Antiparasitic Resistance and Combinations

1. Introduction

Welcome to the FDA Center for Veterinary Medicine Survey on Antiparasitic Resistance and New Animal Drug Combinations. We appreciate your participation. You have been provided access to this survey because it is important that your knowledge and experience are considered by the FDA when making decisions about the approval of antiparasitic drugs.

The purpose of this survey is to gather information from experts involved with research, development, and use of antiparasitic drugs (primarily industry, academicians, and veterinarians) on emerging issues involving antiparasitic drug use, antiparasitic resistance, and new animal drug combinations. The survey is one part of a strategy to set future direction for FDA regulation of veterinary antiparasitic drugs. FDA will share the results of the survey with the public as part of its educational efforts and in order to seek further input from a wider audience.

Please take a few minutes to answer the following questions by selecting the appropriate answer choice or entering the requested information, where applicable. You can advance through the pages of the questionnaire by clicking the "Next" button at the bottom of each page.

Your answers will be anonymous and confidential. Information will be kept confidential in accordance with 18 USC 1905 and 21 USC 331(j), as well as section 301(j) of the Federal Food Drug and Cosmetic Act.

If you have any questions about the survey, please contact Janis Messenheimer, DVM at (240) 276-8348 or janis.messenheimer@fda.hhs.gov.

We anticipate that the survey should take about 20 minutes to complete.

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2. Survey Entry Question

1. Please click 'Yes' below if you consent to taking the survey and are ready to begin. Click "No" to exit the survey.

- ◯ Yes
- ◯ No

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3. Survey Questions Part I- Background of respondents

1. Which of the following options describes your credentials? Select one or more of the options below.

- [ ] DVM
- [ ] PhD or MS in Veterinary Parasitology
- [ ] Other (please specify)

2. Which of the following options describes your current employment type? Select one or more of the options below. For private practice, please select the answer that describes your predominant practice type.

- [ ] Academia/ Research
- [ ] Private practice- Small Animal
- [ ] Private practice- Food Animal
- [ ] Private practice- Equine
- [ ] Private practice- Mixed Animal
- [ ] Government/ Regulatory
- [ ] Industry
- [ ] Other (please specify)

3. In which region of the world is your professional experience based? Select one or more of the options below.

- [ ] United States
- [ ] Canada
- [ ] Europe
- [ ] South America
- [ ] Australia
- [ ] New Zealand
- [ ] Other (please specify)

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4. Which of the following options most accurately describes the climate for the region in which your professional experience is based? Please select one or more of the options below.

- [ ] Moist Tropical: Amazon Basin; Congo Basin of equatorial Africa; East Indies, from Sumatra to New Guinea
- [ ] Wet-Dry Tropical: India, Indochina, West Africa, southern Africa, South America and the north coast of Australia
- [ ] Dry Tropical: southwestern United States and northern Mexico; Argentina; north Africa; south Africa; central part of Australia.
- [ ] Dry Midlatitude: Western North America (Great Basin, Columbia Plateau, Great Plains); Eurasian interior, from steppes of eastern Europe to the Gobi Desert and North China.
- [ ] Mediterranean: central and southern California; coastal zones bordering the Mediterranean Sea; coastal Western Australia and South Australia; Chilean coast; Cape Town region of South Africa.
- [ ] Moist Continental: eastern parts of the United States and southern Canada; northern China; Korea; Japan; central and eastern Europe.
- [ ] Boreal Forest: central and western Alaska; Canada, from the Yukon Territory to Labrador; Eurasia, from northern Europe across all of Siberia to the Pacific Ocean.
- [ ] Tundra: arctic zone of North America; Hudson Bay region; Greenland coast; northern Siberia bordering the Arctic Ocean.
- [ ] Highland: Rocky Mountain Range in North America, the Andean mountain range in South America, the Alps in Europe, Mt. Kilimanjaro in Africa, the Himalayans in Tibet, Mt. Fuji in Japan.

5. Which of the following options describes your area(s) of expertise in parasitology? Select one or more of the options below.

- [ ] Equine
- [ ] Beef Cattle
- [ ] Dairy Cattle
- [ ] Swine
- [ ] Poultry
- [ ] Small Ruminant
- [ ] Small Animal (cats/dogs)
- [ ] Other (please specify)

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4. Survey Questions Part II- General Questions on Antiparasitic Resistance

1. In your professional experience, how do you determine which antiparasitic drug to use for an animal or group of animals? Check one or more of the following, if applicable.

- [ ] I review the label indications to determine if the drug is expected to work for the parasites I am attempting to treat
- [ ] I use information from peer-reviewed scientific journals to help me make the decision
- [ ] I rely on recommendations made at veterinary continuing education meetings
- [ ] I rely on the information contained in marketing and promotional materials for antiparasitic drugs
- [ ] I rely on the experience of other veterinarians in my practice or institution
- [ ] I use what I have used for the animal(s) in the past unless the animal owner gives me information to suggest that the drug is not working anymore
- [ ] I test the drug in the animal population and determine if it is effective based on an evaluation of fecal egg counts
- [ ] I am not involved in making any treatment decisions or recommendations

Other (please specify)

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2. In your professional experience, how do you determine if an antiparasitic drug is effective in the animal or animals you are treating?

- [ ] I conduct a fecal analysis after treatment
- [ ] I evaluate fecal egg counts (eg. Fecal Egg Count Reduction Test, FECRT)
- [ ] I make the determination based on resolution of clinical signs of parasitism (eg. FAMACHA system for H. contortus in small ruminants, ill-thrift, diarrhea, etc), if present at the time of treatment
- [ ] I use production data (milk production, weight gains, reproductive parameters) to determine if the drug is effective
- [ ] If I do not see evidence of parasitism after treatment I conclude that the drug was effective
- [ ] I rely on the opinion of the farmer/producer/animal owner regarding the effectiveness of the antiparasitic drug
- [ ] I am not involved in making any treatment decisions or recommendations

Other (please specify)

3. How do you define antiparasitic resistance?

4. Are you aware of evidence of antiparasitic resistance in the following species/classes in the United States? Select 'yes' or 'no' below. If 'yes', please estimate the prevalence of the antiparasitic resistance as 'high' or 'low'.

	Yes	No
Adult Horses		
Foals		
Adult Cattle		
Calves		
Small Ruminants		
Pigs		
Chickens/Turkeys		
Dogs		
Cats		

Other (please specify)

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5. How would you characterize the level of risk for the development (or expansion, if you answered yes for a target animal class in question #4 above) of antiparasitic resistance in the United States for the following species?

	High risk	Moderate risk	Low risk
Adult Horses	◯	◯	◯
Foals	◯	◯	◯
Adult Cattle	◯	◯	◯
Calves	◯	◯	◯
Small Ruminants	◯	◯	◯
Pigs	◯	◯	◯
Chickens/Turkeys	◯	◯	◯
Dogs	◯	◯	◯
Cats	◯	◯	◯

Other (please specify)

6. I have encountered what I would define as antiparasitic resistance in the following target animal/drug/parasite relationships in the United States. Choose one answer from each drop down menu for each example of parasite resistance that you provide.

	Target Animal/Class	Drug or drug class	Parasite
1			
2			
3			
4			
5			
6			
7			
8			

Other (explanation if 'other' selected above)

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5. Part III: Survey Questions specific to combinations and antiparasitic resi...

1. Do you use two or more antiparasitic drugs at the same time in individual animals?

- ◯ Yes
- ◯ No

If yes, please list the drugs you use together (please specify animal species)

2. In your opinion, which antiparasitic drug combination(s) are needed most in a commercially available formulation in the United States (please specify target animal species/class)?

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3. What role do you believe combinations of antiparasitic drugs play in the development of parasite resistance (promote, discourage, no effect, or unknown effect)? Please fill in the appropriate circle following each of the hypothetical combinations listed below.

Promote: "In my opinion, use of such an antiparasitic combination would promote the development of resistance"

Discourage: "In my opinion, use of such an antiparasitic combination would reduce the development of resistance"

No Effect: "In my opinion, use of such an antiparasitic combination would have no effect on the development of resistance"

Unknown Effect

*** novel-class product = a drug with a new mechanism of action; no documented resistance**

****common-class product = approved drug from the macrocyclic lactone, benzimidazole, imidazothiazole, or tetrahydropyrimidine class**

	Promote	Discourage	No Effect	Unknown Effect
(novel-class product* + novel-class product *)	◯	◯	◯	◯
(novel-class product * + common-class product** with no known resistance)	◯	◯	◯	◯
(novel-class product * + common-class product** with known resistance)	◯	◯	◯	◯
common-class product** with no known resistance + common-class product** with no known resistance)	◯	◯	◯	◯
(common-class product** with no known resistance + common-class product** with known resistance)	◯	◯	◯	◯
(common-class product** with known resistance + common-class product** with known resistance)	◯	◯	◯	◯

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4. In your opinion, how, if at all, do the following characteristics of anthelmintic drugs in a combination contribute to the development of anthelmintic resistance (in particular multi-drug resistant parasites):

	Likely to contribute	Unlikely to contribute	Potential to slow development of resistance	Has no impact
Drugs have activity against several of the same parasite species	☐	☐	☐	☐
Drugs do NOT have activity against the same parasite species	☐	☐	☐	☐
Drugs having the same mode of action	☐	☐	☐	☐
Drugs having different modes of action	☐	☐	☐	☐
Drugs have similar mechanisms of resistance (resistance genes)	☐	☐	☐	☐
Drugs have different mechanisms of resistance (resistance genes)	☐	☐	☐	☐
Drugs having enhanced effectiveness in combination (synergy)	☐	☐	☐	☐

Other (please describe)

5. In your opinion, should commercially available combinations of antiparasitics be available

- ☐ Over-the-counter
- ☐ Prescription only
- ☐ No preference

Explanation, if desired

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6. Part IV: Detection and management of resistance

1. Please select the options below that best describe the fecal examination procedures you use to detect and/or quantify fecal eggs in the target animal/class for which you have experience.

	Target animal/class	Fecal Float Solution	Method/technique
1			
2			
3			
4			
5			
6			
7			
8			
9			

Other (explanation if "other" selected above)

2. Do you use larval cultures to identify parasite species?

- ◯ Yes
- ◯ No
- ◯ I am not familiar with the use of larval culture

3. Do you use the fecal egg count reduction test (FECRT) to determine if resistance is present in the animals you are treating with an antiparastic drug?

- ◯ Yes
- ◯ No
- ◯ I am not familiar with the FECRT

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4. Which of the following statements best describe the fecal egg count reduction test (FECRT) calculation you rely upon to diagnose resistance? Please select one or more of the following statements, if applicable.

- [ ] FECRT calculation based on a comparison of pre- and post-treatment fecal egg counts of a treated group/animal
- [ ] FECRT calculation based on a comparison of post-treatment fecal egg counts of a treated and control group/animal
- [ ] FECRT calculation including pre- and post-treatment fecal egg counts from both a control and treated group/animal
- [ ] Calculation uses arithmetic means (if fecal egg counts of groups of animals are used in the calculation)
- [ ] Calculation uses geometric means (if fecal egg counts of groups of animals are used in the calculation)
- [ ] Fecal egg counts are conducted on a composite fecal sample (fecal samples from individual animals mixed together)
- [ ] Fecal egg counts are conducted on fecal samples from individual animals
- [ ] I do not use the FECRT to diagnose resistance

Other (please specify)

5. Do you use tests/methods other than the fecal egg count reduction test to diagnose anthelmintic resistance

- [ ] Yes
- [ ] No

If, yes, please list the tests you use

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6. Which of the following management practices have you implemented or recommended to slow the development of antiparasitic resistance in your species area of expertise?

- [ ] Proper management of refugia (a portion of a worm population that is not exposed to the anthelmintic and can go on to establish in a host)
- [ ] Implementation of proper quarantine procedures
- [ ] Pasture management- mutispecies grazing, controlling forage height, rotational grazing, etc.
- [ ] Selection for parasite resistant animals
- [ ] Alternative techniques (copper wire particles or fungi, etc)
- [ ] Age specific treatment recommendations (for example, minimizing treatment of adult animals)

Other (please specify)

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7. Part V: Wrap up

1. Which of the following would you like to see on the labeling of antiparasitic products to assist veterinarians and producers/animal owners in addressing antiparasitic resistance?

- [ ] Recommendations for how to detect antiparasitic resistance
- [ ] Warnings regarding antiparasitic resistance, if warranted
- [ ] Management recommendations to minimize the development of antiparasitic resistance
- [ ] Antiparasitic resistance should not be addressed on the labeling
- [ ] Other (please specify)

2. In your opinion, what are the roles/responsibilities, if any, of the following groups in managing the use of antiparasitic products to minimize the development of resistance?

Veterinarians	
Regulatory agencies	
Producers/Animal Owners	
Pharmaceutical companies	

3. Is there any additional information you would like to convey that has not yet been covered in this questionnaire relative to antiparasitic resistance and new animal drug combinations?