I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

On 9 November 1995, the company Intervet International B.V. submitted to the EMEA a letter of intent for an application for a Community Marketing Authorisation for Quadrisol.

During its meeting of December 1995, the Committee for Veterinary Medicinal Products appointed Dr. C. O'Sullivan as Rapporteur and Prof. J. Luthman as Co-Rapporteur for the assessment of the application of Intervet International.

2. Steps taken for the assessment of the product

On 26 April 1996 the company Intervet International submitted an application to the EMEA for the granting of a Community marketing authorisation for Quadrisol in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 3 May 1996.

The centralised procedure started on 7 May 1996.

The Rapporteur and Co-Rapporteur's joint assessment report was circulated to all CVMP Members on 25 July 1996.

The consolidated list of questions as agreed by the CVMP during its meeting held on 16-17 September 1996, was sent to the Applicant at which the time clock was stopped.

The Applicant circulated the responses to the CVMP list of questions on 21 April 1997 thus restarting the time clock.

The joint Rapporteur and Co-rapporteur assessment report on the responses to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 18 May 1997.

The joint Rapporteur and Co-rapporteur assessment report, the summary of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 10 –12 June 1997. The Committee considered that the answers provided did not address satisfactorily the points raised in the list of questions. However, the applicant has committed to provide follow-up data and consequently the CVMP agreed that the applicant need not be invited to provide oral explanations.

The CVMP in the light of the current scientific standards issued on 16 July 1997 a positive opinion for the granting of a Community marketing authorisation for Quadrisol.

II. GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER

Manufacturer responsible for batch release:

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

Manufacturing Authorisation issued on 30 May 1995 by Ministerie van Landbouw, Natuurbeheer en Visserij, the Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

n/a

D. STATEMENT OF THE MRLs WHICH ARE ACCEPTED IN ACCORDANCE WITH COUNCIL REGULATION (EEC) No 2377/90

Annex I of Council Regulation (EEC) No 2377/90[1]

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Vedaprofen	Vedaprofen	Equidae	1000 µg/kg 100 µg/kg 50 µg/kg 20 µg/kg	Kidney Liver Muscle Fat	

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

Pharmacologically active substance	Animal Species	Other provisions
Methylhydroxyethylcellulose [2]	All food-producing species	
Potassium hydroxide[3]		
Propylene glycol[4]		

[1] OJ No. L 110 of 25.04.97
[2] OJ No. L 272 of 25.10.96
[3] OJ No. L 272 of 25.10.96
[4] OJ No. L 045 of 15.02.97