

## **I. BACKGROUND INFORMATION ON THE PROCEDURE**

### **1. Submission of the dossier**

Further to the submission of a letter of intent by CEVA on 5 September 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 4-5 October 2005 that MELOXIDYL was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system.

The CVMP appointed Dr Henrik Holst from Sweden as Rapporteur and Prof. Dr Reinhard Kroker from Germany as Co-Rapporteur for the assessment of the application for MELOXIDYL during its October 2005 meeting.

The company CEVA submitted an application to the EMEA on 7 February 2006 for the granting of a Community marketing authorisation in accordance with Regulation (EC) N. 726/2004.

The application was validated on 21 February 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 19 –22 June 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 MELOXIDYL.

The European Commission granted a marketing authorisation valid throughout the European Union for MELOXIDYL on 15 January 2007.

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

Name and address of the manufacturer responsible for batch release

CEVA SANTE ANIMALE  
Z.I. Très le Bois  
22600 Loudeac  
France

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

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

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

Not applicable

**D. STATEMENT OF THE MRLs**

Not applicable