European Medicines Agency
Press office

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PRESS RELEASE
Review of field safety data by the European Medicines Agency finds a good safety record for inactivated bluetongue emergency vaccines

A European Medicines Agency (EMEA) review of field safety data provided mainly by Member States from the 2008 emergency vaccination campaign against bluetongue disease has shown a good safety record for the vaccines used across the EU Member States during that period. Overall, the frequency of adverse drug reactions was very low (< 1:10 000) and the results support the continued use of inactivated bluetongue vaccines in the 2009 vaccination programme.

Bluetongue is a non-contagious, insect-transmitted, viral disease of domestic and wild ruminants, such as sheep, cattle, goats or deer. Bluetongue is not harmful to man but causes considerable damage to livestock populations. The disease is characterised by inflammation of the mucous membranes, congestion, swelling and haemorrhages. Sheep are generally the worst affected species. Bluetongue can cause severe disease outbreaks and is listed by OIE (Office International des Epizooties) as a disease for which specific control measures are required.

Mass vaccination against Bluetongue is considered as the most effective tool for the control of the disease as it protects susceptible animals from showing signs of disease and limits the spread of infection.

The EMEA's Committee for Medicinal Products for Veterinary Use (CVMP) reviewed data provided by Member States regarding the safety of Bluetongue vaccines used during 2008 as part of Community approved emergency vaccination campaigns to immunise sheep and cattle. The purpose of the review was to provide background information from the extensive use of this class of products. This information was considered helpful to CVMP when assessing the benefit risk balance of potential applications for authorisation under exceptional circumstances of inactivated Bluetongue vaccines. Further outbreaks are anticipated in the European Union during 2009, in particular once the midges that are responsible for spreading the disease become active as the weather starts to get milder. The monitoring of suspected adverse reactions against the vaccines used will continue.

To facilitate the development of inactivated Bluetongue vaccines the EMEA has prepared guidance on the minimum requirements for data to be included in applications for these vaccines for emergency use. The Agency is prepared to grant fee waivers to applicants for these vaccines and the first such product received a positive opinion during the February 2009 meeting of the CVMP (http://www.emea.europa.eu/pdfs/general/direct/pr/10356109en.pdf).

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Notes:

1. The CVMP report 'An overview of field safety data from the EU for Bluetongue virus vaccines serotype 8 emerging from the 2008 national vaccination campaigns' is available: http://www.emea.europa.eu/pdfs/vet/press/pos/65201908en.pdf
2. A press release announcing the EMEA's decision to grant fee waivers is available: http://www.emea.europa.eu/pdfs/vet/press/pr/11197908en.pdf

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3. The 'Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue' is available: http://www.emea.europa.eu/pdfs/vet/iwp/22019308enfin.pdf
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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