HUMAN & VETERINARY MEDICINES BRIEFING GROUP RE. BSE

MINUTES OF MEETING HELD ON 22.2.89 AT 10AM IN THE 19TH FLOOR CONFERENCE ROOM, MARKET TOWERS, TO AGREE ADVICE TO CSM (ON 23.2.89)

Present: Biologicals Subcommittee
Professor Collee (Chairman)
Dr.Minor
Dr.Schild

Invited Experts
Professor Asscher
Professor Sir J Badenoch
Dr.Kimberlin
Dr.Martin
Professor Rawlins

Department of Health Medicines Division
Dr.Adams
Mrs.Alderman
Mr.Bewley
Mr.Hagger
Dr.Jefferys
Mr.Love
Dr.Purves
Dr.Rotblat
Mr.Sloggem

Department of Health (Other)
Dr.Burton
Mr.Colman
Mr.L.Wilson
Ms. Nash
Dr.Pickles
Dr.Salisbury

MAFF
Mr.Bradley
Mr.Kidd
Dr.Little
Mr.Scolan-
Mr.Wilesmith

Apologies for absence were received from Dr.Tyrrell and Dr. Sutton

1. Information Exchange

1.1 It was thought that the Southwood Report would be published on 24.2.89, when a press conference would be held, attended by CMO, CVetO, sir Richard Southwood, and possibly representatives from MAFF.

1.2 The Southwood Committee considered that the most likely cause of BSE in cattle was feeding with protein derived from scrapie infected sheep. Although man has eaten scrapie infected sheep meat for many years, no incidence of BSE has been reported in humans. Because of the lengthy incubation period, no cases of BSE have been seen in humans arising from bovine sources and the Southwood Committee were of the opinion that cattle will prove to be "dead-end" hosts for the BSE causing agent, and it is unlikely that there will be any implications for human health.

1.3 Because of the above, clarification is needed on the acquisition of BSE by cattle via the oral route, which by analogy with scrapie is relatively inefficient. Although it is probably the primary route in cattle, there may be special factors involved eg. damage to the gut from roughage, causing an "injection" of BSE. It was felt that the oral route need not be of undue concern at this stage.

1.4 The slight theoretical risk of BSE being transferred to humans was considered to be more likely from products used parenterally or by implantation than by the oral route. The implications of this for the vaccination programme (vaccines using bovine ingredients in manufacture) could be very serious and result in epidemics if public reaction turned against vaccination.

1.4 The annual incidence of BSE in the UK at 31.12.88 was cited. It represents 1 case per 1000 adult cattle (total population 4 million) but cases have not occurred uniformly throughout the UK.

1.5 Despite the research and investigative studies already carried out on BSE, the cause of the relatively recent appearance of the disease in cattle has not been established and it may be the result of a mutant strain of scrapie being transmitted by the feedstuff. There is a need for more research into BSE and a consultative research committee chaired by Dr.Tyrrell has been set up to carry research initiatives forward.

2. CSM paper

2.1 Joint proposed DH/MAFF draft guidelines

2.1.1 Draft guidelines covering products for use parenterally, in the eye or on open wounds and the source of bovine materials used in their manufacture had been drawn up.

2.1.2. Normally, in matters where there is as little knowledge as there is in the case of BSE, CSM would have been advised to take no action but to monitor the situation. Due to the publication of the Southwood Report, this option is not open. It is not feasible to go to consultation with industry on the matter due to lack of time, and the fact that this might be seen as our being led by industry. VPC had given broad approval to the draft guidelines.

2.1.3. The guidelines themselves were discussed. These are to be seen as a "gold standard", and may be modified in the light of experience. It is intended that they should be parallel with those issued on the veterinary side, but not identical because they have more difficult problems to handle (BSE being a speculative hazard in man).

2.1.4. It was agreed that it would be better to try to eliminate BSE at source. The possibility of the identification of risk-free herds and their certification was discussed. Ideally, bovine materials obtained from calves should be taken from animals less than 6 months old, which have not been fed on ruminant-derived protein. The question of "BSE-free" countries was raised, but there are other pathogens which also need to be taken into consideration in selecting a source.

2.1.5. It was felt that to issue rules on oral products would challenge our concepts on foods, and cause problems with regard to gelatin capsules. The guidelines are a balance between flexibility and standards of ideal practice, and an attempt has been made to major on the question of source.

2.1.6. VPC had expressed anxiety about animal vaccines, and it was felt that in future we may need to ensure that bovine ingredients are not obtained as by-products of abattoirs. The possibility of herds being maintained specifically for this purpose was mentioned.

2.1.7. The question of excluded tissues was discussed. In the case of the intestine, this would eliminate heparin (although most of this is porcine sourced) and catgut. It was felt that the pancreas should not be excluded as this would eliminate bovine insulin.

2.1.8. The section headed "sterilisation" was clarified to refer to equipment used in production, and not to products themselves.

2.1.9. Anxiety was expressed over problems with availability of supply of vaccines if companies could not comply with the guidelines, as failures of supply could lead to epidemics. Drs. Adams and Rotblat had, at the request of the CMO, contacted companies holding licences for vaccines, asking for information on the use of bovine ingredients. Most of the companies were aware of the problems of BSE and some have begun to take action. It was felt that most companied would welcome guidelines on this subject.

2.1.10. The question of unlicensed products involving bovine ingredients was raised. These are not subject to the Medicines Act and are controlled by Supplies Technology Division. Some preliminary screening of these products has taken place, and PD will follow the lead of CSM and issue similar guidelines.

2.2. Letter to licence holders

2.2.1. The draft letter was discussed. MAFF and Department of Health are sending letters separately, those sent by MAFF being S.44 letters.

2.3 Questionnaires

2.3.1. The background to the need for data was discussed, the problem at present being that we cannot identify products using bovine ingredients during the manufacture. The intention is to develop a full database of the use of bovine ingredients in human medicines, and companies will be asked to respond to the questionnaire by 1st May 1989. The questionnaire was seen to be adequate.

3. Consideration of particular product groups

3.1 Product groups likely to use bovine ingredients were listed. An assessment of the theoretical risk involved in the use of vaccines and products in the other groups is required.

4. Proposal for a Working Group on BSE

4.1 It was agreed that a Working Group, associated with the Biologicals subcommittee should be set up, and a proposal of this was to be made to CSM. Suggestions for a core membership were made, with other experts being brought in as needed.

5. Form of statement and briefing for press

5.1 The draft prepared by Medicines Division was discussed, and some amendments suggested.

6. Other business

6.1 Dr.Burton asked to be kept informed as to CSM decisions, and also requested that a letter, guidelines and questionnaire be sent to him as holder of the Secretary of State licences.