European Medicines Agency
Veterinary Medicines and Inspections

London, 20 June 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION*
PROFENDER

International Non-proprietary Names (INN): emodepside & praziquantel

On 18 June 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant an extension to the terms of the marketing authorisation for the veterinary medicinal product Profender. The Marketing Authorisation Holder for this veterinary medicinal product is Bayer HealthCare AG, Germany. Profender is currently authorised as spot-on solutions for cats.

The new extension concerns a new target species (dogs), a new pharmaceutical form (modified release tablets) and a new route of administration (oral use).

There are three different strengths of these modified release tablets: 15 mg (praziquantel) / 3 mg (emodepside) tablets for small dogs; 50 mg / 10 mg tablets for medium dogs; and 150 mg / 30 mg tablets for large dogs. The tablets have a break-line to enable the minimum dose of 1 mg/kg body weight emodepside and 5 mg/kg body weight praziquantel to be more accurately administered.

The benefits of Profender are that a single treatment is effective against the various life stages of the tapeworms and roundworms specified. No side effects were reported in dogs during the clinical trials. However, the product literature includes a number of precautionary warnings.

The agreed indication is: "For dogs suffering from, or at risk from, mixed parasitic infections caused by roundworms and tapeworms of the following species:

Roundworms (Nematodes):
Toxocara canis (mature adult, immature adult, L4 and L3)
Toxascaris leonina (mature adult, immature adult and L4)
Ancylostoma caninum (mature adult and immature adult)
Uncinaria stenocephala (mature adult and immature adult)
Trichuris vulpis (mature adult, immature adult)
Tapeworms (Cestodes):
Dipylidium caninum
Taenia spp.
Echinococcus multilocularis (mature adult and immature)
Echinococcus granulosus (mature adult and immature)"

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the extension to 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 Profender and therefore recommends the granting of the extension to the marketing authorisation.

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* Summaries of opinion are published without prejudice to the Commission Decision.

** 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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