9 November 2018
EMA/CVMP/735427/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Syvazul BTV

Common name: Bluetongue virus vaccine (inactivated) (multistrain: 1-2 strains out of a set of 3)

On 8 November 2018, 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 Syvazul BTV, suspension for injection, intended for:

- the active immunisation of sheep to prevent viraemia and reduce clinical signs caused by bluetongue virus serotypes 1 and/or 8 and/or to reduce viraemia and clinical signs caused by bluetongue virus serotype 4;
- and the active immunisation of cattle to prevent viraemia caused by bluetongue virus serotypes 1 and/or 8 and/or to reduce viraemia caused by bluetongue virus serotype 4.

The applicant for this veterinary medicinal product is LABORATORIOS SYVA S.A.U. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Syvazul BTV is an immunological veterinary medicinal product containing a maximum of two of the following three inactivated bluetongue virus strains as active substance/s: bluetongue virus serotype 1, bluetongue virus serotype 4, bluetongue virus serotype 8 (ATCvet code QI04AA).

The benefits of Syvazul BTV are the stimulation of active immunity in sheep from 3 months of age resulting in the prevention of viraemia and reduction of clinical signs and lesions caused by bluetongue virus serotypes 1 and/or 8, and/or reduction of viraemia and clinical signs and lesions caused by bluetongue virus serotype 4 with an onset of immunity of 39 days and duration of immunity of 12 months; and the stimulation of active immunity in cattle from 2 or 3 months of age resulting in the prevention of viraemia caused by bluetongue virus serotypes 1 and/or 8, and/or reduction of viraemia caused by bluetongue virus serotype 4 with an onset of immunity of 21 days and duration of immunity of 12 months.

[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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The most common side effects are transient local reactions at the injection site (erythema, oedema and nodules of up to 3.8 cm diameter in sheep and 7 cm diameter in cattle); and a transient increase in rectal temperature (not exceeding 2.3 °C) which may occur during the 48 hours following vaccination.

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-risk balance for Syvazul BTV and therefore recommends the granting of the marketing authorisation.