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GRO-C

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PS/Minister for Health and Community Care

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PROPOSED EUROPEAN COMMISSION SURVEY TO EXPLORE THE IMPACT OF EXCLUDING POTENTIAL DONORS WHO HAVE LIVED IN THE UK

Purpose

1. To make the Minister aware that the European Commission is considering deferral of UK Blood Donors and those who have lived in the UK between 1980 and 1996 when BSE in cattle had reached epidemic proportions in the UK.

Timing

2. **As soon as possible.** Colleagues in England have submitted similar advice to their Minister earlier this week.

Background

3. The basis for the proposed exclusion is the risk of transmission of vCJD to those potential donors associated with eating UK beef, and the consequent theoretical risk of transmitting the agent by transfusing their blood or using blood products made from it. There is no scientific evidence that CJD, either classical or variant, is transmitted through blood or blood products.

4. In his submission of 10 August 1999, Michael Palmer informed the Minister of the decision by the United States Food and Drugs Administration (FDA) and Canadian regulatory authority to exclude people who were resident in the UK from 1 January 1980 to 31 December 1996 for 6 months or more (cumulative) from donating blood. Since then Israel, New Zealand and more recently Japan have introduced similar regulation. All these countries have made it clear that the deferral criteria stems from public confidence in their national supplies, and has nothing to do with new information. The FDA in particular published a summary of the science, clearly indicating the lack of any evidence to support this action. As with UK's introduction of leucodepletion and the decision to make blood products from imported plasma, this regulatory action was based on the public safety principle.

Impact of regulation on national blood supplies

5. Countries introducing regulation like this must balance the effect any such regulation might have on the capacity of their blood services to satisfy national demand for blood and the need of their health services. The US and Canada carried out surveys of their donor populations which indicated that the regulation they finally introduced could be tolerated. In the US it meant a 1% drop or about 120,000 units less annually. In Canada, we believe that Quebec (which used one month instead of six for political reasons) is having significant blood supply problems. Where formerly they could in crisis import form the US, their different deferral criteria has in effect ruled this out.

What the Commission is doing -possible impact in Europe

6. The EC is planning a travel survey from Member States to the UK, in an effort to determine what specific deferral criteria might be recommended without compromising national blood supplies and patient safety. The results of the survey are likely to be very different from those carried out in the US with extreme variations in visiting patterns between countries, and much higher visiting and residency rate than for the USA or Canada. It will be difficult therefore to apply a common standard, unless there are significantly less stringent than those introduced by the US.

For example if the US regulation were to apply in the Irish Republic an estimated 60% of the donor population would be ruled out. In certain areas of France the figure would be up to 20 %, and this could rise to 100% in some university towns.

What do Member States think

7. There is considerable concern at Member State level about the impact of this kind of regulation by the EC who have competence in blood safety under Article 152 of the Amsterdam Treaty, which was ratified in May 1999. The Commission carried out a 20 question survey of Member State experts working on a proposed new Blood Directive last October on this issue and, with the exception of Austria, none were in favour.

What the Commission is doing now

8. Despite this the Commission are pushing ahead with their proposal, using the specialist expert committees advising those Directorates which have responsibility for licensing blood products and overseeing blood safety. Of course the Commission will also need to ensure that whatever directive or recommendation they devise does not compromise patient care and maintains public confidence in national blood supplies.

The UK's Dilemma

9. The UK is in a difficult position here because overt opposition on our part risks the accusation that we caused vCJD by adopting the same negative approach to regulation as in the past on BSE. In any case there is no further regulatory action we can take, as there would be no UK blood supply if we were to adopt the US position.

What regulatory action has the UK taken

10. We have done all we can nationally by introducing leucodelpetion and importing plasma from which to make our blood products. As recently as last September/October the Committee for the Safety of Medicines and the Spongiform Encephalopathy Advisory Committee indicated that no further action was required to

reduce the theoretical risk of vCJD transmission through the blood and blood products in the UK. However other Member States may feel exposed by the regulatory action taken by other countries though the push is not coming from them but the Commission.

Why would the UK wish to oppose EC regulatory action

11. There is great concern about the wisdom of this action, the logic behind it, the science such as it is, renewed public concern about CJD, confidence in the blood supply, and the negative impact it is likely to have on voluntary blood donation.

Conclusions and Recommendations

12. In his minute of 10 August 1999 Michael Palmer requested the Minister's view on whether we should formally explore, the possibilities with potential suppliers and in conjunction with colleagues in the other UK territories, of providing an alternative blood supply, so that if challenged we can confirm that every avenue has been explored. This option is still open to us. **However, we recommend that the Minister advises her colleagues in England, Wales and Northern Ireland that the overwhelming difficulties in clinical, scientific, logistical, moral and political terms mean that this option should be discounted from the outset.**

Lines to take are attached.

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LINES TO TAKE

What is the evidence that CJD is transmitted through blood: There is no evidence that CJD or vCJD are transmitted by blood transfusion or blood products. It is for individual countries to consider what action they think necessary to ensure the safety of their blood supply. Like the UK (and the US, Canada, Japan New Zealand and Israel), EC Member States need to consider the balance between the known risks to patients needing blood transfusions of restricting the national blood supply and the theoretical risk of transmitting vCJD through blood and blood products.

What have the Experts advised: A large number of expert bodies including the Working Group 'Blood Quality and Safety' of the EC Scientific Committee on Medicinal products and Medical Devices have reviewed the science. They have all advised that there is no scientific evidence that vCJD is transmitted through blood. They also advise that there is no scientific basis for the precautionary UK action on leucodepletion or making blood products from imported plasma –though of course the UK has taken this precautionary action. This indicates that they see no scientific reason to defer UK donors or people who have visited or resided in the UK between 1980 and 1996.

Would this action make the blood supply safer: There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. Regulatory authorities contemplating this action will need to consider the balance between the known risks to patients of restricting the blood supply and the theoretical risk of transmission of vCJD through blood and blood products. There is no evidence that this regulatory action will improve the safety of the blood supply.

Why isn't the UK taking the same measures: Introducing a regulation like this in the UK would in effect exclude the whole population. This is not, therefore, an option for the UK as we use 3 million units of blood every year. This cannot be replaced and there is no ready international market for blood. Blood is needed in care of patients especially those who are critically ill, suffering severe accidents, patients with cancer and leukaemia, and those needing surgery.

Is UK blood safe: The safety of the UK blood supply is widely acknowledged and verified through independent regulatory systems and audit. However almost every medical treatment or intervention including blood transfusion is associated with some risk. Two recent major studies from SHOT (Serious Hazards of Transfusion) have demonstrated that blood transfusion in the UK is very safe and that it is becoming even safer with improving technology and clinical audit.

What have you done about reducing the risk from vCJD from UK blood: As the experts have advised we have 1) instructed our fractionation laboratories to make blood products only from plasma imported from countries where there is no evidence of vCJD and 2) instituted universal leucodepletion of the blood for transfusion from 31st October 1999. The Spongiform Encephalopathy Advisory Committee (SEAC) and Committee on the Safety of Medicines reviewed current action in September 1999 and advised that no further regulatory action is required.