I STEPS TAKEN FOR THE ASSESSMENT

- The company Novartis submitted an application to the EMEA on 6 June 1997 for the granting of a Community marketing authorisation for Econor in accordance with Council Regulation (EEC) No 2309/93. The application was validated on 17 June 1997.

- The centralised procedure started on 18 June 1997.

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to CVMP Members on 24 August 1997 and 8 September 1997.

- The consolidated list of questions, as agreed by the CVMP during its meeting held on 14 -16 October 1997, was sent to the Applicant on 20 October 1997 and the clock stopped.

- The Applicant circulated the responses to the CVMP list of questions on 10 June 1998 at which point the time clock was restarted.

- 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 the CVMP Members on 9 July 1998.

- The joint Rapporteur and Co-Rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 8 – 10 September 1998. The Committee considered that some of the answers provided did not address satisfactorily the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral explanations. The clock was stopped at day 209 on 8 September 1998.

- The Applicant provided oral explanations on several aspects of the dossier requiring clarification during the meeting of the Committee held on 13 - 15 October 1998 and the clock was restarted on 14 October 1998 at day 210.

- 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 14 October 1998 a positive opinion for the granting of a Community marketing authorisation for Econor.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. MANUFACTURERS RESPONSIBLE FOR IMPORT AND BATCH RELEASE IN THE EEA

Name and address of the manufacturer(s) responsible for batch release

Econor 0.5%, 1%, 10%
Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
BP 224
68332 Huningue cedex
France

Econor 50%
Biochemie GmbH
Schaftenau Plant
A-6330 Schaftenau
Austria

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

Veterinary medicinal product subject to prescription.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

- **OTHER CONDITIONS**

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

The holder of this marketing authorisation should provide the following information:

PSURs should be provided at 3-monthly intervals,

The results of further investigations as to the cause(s) of the adverse reactions should be reported at regular intervals, preferably in conjunction with the 3-monthly PSURs. These studies should include detailed information on the changes in the metabolic capacities of pigs of different ages and breeds.

The holder of this marketing authorisation should encourage all users to report suspected treatment-related reactions.

4. STATEMENT OF THE MRLs

Active substance:

Annex I of Council Regulation (EEC) No. 2377/90

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Valnemulin[1]	Valnemulin	Porcine	100 µg/kg 500 µg/kg 50 µg/kg	Kidney Liver Muscle	

Excipients:

Hypromellose (Hydroxy propyl methyl cellulose, E 464):
Annex II of Council Regulation (EEC) No 2377/90 for all food-producing species [2]

Purified Talc (Talc, E 553b):
Annex II of Council Regulation (EEC) No 2377/90 for all food-producing species [3]

Colloidal Anhydrous Silica (Silicon dioxide, E 551):
Annex II of Council Regulation (EEC) No 2377/90 for all food-producing species [4]

[1] OJ No L 320 of 28.11.98
[2] OJ No. L 272 of 25.10.96
[3] OJ No. L 272 of 25.10.96
[4] OJ No. L 272 of 25.10.96