19 June 2020
EMA/CVMP/307513/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Bluevac BTV

Common name: Bluetongue vaccine (inactivated)

On 18 June 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Bluevac BTV8. The marketing authorisation holder for this veterinary medicinal product is CZ Veterinaria S.A.

Bluevac BTV8 is currently authorised as suspension for injection. The variation concerns the conversion of the Bluevac BTV8 dossier into a multi-strain dossier (Bluevac BTV), and the addition of the strains BTV1 and BTV4 into the multi-strain dossier. Additionally, the MAH takes the opportunity to amend its address together with the address of the manufacturer of the biological active substance and the address of the manufacturer responsible for batch release.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union