I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hoechst Roussel Vet S.A. submitted an application to the EMEA on 03 December 1996 for the granting of a Community marketing authorisation for **HALOCUR** in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 10 December 1996.

During its meeting of October 1996, the Committee for Veterinary Medicinal Products appointed Dr D. Mourot from France as rapporteur and Mme F. Falize from Belgium as co-rapporteur for the assessment of the application. Dr D. Mourot was replaced subsequently by Dr G. Moulin from France.

2. Steps taken for the assessment of the product

- The CVMP accepted on September 1995 that Halocur was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as it was a veterinary medicinal product intended for food-producing animals and its active ingredient, halofuginone, had not been authorised for use in a veterinary medicinal product intended for use in food-producing animals on the date of entry into force of Council Regulation (EEC) No 2309/93 (i.e. on 1 January 1995), as provided for under the last indent of Part B of the Annex to that Regulation.

- The company Hoechst Roussel Vet S.A. submitted an application to the EMEA on 03 December 1996 for the granting of a Community marketing authorisation for **HALOCUR** in accordance with Council Regulation (EEC) No 2309/93.

- The application was validated on 10 December 1996.

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on 18 February 1997.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 9 April 1997 was sent to the Applicant and the clock stopped.

- In relation to an MRL application for Halofuginone in accordance with Council Regulation (EEC) No 2377/90, the applicant was sent a list of questions adopted by the CVMP on 10 April 1997.

- The applicant sent the responses to the list of questions concerning the MRL application to the Agency on 20 April 1998.

- The CVMP came to a decision on the MRL application on 8 July 1998, however the applicant appealed against it.

- The CVMP adopted on 11 November 1998 an Annex III recommendation for halofuginone.

- The Applicant circulated the responses to the CVMP list of questions for Halocur by 19 March 1999 at which point 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 1999.

- The joint Rapporteur and Co-rapporteur assessment report were discussed during the meeting of the Committee held on 12 May 1999. The CVMP agreed that there was no need for an oral explanation.

- 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 16 June a positive opinion for the granting of a Community marketing authorisation for Halocur.

- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 29 October 1999.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

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

Name and address of the manufacturer responsible for batch release

Intervet Production S. A
Rue de Lyons
27460 Igoville
France

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

D. STATEMENT OF THE MRLs

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

Pharmacologically active substance	Marker residue	Animal species	MRLs (*)	Target tissues
Halofuginone	Halofuginone	Bovine	30 µg/kg	Liver
			30 µg/kg	Kidney
			10 µg/kg	Muscle
			25 µg/kg	Fat

[1] OJ No. L 336 of 30.12.00