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Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

Bovilis BTV8

Inactivated bluetongue virus, serotype 8, clone 1

On 16 June 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation under exceptional circumstances for the veterinary medicinal product Bovilis BTV8, suspension for injection, intended for the active immunisation of sheep and cattle for the prevention of viraemia in sheep from 1 month of age and the reduction of viraemia in cattle from 6 weeks of age, caused by Bluetongue Virus, serotype 8.
The applicant for this veterinary medicinal product is Intervet International BV.

The active substance of Bovilis BTV8 is the inactivated Bluetongue Virus (BTV) Serotype 8.

The benefit of Bovilis BTV8 is the stimulation of active immunity in sheep and cattle against bluetongue virus serotype 8, resulting in prevention of viraemia in sheep and reduction of viraemia in cattle. This vaccine has been shown to reduce but not prevent viraemia in cattle. The extent of this reduction has been shown by epidemiological modelling studies to be likely to reduce virus transmission to an extent that can limit the spread of an outbreak in a vaccinated population.

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 Guideline on the Requirements for an Authorisation Under Exceptional Circumstances for Vaccines for Emergency Use Against Bluetongue (EMEA/CVMP/IWP/220193/2008).

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

The most common side effects are a slight rise in temperature (usually not more than 0.5°C, in individual cases up to about 2°C) for up to three days after vaccination, and temporary swellings at the injection site. In sheep these swellings typically last for up to three weeks. In cattle small palpable swellings may still be present up to six weeks after vaccination in approximately one third of the vaccinated animals.

The approved indication is:

"*Sheep*
To stimulate active immunity in sheep against bluetongue virus serotype 8 from 1 month of age to prevent viraemia.*

**(cycling value (Ct) >30 by a validated rRT-PCR method, indicating absence of infectious virus)*

Cattle

*To stimulate active immunity in calves against bluetongue virus serotype 8 from 6 weeks of age to reduce viraemia. **

** (for details see section 4.4)*".

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 Bovilis BTV8 and therefore recommends the granting of the marketing authorisation under exceptional circumstances.[***]

*** 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.