I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by **Chanelle Pharmaceuticals Manufacturing Ltd.** on 24 February 2006, the Committee for Veterinary Medicinal Products (CVMP) accepted on 15 March 2006 that **Rheumocam** was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Regulation (EC) No. 726/2004.

The CVMP appointed **Dr Michael Holzhauser-Alberti** from **France** as Rapporteur and **Dr Anja Holm** from **Denmark** as Co-Rapporteur for the assessment of the application for **Rheumocam** during its meeting of 14-16 March 2006.

The company **Chanelle Pharmaceuticals Manufacturing Ltd.** submitted an application to the EMEA on **1 August 2006** for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on **21 August 2006**.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 12-14 December 2006 was sent to the Applicant and the clock stopped.
- The consolidated list of outstanding issues as agreed by the CVMP during its meeting held on 11-13 September 2007 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 7 November 2007 a positive Opinion for the granting of a Community marketing authorisation for Rheumocam.

The European Commission granted a marketing authorisation valid throughout the European Union for Rheumocam on 10.01.08.

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea,
Co. Galway,
IRELAND.

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.