European Medicines Agency
Veterinary Medicines and Inspections

London, 18 April 2008
Doc. Ref.: EMEA/CVMP/168454/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
RECONCILE

International Non-proprietary Name (INN):
fluoxetine

On 16 April 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Reconcile 8 mg, 16 mg, 32 mg & 64 mg tablets for dogs, intended as an aid in the treatment of separation-related disorders in dogs. The Applicant for this veterinary medicinal product is Eli Lilly and Company Ltd, United Kingdom.

The active substance in Reconcile tablets is fluoxetine hydrochloride, a selective serotonin reuptake inhibitor (SSRI) (ATC vet code: QN06AB03). As a result of inhibiting serotonin reuptake, fluoxetine enhances serotonergic neurotransmission and produces functional effects resulting from increased activation of serotonin receptors.

The approved indication is: "As an aid in the treatment of separation-related disorders in dogs manifested by destruction and inappropriate behaviours (vocalisation and inappropriate defecation and/or urination) and only in combination with behavioural modification techniques."

The benefits of Reconcile are its efficacy in the treatment of separation-related disorders in dogs without causing pronounced sedation. When used in combination with behavioural modification techniques a clinical improvement is usually seen within 1 to 2 weeks and has been demonstrated for up to 8 weeks treatment with fluoxetine. The treatment is given orally once a day and the tablets may be given with or without food. The most common side effects are decreased appetite (including anorexia) and lethargy.

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Reconcile and therefore recommends the granting of the marketing authorisation.

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* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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