EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

ZULVAC 1+8 Ovis

Inactivated bluetongue virus, serotypes 1+8

On 12 January 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation under exceptional circumstances[3] for the veterinary medicinal product ZULVAC 1+8 Ovis, a suspension for injection, intended for active immunisation of sheep from 1.5 months of age for the prevention of viraemia caused by bluetongue virus, serotypes 1 and 8. The applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of ZULVAC 1+8 Ovis is the inactivated bluetongue virus serotype 1 and incativated bluetongue virus serotype 8.

The benefits of ZULVAC 1+8 Ovis are the stimulation of active immunity of sheep from 1.5 months of age for the prevention of viraemia 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 populations, in view of recent and previous outbreaks of BTV1

[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.
[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.

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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 transient increase in rectal temperature, not exceeding 1.2° C, may occur during the 24 hours following vaccination and the fact that vaccination may be followed in most animals by a local reaction at the injection site. These reactions take the form in most cases of a general swelling of the injection site (persisting for not more than 7 days) or of palpable nodules (subcutaneous granuloma, possibly persisting for more than 48 days.

The approved indication is:

"Active immunisation of sheep from 1.5 months of age for the prevention* of viraemia caused by bluetongue virus, serotypes 1 and 8

*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 21 days after completion of the primary vaccination scheme

Duration of immunity: 12 months".

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 ZULVAC 1+8 Ovis and therefore recommends the granting of the marketing authorisation under exceptional circumstances.