safety of Medicines (CSM) has completed its review of the sourcing of blood products, 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 the products individually and has advised that manufactured blood products should not be sourced from UK plasma for the present time. Sam Galbraith, Scottish Office Health Minister, has accepted this advice.

Professor Michael Rawlins, Chairman of the CSM said

"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."

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 whether or not the prion is present.

It is possible that manufacturing processes used to produce blood products may be damaged or destroy the agent thought to cause nvCJD infection. However, no test is currently 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 proved that nvCJD cannot be transmitted through blood products, or that it can be proven that the manufacturing process destroys any infective agent.

Only when the 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, said:

"No new evidence has been reported indicating that the nvCJD can be transmitted via blood products. However, while the risk remains only hypothetical, it cannot be fully discounted.

"The NHS Bio Products Laboratory and 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.

"It is important to note that the use of whole blood, 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."

NOTES FOR NEWS EDITORS

1. Copies of the recommendations of the Committee on the Safety of Medicines are available to the Media by telephone 0131 244 2968

2. Details of the precautionary measures announced on February 26 are contained in news release 0382/98 available from the Information Directorate.

Contact: McKenzie Rhind: GRO-C
News Release: <<News Release Number>>