

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Norbrook Laboratories Limited on 16 April 2007, the CVMP accepted at its meeting of 14-16 May 2007 that Loxicom was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure as provided for under Regulation (EC) No. 726/2004.

The Committee for Medicinal Products for Veterinary Use appointed Dr J. Gabriel Beechinor from Ireland as Rapporteur and Professor Stane Srčič from Slovenia as Co-Rapporteur for the assessment of the application for Loxicom during its meeting of 14-16 May 2007.

The company Norbrook Laboratories Limited 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 consolidated list of questions as agreed by the CVMP during its meeting held on 13-15 May 2008 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 14-16 October 2008 was sent to the Applicant.
- 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 November 2008 a positive Opinion for the granting of a Community marketing authorisation for Loxicom.

The European Commission granted a marketing authorisation valid throughout the European Union for Loxicom on 10 February 2009.

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

Name and address of the manufacturer responsible for batch release:

Norbrook Laboratories Limited
105 Armagh Road
Newry
Co. Down, BT35 6PU
United Kingdom

**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.