I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Eli Lilly and Company Ltd. on 15 November 2006, the Committee for Veterinary Medicinal Products (CVMP) accepted in December 2006 that Reconcile was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Article 3(2)a of Regulation (EC) No. 726/2004.

The CVMP appointed Dr Michael Holzhauser-Alberti from France as Rapporteur and Professor Christian Friis from Denmark as Co-Rapporteur for the assessment of the application for Reconcile during its meeting in December 2006.

The company Eli Lilly and Company Ltd. submitted an application to the EMEA on 27 April 2007 for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004 because it is a new active substance.

The application was validated on 15 May 2007.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 11-13 September 2007 was sent to the Applicant and the clock stopped.
- The Applicant submitted their responses to the CVMPP list of questions on 17 January 2008 and the clock was restarted.
- 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 16 April 2007 a positive Opinion for the granting of a Community marketing authorisation for Reconcile.

The European Commission granted a marketing authorisation valid throughout the European Union for Reconcile on 8 July 2008.

©EMEA 2008

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

Name and address of the manufacturer responsible for batch release

Eli Lilly and Company Ltd
Speke Operations
Fleming Road
Liverpool
L24 9LN
UK

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

©EMEA 2008