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World Association for the Advancement of Veterinary Parasitology (W.A.A.V.P.) guidelines for evaluating the efficacy of ectoparasiticides against biting lice, sucking lice and sheep keds on ruminants

P.A. Holdsworth^{a,*}, J. Vercruyssen^b, S. Rehbein^c,
R.J. Peter^d, T. Letonja^e, P. Green^f

^a *Avcare Limited, Locked Bag 916, Canberra, 2601 ACT, Australia*

^b *Department of Virology, Parasitology & Immunology, Faculty of Veterinary Medicine, Ghent University, Salisburyaan 133, B-9820 Merelbeke, Belgium*

^c *Merial GmbH, Kathrinenhof Research Center, Walchenseestrasse 8-12, D-83101, Rohrdorf, Germany*

^d *Argos Veterinary Science (Pty) Ltd, P.O. Box 1726, Mount Edgecombe, 4300, South Africa*

^e *Center for Veterinary Medicine, 7500 Standish Place, MPN2, Rockville, MD 20855, USA*

^f *9 Murra Street, Jindalee, 4074 Qld, Australia*

Abstract

These guidelines have been prepared to assist in the design, implementation and interpretation of studies for the assessment of the efficacy of ectoparasiticides against biting and sucking lice and sheep keds on ruminants. Information is provided on the selection of animals, dose determination, dose confirmation and field studies, record keeping and result interpretation. These guidelines advocate the use of pen facilities for dose determination and dose confirmation studies for defining therapeutic and persistent efficacy. These guidelines are also intended to assist investigators on how to conduct specific experiments, to provide specific information for registration authorities involved in the decision making process, to assist in the approval and registration of new ectoparasiticides, and to facilitate the world-wide adoption of standard procedures.

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1. Introduction

These guidelines for evaluating the efficacy of ectoparasiticides against lice follow similar publications from the World Association for the Advancement of Veterinary Parasitology (W.A.A.V.P.)

* Corresponding author.

E-mail address: peter.holdsworth@avcare.org.au
(P.A. Holdsworth).

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 world-wide will provide a basis for the harmonization of the studies performed in various countries. These present guidelines are part of a new series of ectoparasiticide guidelines also dealing with efficacy data generation for ticks, biting and nuisance flies, mites and myiasis flies.

The objective of the guidelines is to detail specific advice for the conduct of studies and supply of relevant documentation for the efficacy of new ectoparasitocides. These guidelines attempt to recognize 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 (EMA/CVMP/625/03; <http://www.emea.eu.int/pdfs/vet/ewp/062503en.pdf>); the United States Environmental Protection Agency (EPA-712-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 (Guideline Number 23, <http://www.apvma.gov.au/guidelines/vetguidelines.shtml>) and the South African Bureau of Standards (SOP 5441-141A).

Guidelines aim to address most eventualities however with the passage of time, progress in technology may render sections redundant. If in a particular circumstance an alternative approach to those listed here is deemed more fitting, a reasoned argument for the deviation should be prepared and discussed with appropriate regulatory authorities before initiating the work. The guidance outlined in these guidelines can be fulfilled by a range of protocols and study designs under the principles of “Good Clinical Practice” (VICH GL9, 2000-http://vich.eudra.org/pdf/2000/G109_st7.pdf). Detailed statistical guidance will not be given in these guidelines; it should be sought for each protocol.

Since efficacy 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. Where the test product is clearly not working and satisfactory lice/ ked 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 species or use limitations in relation to age, breed, sex or lactation status should be noted.

All therapeutic and persistent field efficacy studies should be conducted at times consistent with the usual peak parasite seasons for the region.

2. Lice of ruminants

Lice (Phthiraptera) of the suborders Anoplura (sucking lice) and Ischnocera (biting or chewing lice) are commonly occurring ectoparasites of ruminants with their major economic effects being a function of lice density. Biting lice of issue are *Bovicola bovis* (cattle), *B. ovis* (sheep) and *B. caprae*, *B. limbatus* and *B. crassipes* (goats). Sucking lice of issue on cattle are *Haematopinus eurysternus*, *H. quadripertusus*, *H. tuberculatus*, *Linognathus vituli* and *Solenoptes capillatus*; on sheep are *L. pedalis*, *L. africanus* and *L. ovis*; *L. stenopsis* is found on goats.

The two groups of lice have different feeding strategies: all Anoplura are haematophagous ectoparasites, whereas the mallophagan species of domestic ruminants ingest hair, skin and skin products. Lice are hemimetabolous insects, i.e. their life cycle includes an incomplete metamorphosis. The entire life cycle of the lice takes place on the host and comprises the egg, three nymphal stages and the adult louse, the imago. Under optimal conditions the complete life cycle may be as short as 2 weeks, however, on average it may take about 3–5 weeks.

Melophagus ovinus (Diptera, Cyclorrhapha, Hippoboscoidea), the sheep ked is a wingless, blood-sucking ectoparasite that spends its entire life on

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