European Medicines Agency
Veterinary Medicines and Inspections

London, 13 February 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*

CLOSTRIDIUM PERFRINGENS TYPE A TOXOID

On 11 February 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Netvax, emulsion for injection, intended for the active immunization of chickens to provide passive immunisation against necrotic enteritis to their progeny, during the laying period. The Applicant for this veterinary medicinal product is Intervet International B.V.

The active substance of Netvax is *Clostridium perfringens*, Type A toxoid.

The benefits of Netvax are the active immunization of chickens in order to provide passive immunisation against necrotic enteritis to their progeny, during the laying period and the reduction of mortality and the incidence and severity of lesions caused by *Clostridium perfringens* Type A induced necrotic enteritis.

The most common side effect is a moderate swelling of the breast tissue which will resolve within 30 days. Following the second vaccination swelling may persist for at least 35 days.

The approved indication is: "For the active immunization of chickens to provide passive immunisation against necrotic enteritis to their progeny, during the laying period.

To reduce mortality and the incidence and severity of lesions caused by *Clostridium perfringens* Type A induced necrotic enteritis. Efficacy was demonstrated by challenge of chicks approximately three weeks after hatching.

The onset of passive transfer of immunity: 6 weeks following completion of the vaccination procedure

The duration of passive transfer of immunity: 51 weeks following completion of the vaccination procedure".

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.

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* 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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Netvax and therefore recommends the granting of the marketing authorisation.