I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Intervet International BV on 23 May 2006, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted on 20-22 June 2006 that Porcilis PCV was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure as provided for under Regulation (EC) No. 726/2004.

During its meeting of 20-22 June 2006, the Committee for Medicinal Products for Veterinary Use appointed Dr Maria Tollis from Italy as Rapporteur and Prof. Tibor Soós from Hungary as Co-Rapporteur for the assessment of the application for Porcilis PCV.

The company Intervet International BV submitted an application to the EMEA on 31 July 2007 for the granting of a Community marketing authorisation for Porcilis PCV in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 14 August 2007.

2. Steps taken for the assessment of the product

The consolidated list of questions as agreed by the CVMP during its meeting of 11-13 December 2007 was sent to the Applicant and the clock stopped.

The list of outstanding issues as agreed by the CVMP by means of a written procedure on 13 August 2008 was sent to the Applicant and the clock stopped.

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 12 November 2008 a positive Opinion for the granting of a Community marketing authorisation for Porcilis PCV.

The European Commission granted a marketing authorisation valid throughout the European Union for Porcilis PCV on 12 January 2009.

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

Name and address of the manufacturer of the biological active substance

Nobilon International B.V.
Exportstraat 39B
5831 AK Boxmeer
Netherlands

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Name and address of the manufacturer responsible for batch release

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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 SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

The constituents of Porcilis PCV listed below are included in Annex II of Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substances	Animal species	Other provisions
Light liquid paraffin	All food producing species	
Dl-alpha-tocopherol acetate	All food producing species	
Polysorbate 80 (Polyoxyethylene sorbitan monooleate)	All food producing species	
Simethicone (dimethicone)	All food producing species	