To: Catherine Pearson APS/CMO

From: Eileen Lawrence HP-GHP
Date: 22 March 06

cc: List attached

SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE MEETING: 24 February 2006

ISSUE

1. To update CMO on the discussions at the SEAC meeting held on 24th February. My previous submission of 16 February refers.

SUMMARY OF MEETING

2. A summary of the meeting is attached at Annex A. As is usual practice, this is published on the SEAC website (www.seac.gov.uk). I draw your attention to the key health issues discussed.

Current issues

3. Following the report from the SEAC Epidemiology Subgroup, the committee welcomed the Chairman's report that the Department has agreed to set up an expert group to advise on the best approach to determine the prevalence of vCJD infection in the UK population. Officials will now take this forward as a priority in consultation with RDD and the HPA, and involving the Chairman of SEAC as necessary.

4. Professor Noel Gill, HPA, updated the committee on actions taken following the announcement of the third case of vCJD transmission associated with blood transfusion. Members agreed that the case indicates that there is significant risk of transmission of vCJD by blood transfusion. A paper on the case is being prepared by the Transfusion Medicine Epidemiology Review.

Medical implants containing bovine material

5. This item was brought to SEAC initially because of concerns about specific cases of the use of heart valves containing bovine material sourced in the USA (Shelhigh Implants). To set this in context, the discussions at SEAC were broadened to include the risks to human health of TSEs from all medical implants that include bovine material sourced from the USA. This material was used for a wide range of medical devices, some of which are life saving and for which there are no alternative products.

6. SEAC considered that a single risk assessment to cover all products would not be appropriate due to the number of devices that are involved and the varying degrees of risk. The committee concluded that a risk assessment should be developed for each specific medical device.
7. The papers and minutes of the SEAC discussion will be sent to the CJDIP secretariat for them to consider if any further action is needed in respect of the Shelhigh Implant cases. The next meeting of the CJDIP is due to be held on 2nd May.

Methods to evaluate the efficacy of prion reduction filters

8. SEAC commented on experimental models to evaluate prion reduction methodologies that were developed to reduce the potential for vCJD transmission via blood transfusion.
9. SEAC considered that experiments that tested the removal of endogenous infectivity were important and that it was crucial to try and get a model that was as close as possible to the human condition.
10. Of particular note for DH, is that this item re-inforced the need for knowledge of the prevalence of vCJD in the population (para 3 above refers). SEAC noted that understanding of the prevalence was crucial to the risk management issue of implementation of prion reduction filters.

Sheep subgroup report

11. SEAC agreed with the Sheep subgroup's conclusions, ie. that there is currently insufficient data to make any conclusions about the risk to human health from the finding of atypical scrapie in UK and European small ruminant flocks. However, as transmission to humans is theoretically possible, the Subgroup stressed the importance of research on transmission of atypical scrapie in transgenic mice expressing the human prion protein gene to inform on this issue.

Use of livestock and crops from Drayton Farm

12. Defra and FSA asked SEAC to review the arrangements for disposal of manure, crops and livestock from an experimental farm.

13. SEAC concluded that, as there is no evidence that BSE is transmitted through environmental sources, healthy animals could be housed in the disinfected buildings which previously housed cattle experimentally infected with BSE. They agreed also that there is currently no evidence that the crops subsequently grown on the land which received composted excreta from BSE challenged animals pose a significant infectivity risk to humans or animals.

Dentistry and vCJD

14. SEAC considered the findings and implications of a preliminary risk assessment of potential vCJD transmission via endodontic procedures. The committee was updated with preliminary data to assess the oral cavity as a potential route of transmission of vCJD infectivity.

15. SEAC considered that further data was required on the infectivity of oral tissues and the prevalence of vCJD in the population. However, in the absence of this information and as there is a theoretical risk of transmission of vCJD via endodontic procedures, the committee suggested that the use of single use instruments should be seriously considered. We are meeting with dental policy colleagues next week to consider what action, if any, might now be needed.

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ANNEX A

NINETY FIRST MEETING OF THE SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE

The Spongiform Encephalopathy Advisory Committee held its 91st meeting in London on 24th February 2006.

CURRENT ISSUES

SEAC was informed about the following issues:

- The Chair had received a positive response from the Chief Medical Officer on the recommendations made in the SEAC Epidemiology Subgroup statement on the vCJD epidemic[1] and subsequent SEAC statement[2]. SEAC recommended that better data on the prevalence, age and genotype distribution, based on population studies, are required with some urgency. This data could be obtained through testing tissues collected from autopsies. The Department of Health will convene an expert group to consider ethical, practical and legal issues to take the recommendations forward.

- SEAC responded to a consultation from the European Commission. This requested comments on the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks on the safety of human-derived products with regard to vCJD.

- A third case of vCJD transmission associated with blood transfusion was announced by the Health Protection Agency (HPA) on 9th February 2006. The recipient developed symptoms of vCJD about 8 years after receiving a blood transfusion from a donor, who developed symptoms of vCJD about 20 months later. SEAC was informed about the HPA notification exercise, follow up arrangements, and further actions relating to the remainder of the exposed group of 26 individuals. Members agreed that the case indicates that there is significant risk of transmission of vCJD by blood transfusion. A paper on the case is being prepared by the Transfusion Medicine Epidemiology Review.

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[1] http://www.seac.gov.uk/statements/state260106subgroup.htm
[2] http://www.seac.gov.uk/statements/state260106.htm

- Interviews had taken place for two new members for SEAC, submissions to Ministers are in preparation.

BSE UPDATE

SEAC was presented with figures showing the annual number of BSE cases in cattle in Great Britain (GB) since the 1980s and the reductions in the number of cases after the introduction of control measures. Members noted data on BSE cases reported in other countries. In GB, the BSE epidemic peaked in 1992, with over 36 000 cases confirmed, and thereafter the number of cases declined considerably. There have only been 124 cases confirmed in animals born after the introduction of the reinforced ban in 1996. Overall the GB epidemic is in steep decline with only 203 cases confirmed in 2005.

MEDICAL IMPLANTS CONTAINING BOVINE MATERIAL

SEAC considered the risk to human health from medical implants that include bovine material sourced from the USA. This material was used for a wide range of medical devices, some of which are life saving and for which there are no alternative products.

SEAC considered that the source of the animal was crucial to manage the risk. The committee suggested that other precautionary steps be taken where practicable, such as using material from young animals, sourcing material from countries with good surveillance procedures and a low prevalence of disease.

SEAC noted the lack of clarity in the regulations, which did not give an indication of what level of risk is acceptable, and the British Standards Institution committee scheme, which serves to assist judgments of acceptability by determining whether the BSE risk from a medical device utilising bovine material has been minimised. The committee considered that a single risk assessment model would not be appropriate due to the variety of devices and risk control options that are involved and the varying degrees of risk. A risk assessment should be developed for each specific medical device.

METHODS TO EVALUATE THE EFFICACY OF PRION REDUCTION FILTERS

SEAC welcomed the opportunity to comment on experimental models to evaluate prion reduction methodologies that were developed to reduce the potential for vCJD transmission via blood transfusion.

SEAC considered that it was important to replicate the experiments that the companies had done to test the efficacy and reproducibility of the filters. The committee suggested that the use of an additional rodent strain and three different forms of inoculum of TSE agent as the spiking material was important. This may indicate differences in the efficacy of filters against

different strains or TSE agent. It is critical to include the BSE agent in these studies.

SEAC considered that experiments that tested the removal of endogenous infectivity were important and that it was crucial to try and get a model that was as close as possible to the human situation. The committee noted that knowledge of the prevalence of vCJD in the population was important to the risk management issue of implementation of prion reduction filters.

SEAC SHEEP SUBGROUP REPORT

Since the introduction of an ELISA rapid test for active surveillance in 2002, around 100 cases of what is called atypical scrapie have been detected in the UK. The SEAC Sheep Subgroup met on 24th January 2006 to consider emerging scientific developments on atypical scrapie and possible implications for the National Scrapie Plan (NSP) and human and animal health. In its position statement, the Sheep Subgroup concluded that the new scientific data and identification of atypical scrapie, while of concern, do not justify immediate changes to the NSP. Nevertheless, the Subgroup strongly recommended that the NSP should be kept under continuous review as new findings emerge. SEAC concurred with this view.

The Subgroup concluded that there is currently insufficient data to make any conclusions about the risk to human health from the finding of atypical scrapie in UK and European small ruminant flocks. However, as transmission to humans is theoretically possible, the Subgroup stressed the importance of research on transmission of atypical scrapie in transgenic mice expressing the human prion protein gene to inform on this issue.

SEAC agreed with the Sheep Subgroup's conclusions and recommendations and endorsed its position statement. The statement can be accessed at: http://www.seac.gov.uk/pdf/positionstatement-sheep-subgroup.pdf

USE OF LIVESTOCK AND CROPS FROM DRAYTON FARM

Defra and FSA asked SEAC to review the arrangements for disposal of manure, crops and livestock from an experimental farm. BSE research projects in cattle have been ongoing here since 1998 and are nearing completion. The TSE projects in sheep have been ongoing since 2002. SEAC previously advised that waste from orally-challenged animals should be incinerated for the first 28 days, thereafter the excreta should be composted for a year and then could be used to fertilise arable land. The crops grown subsequently could in principle be used for both human food and animal feed.

All excreta from the orally and intracerebrally inoculated cattle were incinerated for the first 28 days after inoculation. A 12 month composting period was introduced for manure from the BSE challenged animals.

However, only short rotation willow coppices were planted on the land onto which the composted manure from the BSE challenged animals was applied.

SEAC considered that, as there is no evidence that BSE is transmitted through environmental sources, healthy animals could be housed in the disinfected buildings which previously housed cattle experimentally infected with BSE. These animals could be used for commercial slaughter or for other purposes. The current animal tracing system will monitor the movements of these animals in the future. There is currently no evidence that the crops subsequently grown on the land which received composted excreta from BSE challenged animals pose a significant infectivity risk to humans or animals.

DENTISTRY AND vCJD

SEAC considered the findings and implications of a preliminary risk assessment of potential vCJD transmission via endodontic procedures. The committee was updated with preliminary data to assess the oral cavity as a potential route of transmission of vCJD infectivity. This item was discussed in the reserved business session as there was consideration of unpublished research.

SEAC considered that further data was required on the infectivity of oral tissues and the prevalence of vCJD in the population. However, in the absence of this information, and as there is a theoretical risk of transmission of vCJD via endodontic procedures, the committee suggested that the use of single use instruments for such procedures should be seriously considered.