I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by S-P Veterinary[1] on 18 October 2006, , the CVMP accepted on 8 November 2006 that Netvax was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

During its meeting of 7-9 November 2006, the Committee for Medicinal Products for Veterinary Use appointed Dr Martin Ilott from United Kingdom as Rapporteur and Dr J. Gabriel Beechinor from Ireland as Co-Rapporteur for the assessment of the application for Netvax. The Rapporteur changed during the procedure and Dr. Brady replaced Dr. Ilott.

The company S-P Veterinary submitted an application to the EMEA on 26 June 2007 for the granting of a Community marketing authorisation for Netvax in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 10 July 2007.

2. Steps taken for the assessment of the product

- The time clock for the evaluation started on 11 July 2007.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 7 November 2007 was sent to the Applicant and the clock stopped.
- The Applicant submitted written responses on 18 July 2008.
- An oral explanation was given to the CVMP by the company on 13 January 2009
- The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 11 February 2009 a positive Opinion for the granting of a Community marketing authorisation for Netvax.

The European Commission granted a marketing authorisation valid throughout the European Union for Netvax on16 April 2009.

[1] Before the adoption of the final opinion there was a transfer of the Applicant MAH to Intervet International B.V.

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)
Schering-Plough Animal Health
33 Whakatiki Street
Upper Hutt
New Zealand

Name and address of the manufacturer responsible for batch release
S-P Veterinary Ltd
Breakspear Road South
Harefield
Uxbridge
UB9 6LS
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

According to Article 71 of Directive 2001/82/EC as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of a national programme for the diagnosis, control and eradication of animal disease, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals
b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

D. STATEMENT OF THE MRLs

Pharmacologically active substance(s)	Animal species	Other provisions
Thiomersal	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
EDTA	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
Formaldehyde	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
Mineral oil	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90
Benzyl alcohol	All food producing species	Annex II of Council Regulation (EEC) No. 2377/90

Triethanolamine (at doses up to 0.25 mg/kg bw) is considered not within the scope of Council Regulation (EEC) No. 2377/90.