I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Merial on 01 January 2003, the CVMP accepted on 11-13 February 2003 that Previcox 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 Council Regulation (EEC) 2309/93.

The Committee for Veterinary Medicinal Products appointed Dr J. G. Beechinor from Ireland as Rapporteur and Dr M. L. Meisel from Portugal as Co-Rapporteur for the assessment of the application for Previcox during its meeting of 11 – 13 February 2003.

The company Merial submitted an application to the EMEA on 2 June 2003 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.

The application was validated on 17 June 2003.

2. Steps taken for the assessment of the product

- The Rapporteur and Co-rapporteur's assessment reports were circulated to all CVMP Members on respectively 26 August 2003 and 10 September 2003.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 15 October 2003 was sent to the applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 18 March 2004 and the clock was restarted on 19 March 2004.
- 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 27 April 2004.
- A written explanation to an outstanding quality issue was provided by the applicant on 12 May 2004.
- 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 2004, a positive opinion for the granting of a Community Marketing Authorisation for Previcox.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

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

Name and address of the manufacturer responsible for batch release

Merial S.A.S.
4 Chemin de Calquet
31300 Toulouse
France

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

Veterinary medicinal product subject to prescription.

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

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

