RESTRICTED POLICY

MSBT 6/5

CJD AND BLOOD DONOR EXCLUSION CRITERIA

Members will be aware that individuals who have CJD or who are considered to be at risk of CJD are excluded from donating blood, organs and tissues. Donors who have been treated with pituitary derived human growth hormone or human pituitary gonadotrophin are excluded as are individuals with a family history of CJD.

Members will recall that the MSBT considered whether individuals who had been treated with human dura mater should also be excluded from blood donations at its meeting on 10 February 1994. Members decided that in view of the very small risk and the problems in identifying and deferring donors, that Ministers should be recommended not to introduce such an exclusion criterion. Ministers accepted this recommendation. The relevant minute is appended as Annex 1.

More recently there have been discussion in various quarters about whether additional groups should also be excluded because of the risk of CJD. Annex 2 gives a summary of the current suggestions from various bodies. The current situation at the time of writing this note was that the Committee for Proprietary Medicinal Products (CPMP) of the EU, which governs criteria for plasma used in fractionated blood products governed by Directive EEC/89/381, has suggested no change from the current exclusion criteria of the Council of Europe, as practised within the UK. MCA will update the Committee at the meeting.

The papers from all the various bodies accept that transmission of CJD by blood or plasma is still only theoretical, and that there are no scientific reports of transmission of CJD by this route.

The CPMP and FDA have particularly been considering whether blood products should be recalled where a donor subsequently develops CJD. CPMP have advised against this, whereas the FDA recommend retrieval and quarantine of blood, blood components and source plasma from donors subsequently diagnosed with CJD or who have been identified as receiving pituitary derived growth hormone, or dura mater transplant or have a family history of CJD. It is also intended that physicians looking after recipients of such blood and blood products be notified so that they can provide counselling "as deemed medically appropriate". The European Plasma Fractionation Association has also prepared a position statement in August 1995, which essentially follows the lead of the FDA both in exclusion criteria as well as recall of blood products.

DECISION REQUIRED

Are members content with the current exclusion criteria for CJD? Has any additional information become available to change the current advice?