WCABP Western Canadian Association of Bovine Practitioners | OABP Ontario Association of Bovine Practitioners | Association des Médecins Vétérinaires Praticiens du Québec

Canadian Association of Bovine Veterinarians (CABV)
Association Canadienne des Vétérinaires Bovins (ACVB)

November 12, 2007

Dr. Warren Skippon
Manager, Animal Welfare & National Issues
Canadian Veterinary Medical Association
L'Association canadienne des medecins veterinaires
339 rue Booth Street
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Email: wskippon@cvma-acmv.org

Dear Dr. Skippon:

RE: Species-Specific Prudent Use Guidelines for the Administration of Antimicrobials in Food Animals – PHASE 2

The Canadian Association of Bovine Veterinarians (CABV-ACVB) recently held its inaugural Board meeting and one of the items on the agenda was the CVMA's prudent use guidelines. After a lengthy discussion there was unanimous agreement that the CVMA should not include extra-label claims in the Phase 2 guidelines. We believe that inclusion of extra-label claims is unwarranted because veterinarians should already be aware of the most commonly used extra-label drug uses. Of greater concern, however, is the optics that CVMA is endorsing extra-label drug uses. This would not be a concern if the dissemination of the guidelines was restricted to veterinarians but we suspect that producers may also gain access to this list and as you can appreciate they may not be fully aware of all the ramifications of using specific drugs off-label. Hence we would encourage the CVMA to only disseminate the guidelines to veterinarians.

The CABV is a strong supporter of the General Prudent Use Guidelines (Phase 1), but we cannot support the Species-Specific Guidelines if they include extra-label drug uses. In regards to the Phase 3 guidelines, it is our understanding that this initiative will involve developing decision trees that provide veterinarians with examples of how to choose the most appropriate antimicrobial. We have no issues with this approach provided the decision trees are generic in nature and do not recommend specific products.

Thank you for allowing us to comment on your guidelines. We appreciate the opportunity to voice our concerns early in the development phase of these guidelines.

Kind regard,

Dr. Tye Perrett
President, CABV-ACVB

TP:pmm
cc Canadian Animal Health Institute (CAHI)

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April 25, 2008

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Dear Dr. Skippon:

RE: CVMA's Proposed Prudent Use Guidelines for Dairy and Beef Cattle

The CABV appreciates the opportunity to comment further on the CVMA's proposed Prudent Use Guidelines (PUGs) for beef and dairy cattle. We readily acknowledge that on January 3, 2008 we provided our "unconditional support" for the PUGs; however, the latest iteration of the Guidelines gives us cause for concern. In this letter I will outline some of our general concerns, while the Appendix provides a list of specific concerns raised by the CABV Board members.

Once again, the CABV would like clarification regarding the target audience for these Guidelines. The CABV has always held the position that these Guidelines should not be disseminated to the general public because extra-label drug use (ELDU) cannot, and should not, be distilled down into a "recipe book". It was our distinct understanding that when this issue was raised in the past that we were given assurances that the primary purpose of the Guidelines was to educate **veterinarians** on ELDU, not producers. However, the preamble to the PUGs states, *"It is anticipated that these Guidelines may be incorporated in whole or in part in some commodity-specific quality assurance programs"*. It is reasonable to assume from this statement that the PUGs will be disseminated to producer groups. We are steadfast in our belief that only veterinarians have the knowledge to prescribe ELDU, and we are not alone in this opinion. The Veterinary Drugs Directorate's (VDD) policy on ELDU in food-producing animals states:

1. ELDU is a recognized tool in the "practice of veterinary medicine" for animals within a "valid" Veterinarian-Client-Patient Relationship, since it facilitates access by veterinary practitioners to certain drugs for the treatment of animals.

2. ELDU in food-producing animals by person other than licensed veterinarians is not recommended except when such use is conducted under the supervision of a veterinarian within the context of a valid Veterinarian-Client-Patient Relationship.
3. ELDU is not recommended with drugs of very high importance to human health, which are listed as Category I Antimicrobials.
4. ELDU should only be undertaken in compliance with the *Food and Drugs Act* and its *Regulations*, which includes but is not limited to, banned substances (C.01.610.1), medicated feeds (C.08.012) and violative residues.

We strongly believe that disseminating these Guidelines to lay people has the real potential to increase the level of ELDU and that many of these decisions will be made without the consultation of a veterinarian. Why would producers consult with a veterinarian when the Guidelines are provided at no charge? Disseminating this information to non-veterinarians effectively removes "prudent" from the Prudent Use Guidelines.

Secondly, it is not completely clear how the ELDU recommendations were determined. Unfortunately, the latest draft of the PUGs leads us to question the scientific rationale behind these Guidelines. For example, the recommended antimicrobials for treating neonatal enteritis are different between the beef and dairy Guidelines. In addition, there are recommendations for which the CABV Board has not been able to find supporting scientific evidence. The CABV feels that it is imperative that all ELDU recommendations be founded on readily available scientific data and that the process for determining the specific recommendations must be more transparent.

Finally, I would like to reiterate that the CABV has always supported the General PUGs but we continue to have significant issues with the Species-Specific Guidelines. We understand that the significant scope and complexity of the Species-Specific Guidelines make it difficult to generate a document that will be acceptable to the entire Canadian veterinary community. However, given the general concerns outlined above and the specific concerns listed in the Appendix, the CABV cannot support the Species-Specific Guidelines at this time.

Kind regards,

Dr. Tye Perrett
President, CABV-ACVB

TP:pmm
Attachment

APPENDIX

The following comments were received from the CABV Board members. We recognize that there may be some repetition in the comments.

1. If extra-label recommendations are to be used, there should be SOME evidence that this dose or this drug will work from scientific literature, otherwise, how can we put this on a recommendation guide?

2. **Neonatal Enteritis** – From current evidence-based recommendations as presented by Dr. Peter Constable BVSC, MS, PHD, DIPLOMATE ACVIM, at the 2008 WCABP Conference:

   Calf diarrhea with bacteremia (systemically ill)
   - Fluoroquinolones
   - Ceftiofur @ 2.2 mg/kg, IM/SC, every 12 or 24 hours
   - Ampicillin trihydrate @ 10 mg/kg, IM, every 12 hours
   - Amoxicillin @ 10 mg/kg, IM, every 12 hours
   - Potentiated sulphonamides @ 25mg/kg, IV/IM, every 24 hours

   - What product is the "potentiated ampicillin"? (Are they thinking of "Synergistin" that was a potentiated amoxicillin?)
   - Is there an injectable amoxicillin product labelled for large animals?
   - Where did they come up with their off label dosing for ceftiofur of 5.0mg/kg which is repeated in other conditions as well?

3. **Use of Oxytetracycline HCl** – They recommend 6.7 mg/kg by injection, once daily for 2-3 days. Does anyone recommend that an antibiotic be given for only 2 consecutive days, especially one that is bacteriostatic? I would like to hear if anyone has saved an animal with toxic mastitis with 2 days worth of oxytetracycline HCL (also mentioned for more serious conditions including toxic metritis, peritonitis/infected surgical wounds).

4. **Pink Eye** – Looking at the "variety" of extra-label treatments written up there, including an IM injection of ceftiofur sodium at 1.0mg/kg which is not a labelled indication, a sub-conjunctival injection of ceftiofur sodium would be more useful in treatment.

5. Are dairy calves and beef calves different? Why are the lists for antimicrobials different for treating bacterial pneumonia in beef and dairy calves?

6. Why is it assumed that dairy calves don't get diphtheria, nephritis/pyelonephritis, otitis media, neonatal septicaemia?

7. We need to add Spectramast to the PUG for IMM therapy against Strep dysgalactiae, E. coli, coagulase negative staph.

8. Interesting that this is entitled "Prudent Use" but they only discuss treatments. There are many other approved uses for antibiotics, and these other uses total a significant percentage of the antibiotics used in animal production. What about:
   - growth promotion
   - metaphylaxis

9. What is the process for the decisions? I can understand where the label recommendations come from, but where do the extra-label use choices come from? For example, tulathromycin for diptheria, but not tilmicosin or florfenicol?

10. I assume the authors would like us to start at the top of the list with a Class III drug?

11. They include enrofloxacin but not florfenicol as a choice for neonatal septicemia, and also not included for neonatal enteritis.

12. Ceftiofur sodium is not included as a treatment for footrot?

13. It would be interesting to compare this to some of the work Mike Apley and others have done along these same lines. I am sure they have developed similar decision trees and we might as well be consistent within N. America.

14. For treatment of pneumonia, both ceftiofur sodium and ceftiofur HCL should be dosed at 1 mg/kg for 3-5 days.

15. Why is the dosage of ceftiofur (Na or HCL) 5 mg/kg for neonatal septicemia and yet the dosage for neonatal enteritis is 1 mg/kg. What is the scientific rationale for these dosages? Why are dairy calves different from beef calves?

16. For keratoconjunctivitis, ceftiofur is effective (extra-label) in dairy but not for beef? Since the Guidelines are quite generous in handing out gratuitous extra-label plugs, let them be consistent.

17. Ceftiofur is not listed as an option for treating interdigital necrobacillosis and yet it has a label claim for this.

18. Only ceftiofur HCL at 5 mg/kg is listed as an extra-label choice to treat ITEME. IF it would work (and I don't know of any studies or clinical experience that it would), then ceftiofur Na at the same dose should work equally well but it is not listed.

19. In the extra-label areas, I wonder how the 5.0 mg/kg dose was arrived at to treat toxic mastitis, peritonitis, adult enteritis, neonatal enteritis and yet the extra-label dose to treat conjunctivitis is 1.0 mg/kg. I don't know of any published papers suggesting/supporting these dosages.

20. They have listed ceftiofur crystalline free acid (EXCEDE) in the treatment of pneumonia with no cautions of not using this in lactating dairy animals.

21. I recently had a conversation with Dr. Ron Erskine at Michigan State U about the 5.0 mg/kg dose of ceftiofur. He knows of no literature to support this dose. In addition, the beta-lactams like ceftiofur are time-dependent antimicrobials; therefore, raising the dose to 2.5 times the highest label dose has little meaning. More important may be the frequency of administration such as been previously reported for treating septicemia in neonatal calves.....but at 2-3 mg/kg 2 times per day and not 5 mg/kg. The more I read these Guidelines, the more I become concerned at this "recipe book" for veterinary treatments. Why not rely on the professional training and scientific scrutiny of practicing vets to make such decisions?

22. Their group needs to go back to their original goals and then review what they have produced and see if their goals are being met. I just don't see how the documents we have seen can be applied in practice with positive results.

23. Really, if they are trying to accomplish Prudent Use and veterinarians starting with the appropriate class of antimicrobials to reduce development of AMR, then just publish a list with which antimicrobial is in each Class. Then veterinarians could just stat at the top and work their way down. Most people inherently do the correct thing as long as they have guidance as to what that is. Then the practitioner will do what he does now.....choose the most appropriate antimicrobial for the given situation, but knowing which would also meet PUG.

24. From the discussions we have had with Warren at CVMA, the underlying driver behind these Guidelines seems to be one of having a document in place that could, if requested, be produced as a demonstration to questioning publics that the CVMA has taken prudent use seriously. Do we really think that a recently graduated or experienced veterinarian is going to rely on these Guidelines to make his or her professional decisions?? I think we all know the answer to this. Therefore, to meet the "political correctness" or "socially responsible" needs, why not publish the document with currently available antibiotics approved for use in the various areas of need and be done with it. No extra label uses listed...period...full stop.

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August 23, 2008

Dr. John Drake, President
Canadian Veterinary Medical Association
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Dear Dr. Drake:

I am following-up on a couple of issues that were raised at our meeting in Vancouver. We would like to confirm that the CABV/ACVB is very interested in having a member on the CVMA's Welfare Committee. We appreciate that this person will not represent our Association per se, but the CABV/ACVB will advance one or more names for the CVMA to consider.

As previously indicated, we are pleased with the final wording of the Beef and Dairy Species-Specific Prudent Use Guidelines and we look forward to being involved in their periodic review in the future. Related to these Guidelines, I have attached some final comments that we received regarding the Dairy and Beef Guidelines. If possible, we would appreciate that they be included in the current round of Guidelines.

Lastly, as promised, we have also attached a copy of the letter we provided to Bioniche in regards to support of their E. coli 0157:H7 vaccine.

Sincerely,

Dr. Tye Perrett
President

TP:pmm
Attachment
cc Dr. Warren Skippon
Mr. Jost am Rhyn

Comments for Dairy PUGs

1. Need to add the milk and meat withdrawal times to Pirsue in the Gram + IMM section (Milk is 48 hours and Meat is 14 days)

2. Ceftiofur crystalline free acid - treatment of pneumonia (BRD). Need to add the same statement as used for tulathromycin (not to be used in lactating cows. Only for use in dairy animals <20 months of age.

Comments for Beef PUGs

1. Need to add Excenel Sterile Powder and Excenel RTU and withdrawal times to the Acute Bovine Interdigital Necrobacillosis section.

2. Fluoroquinolones in neonatal septicemia: VDD requires labeling that clearly indicates that: a) these products should not be used in an extra label manner, b) should not be used in pre-ruminant calves as withdrawal times have not been established, c) should only be used when first choice products have failed. Perhaps these statements should be placed in the Comments section.

3. In the TEME section, it appears that the comment for TMS is misplaced and is beside Tulathromycin.