

May 16, 2019

In This Issue

Risk assessment overview
video (now online)

Renovation alternate solution
for Level A standards

Glove box cleaning guidelines

Gap analysis checklist and
pharmacy declaration deadline

Veterinary compounding
required to meet standards

CompEX webinar

Continuing Education

**SCPP PhT Graduation
Luncheon 2019**
May 24, 2019 - Saskatoon

**Pediatric Acute-Onset
Neuropsychiatric Syndrome
(PANS) Prairie Conference
"Personal Medicine"**
May 30-31, 2019 - Saskatoon
[More info](#)

Pharmacy Experience 2019
June 3-5, 2019 - Toronto
[More info](#)

**SCPP BSP Convocation
Luncheon 2019**
June 6, 2019 - Saskatoon

Welcome to the CompEX Program



Risk Assessment Overview

In our continued work to help our members comply with the NAPRA Model Standards for Pharmacy Compounding, SCPP has produced an in-depth, instructional risk assessment video that walks you through the steps and considerations of completing a risk assessment that includes an example using methadone, providing members with a clear path to understand the determination of Level B for methadone. The link to the video has been provided below, but you will also find it under the CompEX section on the SCPP website.

[Risk Assessment Overview: Methadone \(Video\)](#)

Methadone

SCPP has been working with DPEBB regarding the possibility of Methadose® being added to the formulary. At this point the Drug Plan is fairly confident that Methadose® will be funded on or before the December 31, 2020 deadline, when all pharmacies must be compliant with the NAPRA Model Standards for Pharmacy Compounding.

There is still a possibility that Methadose® will not be approved; therefore, members need to make a decision to renovate or not on their own, taking

For up-to-the-minute information, news and events, visit the homepage of the SCPP website: www.saskpharm.ca.

MicroSCOPE is published by the Saskatchewan College of Pharmacy Professionals (SCPP) and is emailed to all active members of the College. As the newsletter includes decisions on matters such as regulations, drug schedule changes, etc., SCPP expects all members are aware of these matters.

into consideration what type of services they want for their pharmacies and practice now, and in the future.

Level A Solution

An alternative approach to meeting Level A standards if renovating your pharmacy is not possible due to space limitations

If the completion of a risk assessment identifies that your pharmacy's non-sterile compounding falls within a Level A classification, the best practice is to assess your dispensary's compounding area and if space allows for it, to create a separate compounding area that is away from the foot traffic of the main area of the dispensary and far enough away from patient drop-off and patient pick-ups counters.

If it is identified that an appropriate, Level A compliant, separate area cannot be achieved, an alternate option to meet compliance is to use a portable glove box. The glove box defines a separate area for compounding activities to be performed in, while keeping the preparation unaffected by the surrounding environment. Compounding personnel will still be expected to wear proper personal protective equipment, and counter tops and flooring will still be expected to be NAPRA compliant.

Glove Box Cleaning Guidelines

When choosing to use the Level A glove box option, you will want to ensure that the cleaning solutions you use are appropriate and compatible with the glove box you plan to purchase. Some cleaners can actually cause materials to break down. Using appropriate and compatible cleaning solutions will ensure the longevity and integrity of your glove box.

A common "cleaner" of choice that is seen in many pharmacies is isopropyl alcohol.

Please be reminded that isopropyl alcohol:

- does not have any cleaning properties
- is considered a disinfectant when used following proper cleaning activities, but is not always an appropriate disinfectant as it does have properties that can degrade certain materials (i.e. acrylic)

Many glove boxes are made of acrylic, which is not compatible with the use of isopropyl alcohol. When choosing and purchasing a glove box, ensure that the manufacturer is consulted as to how the glove box should be properly cleaned and which solutions are ideal for use.

Gap Analysis Checklists & Pharmacy Declaration

Once members have identified what level of non-sterile compounding their practice falls into, they can use the Gap Analysis Checklist to help them identify the non-compliant areas. These will be the specific items they need to do to reach compliance. The other benefit of the checklist is to identify specific areas that will require extra guidance from the Compounding Inspector.

These checklists will be available on the website for pharmacies to complete periodically as they progress through the implementation process

Reminder - Pharmacy Declarations and Gap Analysis Checklists to be submitted by the end of June.

By the end of June, pharmacies will be expected to have submitted their Pharmacy Declaration and a Gap Analysis Checklist to SPP either by fax at 306-584-9695 or email at info@saskpharm.ca. Gap Analysis Checklists and the Pharmacy Declaration will also be emailed out directly to Pharmacy Managers in the coming week.

- [Pharmacy Gap Analysis - Non-Sterile Compounding](#)
- [Pharmacy Gap Analysis - Non-Hazardous Sterile Compounding](#)
- [Pharmacy Gap Analysis - Hazardous Sterile Compounding](#)
- [Pharmacy Compounding Declaration](#)

Do You Do Veterinary Compounding?

SPP would like to remind members of regulatory changes to [Food and Drug Regulations](#), meant to ensure the responsible use of antimicrobials in animals, which may affect you if:

- You import active pharmaceutical ingredients (APIs) that are set out on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#); and/or
- You are a pharmacy professional who compounds antimicrobial drugs using APIs on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#) for animal use.

The increased oversight on APIs for veterinary use requires:

- manufacturing according to good manufacturing practices (GMPs)
- persons who fabricate, import, package, label and test active pharmaceutical ingredients (APIs) for veterinary use to hold a drug establishment licence (DEL)
- pharmacists, veterinarians or those compounding a drug under the supervision of a licensed veterinarian to hold a drug establishment license (DEL) when importing medically important antimicrobials that are on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#).

Health Canada has established a 14 month transition period to obtain a DEL. If you were already performing activities with respect to API for veterinary use before May 17, 2018, then you must submit a complete DEL application by July 17, 2019. If you were not already undertaking these activities before May 17, 2018, then you cannot conduct licensable activities until you obtain an appropriate DEL.

CompEX Webinar

SPP will be hosting a CompEX webinar in the very near future to give members an opportunity to ask questions about the program, requirements, etc. This will be an excellent way to come together to learn from each others, questions that will be answered by Brittany Sharkey, your CompEX Coach and Compounding Field Officer. Stay tuned for more information about the date and time for this online event.

Resources To Assist You

WEBSITE

- You will find a CompEX section through the Professional Practice tab on the SCPP website, www.saskpharm.ca

Other Channels

- A Webinar date and time is being determined. Stay tuned for further details
- FAQ Sheet will be posted to the website
- Your implementation coach, Brittany Sharkey, is just a phone call or email away to assist you, Brittany.Sharkey@saskpharm.ca or phone at 306-584-4330