15 October 2010
EMA/CVMP/343726/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

BTVPUR AlSap 1-8

Inactivated vaccine against bluetongue virus serotypes 1 and 8

On 13 October 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation under exceptional circumstances for the veterinary medicinal product BTVPUR AlSap 1-8, a suspension for injection, intended for the active immunisation of sheep and cattle to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotypes 1 and 8 respectively. The applicant for this veterinary medicinal product is Merial.

The active substance of BTVPUR AlSap 1-8 is the inactivated blutongue virus, serotype 1 and incativated bluetongue virus serotype 8.

The benefits of BTVPUR AlSap 1-8 are the stimulation of active immunity in sheep and cattle resulting in the prevention of viraemia and the reduction of clinical signs caused by bluetongue virus serotypes 1 and 8.

The CVMP considered that due to the current epidemiological situation of bluetongue regarding serotypes 1 and 8 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 Bluetongue disease is spread by insect vectors and therefore presents particular challenges in terms of control due to an inability to prevent transmission from infected animals other than through insect control combined with reducing or preventing viraemia (virus in the blood) in susceptible animals by means of vaccination
- that Bluetongue disease is epizootic in nature and has the potential to result in high morbidity and mortality in susceptible populations, particularly of sheep
- that there is a remaining epidemiological risk from Bluetongue serotype 1 (BTV1) and serotype 8 (BTV8) for European sheep and cattle populations, in view of recent and previous outbreaks

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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of BTV1 and BTV8 in Europe that constitute an objective need to have authorised products available for use in the coming months.

- that consequently any delay should be avoided where possible in making available safe and effective vaccines that have been demonstrated to be in compliance with the CVMP guideline on Minimum Data Requirements for an Authorisation Under Exceptional Circumstances for Vaccines for Emergency Use Against Bluetongue (EMEA/CVMP/IWP/220193/2008).
- that the application has met the requirements of the CVMP guideline on Minimum Data Requirements for an Authorisation Under Exceptional Circumstances for Vaccines for Emergency Use Against Bluetongue (EMEA/CVMP/IWP/220193/2008).
- that 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 due to the difficulties in conducting large scale trials for a disease that is under community control and the need for any experimental studies to be conducted within high containment facilities

The most common side effects are a small local swelling at the injection site (at most 32 cm² in cattle and 24 cm^2 in sheep) which becomes residual 35 days later (≤ 1 cm^2) and a transient increase in body temperature, normally not exceeding an average of 1.1°C, which 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 bluetongue virus serotype 1 and 8.*

**(below the level of detection by the validated RT-PCR method at 3.68 log_{10} RNA copies/ml, indicating no infectious virus transmission)*

Onset of immunity has been demonstrated 3 weeks after the primary vaccination course.

The duration of immunity is not yet established in cattle or sheep."

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 1-8 and therefore recommends the granting of the marketing authorisation under exceptional circumstances.[3]

[3] 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.