

## **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 25 June 2007, the CVMP accepted on 11 July 2007 that Easotic, ear drops suspension for dogs, was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure under Article 31 of Regulation (EC) No. 726/2004.

The Committee for Medicinal Products for Veterinary Use appointed Prof. Christian Friis from Denmark as Rapporteur and Ms Cristina Muñoz Madero from Spain as Co-Rapporteur for the assessment of the application for Easotic during its meeting of July 2007.

The company Virbac S.A. submitted an application to the EMEA on 20 December 2007 for the granting of a Community marketing authorisation in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

The application was validated on 15 January 2008.

### **2. Steps taken for the assessment of the product**

- The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 25 March 2008 and 9 April 2008 respectively.
- The consolidated list of questions as agreed by the CVMP during its meeting held in May 2008 was sent to the Applicant and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 20 June 2008 and the clock was restarted.
- 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 28 July 2008.
- 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 17 September 2008, a positive Opinion for the granting of a Community Marketing Authorisation for Easotic.

## **II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION**

### **A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer responsible for batch release

VIRBAC S.A.  
1<sup>ère</sup> 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 THE SAFE AND EFFECTIVE USE OF THE PRODUCT**

Not applicable.

### **D. STATEMENT OF THE MRLs**

Not applicable.