

Session 2: How to submit an application or an amendment to a Drug Establishment Licence for veterinary active pharmaceutical ingredients

February 15, 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

Information on How to Comply

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

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 around 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)

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 to 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 Transition and GMP Implementation

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**

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



Recap of Session 1

Session 1 on veterinary active pharmaceutical ingredients was intended for those that were not familiar with Good Manufacturing Practices (GMP) to help in understanding:

- 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

Purpose

This session is intended to provide you with additional information to help understand the GMP requirements for those that conduct veterinary API activities:

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



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

Good Manufacturing Practices

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

- provides interpretations to add clarity to the defined requirements for the GMP of APIs and API intermediates
- designed to facilitate compliance by the regulated industry and to enhance consistency in the application of the regulatory requirements



Currently this guide excludes veterinary drugs from the scope, it will be updated in the near future to include veterinary drugs. You can use this guide to understand expectations for veterinary APIs.

Good Manufacturing Practices for API (GUI-0104)

- Harmonised with international GMP requirements applicable to human and veterinary active pharmaceutical ingredients including:
 - European Commission EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines Part II - Basic Requirements for Active Substances used as Starting Materials
 - PIC/S GMP Guide (Part II: Basic Requirements for Active Pharmaceutical Ingredients)



A version of GUI-0104 currently under revision will allow for improved harmonisation such as allowing other standards for ectoparasiticides.

Good Manufacturing Practices for API (GUI-0104)

Important notes:

- API agents and API brokers are considered wholesalers and need to comply with Health Canada's GMP regulatory requirements.
- Health care professionals who import an API on List A for compounding for veterinary use will need to comply with the requirements for an API importer.
- This guide applies to the manufacture of sterile APIs only up to the point immediately before they are made sterile. It does not cover how to sterilize APIs.
- Importers of Finished Dosage Form drugs must also ensure that APIs used in fabrication of their drugs appropriately satisfy regulatory obligations. Such requirements are detailed in other guidance.

Good Manufacturing Practices for API (GUI-0104)

Section	Regulation	F	P/L	T	I	D	W ¹
Premises	C.02.004	✓	✓		✓	✓	✓
Equipment	C.02.005	✓	✓	✓			
Personnel	C.02.006	✓	✓	✓	✓	✓	✓
Sanitation	C.02.007	✓	✓				
	C.02.008	✓	✓				
Raw material testing	C.02.009	✓		*			
	C.02.010	✓		*			
Manufacturing control	C.02.011	✓	✓		✓		
	C.02.012	✓	✓		✓	✓	✓
Quality control	C.02.013	✓	✓		✓	✓	✓
	C.02.014	✓	✓		✓	✓	✓
	C.02.015	✓	✓	✓	✓	✓	✓

F = Fabricator
P/L = Packager/Labeller
T = Tester
I = Importer
D = Distributor
W = Wholesaler

¹The Regulations specify that agents and brokers are considered wholesalers and must follow Health Canada's GMP requirements.

* Where applicable depending on the nature of the activities.

Good Manufacturing Practices for API (GUI-0104)

Section	Regulation	F	P/L	T	I	D	W ¹
Packaging material testing	C.02.016	✓	✓				
	C.02.017	✓	✓				
Finished product testing	C.02.018	✓	✓	*	✓	✓	✓
	C.02.019		✓				
Records	C.02.020	✓	✓	✓	✓		
	C.02.021	✓	✓	✓	✓	✓	✓
	C.02.022				✓	✓	✓
	C.02.023	✓	✓		✓	✓	✓
	C.02.024	✓	✓		✓	✓	✓
Samples	C.02.025	✓					
	C.02.026	✓					
Stability	C.02.027	✓		*	✓		
	C.02.028	✓		*	✓		

F = Fabricator
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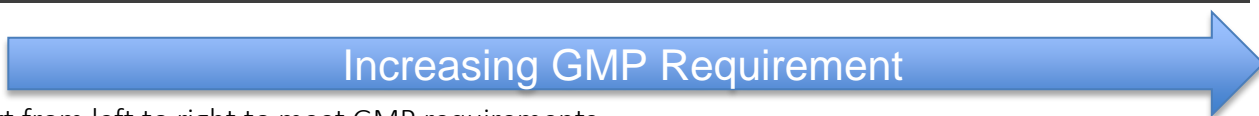
¹ The Regulations specify that agents and brokers are considered wholesalers and must follow Health Canada's GMP requirements.

* Where applicable depending on the nature of the activities.

Good Manufacturing Practices for API (GUI-0104)

- GUI-0104 applies to all the steps in blue

Type of manufacturing	Manufacturing steps ^a				
	1	2	3	4	5
Chemical manufacturing	Production of API starting material	Introduction of API starting material into process ^b	Production of intermediate(s) ^b	Isolation and purification ^b	Physical processing and packaging ^b
APIs derived from animal sources	Collection of organ, fluid or tissue	Cutting, mixing and/or initial processing	Introduction of the API starting material into process ^b	Isolation and purification ^b	Physical processing and packaging ^b
APIs extracted from plant sources	Collection of plants	Cutting and initial extraction(s)	Introduction of the API starting material into process ^b	Isolation and purification ^b	Physical processing and packaging ^b



^a Follow this chart from left to right to meet GMP requirements.

^b These steps are only meant for use at this stage and type of manufacturing.

Good Manufacturing Practices for API (GUI-0104)

- GUI-0104 applies to all the steps in blue

Type of manufacturing	Manufacturing steps ^a				
	1	2	3	4	5
Herbal extracts used as APIs	Collection of plants	Cutting and initial extraction		Further extraction ^b	Physical processing and packaging ^b
APIs made of comminuted or powdered herbs	Collection of plants and/or cultivation and harvesting	Cutting or comminuting			Physical processing and packaging ^b
Biotechnology: fermentation or cell culture	Establishment of master cell bank and working cell bank	Maintenance of working cell bank ^b	Cell culture and/or fermentation ^b	Isolation and purification ^b	Physical processing and packaging ^b
“Classical” fermentation to produce APIs	Establishment of cell bank	Maintenance of the cell bank	Introduction of the cells into fermentation ^b	Isolation and purification ^b	Physical processing and packaging ^b



^a Follow this chart from left to right to meet GMP requirements.

^b These steps are only meant for use at this stage and type of manufacturing.

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 APIs. The associated guidance documents are being updated.

**For more help email
GMP_Questions_BPF@hc-sc.gc.ca**

Good Manufacturing Practices (GMP) – Foreign



Good Manufacturing Practices (GMP) Assessment of Foreign Buildings



- Health Canada assesses the compliance of foreign buildings against Part C, Division 2 of the *Food and Drug Regulations*.
- To add or maintain a foreign building on an importer's DEL, the importer must have evidence to demonstrate GMP compliance.
- The evidence to support the GMP compliance of a foreign building can be:
 - Health Canada foreign building on-site inspection
 - Inspection by a qualified or regulatory authority (paper assessment)

Health Canada Foreign Building On-Site Inspections

- Health Canada has increased the number of foreign on-site inspections it is conducting.
- Health Canada's Drug GMP inspection program has adopted a risk based approach with respect to foreign buildings that manufacture drugs destined for the Canadian market.
- We have adopted this approach to be more agile and present globally while maintaining adequate oversight on domestic establishments
- There are 2 ways in which a foreign building on-site inspection can be initiated:
 - Importer request by submitting Good Manufacturing Practices – Request for Assessment of a Foreign Building Form (0213)
 - Health Canada initiated

Health Canada Foreign Building On-Site Inspections - cont'd

- For a Health Canada initiated on-site inspection, all importers with the foreign buildings listed on their Drug Establishment Licence (DEL) will receive a Health Canada notification of intent to inspect
- The following criteria are considered when selecting sites:
 - type of GMP evidence available for the foreign building
 - foreign buildings compliance history
 - lack of recent GMP evidence
 - medical necessity of the drug product manufactured at the foreign building
 - the date that new GMP evidence is required by
- In both scenarios, if Health Canada's assessment results in a decision to inspect the foreign building, the Foreign Building on-site assessment service agreement form (FRM-0214) must be completed by the importer, Health Canada and the foreign building

Inspection by a qualified or regulatory authority (Foreign Building Paper Assessment)

- Health Canada conducts paper assessments of GMP evidence submitted in support of an application or proactively requested by Health Canada
- Health Canada's [Guidance on Evidence to Demonstrate drug GMP Compliance of Foreign Sites \(GUI-0080\)](#) outlines the evidence required by Health Canada for a paper assessment.
 - Targeted for Canadian importers who want to list a foreign building on their drug establishment licence (DEL).
 - Has been revised and is now available on the Health Canada website as of January 18, 2018.

Scope:

- Drugs for human use
- Drugs for veterinary use
 - Veterinary API
 - AMR (List A)

Inspection by a qualified or regulatory authority (Foreign Building Paper Assessment) cont'd

The type of GMP evidence required is outlined below:

	Required GMP Evidence
FB on FB Annex	Evidence to be submitted with Application
<ul style="list-style-type: none"> Located in MRA country 	<ul style="list-style-type: none"> Certificates of Compliance (CoC)
<ul style="list-style-type: none"> Located in non-MRA country Located in MRA country but products/activities not covered by MRA 	<ul style="list-style-type: none"> Inspection Report from Regulatory Authority (MRA) or Qualified Authority (PIC/S) Corrective action Site Master File
FB on API Annex	Evidence to be submitted upon HC Request
<ul style="list-style-type: none"> Irrespective of location 	<ul style="list-style-type: none"> Inspection Report from Regulatory Authority (MRA) or Qualified Authority (PIC/S) Corrective action Site Master File

Please note: APIs are currently excluded from MRA, however, Health Canada is actively working with regulatory authorities to include APIs in the scope

GMP Evidence

a) **Inspection reports**

- Cover the activities & dosage forms requested
- Recent within **last 3 years**

b) **Corporate/consultant audits**

- When no inspection report by a regulatory/qualified authority within the last 3 years is available, a corporate or consultant audit report may be submitted, provided it meets the requirements outlined in GUI-0080.

c) **Corrective actions**

- Must be signed by a responsible official of the foreign building

d) **Site Master File**

e) **Other evidence**

- May include: Standard Operating Procedures (SOPs), Written Quality Agreements, Annexes/Appendices referred to in the corrective action response(s)

Atypical APIs

Atypical APIs are subject to Divisions 1A and 2 of the FDR; however...

On November 23rd, 2017, Health Canada implemented a more flexible, risk-based approach to reduce regulatory burden for Human APIs* that meet some of the following criteria:

- Low Risk – OTCs and/or topical
- Physical effect - no significant pharmacological effect
- Limited market size – limited exposure
- Used primarily in other industries such as food, chemical, etc...
- Classified as excipients, foods, medical devices, natural health products in other PIC/S jurisdictions

It is the responsibility of:

- API and FDF importers to ensure the quality of atypical APIs imported from abroad
- FDF manufacturer to ensure the quality, safety and efficacy of the drug product

* Until atypical APIs are transferred to a different regulatory framework, Health Canada would apply a lower priority for enforcement actions.

Thank you

- Any questions with respect to GUI-0080 or relating to a Foreign Building, should be sent to:
foreign_site_etranger@hc-sc.gc.ca

Drug Establishment Licence Requirements



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Applying for your DEL

- Complete FRM-0033 - [Drug Establishment Licence Application: Forms and Instructions](#)
- Importers are required to submit a Table A with their application
 - An updated Table A will soon be sent to all DEL holders and people that registered for updates by email.
 - To register for updates send an email to DEL_Questions_LEPPP@hc-sc.gc.ca with subject line “AMR Info Request”.
 - You may also obtain the latest version of Table A by sending an email to DEL_Questions_LEPPP@hc-sc.gc.ca. The updated Table A will be available via email request by May 17, 2018, it will be included in the in the auto-reply

DEL Application – What to apply for

Importers of APIs for veterinary use are required to:

- Apply for a DEL for activity of Import and the applicable drug category(ies)
 - Active Pharmaceutical Ingredient (API) and/or List A API for Veterinary use
- Submit a Table A for all the foreign building that fabricate, package/label and/or test the API you import.

Fabricators, Packagers/Labellers, and Testers of APIs for veterinary use are required to:

- Apply for a DEL for the applicable activities and drug category (API / List A API), however NO Table A is required

Importers of finished dosage form (FDF) drugs for veterinary use are required to:

- Already have a DEL to import pharmaceutical drugs
- Submit an updated Table A that includes all the foreign building that that fabricate, package/label and/or test the API used in the fabrication of the FDF drugs for veterinary use they import.

DEL Application – Transition Considerations

Ensure that you identify your application as a veterinary API application

- Use the cover letter of your application to:
 - Identify that you are submitting an application for veterinary API and
 - State that you were conducting the licensable activities you are applying for prior to May 17, 2018, if applicable
- Make sure to select the veterinary drug class where applicable in Form-0033 and Table A. (A demonstration will be provided in this presentation)

The service standard for rendering a licensing decision on application that are not subject to the transition period is 250 days

- Applications that fall under the transition period will be processed according to a risk based approach as you are authorized to conduct activities without a DEL.

Importers of API will be expected to maintain their Table A up to date while their application is under review.

Canadian building – Transition Considerations

After a DEL application has been submitted to Health Canada, Health Canada will look at your cover letter to verify if you are eligible to the transition period.

For applications that are eligible Health Canada will send you an acknowledgement notice as per the regular process to confirm the application has been received and provide the application number.

After the application has been screened for completeness Health Canada will send you a letter to:

- inform you that the application has been deemed complete and
- that you can continue to conduct activities while Health Canada is reviewing your application.
- For importer of API, an acknowledgement acceptance notice with a copy of your reviewed your Table A listing the foreign building from which you are authorized to import APIs will be included

Health Canada aim to send this letter within 20 business day of the acknowledgement letter.

Applications that are not subject to the transition period will be processed as per the normal process.

Table A – Transition Considerations

Importers of API subject to the transition period will be expected to maintain their Table A up to date while their application is under review.

- When an applicant with an application under review subject to the transition period wants to import a new API or import from a new foreign building, the applicant needs to submit an amended comprehensive Table A including the new API / foreign building.
- The Table A will be reviewed for deficiencies. When no deficiencies are identified an acknowledgement acceptance notice with a reviewed Table A will be issued to the applicant within 20 days of application receipt to replace the previous Table A issued.
 - You can start importing from the new Foreign building once the reviewed Table A has been issued.
 - When deficiencies are identified, the 20 days performance standard does not apply.

Demo - FRM-0033 and TABLE A

API – Best practices

- Contact the Drug Establishment Licensing Unit (DELU) if you are unsure of what needs to be fixed on your Table A in response to a deficiency notice. (Email the officer directly).
- Make sure to enable macros each time you are modifying Table A and add to the table starting in row 7, below the orange bar. This will apply validation rules to your entries and minimize deficiency notices.
- Always send a comprehensive Table A listing all FDF and API with every application.
- Use the pick lists.
- Don't send in a Table A with "N/A" or blanks in required fields. This will result in a deficiency notice and the 20 day performance standard will no longer apply.
- When Inspector ask for revised Table A, always send an up to date Section 5.1 of FRM-0033 with your Table A and send to ELapplicationLE@hc-sc.gc.ca. You may cc. the Inspector on your application.

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

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)</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

Questions?

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