10 June 2011
EMA/CVMP/291025/2011
Committee for Medicinal Products for Veterinary Use

**Summary of opinion**[1]

# ZULVAC 1 Ovis

## Inactivated Bluetongue Virus, serotype 1, strain BTV-1

On 8 of June, 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 ZULVAC 1 Ovis. The applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of ZULVAC 1 Ovis is Inactivated Bluetongue Virus, serotype 1, strain BTV-1, an immunological medicinal product, ATC code QI04AA02 indicates to develop an active immunization of cattle and to prevent viraemia.

The benefits of ZULVAC 1 Ovis includes an active immunisation of sheep from 1.5 months of age and has been shown to prevent viraemia established in animals infected by BTV-1. Prevention of viraemia directly benefits the animal in that this ensures reduction of clinical signs or loss of condition.

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 for the active immunisation of sheep from 1.5 months of age for the prevention of viraemia caused by Bluetongue Virus, serotype 1.

Onset of immunity: 21 days after completion of the primary vaccination course.

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

[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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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 Ovis 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.