13 January 2011
Committee for Medicinal Products for Veterinary Use

**Summary of opinion**[1]

# Zulvac 1+8 Bovis

## Vaccine to prevent viraemia caused by Bluetongue Virus, serotypes 1 and 8

On 12 January 2012, 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+8 Bovis. The applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of Zulvac 1+8 Bovis is the inactivated bluetongue virus, serotypes 1 and 8, an immunological veterinary medicinal product, ATC code, QI02AA08 indicated to develop an active immunisation in cattle and to prevent viraemia. The benefits of Zulvac 1+8 Bovis are its prophylactic immunisation to protect cattle against infection with blue tongue virus serotypes 1 and 8. The vaccine has been proven to prevent viraemia. Prevention of viraemia directly benefits the animal in that this ensures reduction of clinical signs or loss of condition.

The most common side effects is a transient increase in rectal temperature, not exceeding 1.3 °C, may occur during the 48 hours following vaccination.

At the injection site, mild to moderate granulomatous myositis may occur in 30% of animals.

The approved indication is for the active immunisation of cattle from 3 months of age for the prevention of viraemia caused by bluetongue virus, serotypes 1 and 8.

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 be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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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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 Bovis 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.