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MicroSCOPE



CompEX Edition, January 2023

Hi !

Welcome to the latest issue of MicroSCOPE – CompEX Edition.

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Reminder: Expectation for all Pharmacies

Recently, many Level B pharmacies have advised they are receiving prescriptions for simple Level A compounds transferred from another pharmacy and patients are saying that the original pharmacy advised that the pharmacy can no longer compound.

As a reminder *The Pharmacy and Pharmacy Disciplines Act*, section 23 states:

Authorized practices

23 (1) No person other than a licensed pharmacist, licensed pharmacy technician or intern practising under the supervisions of a licensed pharmacy or licensed pharmacy technician, may prepare, compound, dispense or sell drugs in Saskatchewan.

Compounding is an authorized practice that has been granted to pharmacists, pharmacy technicians and pharmacy interns under the supervision of a pharmacist or licensed pharmacy technician. The expectation is that the public should be able to receive a Level A compound at any pharmacy in Saskatchewan in a safe manner that meets the practice standards.



Advertising for Compounds or Compounding Services

With the NAPRA Model Standards for Compounding being adopted in Saskatchewan, members should consider how this legislation impacts advertising practices around compounding services or specific products.

Since compounds are pursuant to a prescription as per the Food and Drug Regulations (C.01A.002) Health Canada's [Policy on Manufacturing and Compounding Drug Products in Canada](#), any compounded drug is covered under Health Canada advertising regulations related to prescription products. Advertising for compounding services is regulated under the SCPP Regulatory Bylaws and Code of Ethics.

All pharmacies in Saskatchewan are required to meet the NAPRA Model Standards for Compounding and be able to compound at a level A standard. Compounding is an authorized practice under *The Pharmacy and Pharmacy Disciplines Act*.

Field Officers have seen recent examples of pharmacy advertising relating to compounding services and compounded products that do not meet the regulation standards.

Print or online media articles, as well as statements posted through social media platforms, would also be considered advertising and be subject to the same standards.

Code of Ethics

8. A member shall be governed in advertising practices by the highest level of professional integrity.

SCPP Regulatory Bylaws Part J Section 17 Advertising

(2) General Prohibition. No pharmacist, pharmacy technician, or any firm, corporation, partnership, organization, or clinic operating a pharmacy, shall publish, display, distribute, or use or cause or permit, directly or indirectly, the publication, display, distribution or use of any advertisement, announcement or information related to professional services, which:

(a) as a result of its content or method or frequency of dissemination, may be reasonably regarded as likely to demean the integrity or dignity of the profession or bring the profession into disrepute; (b) includes information that: (i) is false, misleading, fraudulent, deceptive, ambiguous or confusing or likely to mislead or deceive the public because, in context, it makes only partial disclosure of relevant facts; (ii) is not relevant to the public's ability to make an informed choice, or is not verifiable by facts or can only be verified by a person's personal feelings, beliefs, opinions or interpretations; (c) is likely to create expectations of favourable results or to appeal to the public's fears; or (d) makes any reference to the prices, fees or services of any other member or pharmacy or which would be reasonably regarded as making such reference.

Pharmacies should review their advertising policies and existing advertisements to ensure that all legislative requirements, both federal and provincial, are followed and that the Code of Ethics is adhered to when determining any advertising campaigns.

[Learn more](#)



Policy 51 – Anticipatory Compounding and Compounding Pursuant to a Prescription

Health Canada Policy 51 is a key document that provides a policy framework to assist regulators in distinguishing between compounding and manufacturing activities of drug products in Canada.

This policy applies to all scheduled drugs regulated under the *Food and Drugs Act* and over-the-counter drugs.

When a pharmacy's historical data shows that they consistently fill an average number of prescriptions for the same compound regularly, the pharmacy can prepare a batch of the compound in anticipation of filling those prescriptions.

For example, a pharmacy's data shows it consistently dispenses an average of four prescriptions of diclofenac 10 per cent every two weeks. The pharmacy could prepare a batch once every two weeks in anticipation of filling four prescriptions.

This is considered anticipatory compounding and not manufacturing. When a pharmacy prepares these small batches in anticipation of filling prescriptions, the pharmacy must assign in-house, pharmacy specific lot numbers to ensure tracking of the batch in reference to the lot that was dispensed to an individual patient.

As outlined in prior communications, compounding must be pursuant to a prescription as per the Food and Drug Regulations (C.01A.002) and Health Canada's Policy 51. This includes when all the ingredients of the compound are over-the-counter products.

Compounding should only be done if there is a therapeutic need or lack of product availability and should not be done solely for economic reasons for health care professionals.

Please see [prior communication](#) on prescribing compounded products by pharmacists.



Insanitary Conditions

In addition to complying with the NAPRA Model Standards for Pharmacy Compounding, there is the responsibility for ensuring both the compounding area/room and the dispensary as a whole maintain a distinct level of cleanliness as a business providing health care related services.

As part of ensuring the quality and integrity of the compounds prepared within the pharmacy and dispensed to our patients, it is integral to maintain sanitary environments.

Although product sterility is not a requirement for non-sterile compounded preparations, it is possible for non-sterile preparations to become contaminated at a level that can cause patient harm when compounded within an insanitary environment.

As outlined in Part I, section 11 of the *Food and Drugs Act*:

Unsanitary manufacture, etc., of drug

11 No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions.

As published in the August 2022 edition of SCOPe, there have recently been a number of calls and complaints to the SCPP Complaints team from the public related to concerns over pest infestations in pharmacies. In addition to pest infestations, other examples of insanitary conditions in pharmacies would be:

- Other animals (e.g., dogs) or evidence of their presence;
- Visible contamination (e.g., bacteria, mold) in the area or on equipment;
- Foreign matter visible and present (e.g., rust, glass shavings, hairs, paint chips, dust); or
- Standing water or evidence of water leakage.

The SCPP Field Operations team has recently adopted the use of the U.S. Department of Health and Human Services Food and Drug Administration document, [Insanitary Conditions at Compounding Facilities](#) for reference and guidance on defining and identifying unsanitary conditions within pharmacies both in compounding areas/rooms and the dispensary as a whole. This document outlines insanitary conditions applicable to both sterile and non-sterile compounding.



CompEX Central

See SCPP's dedicated CompEX page with videos, webinars, relevant documents, and newsletters.

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The profession of pharmacy is continually evolving. Information in past publications may likely be outdated, and it is vital and incumbent on pharmacy professionals to seek out the most updated version of SCPP policies, guidelines and [bylaws](#) in more [recent publications](#), the [news section](#), and the [Reference Manual](#). SCPP emails and newsletters are official methods of notification to pharmacists and pharmacy technicians licensed by the College, providing you with timely information that could affect your practice. If you unsubscribe you will not receive important news and updates from the College, including mandatory requirements. Make sure you get the information you need to practise legally and safely by reading College newsletters and ensuring SCPP emails are not blocked by your system.

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