PS(L)

From: **A J McKeon MPI**

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PLASMA PRODUCTS FROM OTHER COUNTRIES WITH vCJD

We discussed the position last week and I undertook to let you and others have a summary of the position in writing.

2. The CSM met on 8 November 2000 and recommended the precautionary measures currently in place for UK source plasma should be extended to include medicinal products with some plasma derived from countries with one or more confirmed cases of vCJD. You decided that before taking action we should:

a) investigate the supply position;
b) await advice from the CPMP which was currently considering the issue.

3. On supply it is clear that:

- Pulmocis. A diagnostic agent in lung perfusion imaging, particularly in detection of pulmonary embolisms which is a life threatening condition. It is used on a daily basis in almost every nuclear medicines department. There is currently no alternative licensed source and discussions with Schering (the license holders) and CIS (the manufacturers) have revealed that as they supply to a number of countries they are not prepared to switch to a non-French plasma solely for the UK. We can seek alternative American sources but these would need to be licensed and is a long term option.

- Vasculocis. A diagnostic agent in blood pool imaging and heart studies. It is not widely used and there are alternatives for most of its uses but withdrawal would result in short term impact in patients. Some plasma volume studies might be impossible but I understand the clinical impact is unlikely to be significant.

- Betafact/Novofact. A Factor IX product. It has only been used at St Thomas' about a year ago. It is not currently used by them. The manufacturers confirm that no other UK centre is sourced by them. It is also not on the Oxford Haemophilia Centre's database of products used in the treatment of haemophiliacs in the UK, nor is it in the guidelines on therapeutics products to treat haemophilia. The Haemophilia Society may be concerned that Ministers have not implemented the CSM's advice and suspended or revoked the licence even though the product is not used in Britain. Alternatives are available.

4. On Europe. The CPMP will consider its Expert Group report at the end of this month. The Expert Group received a report in January to the effect that all products using French source plasma could be considered sufficiently safe and there was no reason to recommend withdrawal. The CPMP are likely to accept this advice. That advice will then be considered by the CSM's Biological Sub-Committee at the beginning of March.

5. CSM. I have spoken to Alastair Breckenridge, Chairman of the CSM. The CSM were aware that five product licences (which relate to three products) might be affected by their recommendations, but they were not aware of the details of any supply problems that might arise. They recognised that the implications of any threat to public health from withdrawal of any of these products would have to be considered before action to implement the recommendations was taken. They also clearly did not have the CPMP view. The CPMP advice has not yet been delivered; it is expected at the end of their meeting on 1st March. Professor Breckenridge believed that the CSM would be willing to review its recommendations in the light of the new information on the supply position and the CPMP's advice.

6. There is a possibility of suspending or revoking the licences for these products on the basis of the CSM's initial advice. However, it could be difficult to justify emergency suspension at this point. Suspension or revocation under the usual "non-emergency" procedures is usually estimated to take up to about six months or more in total because of appeal rights. Distinguishing between the products when licenses are granted and suspended/revoked on grounds of safety, quality and efficacy may also prove difficult. There would also be considerable outcry from Europe if such action was taken but that is a secondary point behind consideration of risk/benefits for patients. Advising the NHS not to purchase particular products would also be subject to challenge and manufacturers might expect to be at least consulted. We would also need to investigate further the legal consequences under the Transparency Directive as we would in effect be excluding products from the NHS.

7. Given this timetable, the problems clearly associated with withdrawing pulmocis and, (to a very much lesser extent) those of vasculocis, the fact that Betafact/Novofact is not used in the UK; the forthcoming CPMP's advice and the outcome of my discussion with Alastair Breckenridge, I suggest that the CSM is asked to give further advice based on full knowledge of the supply position and CPMP's view as soon as possible in March.

8. We can if you wish further strengthen the position on Betafact/Novofact and specifically request that the manufacturers do not export any product to the UK until the issues are resolved, although there are unlikely to be any requests for it given the circumstances outlined above.

9. You indicated that this was your preferred approach. Do you wish to confirm that? Do you wish us to speak again to the manufacturers of Betafact/Novofact as indicated above?

10. As we noted in the discussion, there are one or two lessons to be learnt from the issues raised in this case which I will pursue with colleagues.

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