I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The Committee for Medicinal Products for Veterinary Use appointed Dr J.G Beechinor from Ireland and Dr. M. Holzhauser-Alberti from France as Co-Rapporteur for the assessment of the application for Flexicam during their meeting of 9 – 11 November 2004.

Omnipharm Ltd submitted on 1 December 2004 an application for a Marketing Authorisation to the European Medicines Agency for Flexicam 1.5 mg/ml oral suspension for dogs.

The application concerns a generic medicinal product as defined in Article 13(2)(b) of Directive 2001/82/EC, as amended by Directive 2004/28/EC, and refers to a reference veterinary medicinal product, Metacam, with a Marketing Authorisation granted in the Community.

The application was validated on 14 December 2004.

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 22 February and 9 March 2005 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held on 13 April 2005 was sent to the applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 20 October 2005 and the clock was restarted on 21 October 2005.
- 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 November 2005.
- 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 18 January 2006, a positive opinion for the granting of a Community Marketing Authorisation for Flexicam.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Fisher Clinical Services
Langerhurst Road
Horsham
West Sussex
RH12 4QD
United Kingdom

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable