

WINTER **2023** 



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## CPhM Holiday Messsage

As the year draws to a close, it's a fitting time to reflect on our journey in providing care to Manitoba's patients throughout the challenges and triumphs of 2023. We see evidence...

### December 8, 2023 Council Meeting Updates

Our recent Council meeting on December 8, 2023, brought forth several updates, changes, and implementations. Highlights from the meeting, as featured...

This Newsletter is published four times per year by the College of Pharmacists of Manitoba (CPhM) and is forwarded to every licenced pharmacist and pharmacy owner in the Province of Manitoba. Decisions of the CPhM regarding all matters such as regulations, drug-related incidents, etc. are published in the newsletter. The CPhM therefore expects that all pharmacists and pharmacy owners are aware of these matters.

The mandate of the College of Pharmacists of Manitoba is to serve and protect the public interest.

Our mission is to protect the health and well-being of the public by ensuring and promoting safe, patient-centred and progressive pharmacy practice in collaboration with other health-care providers.

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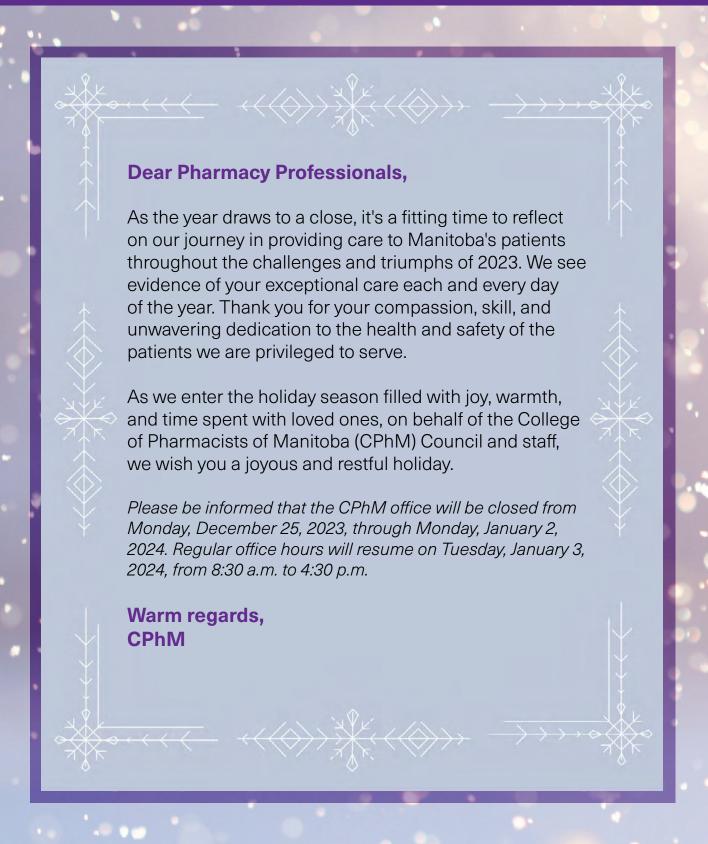








# College of Pharmastis of Manitoba Holiday Message



### **President's Message**

### Dear Colleagues,

On behalf of the College of Pharmacists of Manitoba (CPhM) Council and office staff, I extend warm greetings to you and your loved ones. May this festive season bring you joy, peace, and valuable moments of rest.

Reflecting on the year 2023, it has been a period of reflection and significant progress at CPhM. The Governance Committee, in collaboration with the Council, has undertaken a comprehensive review of our bylaws, refining and modernizing key aspects to better serve our community. To encourage transparency and accountability, CPhM held a 45-day consultation, seeking feedback and comments from stakeholders. Additionally, a virtual town hall will be hosted in the new year, providing an opportunity for the Council to present highlights of the draft bylaws and address questions from participants.

Our recent Council meeting on December 8, 2023, brought forth several updates, changes, and implementations. Highlights from the meeting, as featured in the December 22, 2023 edition of the Friday Five (also available on page 8 of this newsletter), include:

- 1. Approval of amendments to the Patient Profile Practice Direction.
- 2. Standardization of preceptor training.
- 3. Addition of an Extended Practice Pharmacist specialty qualification program.
- 4. Changes to the timing of the Jurisprudence Examination.
- 5. Licensing for out-of-province graduates.
- 6. Discontinuation of Commitment to Professional Development Certificates.
- 7. Extension to the NAPRA Sterile Compounding Exemption for Palliative Care patients with specific guidelines and conditions.

Additionally, I would like to bring your attention to the mandatory webinar on Indigenous Health. Pharmacists are required to view the webinar by December 31, 2023, and pharmacy technicians by May 31, 2024. The following document posted in the 'Announcements' section of your registrant profile, provides essential details for accessing and completing the current and previous mandatory modules: <a href="http://cphm.alinityapp.com/Client/PersonGroup/Open-Doc/1000004?ts=20231219080504">http://cphm.alinityapp.com/Client/PersonGroup/Open-Doc/1000004?ts=20231219080504</a>.

As we anticipate the New Year, let us build on the achievements of the past year and continue advancing pharmacy practice in Manitoba. Take a moment to express gratitude to your team for their dedication and your family for their unwavering support.

May your holiday season be filled with new memories and a chance to recharge. From my family to yours, I wish you a restful and happy holiday!

Warm regards,

#### Jane Lamont



# Education from the Adult Inquest Review Committee Meetings of the Chief Medical Examiner's Office

The College of Pharmacists of Manitoba attends Adult Inquest Review Committee meetings at the Chief Medical Examiner's Office to review deaths which may have involved prescription drugs, focusing on opioids and other drugs of abuse. A de-identified case study based on information obtained from these meetings is presented in each Newsletter to provide an opportunity for education and self-reflection for all pharmacists.

#### Introduction

ND is a 61-year-old male (BMI 28 kg/m2) who was found dead in his apartment on October 13, 2022. There was alcohol in the apartment and his prescription medications appeared to have been taken appropriately. His past medical history included hypertension, right hemithyroidectomy, hyperlipidemia, gastroesophageal reflux disease, major depressive disorder, anxiety, borderline personality disorder, usage of a CPAP, tobacco smoking, "heavy" alcohol use, suicidal ideation, and a medication overdose requiring intubation and ICU admission in 2014. The manner of death was determined to be accidental with the immediate cause of death being combined toxic effects of ethanol, venlafaxine, codeine, trazodone, and zopiclone.

#### Results

The following chart represents the results of the toxicology report. Drugs that were above the therapeutic range are indicated by an asterisk (\*):

Drug	Level in blood (ng/mL)	Therapeutic Range (if applicable) (ng/mL)		
Ethanol	250 mg/dL	N/A		
Codeine (free) Morphine (free)	26 0	10-100 10-80		
Trazodone*	1250	500-1200		
Venlafaxine* O-desmethylvenlafaxine	648 722	62-138 118-252		
Zopiclone	23	25-65		

Of note: tricyclic antidepressants and selective serotonin and norepinephrine reuptake inhibitors undergo post-mortem redistribution and therefore levels can be quite significantly elevated in the toxicology report. This, in addition to the length of the post-mortem interval, affect the interpretation of the post-mortem toxicology.

ND's DPIN history below includes a summary of medications relevant to the toxicology report from the month prior to death:

Generic Name	Date Dispensed	Strength	Quantity	Days' Supply	Prescriber	Pharmacy
Venlafaxine XR	October 10, 2022 October 3, 2022 September 26, 2022 September 19, 2022	150+37.5mg	7 7 7 7	7 7 7 7	Dr. A	ABC Pharmacy
Zopiclone	October 10, 2022 October 3, 2022 September 26, 2022 September 19, 2022	5mg	7 7 7 7	7 7 7 7	Dr. A	ABC Pharmacy
Trazodone	October 10, 2022 October 3, 2022 September 26, 2022 September 19, 2022	100mg	21 21 21 21	7 7 7 7	Dr. A	ABC Pharmacy
Acetaminophen/ caffeine/codeine	October 10, 2022 October 3, 2022 September 26, 2022 September 19, 2022	300/15/30mg	56 56 56 56	7 7 7 7	Dr. A	ABC Pharmacy

#### **Discussion**

The immediate cause of ND's accidental death was determined to be combined toxic effects of ethanol, venlafaxine, codeine, trazodone, and zopiclone. ND had a known history of "heavy" alcohol use. This case will focus on the effects and concerns of combining alcohol with medications and the important role medication counselling can play to inform patients of potential risks.

Alcohol is a depressant that can affect thinking, behaviour, breathing, and heart rate.¹ The effect that alcohol has on the body can differ depending on whether the use is acute or chronic.² Acute alcohol consumption can lead to disinhibition, relaxation, euphoria, agitation, drowsiness, impaired cognition, judgment, and memory, and perceptual and motor dysfunction. Chronic use results in an increased capacity to metabolize alcohol, central nervous system (CNS) tolerance, and physical and psychological dependence may also occur. Regarding pharmacological effects, acute alcohol use decreases hepatic metabolism of other drugs via competition for microsomal enzymes, whereas chronic alcohol use increases hepatic metabolism of co-administered drugs². Metabolism takes place in the liver mainly by alcohol dehydrogenase, CYP2E1, and CYP450 reductase, and by CYP3A4 and CYP1A2. In cases of chronic heavy alcohol use, the activity of CYP2E1 is increased 10-fold.² Drug interactions with alcohol use therefore will vary with acute versus chronic alcohol use.

Drug interactions with alcohol can occur both pharmacodynamically or pharmacokinetically. ND was on multiple medications where drug interactions would have been a concern with alcohol use:

- 1. <u>Venlafaxine XR</u> Alcohol consumption can lead to "dose dumping" in various extended-release formulations of medications, where the rate of drug release is increased, increasing the risk of overdose.<sup>3</sup> Some extended-release SNRI formulations have displayed "dose dumping" by in vitro data and thus prescribing information recommends avoiding concomitant use of alcohol.<sup>4</sup>
- Zopiclone Alcohol should be avoided by patients taking Z-drugs due to the additive CNS effects and increased risk of complex sleep-related behaviours (e.g., sleep-driving, eating, making phone calls).<sup>3</sup>

- Trazodone Trazodone, in combination with other CNS depressants such as alcohol, creates an additive sedative effect.<sup>4</sup>
- **4.** <u>Codeine</u> Opioids, in combination with alcohol, result in additive CNS depressant effects. In high doses, there is also a risk of respiratory depression.
- 5. <u>Acetaminophen</u> The acetaminophen metabolite, N-acetyl-p-benzoquinoneimine (NAPQ), is hepatotoxic and chronic alcohol use can increase its blood levels due to increased metabolism of acetaminophen by CYP2E1.<sup>3</sup> Acute, large consumptions of alcohol can increase the risk of liver toxicity, similar to chronic use.

Adults who have three or more alcohol drinks per day are at risk of liver damage when also taking acetaminophen regularly.<sup>3</sup>

Certain populations of patients may be at an increased risk of experiencing an alcohol-drug interaction. For example, elderly patients are at a higher risk for alcohol-drug interactions as they are more likely to metabolize alcohol at a slower rate and are also at a greater risk of falls and injury with alcohol use itself. As well, it is important to be aware of the increased risk of drug toxicity in patients with alcohol-induced liver impairment or cirrhosis. Blood alcohol levels will also vary depending upon gender, age, and body fluid volume/fat ratio. Furthermore, CNS depressants (especially a combination of sedating agents) should be avoided in individuals with sleep apnea or who require CPAP (as in the case patient), as these agents may increase risk of mortality.

When counselling patients on medications, it is important to remember to ask patients about their alcohol intake and act and/or caution, when appropriate, on concerns present given the medications they are taking, including OTC medications. Patient profiles should be updated with this information, as outlined in the <a href="Patient Profiles">Patient Profiles</a>
<a href="Patient Profiles">Practice Direction</a>. Should a pharmacist discover a potential drug therapy problem, such as an alcohol-drug interaction, appropriate intervention must be taken to help ensure patient safety.

The Canadian Centre on Substance Use and Addiction has <u>screening and treatment</u> resources that pharmacy professionals may find helpful in their practice. Additionally, pharmacists can review the Canadian Clinical Guideline on <u>High-Risk Drinking and Alcohol Use Disorder</u>, developed in partnership between the Canadian Research Initiative on Substance Misuse (CRISM) and BC Centre on Substance Use (BCCSU). The guideline provides 15 evidence-based recommendations to reduce harms associated with high-risk drinking and to support people's treatment and recovery from alcohol use disorder.

#### References:

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### **December 8th Council Meeting Updates**

## Amendments to the Patient Profile Practice Direction

In 2014, the College of Pharmacists of Manitoba Council (Council) implemented a <u>policy</u> on practice directions, which includes the requirement for assessment and regular review at a minimum of every 5 years.

In accordance with the Practice Direction Policy, Council has approved amendments to the Patient Profile Practice Direction (Practice Direction) at their December 8, 2023, meeting. The approval of the amended Practice Direction follows several reviews by the Standards of Practice Division of the Quality Assurance Committee (the committee), a public consultation in the fall of 2022 and collaboration with the Rainbow Resource Centre. CPhM thanks the committee, everyone who provided feedback during the consultation period, and the Rainbow Resource Centre for their feedback and engagement.

#### The amendments include:

- Changes to the mandatory information that must be recorded on a patient profile, and
- The addition of an appendix developed in collaboration with the Rainbow Resource Centre to support pharmacy professionals in delivering inclusive care to gender diverse patients. \*

The amended Practice Direction is available on the <u>CPhM website</u> and the individual amendments to the Practice Direction are outlined in detail <u>here</u>.

The amended Practice Direction is now in effect; all pharmacy professionals must familiarize themselves with the new requirements.

\*CPhM is exploring potential future professional development opportunities for pharmacy professionals to help promote pharmacy environments that are safe and inclusive for 2SLGBTQ+ and gender diverse patients.

### **Required Preceptor/Supervisor Training**

As part of CPhM's Strategic Plan for 2021-2024, Council set a goal of standardizing preceptor training. As of March 1, 2024, all CPhM preceptors of post-graduate interns and supervisors of pharmacy technicians-in-training completing structured practical training programs must complete one of the following approved programs and complete the listed modules:

### Dalhousie Faculty of Health Professions Preceptor eLearning Course

- Module 1 The Role of the Preceptor
- Module 3 Evaluation and Feedback
- Module 4 Supporting Students' Learning Needs
- Module 6 Equity, Diversity and Inclusion

#### **University of Western Ontario**

#### **Preceptor Education Program**

- Module 2 Anti-Oppressive Practices
- Module 3 Developing Learning Objectives
- Module 6 Feedback and Evaluation
- Module 7 Successfully Navigating Conflicts

#### OR

For those who are also preceptors of university pharmacy students and pre-graduate interns, University of Manitoba, Rady Faculty of Health Sciences, College of Pharmacy – Preceptor Development Program Modules

 All modules as required by the College of Pharmacy at time of completion.

Time spent completing the modules are eligible as accredited learning since these programs are provided by Canadian Universities and can be claimed as accredited continuing education units (CEU) in the online PD Log. Preceptors/supervisors who have previously completed one of the above approved programs will not be required to redo the program. A declaration stating completion of a program will be required when applying as a preceptor/supervisor. Individuals are encouraged to complete the required training in advance.

### Addition of Specialty Qualification Program for EPPh Registration

Council approved the American Academy of HIV Medicine: HIV Pharmacist (AAHIVP) certification as an additional Extended Practice Pharmacist (EPPh) specialty qualification program under section 96(g) of the Pharmaceutical Regulation.

An EPPh applicant with this certification must be currently practicing and must have practiced for at least 1,000 hours within the specialty and in a collaborative healthcare setting in the two years before applying for EPPh registration. For more information on how to attain an EPPh designation and the current list of other approved specialty qualification programs, please see the Extended Practice Pharmacist webpage.

#### **Timing of the Jurisprudence Examination**

A motion was passed to allow for pharmacist and pharmacy technician applicants to complete the Jurisprudence (JP) Exam at any time after their application has been submitted to and approved by CPhM. This gives applicants more flexibility and may potentially prevent delays in licensing or listing.

Applicants are still required to complete the JP Modules prior to attempting the exam, however, they may now attempt the exam at any point throughout their internship or structured practical training (SPT) program. The JP Exam must be successfully completed prior to licensure/listing.

# Licensing of Out-of-Province Graduates of a Canadian CCAPP-Accredited Pharmacist Degree Program

Out-of-province pharmacist graduates of a Canadian CCAPP-accredited pharmacy program, who have not been licensed in another Canadian jurisdiction previously, are now able to register and license with CPhM without first licensing in their province/territory of graduation, provided they meet the licensing requirements. This ensures qualified applicants are licensed in Manitoba faster. These applicants must successfully complete a minimum 200-hour internship in Manitoba with an approved preceptor prior to licensure.

For more information, please visit the <u>Pharmacists</u> <u>from Inside Canada webpage.</u>

### Discontinuation of Commitment to Professional Development Certificates

Council made the decision to discontinue the life-long learning recognition program that occurred in conjunction with professional development (PD) obligations that pharmacists are required to fulfill annually. The certificates will be awarded one last time in January for the 2022-2023 PD year.

This is in line with the decision Council made earlier this year to discontinue all awards and recognition programs to ensure impartiality and maintain public trust and confidence.

CPhM Council commends those who have strived to acquire significantly more PD than the minimum 25 CEU per reporting cycle. PD is an important aspect of maintaining competency throughout a professional career.

## **Extension to NAPRA Sterile Compounding Exemption for Palliative Care Patients**

CPhM Council has again approved an extension of the exemption for the drawing-up of comfort care medications for Palliative Care patients in a setting that does not meet the NAPRA Model Standards for Sterile Compounding. Council reviewed the Sterile Compounding Exemption for Palliative Care survey results, along with other information, to inform their decision. Thank you to all the respondents who participated in the survey.

Council will review the exemption again prior to the **new expiry date of January 1, 2026**. Any pharmacy or pharmacist that is considering the utilization of this exemption must be knowledgeable and fully compliant with the following requirements:

## When deciding if the service should be provided:

- The patient must be registered with the palliative care program.
- The medications should be non-hazardous, and the manipulation be low risk (as defined by NAPRA) and prepared from a commercially available sterile source only.
- The preparation should be only a single manipulation (i.e., pre-filling a syringe).
- All possibilities of training a caregiver or family member to draw up medication should be exhausted first before contemplating this option.
- The physician determines that this is the only viable method of effective treatment of the patient and the prescription indicates "for emergency use."
- The benefit vs. risk favours rapid access to the medication.

## Once the decision has been made to provide the service:

 A process for obtaining informed consent must be implemented and followed. This must include a meaningful discussion with the patient/caregiver/ decision-maker on associated risks and alternatives of the provided pharmacy service.

- The product should be monitored for signs of potential contamination at draw-up, and further education should be provided to the patient's agent to monitor before administration.
- Preparation should take place in a designated compounding area following the standards for preparing immediate use preparations (see NAPRA Model Standards for Sterile Compounding).
- The compounder must don minimum personal protective equipment (PPE), including but not limited to sterile gloves (or gloves that have been disinfected with sterile alcohol) and a medical grade mask.
- The preparation must be performed by a pharmacist or regulated pharmacy technician.
- The preparation is limited to a two day supply that must be labelled with a maximum beyond use date of 48 hours from the point of preparation.
- The non-compliant pharmacy is limited to supplying a maximum of 6 days (three occurrences under this exemption).
- Supply of medications beyond the limits must occur from a NAPRA compliant facility. The pharmacy must refer the patient to a compliant facility or obtain medications prepared from a compliant facility.
- The product must be stored appropriately at the pharmacy, and education must be provided to the patient's agent on storage at home.

Prior to consideration of using the above exemption, it is imperative that pharmacists make every effort to seek the services of, or refer a patient to, a pharmacy that can provide sterile compounding that fully meets the NAPRA Model Standards for Sterile Compounding. This is considered ideal, best practice, and in the best interest of patient safety. The exemption is intended to provide timely access to necessary medications in order to offer the pharmacist and patient/caregiver time to source out fully compliant sources of the drug product.

### **In Memorium**

