Steps Taken For The Assessment Of The Product

The Committee for Veterinary Medicinal Products appointed A. Pii from Denmark as Rapporteur and M. Moos from Germany as Co-Rapporteur for the assessment of the application during its meeting of 15-17 July 1997. At the meeting of the Committee of 13-14 January 1998, A. Pii was replaced by H. Hartmann Fries as Rapporteur.

The company Intervet International submitted an application to the EMEA on 21 December 1998 for the granting of a Community marketing authorisation for Porcilis AR-T DF in accordance with Council Regulation (EEC) No 2309/93. The application is in accordance with Part A of the Annex of Council Regulation (EEC) No 2309/93 since this vaccine has been constructed via biotechnological techniques.

The application was validated on 12 January 1999.

The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 23 March 1999 and 7 April 1999 respectively.

The consolidated list of questions as agreed by the CVMP during its meeting held on 12 May 1999 was sent to the Applicant and the clock was stopped.

The Applicant circulated the responses to the CVMP list of questions for Porcilis AR-T DF on 23 March 2000. The clock was restarted.

The joint Rapporteur and Co-Rapporteur assessment report on the responses to the consolidated list of questions was circulated to all CVMP Members on 19 April 2000.

The joint Rapporteur and Co-Rapporteur assessment report was discussed during the meeting of the Committee held on 17 May 2000. The CVMP decided that there was a need for an oral explanation.

The Applicant provided oral explanations on the outstanding issues during the meeting of the Committee held on 21 June 2000.

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 19 July 2000 a positive opinion for the granting of a Community marketing authorisation for Porcilis AR-T DF.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturing Authorisation issued on 5 August 1997 by Ministerie van Landbouw, Natuurbeheer en Visserij, The Hague, The Netherlands.

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

According to Article 4 of Council Directive 90/677/EEC[1] Member States prohibit or/ may prohibit the import, sale, supply and/or use of Porcilis AR-T DF on the whole or part of their territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of national programmes for the diagnosis, control and elimination of animal diseases, 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 product is intended to confer immunity is largely absent from the territory.

D. STATEMENT OF THE MRLs

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	**Animal Species**	**Other provisions**
Sodium chloride [2]	All food-producing species	
Formaldehyde[3]		
dl-α-tocopherol acetate[4]		
Simethicone (Dimethicone) [5]		
Disodium phosphate dihydrate [6]		
Potassium dihydrogen phosphate [7]		
Polysorbate 80[8]		

[1] Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC an the approximation of laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary products (OJ N°L 373 of 31.12.1990)
[2] OJ No. L 290 of 5.12.95
[3] OJ No. L 290 of 5.12.95
[4] OJ No L122 of 12.05.99
[5] OJ No. L 290 of 5.12.95
[6] OJ No L 272 of 25.10.96
[7] OJ No L 272 of 25.10.96
[8] O.J. L 290, of 05.12.95