



13 March 2026
EMA/CVMP/4011/2026
Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

VeroBlue-3

Common name: Bluetongue virus vaccine (inactivated)

On 12 March 2026, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product VeroBlue-3, lyophilisate and solvent for suspension for injection, intended for sheep. The applicant for this veterinary medicinal product is VEROVACCINES GmbH. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

VeroBlue-3 is a vaccine containing Bluetongue virus, serotype 3, VP2 protein as the active substance. The vaccine is intended for the active immunisation of sheep to reduce viraemia and pyrexia caused by the serotype 3 of the bluetongue virus.

The onset of immunity is 14 days after primary basic vaccination. The duration of immunity has not been established.

The most common side effects are related to the injection site: swelling (which resolves within 14 days), nodule (which may persist for more than 35 days), erythema and pain (both for up to 3 days). All of these are observed very commonly.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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 VeroBlue-3 and therefore recommends the granting of the marketing authorisation under exceptional circumstances³.

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.

³ 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.

