




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	Ceftiofur	No change. These products already require a veterinary prescription. Includes products such as:				
		Danofloxacin					
		Enrofloxacin	Baytril	Excenel	Ceftiofur	Spectramast	Special Formula 17900-Forte
Used in the treatment of serious human infections and there are no or limited alternatives.		Polymixin B					
II	High Importance	Erythromycin	Aivlosin 17%	Lincomix 100 Injectable Solution	Neo-Terramycin 50/50 Premix	PenMed Sus IM 300000 IU/ml	Scour Suspension
		Gamithromycin	Aureo S-P 250 G	Lincomix Soluble Powder	Neo-Tetramed	Penpro	Stafac 22, 44 & 500
	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.	Gentamicin	Aureomix 625 G	Lincomycin 44, 44 G, 110 & 110 G Premixes	Neomed 325	Pharmasin Soluble 100	Sulectim Plus
		Lincomycin	Booster P S Conc	Lincomycin Soluble Powder	Neomycin SP & 325 Penpro	Pig Zest	Super Booster
		Neomycin <i>oral</i>	Chlor 250 Granular Premix	Lincomycin Soluble Powder	NeoOxytet SP	Pododerm	Super Chlor 250
		Penicillin G	Component Implants with Tylan (E-C, E-H, E-S, TE 100, TE 200, TE-G, TE-H, & TE-S)	Linco-Spectin 100 Soluble Powder	Neotet Soluble Concentrate	Pot Pen	Granular Premix
		Streptomycin/ Dihydrostreptomycin <i>oral</i>	Depocillin	Linco-Spectin Sterile Solution	Novodry Plus	Pot Pen 500 000 000 & 15 000 000 000	Tilmicosin 200
		Tildipirosin	Gallimycin-50	Lincomycin Spectinomycin 4.4% G Premix	NSE Bolus	Proc Pen LA	Tilmovet Premix
		Tilmicosin	Gallimycin 50 Premix	Lincomycin Spectinomycin 100 Soluble Powder	Pen G Injection	Procaine Aqueous Suspension	Tylan 10, 40 & 100 Premixes
		Tulathromycin	Hi-Pencin 300	Linxmed-SP	Pen Vet 300	Procaine Penicillin G Procillin	Tylan 200
		Tylosin	L-S 20 Premix	Neo-Chlor	Penaqua Sol-G	Propen LA	Tylan Soluble
		Tyvalosin	LincoMed 100	Neo Sulfalyte	Penicillin G Potassium USP Soluble Powder 500 000 000 & 15 000 000 000 IU	Pulmotil Premix	Tylosin 10 & 40 Premixes
		Virginiamycin	Lincomix 44 & 110 Premixes		Penicillin G Procaine 110	Scour Boluses	Tylosin 100
						Scour-Plug	Tylosin Soluble Powder
III	Medium Importance	Apramycin	2 Sulfamed	Compudose	Oxy LA & LP	Sodium Sulfamethazine Solution 12.5% & 25%	T-1%
		Bacitracin	3 Sulvit	Co-Op Calf Scour Tablets	Oxy Tetra A 55mg/gm	Solution 12.5% & 25%	Terramycin-Aqua
		Florfenicol	After-Calf Bolus Alamycin LA	Cyclosol 200 LA	Oxy Tetra Forte 220mg/gm	Spectam Scour-Halt	Terramycin Premixes 50, 100 & 200
		Gentamicin - <i>topical</i>	Albac 110	Denagard	Oxymycine LA, LS, LA 300 & LP	Sulfa 2 Soluble Powder	Tetra 55, 250, 1000 & 4000
		Neomycin - <i>topical</i>	Apralan	Denagard 10% GF Premix, 12.5% Liquid Concentrate & Medicated Premix	Oxysol 62.5	Sulfa 25 & Sulfa 25% Solution	Tetracycline 250
		Spectinomycin	Aureomycin 220 G	Deracin 22% Granular Premix	Oxytet-25	Sulfa MT	Tetraject LA & LP
		Streptomycin/ Dihydrostreptomycin - <i>topical</i>	AVL Topical Spray	Foul Brood Mix	Oxytet 1000 SP	Sulfa Urea Cream	Tetramed 250 & 1000
		Sulfonamides	Bacitracin MD	Kelamycin Intrauterine Suspension	Oxytetracycline 50, 100 & 200 Granular Premixes	Sulfamethazine 25% Solution	Tiamulin 1.78% Premix
		Tetracyclines/ Chlortetracyclines/ Oxytetracyclines	Bio-Mycin 200	Keraplex	Oxytetracycline HCl Soluble Powder 1000	Sulfamethazine Bolus	Tiamulin HF 10%
		Tiamulin	BMD 110 G	Liquamycin LA-200	Oxytetramycin 100 Oxyvet 100 LP, 200 LA & 300 LA	Sulfaquinoxaline Concentrate	Tiamulin Soluble Powder
			BMD Soluble	Nitrofurazone Soluble Dressing	Panolog Ointment	Sulfaquinoxaline 19.2% Liquid Concentrate	Triple Sulfa Bolus
			Calf Scour Tablet	Noromycin LA, LA 300 & LP	Proud Flesh Dust	Sulectim 100	Vetmulin Liquid Concentrate
IV	Low Importance	Amprolium, clopidol, diclazuril, dinitolmide (zoalene), nicarbazine, robenidine, etc.	No change to how these products are purchased. Products such as:				
		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					
These antimicrobials are not used in human medicine.		Ionophores (Lasalocid, Narasin, Salinomycin, Monensin)					
		Flavophospholipols (Bambermycin)					



CONTAINS ANTIMICROBIAL, USE RESPONSIBLY

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FACT SHEET: ACCESSING AND SELLING PRESCRIPTION VETERINARY DRUGS

Responsible use of Medically Important Antimicrobials

CONTEXT

As of December 1, 2018, all [Medically Important Antimicrobials \(MIAs\) for veterinary use](#) will be sold by prescription only. Antimicrobial drugs are important to fight bacterial infections in humans and animals. The responsible use of MIAs is intended to preserve their effectiveness and minimize the development and spread of antimicrobial resistance. **We all have a role to play.**

This fact sheet explains the federal rules on how **prescription (Pr) drugs** (in dosage form) can be accessed and sold in Canada – it does not apply to the non-prescription drug context. It is important to note that the distribution and sale of Pr drugs is a shared authority, and some provinces and/or territories may authorize certain facilities, beyond veterinary clinics and pharmacies, to sell Pr drugs, for example in Quebec where a permit regime exists. Consult your provincial/territorial authority for further details.

TERMINOLOGY

- **Drug premix** is defined in the *Food and Drug Regulations* [C.01A.001] – it means a drug for veterinary use to which a drug identification number (DIN) has been assigned, where the directions on its label specify that it is to be mixed with feed... For clarity of this Fact Sheet, the term used is “**DIN drug premix**”.
- **Wholesale druggist** does not have a regulatory definition. For clarity of this Fact Sheet, examples of wholesale druggists include wholesalers and commercial feed mills (who may access DIN drug premixes to support their operations).
- **Wholesaler** is defined in the *Food and Drug Regulations* [C.01A.001] – it means a person... who sells... a drug that is a prescription drug... other than at retail sale.
- **Commercial feed mill** does not currently have a regulatory definition. For clarity of this Fact Sheet, a commercial feed mill is considered a wholesale druggist and is a facility that mixes and manufactures feed for commercial sale in accordance with the *Feeds Act* and *Regulations*.
- For clarity of this Fact Sheet, **retail stores** include facilities such as livestock medicine outlets, farm supply stores or feed stores – it does not include pharmacies or veterinary clinics.
- For clarity of this Fact Sheet, in the context of veterinarians and pharmacists, **sale** includes dispensing for sale.

INFORMATION FOR ANIMAL OWNERS / END USERS

For animal owners/end users, including food animal producers (who may make their own feed) and companion animal owners, in order to purchase a prescription drug for your animal, you first need to obtain a prescription from your veterinarian.

With a prescription, veterinarians and pharmacists can sell you a **prescription drug** (including DIN drug premixes for mixing in feed, injectables, implants and in-water drugs).

With a prescription, commercial feed mills can sell you a **medicated feed containing a prescription drug**. It must be sold in the form of a complete feed, supplement, macro premix, or micro premix. A veterinarian is also allowed to sell you a Pr medicated feed, but most do not have facilities to produce mixed feeds in these forms.

You cannot give or sell a **Pr drug in any form** to someone else.

INFORMATION FOR DRUG COMPANIES

Drug companies can sell a **prescription drug** (including a DIN drug premix) to:

- Other drug companies (manufacturers)
- Veterinarians
- Pharmacists
- Wholesale druggists (such as other wholesalers and commercial feed mills who may access DIN drug premixes to support their operations)

Drug companies must comply with drug good manufacturing practices (GMP) and obtain a Drug Establishment Licence (DEL) from Health Canada.

A **Pr drug** cannot be sold to a retail store (such as livestock medicine outlets, farm supply stores or feed stores) or to animal owners/end users.

INFORMATION FOR VETERINARIANS AND PHARMACISTS

Veterinarians and pharmacists can sell a **Pr drug** (including a DIN drug premix and medicated feed) to end users (such as food-animal producers with on-farm feed mills and companion animal owners) who have a prescription.

A **Pr drug** cannot be sold to a retail store (such as livestock medicine outlets, farm supply stores or feed stores).

If you wholesale **DIN drug premixes** (for mixing in feed) or **other Pr drugs** (including injectables, implants and in-water drugs), refer to the “Information for Wholesalers” below, and note the GMP and DEL wholesale requirements.

INFORMATION FOR COMMERCIAL FEED MILLS

The term **Commercial feed mill** does not currently have a regulatory definition. For clarity of this Fact Sheet, a commercial feed mill is considered a wholesale druggist and is a facility that mixes and manufactures feed for commercial sale in accordance with the *Feeds Act* and *Regulations*. A **DIN drug premix** (for mixing in feed) can be sold directly to you without a prescription. You can then mix the DIN drug premix with feed ingredients to make medicated feed.

With a prescription, you can sell a **Pr medicated feed** in the form of a complete feed, supplement, macro premix, or micro premix to end users (such as food-animal producers or an on-farm feed mill). These activities do not require you to comply with drug GMPs or obtain a DEL from Health Canada.

You cannot sell a **DIN drug premix** to end users (such as food-animal producers with on-farm feed mills) even with a prescription, unless you are authorized under the laws of a province or territory to do so with a prescription (for example in Quebec where a permit regime exists). If you want to wholesale **DIN drug premixes** to a veterinarian, pharmacist or another commercial feed mill or wholesaler, you need to comply with drug GMP (where products are to be stored and handled in accordance with the label), but you do not need to obtain a DEL.

If you want to wholesale **Pr drugs other than DIN drug premixes** (including injectables, implants and in-water drugs), refer to the “Information for Wholesalers” below, and note the GMP and DEL wholesale requirements.

INFORMATION FOR WHOLESALERS

Drug companies can sell **Pr drugs** (including DIN drug premixes, injectables, implants and in-water drugs) directly to wholesalers without a prescription.

As a wholesaler, you can sell these **Pr drugs** and **DIN drug premixes** without a prescription to:

- Other drug companies (manufacturers)
- Veterinarians
- Pharmacists
- Wholesale druggists (such as other wholesalers and commercial feed mills)

If you wholesale **Pr drugs other than DIN drug premixes**, you need to comply with GMP and obtain a DEL for the activity of wholesale.

If you only wholesale **DIN drug premixes** to a veterinarian, pharmacist or another commercial feed mill or wholesaler, you need to comply with drug GMP (where products are to be stored and handled in accordance with the label), but you do not need to obtain a DEL.

A **Pr drug** cannot be sold to a retail store (such as livestock medicine outlets, farm supply stores or feed stores) or to animal owners/end users.

INFORMATION FOR RETAIL STORES

Retail stores (such as livestock medicine outlets, farm supply stores or feed stores) cannot access or sell **Pr drugs in any form** to anyone (even with a prescription).

FOR MORE INFORMATION

- **For questions about Veterinary prescription drugs**, email: hc.vetdrugs-medsvet.sc@canada.ca.

- **For questions about drug GMP**, email: GMP_Questions_BPF@hc-sc.gc.ca
 - For more information about GMP, click [here](#).
 - For more information about preparing for a GMP wholesaler inspection, click [here](#).

To comply with expectations as a wholesaler of a Pr Drug or DIN Drug Premix you will need to understand obligations in Part C Division 2 of [Food and Drug Regulations](#). You can find more information in Health Canada's [Good manufacturing practices guide for drug products \(GUI-0001\)](#). This includes obligations related to Premises (C.02.004), Personnel (C.02.006), Manufacturing control (C.02.012), Quality control department (C.02.013 -15) and Records (C.02.021-24).

- **For questions about the [Feeds Act](#) and [Regulations](#)**, email: FEED_MILL_INSP@inspection.gc.ca
- **For questions about DELs**, email: DEL_Questions_LEPPP@hc-sc.gc.ca
 - For more information about obtaining an Establishment Licence, click [here](#).
- **For questions about dispensing, licensing or other rules within your province/territory**, contact your provincial/territorial authority directly.

The way you purchase antibiotics is changing

By **December 2018**, you'll need a prescription to buy virtually any livestock antibiotic. Later this year Health Canada will introduce major changes to how livestock producers across Canada can access antibiotics. The new policy does not apply to ionophores, which are not considered to be medically important.

Starting **December 1, 2018**, all livestock producers will need a prescription from a licenced veterinarian before they can buy a medically important antibiotic (MIA) for therapeutic use in livestock production. This applies to all beef cattle sectors - cow-calf operators, backgrounders and feedlots. The new policy doesn't just apply to injectable products, but also includes some boluses, calf scour treatments, in-feed & in-water antibiotics, and implants that contain MIA.

For example, producers will no longer be able to buy a bottle of penicillin or tetracycline to treat common infections such as foot rot, pink eye or mastitis without a valid prescription. Feed mills will only be allowed to sell certain medicated feed formulations if they are given a valid

prescription, and will no longer be able to sell antibiotics directly to producers for on-farm mixing.

MIA (medically important antibiotic):

Drugs considered to be essential for the treatment of bacterial infections in humans, as classified by Health Canada.

VCPR (veterinary-client-patient relationship):

In simple terms, your veterinarian understands your operation, your management practices, your herd, and common health issues well enough to provide meaningful advice and oversight.

All producers will need to establish a vet-client-patient relationship (VCPR) before they can obtain a prescription for a MIA.

Once a valid VCPR and medical need has been established with a licenced veterinarian, a producer will be able to obtain a prescription for a given amount of product over a specified period of time. Prescriptions can be valid for up to a year, allowing producers to refill as needed if that is what the veterinarian advises.

For example, a cow-calf producer can design a herd health protocol with their veterinarian, based on a working knowledge of their operation, health records and herd history. This protocol may anticipate medical need for treatment of specific conditions like pinkeye or footrot, and then a prescription can be written to cover the estimated amount required (X bottles of Alamycin LA or Nuflor) throughout the year. This way, the producer can buy medication as needed up to the estimated amount, or up to the expiry date of the prescription. Producers who already have a strong relationship with their veterinarian likely won't see any change in normal practices.

Where these prescriptions can be filled may vary from province to province. Some provinces may only allow veterinarians or pharmacists to sell antibiotics; others may approve other distribution channels.

A list of the beef cattle products that will be impacted is shown on the reverse.

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Why the change?

This directive from Health Canada, as a part of a worldwide awareness of and response to antibiotic resistance issues, aims to:

1. Ensure antibiotics are used appropriately in animal agriculture to avoid or slow the development of bacteria that are resistant to antibiotics. As a result, currently available antibiotics will remain effective for a longer period of time.
2. Strengthen public trust by demonstrating responsibility and appropriate use; showing that products are only used when needed, at the appropriate dose and duration, and observing proper withdrawal times.

Common Questions

Q: How do I avoid costs and inconvenience?

A: Work with a veterinarian to see how your current preventative health program can be strengthened to reduce the likelihood of sickness and disease. Reviewing your nutrition and feeding program and feed test results with a nutritionist is also important; optimal nutrition is key to keeping animals healthy enough to resist disease, and to ensure optimal vaccine performance.

Veterinarians see a lot of different beef operations, which gives them the opportunity to professionally observe and evaluate a wide variety of management and health programs, see what works (and doesn't), and make appropriate recommendations. For example, veterinarians have the expertise to appropriately customize your vaccination and parasite control programs so that they more effectively prevent the disease risks and challenges your herd faces. In the end, you may find that veterinary costs turn out to be an investment that improves your bottom line.

Q: Will a veterinarian need to directly examine every sick animal on farm before writing a prescription?

A: Not necessarily, provided you have a valid VCPR.

Q: Will a veterinarian need to administer the antibiotic?

A: No, provided you have a valid VCPR. Once the antibiotic has been purchased, producers can continue to administer the antibiotic to their animals themselves.

Q: Will I need a new prescription every time I need to use antibiotics?

A: Not necessarily. Work with your veterinarian to plan ahead, develop a herd health protocol, and have prescriptions on file that can be filled if necessary.

Q: What if a veterinarian does not service my area?

A: You can establish a VCPR with a vet that is not local, provided they are licensed to practice in your province (e.g. consulting veterinarians).

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Cattle products containing antibiotics that will require a veterinary prescription in Canada as of December 1, 2018

Category I - Very High Importance in Human Medicine: Essential for treating serious bacterial infections in people; limited or no effective alternative antibiotics available.

Licenced Drug	Brand Names
Ceftiofur Danofloxacin Enrofloxacin Polymixin B	<i>*Note: The following products already require a veterinary prescription:</i> A180, Baytril, Ceftiocyl, Ceftiofur, Cevaxel, EFICUR, Excede, Excenel, Special Formula 17900-Forte Suspension, Spectramast

Category II - High Importance in Human Medicine: Used to treat a variety of infections in people, including serious infections; effective alternative antibiotics are generally available.

Licenced Drug	Brand Names
Ampicillin Cephapirin Dihydro/streptomycin Gamithromycin Gentamycin Neomycin Benzyl/penicillin Tildipirosin Tilmicosin Trimethoprim Tulathromycin Tylosin	<i>*Note: The following products in bold are currently available over the counter but will require a veterinary prescription as of Dec. 1, 2018. Products in this category that are already prescription-only are not listed.</i> Calf Scour Bolus, Component Implants with Tylan (TE-S, E-C, E-H, E-S, TE-100, TE-200, TE-G & TE-H), Depocillin, DP Booster PWS, Enterolyte, Hi-Pencin 300, Hog Scour Suspension, Keraplex, Neo-Chlor, Neo-Tet, NeoMed 325, Neomycin 325, Neomycin SP, NeoOxytet SP, NeoSulf Plus, Neo-Sulfalyte Bolus, Neorease, Neo-Terramycin 50/50, Premix, Neotet Soluble Concentrate, Neo-Tetramed, Novodry Plus Suspension, NSE Bolus, Pen G Injection, Pen Vet 300, Penpro, Penmed, PolyTonine A Super Booster #1, Proc Pen LA, Procaine Penicillin G, Procillin, Propen LA, Pulmotil Premix, Scour-Plug, Scour Boluses, Scour Solution, Scour Suspension, Scour Treat Liquid, Sulectim Plus, Super Booster, Super Scour Calf Bolus, Tilmovet Premix, Tylan 10, 40 & 100 Premix, Tylan 200, Tylosin 10 Premix, Tylosin 40, Vetpen 300, Vibiomed Booster

Category III - Medium Importance in Human Medicine: Used to treat bacterial infections in people; effective alternative antimicrobials are generally available.

Licenced Drug	Brand Names
Florfenicol Sulfamethazine Chlor/oxy/tetracycline	<i>*Note: The following products in bold are currently available over the counter but will require a veterinary prescription as of Dec. 1, 2018. Products in this category that are already prescription-only are not listed.</i> 2 Sulfamed, 3-Sulvit, After-Calf Bolus, Alamycin LA, Astringent Powder, Aureo S 700 G & S-700 G Drug Premix for Beef Cattle, Aureomycin 220 G, CalfSpan Tablets, Chlor 100 Medicated Premix, Chlor 50 Granular Premix, Chlor S 700 Granular Premix, Chlortet Vitamin Premix Crumbles, Compudose implant, Co-op Aureomycin Vitamin Premix Crumbles, Co-op Calf Scour Tablets, Cyclosol 200 LA, Deracin 22% Granular Premix, Footrot Boluses, Kanadom Tetracycline Hydrochloride, Liquamycin LA-200, Masterfeeds Chlor S-700 Beef Premix Crumbles, Neutral Sulfa 7 & 50, Noromycin LA, LA 300 & LP, Onycin 250 & 1000, Oxy-250 & 1000, Oxy LA Sterile Injectable, Oxy Tetra Forte & Tetra-A, Oxymyline LA, LA 300 & LP, Oxysol 62.5, 110, 220, 440 Premix, Oxytet 1000 SP, Oxytetracycline 50, 100 & 200 Granular Premix, Oxytetracycline HCl Soluble Powder 1000, Oxytetramycin 100, Oxyvet 100 LP & 200 LA, Powder 21, Proud Flesh Dust, Sodium Sulfamethazine Solution 12.5% & 25%, Sulectim Plus, Sulfa 2 Soluble Powder, Sulfa 25, Sulfa-Zinc Powder, Sulfalite Powder Super, Sulfa MT, Sulfa-MT, Sulfa Urea Cream, Sulfamethazine 25% Solution, Sulfamethazine Bolus, Sulfavite, Sulmed Plus, Sustain III Bolus, Terramycin-50, -100 & -200 Premix, Tetra 55, 250, 1000 & 4000, Tetraject LA, Tetracycline 250, Tetracycline Hydrochloride, Tetramed 62.6, 250 & 1000, Triple Sulfa Bolus, Wound Clear Spray, Wound Spray, Wound Treatment

Category IV - Low Importance in Human Medicine: Not currently used in human medicine.

Licenced Drug	Brand Names
Amprolium Decoquinat Lasalocid Monensin Salinomycin Toltrazuril	<i>*Note: These products do not currently require a prescription, and will not require a prescription in the future.</i> Amprol, Ampromed, Avatec, Baycox, Bovatec, Coban, Coxistac, Deccox, Halocur, Kexxtone, Monensin, Posistac, Rumensin

This list, created by the Beef Cattle Research Council and Alberta Beef Producers, is accurate to the best of our knowledge as of March 9, 2018
Visit www.beefresearch.ca/AMR for the most up to date version.