SASKATCHEWAN
COLLEGE OF PHARMACY
PROFESSIONALS

Emergency Enabled Prescribing Authority – Therapeutic Substitutions for ARB Recall

To protect the health and safety of patients in extraordinary circumstances, amendments have been made to the Saskatchewan College of Pharmacy Professionals (SCPP) regulatory bylaws to temporarily expand pharmacist prescribing authority. When enacted, these bylaws permit pharmacists in the retail community setting, to perform therapeutic substitutions (TS) outside of a Collaborative Practice Agreement (CPA), within the terms and conditions set by the Registrar as per Council policy (see Therapeutic Substitutions in Extraordinary Circumstances (TS Policy).

Like other emergency exemptions, these bylaw provisions are enacted at the discretion of the Registrar, and in collaboration with the Ministry of Health, the College of Physicians and Surgeons of Saskatchewan (CPSS), the Saskatchewan Registered Nurses Association (SRNA) and other health system stakeholders.

The Registrar has enacted SCPP regulatory bylaw section 10(5)(e) of Part K to address the current Health Canada recall of multiple angiotensin II receptor blockers (ARBs). This permits licensed pharmacists to prescribe therapeutic substitutions outside of a CPA, within the terms and conditions, specified by the Registrar as per Council policy.

Terms and conditions that apply to all pharmacists in the retail community setting, prescribing TS within a CPA (normal provisions) and without a CPA (emergency provisions)

- Professional Accountability for Prescribing
- Maintaining the Collaborative Practice Environment
- Prescriptive Authority Decision Making Framework (see Therapeutic Substitutions Appendix A in Extraordinary Circumstances for its application to current ARB Recall)
- Standards of Practice for Pharmacist Prescribing

Additional requirements that apply to pharmacists prescribing TS under emergency provisions during current ARB recall

- Time-bound: Effective June 2, 2021, and until March 31, 2022. Subject to change, based on the circumstances (i.e., shortened or extended).
- Performed by licensed pharmacists only (extended/student pharmacist interns are not authorized).
- Patient group: Patients affected by the ARB recall only.
- Prescribing requirements for therapeutic substitution outside a CPA (TS policy, section 5) must be based on reputable evidence-based clinical guidelines (e.g. medSask), however:
    - May only occur within a group of drugs that share a mechanism of action (MOA) or chemical structure which is clinically meaningful based on credible authorities (e.g., WHO ATC classification system); AND
    - On label usage only (i.e., for indications on the official drug product monograph). Note: some of the recommendations in the credible guidelines may not be permitted by Council on-label usage policy.
- Additional training required: none
- Documentation, communication, and notification as specified in the Therapeutic Substitution PAR (TS PAR) (see question 9 below)
- Follow required procedures (see TS PAR and TS Policy, section 6)
- Monitor SCPP communications from the Registrar for more direction as the situation changes.

Pharmacists Prescribing Therapeutic Substitutions within CPAs (Normal Provisions)

Some pharmacists may also be prescribing TS for the ARB recall **within a CPA**, including:

- **Pharmacists in the retail community pharmacy setting, who are prescribing within a CPA**
- **Pharmacists prescribing TS within a publicly funded health care setting** (i.e., Saskatchewan Health Authority (SHA) and the Saskatchewan Cancer Agency (SCA)

SCPP requirements for these pharmacists are also included in this document.

EXTRAORDINARY CIRCUMSTANCES AND STAKEHOLDER RESPONSE

Q1 What is the extraordinary circumstance and the response planned by the SCPP, the CPSS, the SRNA and the Ministry of Health?

Extraordinary Circumstance:

- On May 30, 2021, Health Canada recalled multiple lots of irbesartan, losartan, and valsartan, after tests found an azido impurity above acceptable concentration limits. Not all lots have been impacted, however, it may affect supply of multiple angiotensin II receptor blockers (ARBs) needed by Saskatchewan patients.
- While Health Canada reports no immediate risk to patients taking these medications, there is potential for increased risk of cancer with long-term exposure to the impurity. Not treating the condition may pose a greater health risk.
    - Health Canada suggested that patients who had been using an affected product, may contact their healthcare provider as soon as possible to discuss treatment options. Pharmacists may be able to provide a product not affected by the recall, or their practitioner may prescribe a different medication for their condition.

Response Planned by the SCPP, CPSS, and SRNA:

To maintain patient safety, the SCPP, the CPSS, and the SRNA are recommending that:

- Physicians and nurse practitioners proactively change the patient to another ARB, or
- In the absence of physician or nurse practitioner guidance, the pharmacist may substitute to an alternative ARB at an equivalent dose.
- Where CPAs between the pharmacist and the physician/NP exist, the providers involved will agree on which approach they wish to take.

See TS Policy and Emergency Exemptions for Prescribing Authority for more clarification on extraordinary circumstances and criteria used to guide the Registrar's decisions.

SCOPE OF PRACTICE

Q2 What is the difference between prescribing TS within normal prescribing authority compared with emergency provisions for the current ARB recall?

Normal Prescribing (TS with a CPA):

- Pharmacists in the retail community setting practicing within a CPA - may prescribe a therapeutic substitution for the ARB recall, only if permitted within the CPA, and if done according to the terms and conditions of the CPA and SCPP requirements.

  (See Prescriptive Authority – Pharmacist, TS Policy Appendix "TS Within a CPA" and the SCPP Regulatory Bylaws Part K, section 4.)

- Pharmacists practicing within the SHA or SCA where the therapeutic substitution is a part of the CPA, will be prescribing in accordance with the policy of their respective institutions. (Also see question 5 below and Prescriptive Authority Hospital Pharmacy FAQs).

Emergency Prescribing (TS without a CPA):

Pharmacists in the retail community pharmacy setting, without a CPA, prescribing TS for the current ARB recall must do so within the SCPP terms and conditions communicated by the Registrar. (Also see TS Policy)

SCPP Requirements	Normal (Within a CPA)	Emergency (Outside a CPA)
TS permitted within a group of drugs based on scientific properties	• Mechanism of Action; • Chemical Structure; or • Therapeutic Effect	• Mechanism of Action; or • Chemical structure

(Also see Appendix B - Application of Other COVID-19 Prescribing Exemptions to the ARB Recall)

Q3 How will I know if I am performing TS under normal Level 2 prescriptive authority or under emergency provisions?

You are prescribing under normal Level 2 prescriptive authority if you:

- Have signed a CPA with a prescriber, it is current and includes therapeutic substitution for patients affected by the ARB recall (Note: each pharmacist who prescribes under the CPA must personally have signed the CPA.).

You are prescribing under emergency provisions if you:

- Do not have a CPA;
- Have a CPA but therapeutic substitution is not a permitted pharmacist prescribing activity outlined in your CPA; or
- Have a CPA but the patients impacted by the current ARB recall, are not covered in the CPA.

Q4 Do these emergency provisions override the CPA that I have with prescribing practitioners?

- No, pharmacists practiing within a CPA may continue to do so within the terms and conditions described in their CPA, **so long as the therapeutic substitution prescribed also adheres to the SCPP Council Policy for TS within a CPA**.
- However, if the CPA does not cover patient groups impacted by the ARB recall, any therapeutic substitutions prescribed by the pharmacist would be done under the emergency provisions and must meet the terms and conditions specified by the Registrar for the current ARB recall.

PRESCRIBING THERAPEUTIC SUBSTITUTIONS WITHIN PUBLICLY-FUNDED SETTING (NORMAL)

Q5 How do these emergency provisions apply to pharmacists in the Saskatchewan Health Authority (SHA) and the Saskatchewan Cancer Agency (SCA)?

The SCPP emergency provisions and TS Policy only apply to the retail community pharmacy setting.

- The SCPP regulatory bylaws include special provisions for public health care institutions (i.e., SHA or SCA), where CPAs can be made in accordance with the policy of the institution.
- Pharmacists practising in CPAs with the SHA or the SCA will continue under normal prescribing authority.

See Prescriptive Authority — Pharmacist for expectations that apply to all pharmacist prescribing, Prescriptive Authority for Pharmacists – Hospital Pharmacy, SCPP Regulatory Bylaws Part K, section 4, and TS Policy Appendix "TS within a CPA."

PRESCRIBING THERAPEUTIC SUBSTITUTIONS WITHOUT A CPA (EMERGENCY)

Q6 What additional training is required for prescribing TS under the current emergency provisions?

None, however, pharmacists who prescribe a TS must be competent and current in the clinical guidelines pertaining to the condition being treated, including but not limited to understanding the goals of therapy, and the pharmacology of the drugs being substituted (TS policy, section 5.3.2);

- Additionally, the SCPP expects pharmacists prescribing the TS to be aware of the TS policies and agree to abide by them (TS Policy, section 5.3.1).
- Failure to abide by these could result in change of eligibility as determined by the Registrar (TS policy, section 3), non-coverage by malpractice insurance because the pharmacist is not practicing within the terms and conditions set by the SCPP, or subject to complaints and discipline.

Q7 What drugs can I prescribe for the ARB recall outside of a CPA (under emergency provisions)?

Selecting alternative drugs for patients using the TS policy may be counterintuitive for some pharmacists as it contains requirements for discrete steps in the clinical assessment process. The TS policy requires that pharmacists prescribing TS must:

- Use current reputable evidence-based literature/guidelines (e.g., RxFiles, RxTx, medSask Drug Shortages);
- Confirm that selected drug shares MOA or chemical structure, with original prescription, in a clinically meaningful way using credible authorities (e.g., WHO ATC classification system);
- Confirm that indication is on the product monograph for the patient's diagnosis.

Also see Prescriptive Authority Decision Making Framework and Appendix A below for its application to the ARB recall.

Why can't we just prescribe TS within the same pharmacologic class?

Although the term "pharmacological class" is intuitively understood by all pharmacists, it is problematic when used to give clear boundaries for prescribing TS in extraordinary circumstances.

When referring to "pharmacologic class," pharmacists may be referring to three different scientific properties:

1. Mechanism of Action (MOA),
2. Physiologic effect/therapeutic effect/therapeutic equivalence/clinical equivalence (PE) or
3. Chemical structure

Under extraordinary circumstances, and outside of a CPA, pharmacists may therapeutically substitute a prescribed medication within a group of drugs with similar mechanisms of action or chemical structure.

They are not permitted to substitute within a group of drugs based on physiologic or therapeutic equivalence.

See TS Policy, definition of "Pharmacologic Class" for more information.

Example: Selecting Alternate ARB for Post-Myocardial Infarction (MI) Using medSask Guideline

Below is an example demonstrating how a pharmacist would review alternative ARBs for a post-MI patient impacted by the recall, as per the TS policy:

- Patient's valsartan is confirmed to be indicated for post-MI
- medSask ARB Comparison chart provides list of alternative drugs and indicates candesartan as an alternative for post-MI
- WHO-ATC confirms the candesartan and valsartan share similar chemical structure, BUT
- Product monograph (and medSask's chart denoted by *) for candesartan does not include indication for post-MI; THEREFORE,
- **Pharmacist is not permitted to prescribe candesartan (off label usage)**
- Pharmacist must refer patient to their practitioner (primary or specialist) because no other on-label alternatives exist.

Caution:

- Guidelines may present drug options in a way that looks like they share a MOA or chemical structure, however this may not be the case. The scientific properties must be verified using a credible source (e.g., WHO ATC) to ensure that is permitted by Council. The SK formulary does not provide verification of scientific properties and therefore must not be used for this step.
- Clinical guidelines are created for multiple health care practitioners, who have different scopes of practice. These resources may present therapeutic options that do not align with the pharmacist scope of practice for TS outside of a CPA (e.g., may include off-label recommendations which are not permitted by Council).

- Pharmacists must ensure they have the correct indication of the original ARB prescription to make an informed decision around the substitution. If the pharmacist is uncertain of the original indication, they risk prescribing a therapeutic substation that is not clinically appropriate (e.g., all ARBs are indicated for hypertension, however only candesartan and valsartan are indicated for congestive heart failure. (Also see Appendix A "Gathering Appropriate Information").

The onus is on the pharmacist to ensure they only select drugs that are within Council policy and as specified by the Registrar.

OTHER

Q8 What follow-up is required when I have prescribed a TS?

Monitoring the patient's response and following up as needed is a standard of practice for **all** pharmacist prescribing, in normal and extraordinary circumstances.

The emergency TS Policy includes specific expectations for monitoring and following up, which have been built into the TS PAR. They include:

- **Pharmacist follow up with the patient** – to ensure safety and tolerability of the prescribed drug. Must occur within best practice timeframes for the drug, or within 3-7 days (whichever is shorter);
- **Referral to Primary Care Provider** as appropriate, including:
  - When the monitoring and follow up needed is beyond a pharmacists' scope of practice (e.g., ordering laboratory tests) (TS Policy, section 7.4), **and**
  - As soon as possible, or within two or three weeks (See joint memo from the SCPP, CPSS and SRNA.)

Q9 What documentation, communication and notifications are required?

Some SCPP requirements apply to **all** pharmacist prescribing, including those prescribing TS under these emergency provisions.

Some SCPP requirements apply **only** to TS prescribing under the emergency provisions.

Mandatory requirements for both normal and emergency provisions are included in the TS PAR.

Normal provisions that apply to all pharmacist prescribing include:

- Standards of Practice noted in Prescriptive Authority – Pharmacist section 5; (including verifying informed consent, entering the pharmacist's name in the prescriber field of the pharmacy software system); and
- Storing documentation as per SCPP's Summary of Record Keeping Requirements.

Emergency provisions - all pharmacists prescribing TS under emergency provisions must also:

- Complete the TS PAR (which provides space to document diagnosis, clinical assessment, evidence-based guidelines used, procedures followed before prescribing TS, and follow up); and
- Notify the patient's primary care provider through the TS PAR.

Note: When prescribing a TS under emergency provisions, the patient's primary practitioner must always be notified of the pharmacist's prescribing a therapeutic substitution. This is similar to the mandatory notification requirements for drugs monitored through the Prescription Review Program.

Q10 What happens after the Health Canada ARB recall has ended?

- Pharmacists who have a CPA with the patient's practitioner may continue to practice within the terms and conditions of the CPA.
- For all other pharmacists in the retail community setting, the decisions to maintain current therapy or revert back to the original prescription must be made by the practitioner who initiated the original prescription (TS Policy, section 6.1.3 and 7.4), unless authorized by the Registrar. Monitor the SCPP website and communication from the Registrar for more direction.

Q11 What is required of proprietors?

- Proprietors are responsible to put the safety of their patients first and are expected to support pharmacists' professional autonomy in their decision-making for TS. Business-related influence (e.g., quotas for service fees) are not in the best interest of the patient and may be deemed as proprietary misconduct.
- It is the expectation of the SCPP that all licensed members, pharmacies and proprietors collaborate in the best interest of the patient and that proprietors will support pharmacists to fulfill the requirements of the TS Policy (see, section 6 "Proprietor Responsibility to Support Patient-Centred Care").

Q12 Where can I find information on reimbursement for prescribing TS?

- Reimbursement for professional services is negotiated by PAS and with the Ministry of Health. Pharmacists should monitor communication from PAS and MoH regarding reimbursement processes and criteria.

Q13 How will prescribing under these emergency provisions impact my malpractice insurance?

- It is expected that pharmacists will be covered by their malpractice insurance when they prescribe under these emergency provisions, so long as they are practicing within the parameters specified by the Registrar and following conditions that apply to all prescribing practices.
- Pharmacists who prescribe TS outside of these parameters may not be covered by their malpractice insurance.
- The SCPP is not an insurance provider and therefore recommends that pharmacists confirm coverage requirements with their insurance provider.

Q14 What oversight is being performed to maintain patient safety during these emergency overrides?

- The SCPP is collaborating with the Drug Plan and Extended Benefits Branch in the Ministry of Health to monitor and audit prescribing practices to ensure that pharmacists are following the emergency provisions.
- Any prescribing outside of the conditions established by the SCPP are subject to the disciplinary process.
- See TS Policy, section 8 for a list of the tools that will be used to provide this oversight, which may include auditing TS PARs, Quality Improvement Reviews, and reviewing data to support complaints investigations and/or conduct monthly audits as is typically conducted for special exemptions.

Q15 Where can I find more information?

Monitor the SCPP website and communication from the SCPP Registrar. Questions may be directed to info@saskpharm.ca.

APPENDIX A – Example Decision Making in Therapeutic Substitution of an ARB

Steps in the Decision-Making Process	Application to ARB Recall
Pharmacists' Knowledge & Competence	• Read and understand TS Policy. • Monitor communication from the SCPP (re: terms and conditions enacted by the SCPP Registrar). **Note:** Must be competent and current in the clinical guidelines pertaining to the condition being treated, understand the goals of therapy, and the pharmacology of the drugs being substituted.
Gathering Appropriate Information	• Consult with the patient and review the patient's medication profile/history for relevant information. • Obtain the patient's diagnosis to make an informed decision on therapeutic alternatives. Note: Patient may not know their diagnosis for the ARB (e.g., hypertension vs. congestive heart failure). If in doubt, the pharmacist must confirm the patient's diagnosis with the primary practitioner or refer to another prescriber. (TS Policy, section 7.4)
Selecting Alternative Drug for Patient	• Use current reputable evidence-based literature/guidelines (e.g. RxFiles, RxTx, medSask Drug Shortages). • Confirm that selected drug shares MOA or chemical structure, with original prescription, in a clinically meaningful way using credible authorities (e.g. WHO ATC classification system); • Confirm that indication is on the product monograph for the patient's diagnosis. See question 7 for an example of applying the TS Policy. **Caution:** • Guidelines may present drug options in a way that looks like they share a MOA or chemical structure, however this may not be the case. The scientific properties must be verified using a credible source (e.g. WHO ATC) to ensure that is permitted by Council. The SK formulary does not provide verification of scientific properties and therefore must not be used for this step. • Clinical guidelines are created for multiple health care practitioners, who have different scopes of practice. These resources may present therapeutic options that do not align with the pharmacist scope of practice for TS outside of a CPA (e.g., may include off-label recommendations which are not permitted by Council). • **The onus is on the pharmacist to ensure they only select drugs that are within Council policy and as specified by the Registrar.**
Prescribe the Therapeutic Substitution	• Quantity must not exceed amount remaining or duration of the original prescription (TS Policy, section 7). • For prescribing exemptions currently enacted see Practice Changes for Community Pharmacy During COVID-19 Pandemic. • Monitor SCPP website and communications from the Registrar to stay current on exemptions enacted.
Documentation and Notification of Patient's Primary Practitioner	• Pharmacists must complete the TS PAR. • Notification to the patient's primary practitioner with the completed TS PAR is **always mandatory**. • Store documentation as per SCPP's Summary of Record Keeping Requirements.

APPENDIX B – Application of Other COVID-19 Prescribing Exemptions to the ARB Recall

The current emergency prescribing exemptions (see a, b and c below) may **not** be applied to TS for ARBs as it would go against patient safety measures put in place by the TS Policy to ensure patient receives monitoring and follow up by their primary care practitioner.

Current Exemption	Reason Current Exemption Does Not Apply to TS for ARBs
a. Pharmacist may prescribe quantities that exceed the previous prescription. [Part K section 10(5)(a)]	Not permitted under TS Policy, section 7.2. (i.e., quantity not to exceed the amount remaining, or the duration of the original prescription). This ensures that the patient receives proper monitoring and follow-up by their primary care provider.
b. Pharmacist may prescribe when the previous prescription was issued by a pharmacist. [Part K Section 10(5)(b)]	Back-to-back prescribing of therapeutic substitutions is not permitted as TS Policy, section.7.4. requires referral of patient to their primary care provider for appropriate monitoring and follow up. For ARB recall, the pharmacist must instruct the patient to follow up with their primary care provider as soon as possible, usually within two or three weeks (see joint memo from the SCPP, CPSS and SRNA). **Continue to monitor the SCPP website and communication by the Registrar should additional direction be provided.**
c. Pharmacists may prescribe when an active patient practitioner relationship no longer exists. [Part K Section 10(5)(c)]	This exemption does not apply as presumably an active patient practitioner relationship has existed within the past year as a valid prescription for the ARB exists. However, if referral back to the patient's last prescriber is not possible, then the following may guide the pharmacists' next steps: • The pharmacist may communicate with more than one practitioner involved in the patient's care; • See Prescription Validity – When Prescriber No Longer Practising for guidance on dispensing new prescriptions or refills when a prescriber passes away, retires or otherwise ceases practice; or • Patients could be referred to an available practitioner (e.g., walk-in clinic, or virtual practitioners) to ensure there is proper follow-up after a change in medication occurs. Also see rationale in (b) for the spirit and intent on maintaining a collaborative practice environment.

See Practice Changes for Community Pharmacy During COVID-19 Pandemic for information and scenarios regarding prescribing exemptions currently in place.