**STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT**

The CVMP accepted on16-18 March 1999 that Eurican Herpes 205 was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to that Regulation.

The company submitted an application to the EMEA on 29 June 1999 for the granting of a Community Marketing Authorisation for Eurican Herpes 205 in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 13 July 1999.

The Rapporteur's and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 15 September 1999 and 6 October 1999 respectively.

The consolidated list of questions, as agreed by the CVMP during its meeting held on 9 –11 November 1999, was sent to the Applicant on 11 November 1999 at which time the clock was stopped.

The Applicant circulated the responses to the CVMP list of questions for Eurican Herpes 205 by 21 April 2000 at which point the clock was restarted.

The joint Rapporteur and Co-rapporteur's 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 22 May 2000.

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 20-22 June 2000.

The Committee considered that some of the answers provided did not satisfactorily address 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 on 20 June 2000.

The Applicant provided oral explanations on 11 October 2000 on a number of outstanding issues during the meeting of the Committee held on 10-12 October 2000 and the clock was restarted on 12 October 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 8 November 2000, a positive opinion for the granting of a Community marketing authorisation for Eurican Herpes 205.

## GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

### 1. Manufacturing authorisations and inspection status

Name and address of the manufacturer of the biological active substance(s)

MERIAL
Laboratoratoire Lyon Gerland,
254 rue Marcel Mérieux,
69007 Lyon,
France

Name and address of the manufacturer responsible for batch release

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 SAINT PRIEST
France

### 2. Proposed conditions or restrictions of supply and use

Veterinary medicinal product subject to prescription.