23 September, 1997

As distribution

Technical Div Fax:
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Your ref: Our ref: Direct line: GRO-C E-mail address: GRO-C

Dear ,

Creutzfeldt-Jakob Disease - actions necessary in respect of post-donation advice of a donor determined retrospectively to have been in a risk category for C-JD at the time of donation.

The purpose of this letter is to confirm a requirement for advice to BPL of information which becomes available to Centres in respect of donors whose plasma has been sent to BPL, and which indicates that the donor may have been in a risk category for for C-JD at the time of donation.

Donor selection currently satisfies the requirements of UK Guidelines on the Medical Assessment of Donors (MAD Guidelines) and Recommendation R(95)15 of the Council of Europe on "the preparation, use and quality assurance of blood components". Consistent with these requirements, a donor would be considered to have been in a risk category for C-JD at the time of donation if, at any time subsequent to donation, it is determined that:

i. the donor had been treated in the past with extracts derived from human pituitary glands;
ii. the donor confirms a family history of C-JD;
iii. the donor is identified as suffering from, or as having died after suffering from, C-JD (irrespective of the nature of the disease - new variant, sporadic or familial C-JD).

The information in respect of such donors should be supplied to BPL Control Unit, by the mechanism in place for post-donation advice of risk of viral infectivity. The BPL procedure for "Review of Viral Infectivity" is presently being revised, and will be re-issued as a procedure on "Review of Post-donation Advice" incorporating the above requirements in respect of C-JD.

The action taken by BPL in respect of post-donation advice of C-JD risk will be determined in the context of current requirements of the Committee on Proprietary Medicinal Products (CPMP), and following appropriate consultation with relevant competent authorities. At the time of writing, CPMP has determined that "there is no experimental or epidemiological evidence of transmission by plasma-derived products" (Press Release CPMP/938/95). This position is under continuous review, and the advice mechanism defined above will allow BPL to respond rapidly to any change in perception.

In respect of donors identified as having suffered from new variant C-JD, I appreciate that this information will not be immediately available to you. Arrangements have been made for such donors to be identified through the liaison between national blood services and the C-JD Surveillance Unit. I have written separately to Dr Pat Hewitt, asking that Centres be advised of the identity of individuals

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NOT RELEVANT

who were donors who have died after suffering from new variant C-JD. Please undertake a review of plasma previously supplied to BPL from such donors and advise BPL accordingly.

Yours sincerely,

Terry Snape,
Technical Director (BPL).

Distribution: QA Managers, English Blood Centres
QA Manager, Welsh Blood Service
cc: National Medical Directors
Zonal Clinical Directors
Zonal Operations Directors

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