RESTRICTED-POLICY

To: Secretary of State
Baroness Jay

From: Dr Graham Winyard
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New Variant CJD(nvCJD) & BLOOD

There is a theoretical risk that nvCJD can be transmitted through blood and blood products. This has led to growing concern about the safety of UK blood and blood products at home and abroad. Over the next few weeks this is likely to be exacerbated by fresh advice from the European Committee on Proprietary Medicinal Products (CPMP), a growing head of steam in Europe (effectively leading to a ban of UK blood products), and any further recall of licensed blood products derived from suspected nvCJD donors (there have been three so far). This is in addition to any action needed to follow up SEAC's advice on blood once the risk analysis is available. The attached background paper sets out the issues in some detail and a range of possible ways in which we might respond to these pressures.

2. The Government will need a robust position on these issues by the end of February when action at European level will demand a response. All the possible options require significant additional funding which will need discussion with the Treasury. Also we shall need to agree a common position with the other UK Health Departments, and forewarn our EU partners, the Commission and WHO, of any action we plan to take. An urgent meeting to discuss the issues is requested.

Scientific Position

3. In brief, there is very little hard evidence about nvCJD, and the research programmes in place will take several years to deliver. However, we do know that nvCJD behaves differently from classic CJD (in that it affects younger age groups and has a longer 12-24 month course). The agent associated with nvCJD is indistinguishable from that which causes BSE in cattle, and there is some evidence that disease development is facilitated by the lymphatic system, probably by the white blood cells which remain in blood for transfusion and

perhaps in fractionated blood products. Because of this, the UK has had to, and will certainly in future need to, recall blood products from suspected nvCJD donors.

4. In addition, Ministers decided in November, on the advice of SEAC and MSBT (Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation), that:

- an assessment of the risks of nvCJD transmission through blood and blood products should be carried out urgently;

- the NBA should prepare a strategy to remove white cells from blood (leucodepletion) if the risk assessment showed this to be necessary.

5. We are keeping the Commission and our EU partners informed of developments. Both the risk assessment and the NBA's leucodepletion strategy will be completed by the end of February. However, it now looks as though the risk assessment will be unable to reach firm conclusions.

Public Health Perspective

6. The basic science will not deliver any definite assessment of the risk of human to human transmission of nvCJD for some time; in the absence of firm knowledge a more precautionary, public health based approach would suggest that further steps should be taken to avoid potential risks. This would be the stance favoured by the Commission and our EU partners and which has lead the UK and EU advisory committees on pharmaceuticals to develop risk avoidance strategies.

7. In particular the Committee for Proprietary Medical Products (CPMP), the EU Member States' advisory committee on pharmaceuticals, is preparing fresh advice for issue on 27 February. This will recommend further precautionary measures in the case of implicated blood products, including extending recall action to:

- products where blood components are used as an excipient (stabiliser) as well as those where they are the active ingredients eg some vaccines;

- patients who are 'strongly suspected of' as well as those 'confirmed as' having nvCJD;

and that to avoid unnecessary recalls

- products using blood components as an excipient should be sourced wherever possible from non nvCJD affected areas (ie not the UK).

Although these recommendations are not expected to be made public until 27 February the information is already beginning to filter out and pressure to take action is likely to grow.

8. At the same time the Committee on Safety of Medicines (CSM), the UK pharmaceuticals committee which advises Ministers in its role as the UK Licensing Authority, has reached a similar conclusion and is likely to recommend a move away from licensed blood products made from UK plasma wherever possible. The Committee will be looking at the range of products licensed here and making specific recommendations on a case by case basis over the next 3-6 months.

Public Reactions

9. Some companies (in France, Portugal, Switzerland and Germany) have taken commercial decisions not to buy UK sourced products, partly in reaction to the recalls of blood products in the UK. These have fuelled a widespread belief in some parts of Europe that we are reluctant to face up to the full implications of BSE. UK recalls reverberate in all EU Member States, as well as worldwide, and health ministries understandably want to know whether their populations have been exposed.

10. These concerns are also reflected at home where the media continue to highlight the possible risks of UK blood and blood products, and where the UK Haemophilia Directors (understandably in the light of their experience with HIV and Hepatitis B and C) have used the opportunity to press their case for full funding of recombinant (artificial) products for haemophiliacs. These pressures are likely to increase with the publication of the CPMP recommendations and completion of the risk assessment at the end of February, and consideration by SEAC on 9 March.

11. We are thus faced with a major loss of confidence in UK blood and blood products at home and abroad, consequent threats to the UK blood supply, and the possible financial collapse of BPL. The Government will need a robust position on these issues, and to give advance warning to our EU partners and WHO, by 27 February.

Options

12. For the *labile components* of blood - red cells, platelets, and fresh frozen plasma for which no alternative sources exist - the only safe option would appear to be leucodepletion on precautionary grounds as the risk assessment now looks likely to be inconclusive. The leucodepletion strategy is driven by demand for labile products and will not be affected by any action we take in respect of blood products. Implemention will take about 12 months and will cost an estimated minimum £75m per annum.

13. In addition, we shall need to position ourselves on the safety of blood products. Paragraph 28 of the attached paper sets out in detail the four main options. They are all costly - ranging from an additional £30-£50 million - as they involve industrial scale manufacturing requiring 600 tons of plasma annually, loss of home and export markets, outsourcing of alternative 'raw material' as well as the provision of more expensive blood products. The options fall into two categories, those based on pure science and those based on public health and public confidence.

14. The options based purely on science and logic are to:

(i) wait for the outcome of the risk assessment;

(ii) and if that is inconclusive, await firm scientific evidence before deciding on next steps.

15. However these measures in isolation are unlikely to restore public confidence and would leave the Government at the mercy of events and public pressure. Moreover, either option would cost in the region of £22-31m in 1998/99 rising to £28 -39 m in 1999/00 (in addition to £75m for leucodepletion) because confidence in products made from UK plasma would be likely to continue to fall.

16. The alternative approach would be to take the wider view, accept that there is a potential problem and take action to minimise risk. The main options here would be to:

(iii) allow BPL to import non-UK plasma to make the full range of products and, at the same time, to provide limited funding of recombinant Factor VIII products for children and new previously untreated patients with haemophilia (estimated additional cost - £ 27.6m per annum);

(iv) state publicly that we propose to move away from plasma derived Factor VIII for haemophilia and from blood products made from UK plasma in all other cases (estimated additional cost - £49.5m in 1998/99, rising to £56 in 1999/00).

17. These options are more likely to be seen as effective in restoring public confidence and as proactive management of a difficult position. But both are expensive and the diversion of NHS funds to pay for them would be seen as running counter to the evidence-based approach to decision taking that we have encouraged in the NHS. One way of mitigating this latter point would be to fund the additional costs centrally as part of an exceptional public health initiative, rather than through general revenue allocations in the first instance.

Action

18. A summary of the options and costs are at **Annex D** of the attached paper. They all require sensitive handling and significant additional funds which could need to be sought from HMT. (We are working with Finance Colleagues to substantiate the cost estimates.) They also have implications for the other UK Health Departments and for our relations with Europe and WHO.

19. We would urge an early meeting with Ministers to discuss.

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