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8 October 1997

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RISK OF TRANSMISSION OF nvCJD BY BLOOD PRODUCTS

1. Events this week have expedited consideration of whether blood and blood products are a risk factor for transmission of nvCJD. As regards sporadic CJD the CPMP has an established view, and does not advise the withdrawal of blood products when it is discovered that a donor who has subsequently developed CJD contributed plasma to the relevant plasma pool. This is in line with the risk assessment of some other bodies, but not the US Food & Drug Administration.

2. There is no data on the risk of blood products transmitting nvCJD.

3. The NBA and CJD Surveillance Unit are currently tracing what happened to the donations from the three (possibly four) blood donors who have developed nvCJD.

4. It is possible that this look-back will show that some blood products with a long shelf life are still unused. If so, the immediate question is whether these should be withdrawn, provided of course alternative sources of the same product are available.

5. The UK could act unilaterally, and withdraw such products on grounds of risk to the public. But to follow this course would trespass into domains where the CPMP have an interest, as blood products are licensed as medicines, albeit on a national basis.

6. The immediate question is one of tactics. Would it be better to involve the CPMP now, via its biotech sub-committee; or leave the Committee on the sidelines until we are forced to decide whether to withdraw blood products to which an nvCJD donor has contributed plasma.

7. Last year the Commission reacted adversely when in another sector the UK took unilateral action and only later informed them. The CPMP and the Commission cannot have failed to notice the media interest in CJD and blood this week. If the UK was to take unilateral action to withdraw blood products without a whisper to CPMP, they may well complain.

8. On balance it appears preferable to raise the nvCJD blood products issue with the Biotech Working Party of CPMP at their meeting next week. They cannot then complain of non-consultation or communications. They may also have some helpful advice on the scientific risk assessment.

9. Before putting a paper to CPMP we will need to clear this action with Ministers. MS(L) is already aware of the problem. If Ministers agree, we need next to forewarn FCO and UKREP.

10. To start the process we need from MCA colleagues a paper setting out the scientific questions, on which a CPMP input would be helpful, and from HSD a draft submission to set the MCA paper in its NBA/BPL context.

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