

NOTICE

CEFOVECIN

[in the product: Convenia Antibiotic Injection]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Pfizer Animal Health, a division of Pfizer Australia Pty Ltd, for the approval of a new active constituent, Cefovecin. The APVMA also has before it an application from the same applicant, for the registration of a new product, CONVENIA ANTIBIOTIC INJECTION ('the product') containing the above active constituent. The product is for the treatment of folliculitis, wound infections, abscesses and urinary tract infections in dogs and cats caused by organisms susceptible to Cefovecin.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the APVMA should grant the application for approval of the active constituent and registration of the product. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. The APVMA must receive comments within 28 days of the date of this notice.

Particulars of the Application

Proposed product name:	CONVENIA ANTIBIOTIC INJECTION
Applicant company:	Pfizer Animal Health, a division of Pfizer Australia Pty Ltd
Name of active constituent:	Cefovecin
Signal heading:	Schedule 4 Prescription Animal Remedy
Statement of claims:	For the treatment of folliculitis, wound infections, abscesses and urinary tract infections in dogs and cats caused by organisms susceptible to Cefovecin.
Pack sizes:	10mL glass vial
Withholding period:	Not applicable

Summary of the APVMA's evaluation of CONVENIA ANTIBIOTIC INJECTION in accordance with Section 14(3)(e) and (f) of the *Agricultural and*

Veterinary Chemicals Code ('the Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of Cefovecin in the product is not likely to be harmful to human beings if used according to the product label directions.

The Office of Chemical Safety (OCS) in the Department of Health and Ageing assessed the toxicological aspects of Cefovecin sodium and found it to have low acute oral and dermal toxicity in rats and dogs. The OCS advised that Cefovecin sodium is a slight eye irritant, but not a skin irritant in rabbits and that it is likely to be a skin sensitiser. The toxicological studies indicate that Cefovecin sodium is not genotoxic or mutagenic. The OCS did not consider that studies relating to long-term toxicity, carcinogenicity, reproductive and developmental toxicity were necessary because of the intended use pattern of the product in companion animals by registered veterinary surgeons or other persons under veterinary supervision.

The National Drugs and Poisons Scheduling Committee assessed the product and has included it in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons.

The product will be manufactured overseas and imported already labelled. OCS concluded that occupational health and safety risk assessment was not required. The OCS advised that the product can be used safely because it is an antibiotic injection for administration to companion animals under veterinary prescription.

The Expert Advisory Group on Antimicrobial Resistance in the National Health and Medical Research Council (NHMRC), assessed the antibiotic resistance aspect of the product application. The product has been developed specifically for use in veterinary medicine. The NHMRC has advised that it supports the statement of claims and the restraint statements which will be printed on product labels:

DO NOT USE in food producing animals.

FOR USE ONLY in dogs and cats where indicated by antibiotic sensitivity testing according to principles of prudent use.

The APVMA accepts the findings and recommendations from the NHMRC on this criterion.

- (ii) The APVMA is satisfied that the proposed use of the product will not be an undue hazard to the safety of people using anything containing their residues. The OCS determined that because the product is for use in dogs and cats only, Cefovecin is unlikely to enter the food chain, and therefore the determination of an Acceptable Daily Intake (ADI) was unnecessary.
- (iii) The APVMA is satisfied that the proposed use of the product would not be an undue hazard to the safety of people exposed to it during handling and use.

OCS assessed the application and concluded that occupational exposure during manufacturing and formulation is unlikely because the product is self-contained. Veterinary surgeons will administer Convenia and dermal exposure is only possible through accidental self-injection during administration. The product will be formulated in the USA and repackaging will not be required in Australia.

- (iv) The APVMA is satisfied that the proposed use of the product in dogs and cats is not likely to have an unintended effect that is harmful to animals, plants or the environment.

Data from trials supporting the host animal safety of the product adequately demonstrate that the product is safe in dogs and cats for the proposed uses and when used according to the label directions.

The Department of the Environment Water and Heritage and the Arts (DEWHA) has assessed data in support of Cefovecin in the product. In considering the proposed use pattern and the relatively low amount proposed for use, DEWHA has concluded that this will not result in a significant environmental hazard.

The APVMA accepts the findings and recommendations from DEWHA on this criterion.

- (v) The APVMA is satisfied that the proposed use of Cefovecin in the product would not adversely affect trade between Australia and places outside Australia because the product is for use in dogs and cats only.
- (vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that the data from trials supporting the efficacy of the product adequately demonstrate that this product is effective for the proposed uses.

Written submissions on the APVMA's proposal to grant the applications for approval of the new active constituent Cefovecin and registration of the product should be addressed to:

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