I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by **Janssen Pharmaceutica N.V.** on 14 March 2006, the Committee for Veterinary Medicinal Products (CVMP) accepted on 20 April 2006 that **Meloxivet** 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 J. G. Beechinor** from **Ireland** as Rapporteur and **Prof. S. Srčič** from **Slovenia** as Co-Rapporteur for the assessment of the application for **Meloxivet** during its meeting of 18-20 April 2006.

The company **Janssen Pharmaceutica N.V.** submitted an application to the EMEA on **5 December 2006** for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

The application was validated on **19 December 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 17-19 April 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 12 September 2007 a positive Opinion for the granting of a Community marketing authorisation for Meloxivet.

The European Commission granted a marketing authorisation valid throughout the European Union for Meloxivet on 14 November 2007.

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

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

Lusomedicamenta S.A.
Estrada Consiglieri Pedroso, 69 B Queluz de Baixo
2730-055 Barcarena
Portugal

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.

