

19 February 2016  
EMA/CVMP/66986/2016  
Committee for Medicinal Products for Veterinary Use

### Summary of opinion<sup>1</sup> (post-authorisation)

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## BTVPUR AISap 1-8

Common name: inactivated adjuvanted vaccine against bluetongue disease virus serotypes 1 and 8

On 18 February 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product BTVPUR AISap 1-8. The marketing authorisation holder for this veterinary medicinal product is MERIAL.

The change agreed by the CVMP concerns:

- establishing a multi strain dossier and adding a new serotype BTV4

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.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision.

<sup>2</sup> 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.