I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by **Omnipharm Ltd**. on 8 November 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 18 January 2006 that **Acticam** was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Article 3(2)a of Regulation (EC) No. 726/2004.

The CVMP appointed Dr J. Gabriel Beechinor from Ireland as Rapporteur and Dr Michael Holzhauser-Alberti from France as Co-Rapporteur for the assessment of the application for Acticam during its meeting of 17-18 January 2006.

The company Omnipharm Ltd. submitted an application to the EMEA on 6 September 2007 for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on 20 September 2007.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 15-17 January 2008 was sent to the Applicant and the clock stopped.
- 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 15 October 2008 a positive Opinion for the granting of a Community marketing authorisation for Acticam.

The European Commission granted a marketing authorisation valid throughout the European Union for Acticam on 9 December 2008.

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

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

Fisher Clinical Services UK Ltd
Langhurstwood Road
Horsham
West Sussex
RH12 4QD
UK

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

To be supplied only on veterinary prescription.

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

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.