European Medicines Agency
Veterinary Medicines and Inspections

London, 13 February 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION [2]
BTVPUR ALSAP 8

BLUETONGUE VIRUS SEROTYPE 8 ANTIGEN

On 11 February 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[3] recommending to grant a marketing authorisation under exceptional circumstances for the veterinary medicinal product BTVPUR Alsap 8, Suspension for injection, intended for the active immunisation of sheep and cattle to prevent viraemia and to reduce clinical signs caused by the bluetongue virus serotype 8. The Applicant for this veterinary medicinal product is Merial S.A.S.

The active substance of BTVPUR Alsap 8 is the inactivated bluetongue virus Serotype 8.
The benefit of BTVPUR Alsap 8 is the stimulation of active immunity in sheep and cattle against the bluetongue virus, serotype 8.

The CVMP considered that due to the current epidemiological situation of bluetongue and the consequent threat to animal health there are objective and verifiable reasons for recommending the granting of a Marketing Authorisation under exceptional circumstances for this product, namely that

- the remaining epidemiological risk for European sheep and cattle populations constitutes an urgent and objective need to have authorised products available for use in the coming months.
- the application has met the requirements of the CVMP Reflection Paper on Minimum Data Requirements for an Authorisation Under Exceptional Circumstances for Vaccines for Emergency Use Against Bluetongue (EMEA/CVMP/ /IWP/105008/2007).
- the Applicant has agreed to the necessary post-authorisation commitments and specific obligations, to assure the safe use of the product in the field.
- the Applicant cannot reasonably be expected to provide the results from certain trials on the target species for duly substantiated reasons.

1 Correction to include reference to specific obligations required for the applicant

2 Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

3 Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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The most common side effects are a potential small local swelling at the injection site for a short period and a transient increase in body temperature, normally not exceeding an average of 1.1°C, may occur within 24 hours after vaccination.

The approved indication is: ‘‘Active immunisation of sheep and cattle to prevent viraemia* and to reduce clinical signs caused by the bluetongue virus serotype 8.
*(below the level of detection by the validated RT-PCR method at 3.14log10 RNA copies/ml, indicating no infectious virus transmission)’’

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for BTVPUR Alsap 8 and therefore recommends the granting of the marketing authorisation under exceptional circumstances.[4]

[4] Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.