European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends authorisation of two additional Bluetongue vaccines through the centralised procedure

The European Medicines Agency has recommended the granting of marketing authorisations under exceptional circumstances for two inactivated Bluetongue vaccines for sheep and cattle respectively through the centralised procedure. These recommendations will add two additional vaccines to the therapeutic arsenal of bluetongue vaccines. This will ensure the widespread availability of safe and efficacious vaccines for use in vaccination campaigns across the European Union, and, consequently, contribute to the protection of animal health in Europe.

The vaccines Zulvac 8 Ovis and Zolvac 8 Bovis, from Fort-Dodge Animal Health Ltd, are intended for the active immunisation of sheep and cattle respectively, to prevent viraemia (the presence of virus in the blood stream) 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 (World Organisation for Animal Health) as a disease for which specific control measures are required.

The Agency's recommendation, established through its Committee for Medicinal Products for Veterinary use, CVMP, will now be sent to the European Commission for the adoption of a formal marketing authorisation decision.

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Notes:

1. A summary of opinion for Zulvac 8 Ovis and Zulvac 8 Bovis are available:
   Zulvac 8 Ovis: http://www.emea.europa.eu/pdfs/vet/opinion/66579508en.pdf
   Zulvac 8 Bovis: http://www.emea.europa.eu/pdfs/vet/opinion/66581508en.pdf
2. The first bluetongue vaccine, BTVPUR Alsap 8 produced by Merial S.A.S., was authorised throughout Europe on 17 March 2009. The Agency's press release can be found here: http://www.emea.europa.eu/pdfs/general/direct/pr/10356109en.pdf
3. A press release announcing the Agency's decision to grant fee waivers for bluetongue vaccines is available here: http://www.emea.europa.eu/pdfs/vet/press/pr/11197908en.pdf
4. 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
5. 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.
6. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

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