DEPARTMENT OF HEALTH

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FURTHER PRECAUTIONARY MEASURES ON BLOOD PRODUCTS ANNOUNCED

Further precautionary measures to protect patients against the theoretical risk of contracting new variant CJD from blood products were announced today by Frank Dobson, Secretary of State for Health.

This action follows three recalls of blood products last November because donors contributing to the plasma used in them subsequently developed nvCJD. It was made clear then that the Government would follow the recommendations of the relevant scientific committees to maximise the safety of the blood supply.

The further precautionary measures were announced after advice today from the UK Committee on Safety of Medicines (CSM), which considered all the current data, including the conclusions of this week's meeting of the Committee on Proprietary Medicinal Products (CPMP).

The CSM advice signals a review of the use of UK-sourced plasma, a component of blood used in the manufacture of a variety of blood products. The CSM will accordingly be looking at all products individually to ensure a safe and sufficient supply of blood products to the NHS.

The CSM also advised an extension of blood product recalls to include donors subsequently identified as being strongly suspected of having nvCJD. Previous recalls were based on confirmed cases only.

Mr Dobson said: "These measures recommended by the CSM are precautionary. They do not mean that UK blood and blood products are unsafe. We have no evidence to show that nvCJD can be transmitted via blood products or blood - the risk remains only hypothetical. But we must proceed on the principle that it is better to be safe than sorry.

"I fully accept the advice of the CSM. I have decided that the NHS Bio Products Laboratory (BPL), part of the National Blood Service, will be allowed to import plasma to manufacture blood products. This will reduce the possibility of repeated recalls of blood products in the future, and thereby help to maintain public confidence in these products.

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"We have always taken and will continue to take all practicable precautions to protect patients and the public health. If there is even a hypothetical risk and there are available safe alternative sources of products, then it makes sense to use them.

Mr Dobson also announced the outcome of a review of the NHS's provision of the blood product Factor VIII, used in the treatment of haemophilia. He said:

"The Haemophilia Society, amongst others, have highlighted their concern about blood borne infections and, in particular, the effect which those concerns have on families with haemophiliac children. Though the risk of nvCJD transmission is hypothetical, nevertheless the fear of it is very real to this group which has previously been affected by both HIV and Hepatitis C transmitted from Factor VIII.

"So I have decided that all health authorities must make arrangements to ensure that the synthetic version of Factor VIII, known as recombinant, is made available to those children under the age of 16 who are not already receiving it, and to new patients.

Dr Jeremy Metters, Deputy Chief Medical Officer, said:

"The use of imported plasma is a purely precautionary public health measure.

"The blood products which may now be manufactured from that imported plasma include the clotting agent Factor VIII, used in the treatment of haemophilia, immunoglobulins, which are used in the treatment of a range of diseases such as tetanus and the prevention of haemolytic disease of the newborn through treatment of rhesus negative mothers; and albumin, used in the treatment of burns and serious accidents, and as a stabiliser in some vaccines. Vaccines currently used in the UK childhood immunisation programme do not contain UK albumin.

"The Chief Medical Officers in Scotland, Wales, Northern Ireland and I support the CSM's precautionary approach.

"Whole blood, used in blood transfusions, is not affected by today's measures. The Government has made it clear that it will take all practical steps recommended by the relevant expert committee (SEAC) to maintain safety.

"In line with that commitment, the National Blood Authority have already been instructed to prepare a strategy for the possible removal of white blood cells from donations by the process of leucodepletion, should it be required.

"There is absolutely no question of any risk to blood donors of contracting nvCJD. We still need just as much blood for transfusion as before. Donated blood is vital to the work of the NHS and I urge all donors to continue their life-saving work."

NOTES FOR EDITORS

1. Plasma is the fluid in which the blood cells (red cells, white cells and platelets) are suspended. It is separated off when whole blood is centrifuged.

2. Imported plasma will be subject to thorough checks and inspections by the Medicines Control Agency acting on behalf of the CSM.

3. Blood products include Factors VIII and IX, used in the treatment of haemophilia, immunoglobulins used to treat immunodeficiency, and a range of less commonly used products. Blood products are made from pools of plasma, derived from between 20,000 and 66,000 donations.

4. The CSM is the UK Committee on the Safety of Medicines, set up following the Medicines Act 1968. It advises Ministers on regulatory matters. The full advice of the CSM is attached.

5. The CPMP is the European Committee on Proprietary Medicinal Products. It advises the European Commission on regulatory matters in a specific group of pharmaceuticals, notably those derived from biotechnology and high technology.

6. The BPL is the Bio Products Laboratory, which is part of the National Blood Authority and which produces blood products from plasma for use in the NHS and for export when NHS need has been met.

7. SEAC is the Spongiform Encephalopathy Advisory Committee which advises ministers of UK health and agriculture departments on all aspects of spongiform encephalopathies.

8. Recombinant Factor VIII is a synthetic form of Factor VIII used in the treatment of haemophilia.

9. There have been 23 cases of new variant CJD.