European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends authorisation of first bluetongue vaccine through centralised procedure

The European Medicines Agency (EMEA) has for the first time recommended granting a marketing authorisation under exceptional circumstances for an inactivated bluetongue vaccine through the centralised procedure. Given the recent epidemiological situation in Europe and the high risk of recurrence of outbreaks of bluetongue disease due to serotype 8 in the coming months, the EMEA's recommendation is an important step towards the availability of safe and efficacious vaccines for use in vaccination campaigns across the European Union, and, consequently, towards the protection of animal health in Europe.

The vaccine BTVPUR AlSap 8, suspension for injection, from Merial S.A.S., is intended for the active immunisation of sheep and cattle to prevent viraemia (the presence of virus in the blood stream) and to reduce clinical signs caused by the bluetongue virus serotype 8.

Bluetongue is a non-contagious, insect-transmitted viral disease of domestic and wild ruminants, such as sheep, cattle, goats or deer. The disease is not harmful to man but causes considerable damage to livestock populations. Bluetongue 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.

Following a review of all available data, the Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of BTVPUR AlSap 8 are greater than its risks, and recommended granting of a marketing authorisation under exceptional circumstances.

This was based on the CVMP's considerations that:

- there is an urgent and objective need to have authorised vaccines available for use in the coming months, because of the epidemiological risk to European sheep and cattle populations;
- the application has met the requirements set out in the CVMP 'Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue';
- the applicant agreed to the necessary post-authorisation commitments and specific obligations to assure the safe use of the product in the field.

The CVMP's recommendation will now be sent to the European Commission for the adoption of a formal marketing authorisation decision.

During its February 2009 meeting, the CVMP also concluded a review of 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. More information about this review will be published shortly.

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Notes:

1. A summary of opinion for BTVPUR AlSap 8 is available here: http://www.emea.europa.eu/pdfs/vet/opinion/68557108en.pdf

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2. A press release announcing the EMEA's decision to grant fee waivers is available here: http://www.emea.europa.eu/pdfs/vet/press/pr/11197908en.pdf
3. The 'Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue is available here: http://www.emea.europa.eu/pdfs/vet/iwp/22019308enfin.pdf
4. Marketing authorisations under exceptional circumstances are used to authorise medicines for which the applicant can demonstrate that there is an urgent need but that comprehensive data cannot be provided immediately, as long as it can be demonstrated that the benefits outweigh the risks.
5. 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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