



College of Veterinarians of British Columbia

Changes to Health Canada Regulations: Medically-Important Antimicrobials

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Important Updates

1. Own-Use Importation Restrictions

As of November 13, 2017, Health Canada has restricted the personal importation of medically-important antibiotics (“Own-Use Importation”) for food-producing animals or animals intended to be consumed as food (including horses).

2. Drug Establishment Licenses are required, as of May 17, 2018, for any premise in which drugs are compounded from imported Medically-Important Antimicrobial Active Pharmaceutical Ingredients (API).

Please see this CVMA page that has important links regarding Drug Establishment Licenses and Good Manufacturing Practices: [Information for Vets Who Compound Antimicrobial Drugs](#).

3. All Medically-Important Antimicrobials (including those meant to be administered in feed) will be available by prescription only as of December 1, 2018.

This means that a valid VCPR must exist before an MIA can be prescribed. Health Canada recognizes that only veterinarians, operating within a valid VCPR, have the necessary training to assess the health of animals and to diagnose disease conditions, and, therefore, to determine the need for antimicrobial treatment and to ensure that the **right** antibiotics at the **correct** doses are prescribed and administered to effectively manage disease in animals.

[CVMA – Importance of the VCPR](#)

[CVMA – Requirements for Veterinarians issuing a Prescription](#)

As of December 1, 2018, the drugs in [this list](#) will be moved to prescription status. You may have already started to see some label changes on affected products as Health Canada approves the new labels and the manufacturers start to use them, even though the regulations

do not take effect until December 1st. Please see this helpful document on managing your inventory during this transition period:

[CAHI – Managing Inventory during the Transition Period](#)

One of the significant changes to practice that will arise from these new regulations is that those individuals who, because of the historical availability of OTC antimicrobials, have been able to manage their animals without involving a veterinarian will now need to establish a VCPR with a veterinarian. Apiculturists and keepers of back yard flocks are two groups that will be affected in this manner. A document regarding the oversight of antimicrobial treatment in honey bees is currently in production and will help to address the nature/requirements of a VCPR in these situations. The CVMA’s annual convention in July (held in Vancouver from July 5-8, 2018) will include a series of lectures on honey bees (the “Honey Bees for Dummies: A Primer for Veterinarians” track, scheduled for the afternoon of Sunday, July 8): *“Basic Aspects of Honey Bee Biology and Beekeeping Practices Relevant to Honey Bee Health/Disease”* and *“Important Diseases of Honey Bees that Future Bee Vets Should Know About: Parts 1 & 2”*

4. Extra-Label Drug Use (ELDU)

In Canada, veterinarians have the privilege of ELDU in certain situations to accommodate the limited range of approved drug doses for treating disease in different animals. The right of veterinarians to prescribe drugs for use in an extra-label manner will be maintained under these new regulations, in the interest of protecting animal health and welfare while also protecting human health. Page 22 of the CVMA’s [“Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians”](#) outlines the expectations for ELDU.

Resources

Health Canada: [“Responsible Use of Medically-Important Antimicrobials in Animals”](#)

CVMA: [“Veterinary Oversight of Antimicrobial Use in Animals in Canada”](#)

CAHI: “Antimicrobials Requiring a Veterinary Prescription” (see next page)



Antimicrobials Requiring a Veterinary Prescription

as of December 1, 2018

Based on the antimicrobial categorizations determined by Health Canada in relation to their importance to human medicine

Category	Licensed Drug	Brand Names				
I Very High Importance Used in the treatment of serious human infections and there are no or limited alternatives.	Ceftiofur Danofloxacin Enrofloxacin Polymixin B	No change. These products already require a veterinary prescription. Includes products such as:				
		Baytril	Excenel	Ceftiofur	Spectramast	Special Formula 17900-Forte
II High Importance Used in the treatment of serious human infections and have some alternatives. All of these previously over-the-counter products will require a veterinary prescription and will only be available through your veterinarian. If a product does not appear on this list, it may already require a veterinary prescription.	Erythromycin Gamithromycin Gentamicin Lincomycin Neomycin <i>oral</i> Penicillin G Streptomycin/ Dihydrostreptomycin <i>oral</i> Tildipirosin Tilmicosin Tulathromycin Tylosin Tyvalosin Virginiamycin	Aivlosin 17% Aureo S-P 250 G Aureomix 625 G Booster P S Conc Chlor 250 Granular Premix Component Implants with Tylan (E-C, E-H, E-S, TE 100, TE 200, TE-G, TE-H, & TE-S) Depocillin Gallimycin-50 Gallimycin 50 Premix Hi-Pencin 300 L-S 20 Premix LincoMed 100 Lincomix 44 & 110 Premixes	Lincomix 100 Injectable Solution Lincomix Soluble Powder Lincomycin 44, 44 G, 110 & 110 G Premixes Lincomycin Soluble Powder Linco-Spectin 100 Soluble Powder Linco-Spectin Sterile Solution Lincomycin Spectinomycin 4.4% G Premix Lincomycin Spectinomycin 100 Soluble Powder Linxmed-SP Neo-Chlor Neo Sulfalyte	Neo-Terramycin 50/50 Premix Neo-Tetramed Neomed 325 Neomycin SP & 325 Penpro NeoOxytet SP Neotet Soluble Concentrate Novodry Plus NSE Bolus Pen G Injection Pen Vet 300 Penaqua Sol-G Penicillin G Potassium USP Soluble Powder 500 000 000 & 15 000 000 000 IU Penicillin G Procaine 110	PenMed Sus IM 300000 IU/ml Penpro Pharmasin Soluble 100 Pig Zest Pododerm Pot Pen Pot Pen 500 000 000 & 15 000 000 000 Proc Pen LA Procaine Aqueous Suspension Procaine Penicillin G Procillin Propen LA Pulmotil Premix Scour Boluses Scour-Plug	Scour Suspension Stafac 22, 44 & 500 Sulectim Plus Super Booster Super Chlor 250 Granular Premix Tilmicosin 200 Tilmovet Premix Tylan 10, 40 & 100 Premixes Tylan 200 Tylan Soluble Tylosin 10 & 40 Premixes Tylosin 100 Tylosin Soluble Powder Vibiomed Booster Virginiamycin 44 Premix
	III Medium Importance Are not the preferred treatment for serious human infections and there are alternatives available. All of these previously over-the-counter products will require a veterinary prescription and will only be available through your veterinarian. If a product does not appear on this list, it may already require a veterinary prescription.	Apramycin Bacitracin Florfenicol Gentamicin - <i>topical</i> Neomycin - <i>topical</i> Spectinomycin Streptomycin/ Dihydrostreptomycin - <i>topical</i> Sulfonamides Tetracyclines/ Chlortetracyclines/ Oxytetracyclines Tiamulin	2 Sulfamed 3 Sulvit After-Calf Bolus Alamycin LA Albac 110 Apralan Aureomycin 220 G AVL Topical Spray Bacitracin MD Bio-Mycin 200 BMD 110 G BMD Soluble Calf Scour Tablet CalfSpan Tablets CalfStrong Tablets Chlor 50 & 100 Granular Premixes	Compudose Co-Op Calf Scour Tablets Cyclosol 200 LA Denagard Denagard 10% GF Premix, 12.5% Liquid Concentrate & Medicated Premix Deracin 22% Granular Premix Foul Brood Mix Kelamycin Intrauterine Suspension Keraplex Liquamycin LA-200 Nitrofurazone Soluble Dressing Noromycin LA, LA 300 & LP Onycin 250 & 1000 Oxy 250 & 1000	Oxy LA & LP Oxy Tetra A 55mg/gm Oxy Tetra Forte 220mg/gm Oxymyline LA, LS, LA 300 & LP Oxysol 62.5 Oxytet-25 Oxytet 1000 SP Oxytetracycline 50, 100 & 200 Granular Premixes Oxytetracycline HCl Soluble Powder 1000 Oxytetramycin 100 Oxyvet 100 LP, 200 LA & 300 LA Panolog Ointment Proud Flesh Dust	Sodium Sulfamethazine Solution 12.5% & 25% Spectam Scour-Halt Sulfa 2 Soluble Powder Sulfa 25 & Sulfa 25% Solution Sulfa MT Sulfa Urea Cream Sulfamethazine 25% Solution Sulfamethazine Bolus Sulfaquinoxaline Concentrate Sulfaquinoxaline 19.2% Liquid Concentrate Sulectim 100 Sulfavite Sulmed Plus Sustain III
IV Low Importance These antimicrobials are not used in human medicine.		Amprolium, clopidol, diclazuril, dinitolmide (zoalene), nicarbazine, robenidine, etc. Ionophores (Lasalocid, Narasin, Salinomycin, Monensin) Flavophospholipols (Bambermycin)	No change to how these products are purchased. Products such as:			
		Coban Premix, Kexstone, Monensin Premix, Rumensin CRC, Rumensin Premix, Flavomycin 4 Amprol 9.6% Solution, Amprol 25% Feed Mix, AmproMed, Avatec 20 Medicated Premix, Bovatec 20 Medicated Premix, Coxistac 6% Premix, Coxistac 12% Granular, Maxiban Premix, Monteban 100, Posistac 6% Premix, Sacox 120, Salinomycin 60 Premix				

Other products in any category may be affected by these changes and not listed here. Consult with your veterinarian for further information.

CONTAINS ANTIMICROBIAL, USE RESPONSIBLY

