Note of the Teleconference 15 November 2000 at 4.00pm

Department of Health

Dr Pat Troop, DCMO
Miss Isabelle Izzard, MPI
Mr Charles Lister, HSD
Mr Alan Harvey, PH6

Medicines Control Agency

Dr Alex Nicholson, Director of Licensing
Dr S P Lam Group Manager, Licensing Division
Dr Lincoln Tsang, Unit Manager Biologicals/Biotechnology

1. This telephone conference was to discuss matters arising from the MCA submission to Lord Hunt about blood products with plasma sourced from countries with prevalent vCJD.

2. Dr Troop expressed quite serious concerns about the use of the term, "sub-clinical", in the submission. In her view, "sub-clinical" inferred that the disease was present but that it **never** became clinically manifest. This was different from, "pre-clinical": the period when the disease was in its early stages and before clinical expression of the disease. [MCA listened to this with surprise but made no contrary comments]. Her concern was that experts in the field did not believe that there was any evidence that "sub-clinical" vCJD was an entity and that to suggest otherwise could raise unwarranted concern. Moreover, she felt that CSM should not go into this area of defining pre-clinical or sub-clinical of the disease without consultation with the National CJD Surveillance Unit in Edinburgh and SEAC. MCA confirmed that the CSM *ad hoc* group included appropriate experts. Dr Troop urged caution in proceeding to consider vCJD-free countries with BSE. She would much rather this consideration took place under a European umbrella. MCA had no difficulty in agreeing with this approach.

3. Dr Troop wondered why CSM were making a distinction between active albumin and excipient albumin. She questioned that this was not the approach that had been used for UK-sourced bovine material. MCA suggested that CSM may have been concerned about a potential supply problem. Dr Troop took the view that CSM should give 'pure' advice on safety, that is to say, not taking into account any supply problems. MCA agreed with this view.

4. Dr Troop further suggested that the next step would be

- to identify all products that might be affected by a ban on French-sourced albumin as an excipient,
- to consider the supply for each product, and
- to perform an assessment of the effect on public health if there is a shortage in supply for each of these products because of the ban.

Dr Troop said that DH should collaborate with MCA to undertake these actions. Dr Troop asked for some forecast as to when the necessary information on products affected by an excipient ban would be available. MCA said at least 'one week from now.' Dr Troop did not express any concern about that timescale.

5. The 'Irish' case was discussed. There was uncertainty about where this individual contracted the disease, i.e. whether this individual had contracted the disease in UK before symptoms developed in Ireland. Neither side could give a definitive answer. PH6 would try to find out more about the background of this case.

6. To summarise:

- Wider DH are now fully aware of the potential supply problems if CSM advice on active constituents of French plasma-derived products is implemented.

- Wider DH are now aware of the potential scale of the problem related to the extension of CSM advice to include excipient French-source albumin. It is for MCA to give them the specifics when we know the source of excipient albumin for all products potentially affected by a ban (about 100). In the interim, CSM should be asked to give 'pure' advice; i.e. not taking into account any potential supply problems.

- DCMO is not in favour of any unilateral consideration of the source of plasma derivatives from vCJD-free but BSE prevalent countries. This should take place within a European framework.

- PH6 will pursue details of the 'Irish' vCJD case.

Dr Lincoln Tsang
Head of Biologicals/Biotechnology
15 November 2000

copy:

MCA attendees
Board members

Notes:

Dr Troop's distinction between 'sub-clinical' and 'pre-clinical' is not supported by medical dictionaries (Butterworths and Dorlands). Nor, in the context of concern about asymptomatic disease, is it obvious that such a distinction is relevant. (contd) Professor Breckenridge has agreed to put excipient albumin on the next CSM agenda

(Notes added by Alex Nicholson)