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World Association for the Advancement of Veterinary Parasitology (W.A.A.V.P.) guidelines for evaluating the efficacy of acaricides against ticks (Ixodidae) on ruminants

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Abstract

These guidelines have been prepared to assist in the planning, conduct and interpretation of studies for the assessment of the efficacy of acaricides (excluding vaccines and other bio-control agents) against single and multi-host ticks (Ixodidae) on ruminants. Information is provided on the selection of animals, dose determination, dose confirmation and field studies, record keeping and result interpretation. The use of pen facilities is advocated for dose determination and confirmation studies for defining therapeutic and persistent efficacy. A minimum of two studies per tick species for which claims are sought is recommended for each dose determination and dose confirmation investigation. If dose confirmation studies demonstrate greater than 95% efficacy the sponsor may proceed to field studies, where a minimum of two studies per geographical location is preferred to confirm the therapeutic and persistent efficacy under field conditions. If dose confirmation studies demonstrate less than 95% efficacy then longer-term field studies can be conducted over two tick seasons with a minimum of two studies per geographical location. These studies can incorporate other control methods such as tick vaccines, to demonstrate stable long-term tick management. Specific advice is also given on conducting studies with paralysis ticks. These guidelines are also intended to assist investigators on how to conduct specific experiments, to provide specific information for registration

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authorities involved in the decision-making process, to assist in the approval and registration of new acaricides, and to facilitate the worldwide adoption of standard procedures.

Keywords: Acaricides; Ruminants; Ticks; Therapeutic efficacy; Persistent efficacy; Strategic management program; Guidelines

1. Introduction

These guidelines for evaluating the efficacy of acaricides against ticks (Ixodidae) follow similar publications from the World Association for the Advancement of Veterinary Parasitology (W.A.A.V.P.) guidelines for anthelmintic efficacy data generation in a variety of species (Jacobs et al., 1994; Wood et al., 1995; Duncan et al., 2002; Yazwinski et al., 2003; Hennessy, pers. comm.) together with the guidelines pertaining to anticoccidial efficacy data generation in chickens and turkeys (Holdsworth et al., 2004). The acceptance of these guidelines by regulatory authorities worldwide will provide a basis for the harmonization of the studies performed in various countries. These guidelines are part of a new ectoparasiticide guideline series also dealing with efficacy data generation for mites, biting and nuisance flies, lice, sheep keds and myiasis flies.

The aim of these W.A.A.V.P. guidelines is to establish consensus on international standards on the efficacy of new acaricides. These guidelines attempt to recognise and reflect principles recommended by the scientific community as appropriate and necessary for the collection of scientific data. Many sources have been used in the collation of the information used in these guidelines. Consideration was given to the regulatory requirements for the generation of efficacy data as given by the European Union (EMEA/CVMP/625/03, http://www.emea.eu.int/pdfs/vet/ewp/062503en.pdf), the United States Environmental Protection Agency (EPA712-C-98-409, http://www.epa.gov/opptsfrs/OPPTS_Harmonized/810_Product_Performance_Test_Guidelines/Series/810-1000.pdf); the Australian Pesticides and Veterinary Medicines Authority (formerly the NRA) (Guideline Number 20, http://www.apvma.gov.au/guidelines/vetguidelines.shtml) and the South African Bureau of Standards (SOP 5441/E100B and 5441/E160C and D).

There have been considerable developments in relation to the application of new acaricides as well as the targets of such ectoparasiticides. These developments are likely to impact on the effects on the parasitic stages of the tick. To cater for such developments and in recognition that it is not possible to consider all potentialities, strict adherence to these guidelines is not mandated for all potential new acaricides.

Testing of efficacy should be carried out according to the principles of ''Good Clinical Practice'' (VICH GL9, 2000, http://vich.eudra.org/pdf/2000/Gl09_st7.pdf). Statistical guidance will not be given in these guidelines; it should be sought for each protocol.

Since acaricide studies cannot be undertaken without the use of host animals care must be taken to ensure the welfare of all animals used in the studies. Parasite levels on the animals must not become so high that they cause undue stress. Studies should not extend for unnecessarily long periods of time. Where the test product is clearly not working and satisfactory tick management is not achieved, the study should be terminated.

Results from all studies conducted with the test product should be documented. Extenuating circumstances, which could explain anomalous results should be detailed. Adverse effects causing discomfort to particular host species or use limitations in relation to age, breed, sex, fat composition or lactation status of hosts should be noted.

All therapeutic and persistent efficacy field studies should be conducted at times consistent with the usual peak tick seasons for the region. Dose determination and dose confirmation studies which utilize artificial infestations of ticks may be conducted out of peak tick seasons so that study data would be available to initiate field studies at the following peak tick season. This approach can be a useful time saver.

These guidelines have been established to provide recommendations for evaluation of acaricides against single-host ticks and multi-host ticks with additional guidance supplied specifically for paralysis ticks. Protocols listed in Appendices A–C can be used to develop study plans for efficacy studies.