

on "the nature of advice to be given to patients who have been treated with plasma products manufactured from a plasma pool which includes plasma from a donor suffering from nvCJD"

1 **SCOPE**

Too little is known about nvCJD to allow a position to be defined which can be assumed to be indefinitely valid. The position outlined is defensible in the context of the stated premises. In the event that one or more of these premises is disproved or modified, the position must be assumed to be invalid (or, at best, unreliable pending urgent review).

2 **PREMISES**

- 2.1 There is no evidence that nvCJD has ever been transmitted by blood or blood products.
- 2.2 There is no available test to determine whether a given batch of product contains the infective agent for nvCJD.
- 2.3 There is no available test for pre-clinical infection with nvCJD.
- 2.4 There is no available prophylaxis against the development of clinical nvCJD.
- 2.5 There is no available treatment for clinical nvCJD.

3 **POSITION**

In the event that post-donation advice indicates that an individual subsequently identified as suffering from nvCJD has contributed to a plasma pool:

- 3.1 derived products should be withdrawn in accordance with current BPL procedures and in consultation with MCA;
- 3.2 no attempt should be made to advise individual recipients that they may have been treated with product from an affected batch;
- 3.3 this position, and its basis, should be explained to consignees as part of the withdrawal action;
- 3.4 consignees seeking advice on patient follow-up should be reminded that:
 - 3.4.1 a confidential permanent record of any human recipients, date of transfusion event, product and batch number of material transfused needs to be kept for future reference if necessary;
 - 3.4.2 for any patient transfused/treated with blood, blood components or plasma products (including albumin, immunoglobulins, vaccines, coagulation factor concentrates), record in the patient's medical record -
(i) the product, (ii) date given, (iii) unit/batch number.

4 **BASIS FOR THE POSITION**

- 4.1 The Lothian Ethics Committee, which reviewed the ethical basis of decision making in respect of the follow-up study being undertaken by the national CJD Surveillance Unit, determined that no attempt should be made to trace recipients, or to tell them they had received CJD-implicated donations.
- 4.2 The Ethics Committee was subsequently asked to advise on policy in respect of recipients of fractionated products from pooled plasma containing an nvCJD donor, and reiterated its earlier advice.
- 4.3 It is possible that the very act of advising a recipient in these circumstances would itself be construed as an injury, given the mental suffering that would undoubtedly result and given the probable impact on the recipient's status with respect to life/healthcare insurance.

5 **COROLLARY**

It follows from the above that there is no basis for assuming that individuals in receipt of therapeutic material from an implicated batch of plasma product should be considered to be in an "at risk" category with respect to blood donation, provided in all other respects they meet our current donor selection criteria.

6 **REVIEW**

This position will be reviewed at least annually by the National Medical Director of the NBA, and on any other occasion if the underlying premises change.