nvCJD file.

DEPARTMENT OF HEALTH

1999/0094 Thursday 18th February 1999

PUBLIC SUMMARY OF SEAC MEETING - 11 JANUARY 1999

The Spongiform Encephalopathy Advisory Committee (SEAC) met on 11 January 1999. A summary of the meeting is published today in line with recommendations of the SEAC review (published September 1997).

The Committee hold press briefings when these summaries are published and the Chairman, Professor Sir John Pattison, hosted today's briefing.

PUBLIC SUMMARY OF COMMITTEE MEETING - 11 JANUARY 1999

The Spongiform Encephalopathy Advisory Committee (SEAC) met at the offices of the Ministry of Agriculture, Fisheries and Food, Tolworth on 11 January 1999.

The Committee conducted its regular review of research findings and epidemiological information on BSE and vCJD.

The Committee noted that the total number of vCJD cases in the UK was 35. The number of cases of BSE continues to decline in line with predictions about the decay in the epidemic.

The Committee had been asked to consider the potential use of Pentosan Polysulphate as a prophylactic against vCJD. Dr. Stephen Dealler attended the Committee, made a presentation and took part in the discussion. Following this the Committee has provided advice to Ministers and a copy is attached.

The Committee had been asked by the Chief Medical Officer of England to consider the risk associated with cheek meat for human consumption removed in Northern Ireland from bovine heads imported from the Republic of Ireland. They noted that a decision of the courts in Northern Ireland meant that the importation of such bovine heads by one specific company for the removal of cheek meat for human consumption had now been permitted pending the outcome of an appeal against this decision to the European Court of Justice. The Committee considered that it would be preferable that cheek meat imported into the UK came only from animals from countries which have no cases of BSE and that bovine heads from which cheek meat was removed within the borders of the UK also came only from such countries. However SEAC recognised that imports are controlled by EU law. With respect to UK cattle over six months old the Committee reaffirmed its advice that the whole head, other than the tongue, should continue to be treated as specified risk material (SRM). The Chairman of the Committee has written to the Chief Medical Officer of England summarising these discussions and conclusions.

The Committee considered a report from Det Norske Veritas (DNV) on the Assessment of the Risk of Exposure to vCJD Infectivity in Blood and Blood Products. The Committee agreed that because of the many uncertainties preparation of this Report had been a demanding task for DNV and it was difficult to draw any clear conclusions. The Report provided a great deal of useful background information on the sourcing, processing and use

of human blood and blood products. The Committee welcomed the intention to publish the report and suggested one or two minor revisions. The Committee saw no reason to revise its earlier precautionary advice to Ministers recommending leucodepletion of blood destined for transfusion.

The Committee, in common with other food safety Advisory Committees, had been asked for its comments in relation to the proposal for an overall framework for the handling of risk analysis, risk management and risk communication across a range of food and food safety issues. The Committee had a preliminary discussion but decided to postpone further discussion until after the BSE Inquiry had reported so that its findings could be taken into account.

ADVICE TO MINISTERS ON THE POSSIBLE USE OF PENTOSAN POLYSULPHATE (PS) AS A PROPHYLACTIC AGAINST vCJD

Pentosan Polysulphate (PS) is a member of a group of complex compounds, a number of which have been shown to have an effect on the natural history of scrapie in experimental animal models. The limited experimental evidence suggests the effects are likely to vary according to both the strain of the TSE agent and the species of the host. Therefore, it is difficult to extrapolate the results of scrapie studies in rodents to assess the likely effect of early treatment with this group of compounds on the natural history of vCJD in humans.

In rodent experiments PS has been shown to delay the time at which clinical signs first appear after exposure to the scrapie agent. Experimental evidence also suggests that once the infectious agent has entered the central nervous system PS is unlikely to have any significant effect on development of clinical disease. Consequently, whilst it might be effective during the early stages of infection in preventing progression to the central nervous system it seems unlikely that PS would have a role in the treatment of clinically affected patients or those at the later stages of incubating the disease.

Recent rodent studies had shown the route of administration of PS to be important. There was an effect on the incubation period following intravenous administration but none following oral administration. Further investigation of the kinetics of uptake and subsequent distribution in both animals and humans were needed.

The Committee agreed that there was some scientific evidence that compounds in the PS group might have potential for use as prophylactic agents against vCJD in humans. However, efficacy data were limited and were restricted to animal models using selected strains of the scrapie agent and their applicability to BSE or vCJD was unknown. Safety data currently available on the human use of PS is also restricted to about 10,000 patients treated for unrelated conditions by oral administration.

Further research should be carried out, ideally using BSE and vCJD in experimental animal models, such as transgenic mice carrying the human PrP gene, that may give a better indication of the likely effects of the drug in humans. In addition, since the peripheral pathogenesis of TSE infection in mice might be significantly different to that in man, studies in primates should also be considered.

We recommend to Ministers that research on this issue should be accorded a high priority. We note that the MRC and DH intend to form a group to consider therapeutic interventions against vCJD, including consideration of PS. We stress the urgency with which this work should be taken forward because we do not know the number of persons who are currently incubating vCJD and consequently the possible risks of transmission of this disease via transfusion from blood donors who are incubating the infection.

Further consideration of the use and safety of PS will need to be given by the Committee on the Safety of Medicines (CSM) and the Committee welcomes the setting up of a CSM Sub-Group that will involve SEAC members to take this forward.

In the absence of further data on efficacy and safety, SEAC did not consider that it was justified to recommend the wide use of Pentosan as a possible prophylactic against vCJD. In certain circumstances, where there is a tangible risk as a consequence of direct exposure to infectivity (such as an accident in a laboratory), there might be a case for administration of Pentosan. This could be done on a "named patient" basis but this would require more information about the bioavailability and toxicity of Pentosan to be available so that both physician and patient can make a well informed decision. Based on present evidence, there is no justification for the use of Pentosan as a treatment once clinical signs of vCJD are present.

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