8 September 2017
EMA/CVMP/506378/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Bovilis Blue-8

Common name: Bluetongue virus vaccine (inactivated) serotype 8

On 7 September 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Bovilis Blue-8, a suspension for injection, intended for the active immunisation of cattle and sheep from 2.5 months of age to prevent viraemia in both species and to reduce clinical signs in sheep caused by bluetongue virus serotype 8. The applicant for this veterinary medicinal product is INTERVET INTERNATIONAL B.V.

Bovilis Blue-8 is an inactivated bluetongue virus vaccine for bovine and ovine species. It contains an inactivated bluetongue virus serotype 8 (ATCvet code Sheep: QI04AA02; Cattle QI02AA08) as active substance. This vaccine stimulates active immunity against bluetongue virus, serotype 8.

The benefits of Bovilis Blue-8 are the active immunisation of sheep from 2.5 months of age to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotype 8 and the active immunisation of cattle from 2.5 months of age to prevent viraemia caused by bluetongue virus serotype 8. The onset of immunity for sheep is 20 days after the second dose and for cattle 31 days after the second dose. The duration of immunity is 1 year for both sheep and cattle. The most common side effects are an average increase in body temperature varying between 0.5 and 1.0 ºC in sheep and cattle. It lasts not longer than 24 to 48 hours. Transient fever was observed in rare cases. Temporary local reactions occur in very rare cases at the injection site in the form of a normally painless nodule of 0.5 to 1 cm in sheep and of 0.5 to 3 cm in cattle, which disappears within 14 days at the latest. Loss of appetite can occur in very rare cases. Bovilis Blue-8 is generally well tolerated at the recommended dose.

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

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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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favourable benefit-risk balance for Bovilis Blue-8 and therefore recommends the granting of the marketing authorisation under exceptional circumstances.