



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 February 2026
EMADOC-1700519818-2907706
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion¹ (post-authorisation)

Bluevac BTV

International non-proprietary name (INN): Bluetongue virus vaccine (inactivated)

On 12 February 2026, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Bluevac BTV. The marketing authorisation holder for this veterinary medicinal product is CZ Vaccines S.A.U.

Bluevac BTV is currently authorised for active immunisation of sheep to prevent viraemia caused by bluetongue virus serotype 1 and/or 4 and/or 8 and to reduce clinical signs caused by bluetongue virus serotype 8 (combination of maximum 2 serotypes), and for active immunisation of cattle to prevent viraemia caused by bluetongue virus serotype 1 and/or 4 and/or 8 (combination of maximum 2 serotypes).

The aim of these grouped variations is to allow up to the combination of a maximum of three different inactivated bluetongue virus serotypes (instead of a maximum of two serotypes), to be included in a final vaccine for sheep, and to align the product information with the latest version of the QRD available (version 9.1).

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 Union Product Database (UPD) 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.

