I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by **Virbac S.A.** on 29 April 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 17-19 May 2005 that **Cortavance** was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) No 2309/93.

During its meeting of 17-19 May 2005, the Committee for Medicinal Products for Veterinary Use appointed Prof. Christian Friis from Denmark as Rapporteur and Prof. Margarita Arboix from Spain as Co-rapporteur for the assessment of the application for Cortavance. Following the resignation of Prof. Arboix from the CVMP in early 2006 Dr. Cristina Muñoz was appointed as Co-Rapporteur for the application.

The company Virbac S.A. submitted an application to the EMEA on 27 October 2005 for the granting of a Community marketing authorisation for Cortavance in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 15 November 2005.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 14-16 March 2006 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 8 November 2006 a positive Opinion for the granting of a Community marketing authorisation for Cortavance.

The European Commission granted a marketing authorisation valid throughout the European Union for Cortavance on 09/01/2007.

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

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

VIRBAC SA
1ère Avenue - 2065 m – L.I.D
06516 Carros, France

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 SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

