The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

London, 28 February 2001
Doc. Ref: EMEA/CPMP/BWP/476/01

Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE)- risk via the use of materials of bovine origin in or during the manufacture of vaccines

Since recognition of BSE in the 1980's, the use of bovine material in the manufacture of medicinal products, including many vaccines, prompted action by European and National regulatory authorities to assure the continued safety of these products. The appearance of new variant Creutzfeldt-Jakob Disease (vCJD) and its association with BSE, underlined the importance of the measures taken and increased concern regarding any potential risk associated with the use of bovine material.

Any bovine-derived material used in the manufacture of a vaccine is regulated according to a Committee for Proprietary Medicinal Products (CPMP) Note for Guidance (NfG) which was adopted in 1991 and came into force in 1992. This NfG has been continuously updated in the light of scientific knowledge[1]. The criteria by which safety is assured involves controlling the geographical source of the animals used, the nature of the tissue used and the method of production. Safe geographical sourcing of animals is based on the latest Organisation Internationale des Epizooties and the European Commission's DG Sanco Scientific Steering Committee classification of countries according to their BSE status[2]. The nature of the tissue used is based on scientific data showing in which parts of the animal BSE infectivity is located whilst other scientific data demonstrates which manufacturing processes can/might inactivate BSE infectivity.

In addition to the above measures, the CPMP and regulatory authorities within member states of the European Union undertake benefit/risk assessments before any medicinal product or vaccine is authorised. These bodies continuously review all medicinal products in the light of scientific progress and will take any additional precautionary measures as appropriate to assure the quality, safety and efficacy of medicinal products. In this context, the CPMP and its experts recently conducted a survey on the use of bovine material in the manufacture of vaccines licensed within the EU to ensure that the sourcing of animals and of tissues used was according to the NfG. There is no evidence to implicate vaccines in the development of vCJD.

Based on the above measures being taken, the CPMP considers that the risk of BSE contamination of vaccines used within the EU to be extremely low, to the point of being theoretical. Nevertheless, in order to combat even a theoretical risk, manufacturers have initiated programmes to replace bovine material of European origin by material of non-European origin.

The CPMP considers, quite strongly, that the benefits of vaccination outweigh any hypothetical risk of BSE contamination. Consequently, on the basis of current scientific evidence and of measures being taken to avoid any possible contamination of vaccines with BSE, the CPMP is of the view that no further action is necessary to protect public health. Vaccines currently in use have an excellent safety record and any undermining of public confidence in vaccination will result in low take-up of vaccines and the risk of spreading damaging or fatal diseases as a result is real.

[1] CPMP/CVMP Note for Guidance for minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (February 2001, EMEA/401/01-Final).

[2] Both the OIE and the Scientific Steering Committee of DG Sanco of the European Commission have developed and continuously update criteria for classification of a country or zone according to their BSE status. The most recent information can be found on the websites of these organisations: http://www.oie.int and http://europa.eu.int/comm/food/fs/sc/index_en.html. These classifications take into account criteria such as the number and the origin of the BSE cases, the compulsory notification, the ban on feeding of ruminant protein to ruminants, the educational program in place.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eudra.org http://www.eudra.org/emea.html

In the same vein, the US Food and Drug Administration and its Center for Biologics Evaluation and Research, have reached the same conclusion that the risk of transmission of BSE through the use of bovine material during vaccine manufacture is very remote and theoretical (http://www.fda.gov/cber/index.html). They similarly recommend that all children and adults continue to be immunised according to current immunization schedules and that public confidence in vaccines should be maintained.