Secretary of State

From: Glyn Austin PH1.1
Date: 15 February 1999
cc: Ms Rogers PS/SofS
Mr Macnaught PS/M(PH)
Mr Stevens SpAdv
Professor Donaldson CMO
Dr Metters DCMO
Dr Rubery PH
Dr Jones MCA
Dr Powell MCA
Ms Birrane COMMS-DIR
Mr Chan Parly
Mr A Smith PH1
Dr Wight PH1.1
Mr Skinner PH1.1
Dr Wingfield RD2
Dr McGovern HSD1
Mrs Skinner HSD1
Mr Eddy MAFF
Dr Nolan MAFF
Mr Lawson JFSSG
Dr Mitchell DHSS NI
Dr Riley SO
Dr Smith WO

FINAL REPORT FROM DET NORSKE VERITAS RISK ON:

"ASSESSMENT OF THE RISK OF EXPOSURE TO nvCJD INFECTIVITY IN BLOOD AND BLOOD PRODUCTS"

Purpose

1 To inform you of:

i) the proposals for the publication of the final report from Det Norske Veritas (DNV) on the *"Assessment of the Risk of Exposure to nvCJD Infectivity in Blood and Blood products"*;

and the

ii) arrangements for handling issues that might emerge as a result of publication.

Background

2 At its meeting on 24 October 1997 the Spongiform Encephalopathy Advisory Committee (SEAC) reviewed the issue of the safety of blood and blood products. The Committee recommended that the Government consider, as a precautionary measure, the extension of leucodepletion of blood and blood products as far as is practicable and that a risk assessment be carried out in order to try and estimate more accurately the risk of transmitting nvCJD through human blood and blood products. On 6 November 1997 the Government announced

once it was available. A copy of the Department's press release is attached at Doc 1. DNV were commissioned to carry out a risk assessment and the National Blood Authority (NBA) were instructed to develop a strategy for the possible extension of leucodepletion of blood in the event that the risk assessment indicated that this would be a sensible precautionary measure.

3. In parallel, the Committee on Safety of Medicines was considering advice to Ministers on the safety, quality and efficacy of licensed blood products with regard to nvCJD. In February 1998, following advice from the CSM, Ministers authorised the NBA's Bio Products Laboratory to import plasma for the manufacture of blood products. The CSM then carried out its own assessment of medicinal products containing components derived from pooled human plasma, and in May 1998 the committee confirmed that manufactured blood products should not be sourced from UK plasma for the present time. A copy of the press release is attached at Doc 2.

4 After considerations SEAC recommended that on balance, and as a precautionary measure, the Government should extend the use of leucodepletion for all blood destined for transfusion. On 17 July 1998 the Government announced that it had accepted this recommendation and action was taken to implement the strategy that had been developed by the NBA. A copy of the press release is at Doc 3.

The Final Report

5 SEAC met on 11 January 1999 and received a final draft Report from DNV on the risks of transmission from human blood and blood products. This Report has been subjected to review by external experts. The Committee suggested some minor textual changes and these have been accepted by DNV. A copy of the final report is attached.

6 The Committee agreed that because of the many uncertainties surrounding this issue DNV had been faced with a demanding task and it had remained difficult to draw any firm conclusions. However, the report does provide a great deal of useful background information on the sourcing, processing and use of human blood and blood products against which emerging scientific data could be judged.

Key conclusions

7 The report includes a review of the available evidence regarding nvCJD infectivity in blood. The authors conclude that blood from people with nvCJD <u>may</u> contain infectivity that could be transmitted through blood transfusion. However, they state that this has not been proved conclusively. The aim of the report <u>was not</u> to ascertain whether or not nvCJD infectivity could be transmitted through human blood or blood products but rather to assess which components of human blood and blood products are risk factors to human health by analysing the processes involved in blood transfusion and the production and use of blood products assuming that infectivity was present. DNV were also asked to identify those groups of patients who might be at higher risk from blood or blood products and to consider the what measures might be available to reduce any risks that are identified.

8 The assessment required DNV to make a range of assumptions including wide variations for the numbers in the population incubating disease, the levels of infectivity in blood and the effect that the processing of blood has on levels of infectivity. As a consequence it has not been possible to provide an absolute level of risk and the results are presented in terms of the risks per infected donation. Using the various assumptions about the estimates of infectivity the authors conclude that each infected donation could lead to up to 2.6 new infections of which they predict 0.8 would live long enough to develop clinical nvCJD. About half the new infections are predicted to be due to blood transfusions and half to plasma derivatives.

9 The assessment considers a range of measures that would reduce the risks of infection. A number of these including a reduction or better use of blood and blood products and not allowing people who have received blood or blood products to donate blood are predicted to be moderately effective in reducing risk. However, for the latter case this needs to be balanced against the need to avoid adverse impacts on the overall blood supply.

10 In relation to the risk to patient groups DNV have identified two groups that have a significantly greater risk than others. These are patients are receiving treatments using intravenous immunoglobulin and those receiving blood clotting agents for the treatment of Haemophilia A. DNV estimate that the number of patients in these groups is 102,400 and 1,800 respectively.

11 The authors identify two measures that would be likely to have a significant impact on the reduction of risk. These are;

i) leucodepletion where, although the benefits are uncertain, there are some scenarios where it would have significant benefit (there are also other health benefits from this practice);

and

ii) the elimination of UK sourced plasma products which, provided plasma was imported from countries without nvCJD, would totally eliminate the risk.

12 After consideration of the Report SEAC concluded that it saw no reason to change its earlier advice recommending the leucodepletion of blood. The Committee welcomed Ministers decision to publish the Report.

Next steps

13 DNV have agreed to handle publication of the Report and make copies available. They will also place the document on the Internet.

14 It is suggested that an announcement about the availability of the Report by way of a Press Release timed to coincide with the publication of the SEAC Public Summary and press briefing that is scheduled for Thursday 17 February at 2.00pm. A draft Press Release is at Annex A. Copies of the Report will also be placed in the Library.

15 It is difficult to anticipate the response to the publication of the Report. There was little negative reaction to the decisions to accept and implement the recommendations of SEAC and

the CSM regarding the safety of blood and blood products and no further recommendations have been made. There has, however, been some recent criticism about the implementation of these recommendations and publication of the Report may present an opportunity for these to be revived. We have prepared "Lines to Take" for this contingency and a copy is at Annex B.

Conclusions

16 You are asked to:

i) agree the Press Release setting out the arrangements for the publication of the DNV Report

ii) note the arrangements for handling any reaction.

GRO C

Room 502A
Skipton House
Ext GRO C