



10 June 2011  
EMA/CVMP/396064/2011  
Committee for Medicinal Products for Veterinary Use

## Summary of opinion<sup>1</sup>

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### Proteq West Nile

#### West Nile recombinant canarypox virus (vCP2017 virus)

On 9 June 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,<sup>2</sup> recommending the granting of a marketing authorisation for the veterinary medicinal product Proteq West Nile. The applicant for this veterinary medicinal product is MERIAL.

The active substance of Proteq West Nile is West Nile recombinant canarypox virus (vCP2017 virus).

The benefits of Proteq West Nile are the active immunisation of horses from 5 months of age against West Nile disease by reducing the number of viraemic horses. If clinical signs are present, their duration and severity are reduced.

Onset of immunity: 4 weeks after the first dose of the primary vaccination course. In order to achieve full protection, the full vaccination course of two doses must be given.

Duration of immunity: 1 year after a full primary vaccination course of two injections.

The most common side effect is a transient swelling (max. diameter 5 cm) which resolves within 4 days may appear at the injection site.

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 to risk balance for Proteq West Nile and therefore recommends the granting of the marketing authorisation.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.

<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.

