



Friday Five

June 14, 2019

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Health Canada Requirements - Antimicrobials in Veterinary Compounding

To promote prudent use of antimicrobials in food production, Health Canada introduced amendments to the Food and Drug Regulations which will increase oversight of the importation and sales reporting of medically important antimicrobial active pharmaceutical ingredients (APIs) for veterinary use.

Pharmacists, veterinarians or those compounding a drug under the supervision of a licensed veterinarian must hold a drug establishment license (DEL) when importing medically important antimicrobials that are on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#).

Additionally, compounders and importers will be required to report annual sales of these antimicrobials including the total quantity sold or compounded. Please see the following links for more information on the [amendments](#).

This article serves as a reminder that the application deadline for the DEL transition is July 17, 2019.

Professional Development Opportunities

Opioid Replacement Therapy 101 Introduction to Clinical Practice
[June 20 & 21, 2019 \(Thompson\)](#)
[September 13 & 14, 2019 \(Winnipeg\)](#)
[November 7 & 8, 2019 \(Morden/Winkler\)](#)
[December 5 & 6, 2019 \(Winnipeg\)](#)

[The 28th Annual Palliative Care Conference](#)
September 12 & 13, 2019

Online Programs:

[Ordering Lab Tests for Manitoba Pharmacists](#)

Visit www.cphm.ca for more information on [Expanded Scope of Practice](#) training.

[Self-Limiting Conditions Independent Study Program](#)
Visit www.cphm.ca for more information on [Expanded](#)

Please refer to this [Q&A document](#) if you have any questions regarding these requirements.

Vanessa's Law

The Protecting Canadians from Unsafe Drugs Act, also known as Vanessa's Law, was enacted in 2014 to strengthen the regulation of therapeutic products and improve the reporting of adverse drug reactions by healthcare institutions. Vanessa's Law honours the memory of Vanessa Young, a 15-year-old who died in the year 2000, due to an adverse drug reaction to Cisapride.

Vanessa's Law includes a provision for mandatory reporting by hospitals of serious adverse drug reactions (ADRs) and medical device incidents (MDIs), a requirement that will come into force in late 2019. It will require all hospitals to perform mandatory reporting of all Adverse Drug Reactions (ADRs) and Medical Device Incidents (MDIs) to Health Canada within 30 days. The aim is to improve the quality and volume of such reports provided to Health Canada.

It is important to note that medication incident reporting remains separate and available for all Canadians to voluntarily report through [The Canadian Medication Incident Reporting and Prevention System](#).

More information will be shared with members as it becomes available. For additional reading, please see the [Government of Canada Website](#).

Gentian Violet - Health Canada Safety Alert

On June 12, 2019, Health Canada issued a safety alert regarding the potential cancer risk associated with gentian violet. Gentian violet is an antiseptic dye used to treat fungal infections in humans, and is also found in some veterinary drugs.

Health Canada has advised Canadians to stop using all drug products that contain gentian violet, including on animals. Health Canada has also advised Canadians to return gentian violet products to a

[Scope of Practice](#) training.

All PD opportunities are listed on the College website under

[Upcoming Professional Development Opportunities](#)

pharmacy for proper disposal.

Health Canada's alert regarding gentian violet can be found [here](#).

Reminder - Implementation of Sterile and Non-Sterile Compounding Standards

On December 10, 2019, College Council approved the National Association of Pharmacy Regulatory Authorities (NAPRA) Standards for Pharmacy Compounding of **Non-sterile** Preparations with implementation timelines for compliance. Council has approved a 4-phased implementation approach for existing pharmacies in Manitoba, and phase 1 must be complete by April 1, 2020.

Effective April 1, 2019, all new pharmacies in Manitoba must be in full compliance with these NAPRA standards for non-sterile compounding. Please see further information regarding the four phases and compliance timelines [here](#) on the College website.

On February 6, 2017, College Council approved the NAPRA Standards for Pharmacy Compounding of Hazardous and Non-Hazardous **Sterile** Preparations with a 3-phase implementation timeline for compliance. The first two implementation timelines for compliance have now passed (January 1, 2019, and June 1, 2019), and College inspectors are in the process of conducting audits of pharmacies engaged in sterile compounding regarding the implementation of these first two phases. Additionally, inspectors are providing education and guidance regarding the final implementation phase and feedback regarding the implementation of the first two phases. Please see further information regarding the hazardous sterile compounding standards [here](#), and non-hazardous sterile compounding standards [here](#).

In the event that your pharmacy is engaged in sterile compounding and the College has not been in contact with you regarding your pharmacy audit, please contact the College office.

This suite of National Compounding Standards were developed due to, in part, recommendations from the [Thiessen Report](#), following an oncology under-dosing

incident in Ontario and New Brunswick. Additionally, international compounding incidents causing patient harm and death have highlighted the need for current compounding standards to protect patients and compounding personnel.

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The *Friday Five* e-bulletin is published by the **College of Pharmacists of Manitoba** and is forwarded to every licenced pharmacist and pharmacy owner in the Province of Manitoba. Decisions of the College of Pharmacists of Manitoba regarding all matters such as regulations, drug-related incidents, etc., are published in the *Friday Five*. The College of Pharmacists of Manitoba therefore assumes that all pharmacists and pharmacy owners are aware of these matters.

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