MEDICINES CONTROL AGENCY

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From: Dr. Jefferys MCA/L

Date: 23 October 1997

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CPMP DECISION ON THE ACTION TO BE TAKEN TO MINIMISE THE RISK OF TRANSMISSION OF nvCJD VIA PLASMA DERIVED MEDICINAL PRODUCTS

1. Secretary of State agreed that the Medicines Control Agency should put a paper to the Biotechnology Working Party of the CPMP (Committee on Proprietary Medicinal Products). The Working Party met last week and supported the UK recommendation that there should be a recall of batches of blood products if a blood donation to a plasma pool was subsequently found to have been made from a person who developed nvCJD. The Working Party deferred making a recommendation on the possible recall when plasma derived products are used as excipients in vaccines, cytokines and other medicinal products.

2. The plenary CPMP at its meeting this week accepted the recommendation from the Biotechnology Working Party. It decided that this decision should not be promulgated via a press release, but would be recorded in the minutes of the Committee and Member States would be informed. A meeting of experts is to be convened during November to address the more difficult issue of the possible withdrawal of products containing plasma derived excipients. It is likely that this group will involve several key UK experts such as Professor Pattison (the Chairman of SEAC), Professor Collinge and Professor Will.

3. The CPMP confirmed its current stance that there should not be a recall in the event a donation being identified from a patient who had developed classical CJD.

4. A further submission will be put to Ministers after the meeting of the expert group and the subsequent consideration by the CPMP. It is probable that these meetings will not be held before December.

5. Ministers are invited to note the action which has been taken and that the UK's recommendation has been endorsed by the CPMP.

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