European Medicines Agency
Veterinary Medicines and Inspections

London, 11 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION*
CONVENIA

International Non-proprietary Name (INN):
cefovecin

On 9 December 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a variation to the terms of the marketing authorisation for the veterinary medicinal product Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats. The Marketing Authorisation Holder for this veterinary medicinal product is Pfizer Limited.

The change agreed by the CVMP is for an additional indication in dogs 'As adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues associated with *Porphyromonas* spp. and *Prevotella* spp.'. The dose is a single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight). The product literature emphasises that the product should be used only for infections which require prolonged treatment (as the antimicrobial activity of Convenia following a single injection lasts for up to 14 days) and that 'The fundamental requirement of the treatment of periodontal disease is mechanical and/or surgical intervention by the veterinarian.'

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 variation 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 this additional indication for Convenia and therefore recommends the granting of this variation to the marketing authorisation.

* 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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