European Medicines Agency
Veterinary Medicines and Inspections

London, 19 September 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
DUVAXYN WNV

International Non-proprietary Name (INN):
Vaccine to aid in prevention of West Nile virus

On 17 September 2008 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Duvaxyn WNV - emulsion for injection for horses. Duvaxyn WNV contains inactivated West Nile virus strain VM-2 and is indicated for active immunisation of horses of 6 months of age or older against West Nile Virus disease by reducing the number of viraemic horses.

The Applicant for this veterinary medicinal product is Fort Dodge Animal Health.

The benefits of Duvaxyn WNV are its usefulness to reduce and prevent clinical signs in horses. The most common side effects are transient local reactions in the form of a mild, local swelling at the injection site post vaccination (maximum 1 cm in diameter) that resolve spontaneously within 1 to 2 days. In some cases hyperthermia may occur for up to 2 days.
The approved indication is:
"For the active immunisation of horses of 6 months of age or older against West Nile Virus disease by reducing the number of viraemic horses."

Onset of immunity: 3 weeks after primary vaccination course.
Duration of immunity: 12 months after primary vaccination course.

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 Duvaxyn WNV and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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