

Session 1: An introduction to the new requirements under the Food and Drug Regulations affecting industry and health care practitioners who compound veterinary drugs

February 13, 2018

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Webinar Presentation Plan

Overview of the Regulatory Amendments

- Good Manufacturing Practices (GMP) and Drug Establishment Licences (DEL)
- List A
- DEL Transition period

Introduction to requirements:

- Veterinary Antimicrobial Sales Reporting
- Drug Establishment Licences (DEL)
- Good Manufacturing Practices (GMP)

DEL and GMP Anti-Microbial Resistance Regulatory Amendment

Several DEL and GMP changes are [coming into effect](#) on **May 17, 2018**:

- **Importer, fabricator, packager/labeller and tester** of veterinary Active Pharmaceutical Ingredients (API) for veterinary use **will need a Drug Establishment License (DEL) and** will need to comply with Good Manufacturing Practices (**GMP**)
 - Importers of API and finished dosage form drugs for veterinary use will be required to list foreign fabricators, packagers/labellers and testers of APIs on their DEL
 - The APIs used in the fabrication of a finished dosage form drug for veterinary use will be required to be GMP compliant
 - A new drug category will be required on the license of those that conduct activities with regards to “List A API for veterinary use”.
 - Veterinarian and Pharmacist importing List A API for veterinary use will require a DEL
- **Distributors and wholesalers** of veterinary Active Pharmaceutical Ingredients (API) for veterinary use **will not require a DEL but will need** to comply with Good Manufacturing Practices (**GMP**)
- Veterinary Health Products (VHPs) are a new product type, exempt from the DEL and GMP requirements

List A: Certain antimicrobial active pharmaceutical ingredients

- List A has been established - [List of Certain Antimicrobial Active Pharmaceutical Ingredients](#)
- Drugs listed on List A include:
 - antimicrobials (category I, II, III) that meet the categorization criteria for medically-important antimicrobials
 - first in-class antimicrobial entities not yet categorized
- A number of measures are in place to help limit the development of resistance to these medically-important antimicrobials (MIAs) to help protect public health and food safety
 - List A ingredients have restrictions for personal importation
 - Requirement for reporting sales volume of List A ingredients for veterinary use
 - Requirement for all importers of List A ingredient for vet use to hold a drug establishment license (including veterinarians and pharmacists)
 - Drugs that are OTC and are made using List A APIs for veterinary use are in the [process of changing to prescription-status](#) (effective date December 1, 2018)

What is an Active Pharmaceutical Ingredient?

pharmaceutical means a drug other than a drug listed in Schedule C (radiopharmaceuticals) or Schedule D (biologics) to the Act.

active pharmaceutical ingredient means an active ingredient that is used in the fabrication of a pharmaceutical.

[See C.01A.001 in the Food and Drug Regulations](#)

DEL Transition Period

The DEL transition period is 14 months: **May 17, 2018 to July 17, 2019**

If you are conducting activities prior to May 17, 2018:

- You may continue to do so without an establishment license
- You are required to submit a complete drug establishment license application by July 17, 2019
- You may continue to conduct activities without a DEL until a decision is rendered on your application

If you are not conducting activities prior to May 17, 2018:

- The transitional provisions included in the regulatory amendment do not apply to you
- You **cannot** conduct licensable activities until you obtain the appropriate drug establishment license

DEL and GMP Implementation Periods

May 17, 2018

July 17, 2019

If you conduct activities prior to May 17, 2018 you may continue to do so – you must submit an application between May 17, 2018 and July 17, 2019.

You may continue to conduct activities until a decision is rendered on your application

You cannot conduct activities without a DEL if you have not submitted an application before July 17, 2019

Establishments that have not commenced activities prior to May 17, 2018 must possess a licence prior to commencing licensable activities

GMP Requirements

Importation considerations

If you began importing veterinary API, including List A APIs ...

... before May 17, 2018

- You may import up to July 17, 2019 as you were previously.
- As of July 17, 2019 you may continue to import if :
 - you have submitted a DEL application prior to July 17, 2019 for Import Pharmaceutical API and/or List A API and your application is under review with Health Canada and your table A is up to date

OR

- You have been issued a DEL for the activity of Import Pharmaceutical API and/or List A API as appropriate

... on or after May 17, 2018

- You will be required to hold a valid DEL for import of API and/or List A API as appropriate prior to commencing importation.



**If you do not comply with the above requirements
you may be subject to refusal at the border**

Veterinary Antimicrobial Sales Reporting Requirements



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Veterinary Antimicrobial Sales Reporting

Why we are collecting this information

Following international best practices, we will be collecting reports on the sale of veterinary antimicrobials considered to be important in human medicine. This information helps:

- give a better understanding of the volume of antimicrobials available for use in animals
- support surveillance and interpretation of patterns and trends of antimicrobial resistance (AMR)
- provide relevant information that could help assess the impact on human health from the use of specific antimicrobials in animals

Who must submit sales reports?

- **Importers** - anyone importing a drug into Canada for sale
- **Manufacturers** - the person who owns the trade name (or other mark controlled by them) and sells the product in Canada
- **Compounders** - individuals who compound a product using APIs on List A. For example, a pharmacist or a veterinarian

Veterinary Antimicrobial Sales Reporting

How to submit sales reports

- An electronic data collection tool is being developed and is intended to be implemented in fall 2018 in collaboration with the Public Health Agency of Canada (PHAC) to facilitate e-reporting
- To facilitate data recording this year, an Excel spreadsheet format with instructions, variable explanation, data entry tabs is available upon request
- **Major fields of data to be collected:** Product information; Species information; Sales information; Ingredient information
- **For questions:** hc.VAMSR-VAMVR.sc@canada.ca

Rules for sales reporting

The first reporting year is 2018, where sales data from January to December 2018 will need to be submitted by March 31, 2019.

Sales reports of drugs on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#) for veterinary use must include:

- the total quantity sold or compounded
- the approximate quantity sold or compounded for each intended animal species

This includes antimicrobials imported or sold in Canada as products for veterinary use that contain an API set out on List A including compounded products.

Veterinary Antimicrobial Sales Reporting

○ Product information

- Drug Identification Number (DIN)
- Brand Name
- Dosage Form
 - oral powder, premix, injectable, etc
- Package size
- Units of package
 - kg, mL, bolus
- ATC_{vet} code

D	E	F	G	H	I
PRODUCT INFORMATION					
Drug Identification Number	Product Name	Formulation	Package Size	Units of Package	ATCVET Code

Veterinary Antimicrobial Sales Reporting

○ Species information

- Animal categories
 - cattle (dairy), cattle (beef), pigs, chickens, turkeys, horses, aquaculture, companion animals, other animal species
- Provide % low and % high estimates of total sales for each species

T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH
SPECIES INFORMATION														
Turkeys		Horses		Aquaculture (Finfish and Shellfish)		Small Ruminants		Companion Animals		Other Animal Species		If known, please provide more details of 'other animal species'	Explanation of how estimates of sales by species are generated	% sold by animal species validation
Low %	High %	Low %	High %	Low %	High %	Low %	High %	Low %	High %	Low %	High %			<i>(automatically calculated - do not enter data in this cell)</i>
0	0	0	0	0	0	0	0	0	0	0	0			0

Veterinary Antimicrobial Sales Reporting

○ Sales information

- Packages sold to distribution centres (provincial)
- Packages sold for direct sales in province (provincial)
- Packages sold for use in Canada (national)
 - Should equal sum of provincial data
- Packages exported (national)

AI	AJ	AK	AL
Packages Sold for use in Canada (national)	Packages Exported (national)	Packages Sold to Distribution Centres within the Province	Packages Sold for Direct Sales within the Province

Veterinary Antimicrobial Sales Reporting

○ Active ingredient information

- Name
- Strength/Strength units
 - mg/kg, IU/mL
- Content of active ingredient in package (in g)
 - package size * strength (*any required conversion factors)
- Kg sold per province
 - total packages sold * content (g) * (1 kg/1000 g)

AM	AN	AO	AP	AQ	AR	AS	AT	AU
INGREDIENT 1								
Active Ingredient Name	Salt Name	Prodrug Name	Strength	Strength units	Conversion Factor for IU (enter '1' if strength units are not IU)	Conversion Factor for ProDrug (enter '1' if not a prodrug)	Content of Active Ingredient in the Package in Grams =package size*strength*conversion factors if needed	kg sold per province

For questions: hc.VAMSR-VAMVR.sc@canada.ca

Introduction to the Drug Establishment Licence (DEL) Application Requirements



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DEL Applications

Health Canada will begin to accept DEL applications for veterinary API starting May 17, 2018

- If you have been conducting activities prior to May 17, 2018, ensure that you clearly indicate on your application that you have been conducting activities and are applying for veterinary API.
- This will help Health Canada can identify you as a company subject to the transition period.



You must be ready for your Health Canada GMP inspection at the time you submit a DEL application



DEL Application forms

- To apply for a DEL you must complete [FRM-0033 – Drug Establishment Licence Application](#) and Table A when applicable.

The form will be updated soon to include fields for the new requirements. The form will be presented in session 2.

- The information required includes:
 - Eligibility under the transition period
 - The addresses of all buildings where licensable activities are conducted
 - The activities conducted at each building
 - Categories of drugs (API and/or List API for veterinary use)
 - The dosage forms of those drugs, and if they are sterile
 - Evidence of GMP compliance
 - Domestic establishment will be subject to a Health Canada GMP Inspection
 - Foreign establishments must submit GMP evidence as per [GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices](#)

DEL Application continued

- The service standard for rendering a licensing decision is **250 days** for applications that are not subject to the transition period.
- Your ability to demonstrate compliance with Good Manufacturing Practices is required in order to issue a DEL
 - That is to say, Part C, Division 2, 3 and 4 of the Food and Drug Regulations
- The outcome of a DEL application is a decision either resulting in the **Issuance of the DEL, the Refusal to Issue, or Issuance with Terms and Conditions**



A Health Canada GMP Inspector must determine that you are in compliance with GMP to be issued a DEL

DEL - Where to get more information

- [GUI-0002 - Guidance on Drug Establishment Licences and Drug Establishment Licensing Fees](#)
- The Drug Establishment Licensing Unit's [*Frequently Asked Questions - Drug Establishment Licensing and Fees*](#)
- If you have any additional questions, please email DEL_Questions_LEPPP@hc-sc.gc.ca

Introduction to Good Manufacturing Practices (GMP) for Veterinary Active Pharmaceutical Ingredients (API)



Purpose

This section of the presentation, will help you understand:

- Who is required to comply with GMP requirements for veterinary active pharmaceutical ingredients (API)
- What is GMP
- What to expect during an GMP inspection
- Where more information can be found

Good Manufacturing Practices

New regulations published on May 17, 2017 in Canada Gazette II will require that veterinary API activities be performed according to GMP:

- fabricate
- package/label
- test
- import
- distribute
- wholesale



Health care professionals who import an API on List A for compounding for veterinary use are required to comply with the requirements for API importers.

Good Manufacturing Practices

The GMP requirements are described in Part C Division 2 of the [Food and Drugs Regulations](#).

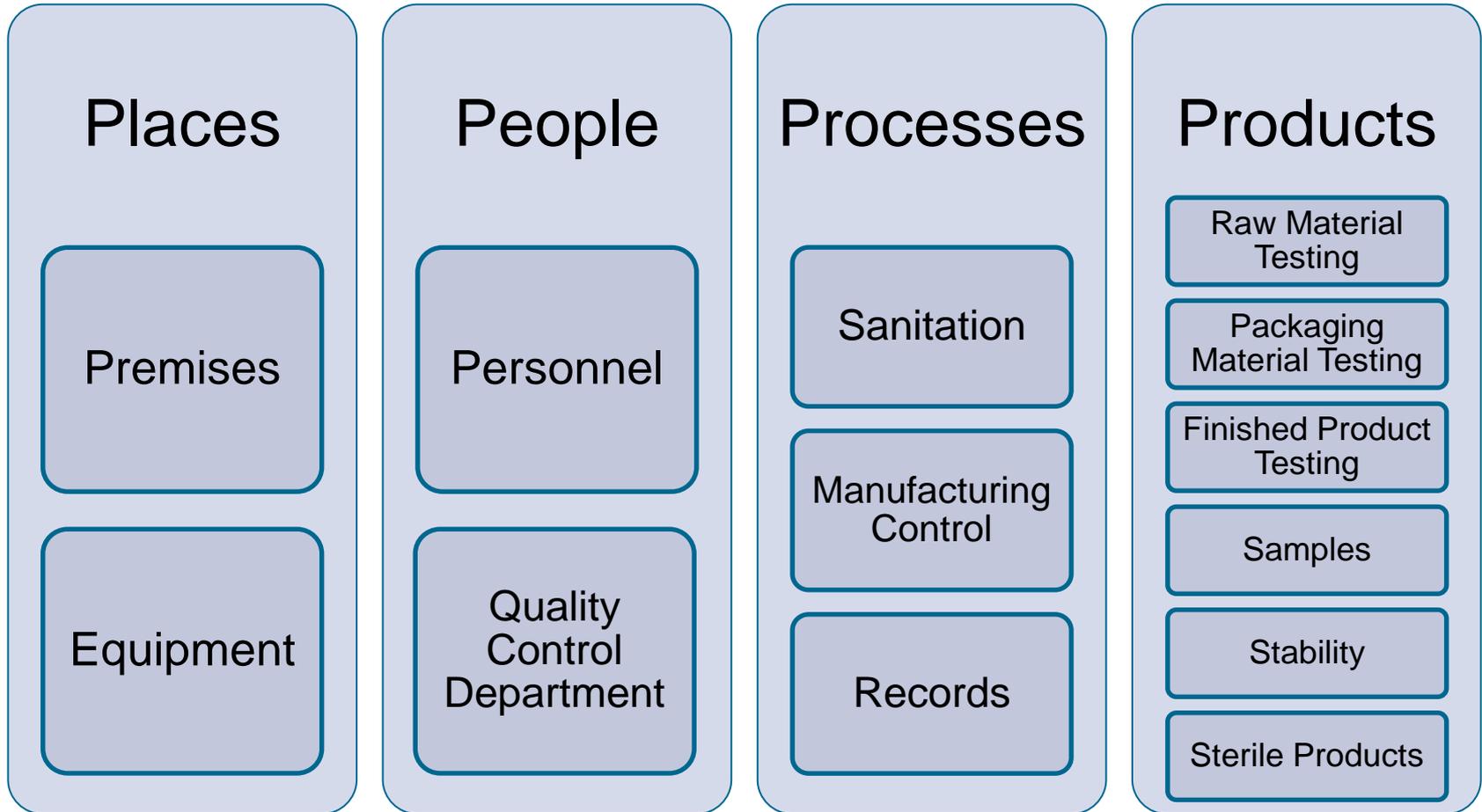
GMP is:

- part of quality assurance
- concerned with both production and quality control
- ensure that drugs are consistently produced and controlled



The GMP requirements for veterinary API come into force on May 17, 2018 — there are no transition periods.

Good Manufacturing Practices



Good Manufacturing Practices

You can find more information on Health Canada's website.

[Good manufacturing practices \(GMP\) for active pharmaceutical ingredients \(GUI-0104\)](#)

- to help you if you fabricate, package/label, test, import, distribute, wholesale, or re-package/re-label APIs (including their intermediates)

[Good manufacturing practices for drug products \(GUI-0001\)](#)

- a new version will be published soon to help you understand API considerations for importers of a finished dosage form

[Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#)

- to help importers understand the type of information that you should submit to list a foreign building on a DEL

Good Manufacturing Practices

You can find more information on Health Canada's website.

[Drug Establishment Good Manufacturing Practices - Pre-Application Package \(Importers, Distributors and Wholesalers\)](#)

- to help you prepare for an initial drug GMP inspection

[Active Pharmaceutical Ingredients - Good Manufacturing Practices - Questions and Answers](#)

- to help with frequently asked questions



Current Health Canada GMP and DEL guidance documents for human API can be applied to veterinary API. The associated guidance documents are being updated as needed. For more help email GMP_Questions_BPF@hc-sc.gc.ca

GMP Inspections

- An initial inspection of an establishment conducting licensable activities is triggered by the receipt of a Drug Establishment Licence Application.
- The scope of the inspection is dependent on the licensable activities being assessed.
- The length of an on-site inspection depends on the activity being conducted, as well as the category and dosage form class of products involved.
- It is important to note that it is expected that all documentation be available on site at your establishment.



Your Licence Application will be refused if Health Canada determines that your site is not ready for an inspection following an assessment of your Drug Establishment Licence Application.



GMP Inspections



Questions

For questions about Drug Establishment Licenses:

DEL_Questions_LEPPP@hc-sc.gc.ca

For questions about Good Manufacturing Practices:

General questions:

GMP_questions_BPF@hc-sc.gc.ca

Questions about foreign building GMP:

Foreign_site_etranger@hc-sc.gc.ca