The New Rules on Active Pharmaceutical Ingredients

FAAST
FARMED ANIMAL ANTIMICROBIAL STEWARDSHIP

Veterinarian FAASTsheet 6 of 11

What Is Changing and When?

What?

Health Canada is increasing its oversight of medically important antimicrobial Active Pharmaceutical Ingredients (**APIs**) (List A) (see appendix) for veterinary use, including their import, manufacture, formulation, and distribution. The federal regulatory changes now require all importers, fabricators, packagers/labellers and testers of List A APIs for veterinary use to:

1. Obtain a Drug Establishment License (**DEL**)
2. Comply with Good Manufacturing Practices (**GMP**)
3. Report all sales of antimicrobial API products to Health Canada on an annual basis

When? May 17th, 2018

(with a 14-month implementation period to **July 17th, 2019**)

What are GMPs?

International quality assurance standards for production and quality control GMPs ensure that drug manufacturing and compounding are controlled and consistent (i.e. raw material and finished product testing, stability, sterility, records, etc.)

Why Is This Changing?

Prior to May 17, 2018, licensed veterinarians, those acting under the supervision of a licensed veterinarian, and pharmacists were allowed to import and compound APIs for veterinary use without any additional licensing or oversight.

Active Pharmaceutical Ingredients are the substances used in the fabrication of pharmaceutical drugs responsible for beneficial health effects produced by use of the product. An example of an API in veterinary medicine would be trimethoprim-sulfadoxine contained in the products Borgal, Trivetrin, or Trimidox.

Regulators must have an accurate picture of antimicrobial use in order to promote responsible antimicrobial use and slow the emergence of antimicrobial resistance. Increased monitoring of compounding and distribution of APIs will contribute to a more complete picture of the use of medically important antimicrobials in Canada.

What Do These Changes Mean for Veterinarians?

These changes will only directly affect those veterinarians who **import, compound, and/or distribute APIs.**

Remember, when there are registered veterinary products to treat specific conditions, veterinarians have the professional responsibility to prescribe these products, rather than using compounded products.

Those who wish to engage in or continue these activities will need to:

1 Obtain a Drug Establishment License (DEL)

- Apply to Health Canada (see additional resources section)
    - **If you were importing/compounding PRIOR to May 17, 2018**
        - Submit an application by July 17, 2019
        - You may continue to conduct activities until a decision has been rendered on your application
    - If you were NOT importing/compounding prior to May 17, 2018
        - Submit an application at any time
        - Must await approval of DEL before conducting licensable activities
    - Typical service standard for decision = 250 days

2 Comply with Good Manufacturing Practices (GMPs)

- This applies to anyone who fabricates, packages/labels, tests, imports, distributes, or wholesales **List A APIs** for use in veterinary species
- Federal inspection of facilities required
- See additional resources for detailed references on GMP compliance

3 Report Information on Antimicrobial Sales to Health Canada

- Applies to anyone who imports, manufactures, and/or compounds API drugs List A

- Information reported must include:
    - ***Species information*** (e.g. dairy, beef, pigs, etc.) – estimation of % total sales for each API
    - **Sales information** (e.g. packages sold to distribution centers, packages exported)
    - ***Active ingredient information*** (e.g. name, strength, kg sold per province)

- **See Veterinarian FAASTsheet #10 for more information**
- For questions on submitting sales data email: hc.VAMSR-VAMVR.sc@canada.ca

How Does This Impact Your Clients?

Some clients may regularly use products dispensed by a veterinarian or pharmacist that are compounded from imported APIs. While these changes will not affect clients directly, it is necessary for the dispensers of such products to ensure they are in compliance with the new regulations in order to continue to provide these products to clients.

For More Information

Visit www.amstewardship.ca

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Appendix

List A: List of Certain Antimicrobial APIs - Effective November 13, 2017.
List A antimicrobial APIs is a list of all antimicrobials classified as Category 1-3 (those of importance to human medicine)

CLASS	EXAMPLE
Aminocyclitols	Spectinomycin
Aminoglycosides	Amikacin
Beta-lactamase inhibitors	Clavulanic acid
Carbapenems	Imipenem
Cephalosporins – 1st -5th generations	Cephalexin Cefoxitin Ceftiofur Cefquinome Ceftolozane
Coumarins	Novobiocin
Diaminopyrimidines	Trimethoprim
Fluoroquinolones	Enrofloxacin
Fosfomycins	Fosfomycin
Fusidic acid	Fisidic acid
Glycopeptides	Vancomycin
Glycyclines	Tigecycline
Ketolides	Telithromycin
Lincosamide	Lincomycin
Lipopeptides	Daptomycin
Macrocyclics	Fidaxomicin
Macrolydes	Tulathromycin
Monobactams	Aztreonam
Nitrofurans	Nitrofural
Nitroimidazoles	Benznidazole
Orthosomycins	Avilamycin
Oxazolidinones	Linezolid
Penicillins	Amoxicillin Penicillin
Phenicols	Florfenicol
Pleuromutilins	Tiamulin
Polymyxins	Colistin
Polypeptides	Bacitracin
Pseudomonic acids	Mupirocin
Quinolones	Nalidixic acid
Rifamycins	Rifampin
Streptogramins	Virginiamycin
Sulphonamides	Sulfadoxine
Tetracyclines	Oxytetracycline
Therapeutic agents vs TB	Ethambutol