



PRINCE EDWARD ISLAND
PHARMACY BOARD

**Standards of Practice
Prescription Renewal
Prescription Adaptation and Therapeutic
Substitution by Pharmacists**

December 2013

ACKNOWLEDGEMENTS

This Standards of Practice document has been developed by the Prince Edward Island Pharmacy Board with the assistance and guidance of many individuals and organizations.

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These regulatory bodies shared their Standards of Practice and experience regarding pharmacist prescribing to assist with the development of the Prince Edward Island Standards of Practice and to support inter-provincial consistency.

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Prince Edward College of Physicians and Surgeons
Medical Society of Prince Edward Island
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Prince Edward Island Dental Association
College of Optometrists of Prince Edward Island
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INTRODUCTION

Proposed regulations to enable pharmacists in the province to more fully apply their skills and competencies within the health care system as experts in medication therapy management are underway. In the interests of the health and well-being of Prince Edward Islanders, pharmacists prescribing provides the opportunity for pharmacists to further support the current objectives and challenges of health care delivery in the province, including:

- Patient-centered model of care,
- Patient access to timely and appropriate health care,
- Efficient delivery of health care services,
- Best use of health care human resource capacity,
- Inter-professional collaboration, and
- Optimal drug therapy outcomes and safety.

Regulations and the accompanying Standards of Practice would allow pharmacists to provide expanded services associated with prescribing drugs and to more effectively fulfill the intent and purpose of the Pharmacy Act which is that pharmacists are responsible for the provision of optimal patient care, monitoring drug therapy and ensuring the pharmaceutical and therapeutic appropriateness of drug therapy.

Under the authority of regulations, the proposed *Standards of Practice – Prescribing of Drugs by Pharmacists* establishes clear accountabilities and responsibilities of pharmacists with respect to the prescribing of drugs. Pharmacists will undertake the prescribing of drugs in accordance with these Standards of Practice as well as existing legislation, regulations, the Code of Ethics, other standards of practice and policy directives and guidelines relevant to pharmacy practice in Prince Edward Island.

This Standards of Practice document, relating to prescription **Renewal (Continued Care Prescribing), Adaptation and Therapeutic Substitution** includes the following:

- Definitions – glossary of terms referenced in the standards,
- General Standards of Practice – overall requirements and expectations for pharmacists when prescribing,
- Additional Standards of Practice – specific requirements for each type of prescribing activity, and
- Appendices – supporting tools and documents.

This Standards document will continue to evolve as we move forward in further expanded scope of practice.

2 DEFINITIONS

Definitions for terms represented in the *Standards of Practice – Prescribing of Drugs by Pharmacists* are provided in the following table.

Term	Definition
Current Prescription	A prescription that is not over one year old and has not been dispensed, has refills remaining or has an unused portion of a dispensed prescription remaining.
Original Prescriber	Refers to the prescriber who authorized the original prescription.
Original Prescription	The first fill of a prescription, which may or may not be for a new drug therapy.
Provincial DIS	An interoperable system that enables authorized health care providers to access, manage, share and safeguard patient’s medication histories. It is a key component of the provincial electronic health record (EHR).
Regulated Health Care Professional	An individual who is licensed to provide specific health care services to patients, including but not limited to dentists, nurses, optometrists, pharmacists and physicians.
Schedule I Drugs	<p>Drug Schedules Regulations under the Pharmacy Act define Schedule I as the following:</p> <p>The drugs and medicines in this Schedule are the drugs listed from time to time in Schedule I of the National Drug Schedules, which are part of Canada’s National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as that Schedule is from time to time amended.</p> <p>The drugs and medicines in this Schedule require a prescription as a condition of sale, other than drugs listed in the <i>Prescription Drug List that Require a prescription for Veterinary Use</i> of the Food and Drug Regulations (Canada) that are not in a form suitable for use by a human or for which the main product panel of both the inner label and the outer label clearly indicate that the drug is for veterinary use only.</p> <p>The drugs and medicines in this Schedule, which are listed in the Controlled Drugs and Substances Act (Canada) and its Regulations, must be sold in accordance with the Controlled Drugs and Substances Act (Canada) and its Regulations, and the standards of practice from time to time approved by Council. The drugs and medicines in this Schedule, which are not listed in the</p>

	Controlled Drugs and Substances Act (Canada) and its Regulations, must be sold in accordance with the Food and Drugs Act (Canada) and its Regulations, and the standards of practice from time to time approved by Council.
Schedule II Drugs	The drugs and medicines in this Schedule are the drugs listed from time to time in Schedule II of the National Drug Schedules, which are part of Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as that Schedule is from time to time amended. The drugs and medicines listed in this Schedule do not require a prescription as a condition of sale, but are only available from a pharmacist and must be kept within an area of the pharmacy to which there is no public access and no opportunity for self-selection. The direct involvement and professional intervention from a pharmacist or certified dispenser is required prior to the release of the drug to the patient or the patient's agent.
Schedule III Drugs	Drug Schedules Regulations under the Pharmacy Act define Schedule III as the following: The drugs and medicines in this Schedule are the drugs listed from time to time in Schedule III of the National Drug Schedules, which are part of Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as that Schedule is from time to time amended. The drugs and medicines listed in this Schedule do not require a prescription as a condition of sale, but are sold from the self-selection area of the pharmacy maintained under the personal supervision of a pharmacist or certified dispenser. A pharmacist or certified dispenser must be available to assist the patient in making an appropriate self-medication selection.
Therapeutic Class	Classifying drugs according to their function, grouped for the intended medical condition they treat. The most common class system is the <i>Anatomical Therapeutic Chemical (ATC) Classification System</i> , maintained by the World Health Organization. The ATC classifies each drug in a series of categories, starting with a group of 14 categories organizing drugs according to the system of the body that the medication is meant to affect, such as the nervous system, immune system, or respiratory system. Drugs are then classified into broad therapeutic groups according to their function, for example, analgesics or antipsychotics. The next category indicates the drug's pharmacological or therapeutic subgroup, while the last two indicate the active ingredient's chemical group and the specific chemical used, respectively.

3 GENERAL STANDARDS OF PRACTICE – PHARMACIST PRESCRIBING

The general Standards of Practice represent overall requirements for pharmacist prescribing. For reference, a Prescribing Decision Framework is provided in Appendix A. This framework provides a decision-making tool representing the key elements of these standards of practice to help a pharmacist determine whether or not to proceed with prescribing for a patient.

3.1 FOCUS ON HEALTH CARE NEEDS OF PATIENT

3.1.2 A pharmacist’s decision to prescribe shall be in the best interest of the patient’s health and safety.

3.1.1 A pharmacist shall prescribe the most appropriate drug considering the patient’s symptoms, medical history, health status, allergies/ intolerances and safety considerations. In addition, a pharmacist shall consider the patient’s personal circumstances, practical needs, values and preferences, where applicable

3.1.2 A pharmacist shall involve the patient in the prescribing process and decisions within a shared decision making environment.

3.2 UNDERSTAND AND TAKE ACCOUNTABILITY

3.2.1 A pharmacist shall recognize and accept legal accountability for their prescribing decision. A pharmacist cannot delegate this accountability to another individual.

3.2.2 A pharmacist shall not prescribe when the prescribing decision process indicates that there is insufficient information or added risks to the patient to provide a prescription.

3.2.3 A pharmacist shall recognize and accept responsibility for the impact of their prescribing activities on the overall costs and sustainability of the health care system.

3.3 USE KNOWLEDGE AND UNDERSTANDING

3.3.1 A pharmacist shall comply with the Standards of Practice: Adaptation, Renewal, and Therapeutic Substitution as well as existing legislation, regulations, the Code of Ethics, agreements, other standards of practice and policy directives relevant to pharmacy practice in Prince Edward Island. A pharmacist may only undertake the prescribing of drugs in specific circumstances to carry out:

- prescription renewal,
- prescription adaptation,
- therapeutic substitution, or

3.3.2 A pharmacist shall only undertake the prescribing of drugs in accordance with:

- the pharmacist's scope of practice,
- and the knowledge, skills, competencies and experience of the pharmacist.

The onus is on the pharmacist to judge whether or not the specific circumstances of each potential instance of prescribing are in accordance with their scope of practice, knowledge, skills, competencies and experience.

3.3.3 A pharmacist shall have the appropriate knowledge and understanding of the following:

- The patient (e.g. his/her symptoms, medical history, health status, allergies/intolerances and safety considerations; and, where applicable, consider his/her personal circumstances, practical needs, values and preferences),
- The condition being treated and
- The drug being prescribed.

A pharmacist shall be satisfied that the intended use of the prescribed drug reflects an indication approved by Health Canada. Otherwise, the pharmacist shall be satisfied that the intended use of the prescribed drug is:

- accepted as best practice in Canada and supported by medical literature; or
- consistent with a research protocol in which the patient is enrolled.

3.3.4 A pharmacist shall use professional judgment to determine the appropriateness of their knowledge and understanding to prescribe in a specific situation, considering whether or not:

- sufficient information, including benefits and risks, is available such that assumptions are not required,
- the decision to prescribe can be justified,
- the decision will withstand a test of reasonableness, i.e. the majority of pharmacists would make the same decision in this situation, and
- the pharmacist can accept responsibility for the decision.

3.3.5 A pharmacist shall maintain current certification in Cardiopulmonary Resuscitation (CPR) and First Aid as required qualifications for prescribing drugs (refer to Appendix C for specific information regarding First Aid and CPR certification requirements).

3.4 COLLABORATE WITH OTHER HEALTH CARE PROFESSIONAL

3.4.1 A pharmacist prescribing a drug may collaborate and consult with other pharmacists, the patient's primary healthcare provider, the original prescriber (if applicable and different from the primary health care provider) and other health care professionals when practical and where it is beneficial to serve the best interest of the patient (e.g. prescribing decisions, monitoring/follow-up, ordering/interpreting lab tests).

3.4.2 A pharmacist shall recommend that the patient seek the care of another appropriately qualified regulated health care professional when:

- the pharmacist does not have the knowledge, skills, competencies and experience necessary to address the patient's needs,
- the condition of the patient cannot be effectively treated within the scope of practice of the pharmacist,
- the patient's condition has not responded to drug therapy or other therapy within the pharmacist's scope of practice, or
- the patient's needs are better addressed by another health care professional who can be accessed in a timely manner.

3.4.3 In addition to providing a prescription, a pharmacist shall recommend that the patient seek the care of another healthcare professional for additional care, as appropriate for the situation.

3.5 MAINTAIN PROFESSIONAL INDEPENDENCE

3.5.1 A pharmacist shall neither prescribe under conditions that compromise the pharmacist's professional independence, judgment or integrity, nor impose such conditions on other pharmacists or health care professionals.

3.5.2 When prescribing, a pharmacist shall not prescribe, except in extraordinary circumstances when a conflict of interest compromises the pharmacist's professional independence, judgment or integrity:

- accepting gifts, inducements or other benefits from a patient, other health care professional, pharmaceutical manufacturer, supplier or other organization/person, or
- forming an association with a patient, other health care professional, pharmaceutical manufacturer, supplier or other organization/person.

3.5.3 A pharmacist shall not prescribe for themselves, a family member or anyone with whom the pharmacist has a close personal relationship, except in extraordinary circumstances when:

- no other prescriber is available and

- drug treatment is required to save a life or avoid serious deterioration to the patient's health.

When prescribing in an extraordinary situation, a pharmacist shall document the relationship to the patient and the exceptional circumstances and no fee shall be charged for the prescribing service.

3.5.4 A pharmacist's decision to prescribe and the choice of drug shall be based on clinical suitability, cost effectiveness and what is in the best interest of the patient and not on the demands of the patient. Prescribing decisions based on bias-oriented information or on providing financial advantage to the pharmacist and/or pharmacy without providing benefit to the patient may be regarded as professional misconduct.

3.5.5 When a pharmacist proceeds to both prescribe and dispense a drug, the pharmacist shall:

- inform the patient about the benefits of another pharmacist or health care professional reviewing the appropriateness of the prescription;
- obtain the patient's consent for the pharmacist to dispense the drug which he/she prescribed; and
- document the patient's consent on the prescription record. Consent may be given by a patient or patient's agent and consultation can be done over the phone if appropriate/required.

3.6 ENABLE INFORMED DECISIONS

3.6.1 A pharmacist shall provide the patient or patient's agent with information, benefits and risks that are understandable and sufficient to allow him/her to make an informed decision to accept or decline the pharmacist prescribing. To support his/her decision, the pharmacist shall provide the opportunity for the patient or patient's agent to ask questions and obtain responses about the pharmacist prescribing process.

3.6.2 The pharmacist shall be satisfied that the patient or the patient's agent, if applicable, has sufficient information and understanding to participate in the prescribing process and decision making.

3.6.3 In order to support pharmacist prescribing, the pharmacist shall obtain informed and voluntary consent for the prescribing service being provided, including the following:

- consent for the pharmacist to undertake the prescribing process, including the associated assessment, where applicable, as well as the pharmacist's prescribing decision (supported by discussing the proposed prescription, any use of the drug for an indication beyond those approved by Health Canada, therapeutic options, benefits, risks and any other factors specific to the patient's circumstances), and
- consent for the pharmacist to communicate the prescription decision and details as well as any follow-up results (if applicable) to other appropriate health care professionals (e.g. primary health care provider).

3.6.4 A pharmacist shall obtain informed and voluntary consent from the patient or the patient's agent (i.e. substitute decision maker) and disclose patient information in accordance with applicable legislative requirements (refer to Appendix D for Patient Consent and Disclosure Requirements).

3.6.5 When a patient is represented by an agent, a pharmacist shall apply the standards for the relationship with the patient to the relationship with the agent, as appropriate.

3.6.6 The pharmacist shall deal directly with the patient except when:

- it is considered appropriate and in the patient's best interest to deal with the patient's agent, or
- the pharmacist deals with a regulated health care professional who is providing personal and/or supervisory care to the patient (provided the patient or patient's agent has given consent to do so).

3.7 COMPLETE MONITORING

A pharmacist shall establish an appropriate follow-up plan, which specifies the therapeutic goal(s) to be monitored. For each goal, the follow-up plan includes the following (as applicable):

- description of the therapeutic goal,
- monitoring process (i.e. how the monitoring will be conducted, e.g. patient call back),
- date for follow-up,
- individual responsible for follow-up, and
- monitoring results and date (once completed), including documentation of any subsequent follow-up requirements.

3.8 COMMUNICATE EFFECTIVELY

3.8.1 The pharmacist shall communicate directly with the patient or their agent about the patient assessment details/findings, prescribing decision, associated rationale, follow-up plan and any notification that will be provided to other health care professionals.

3.8.2 In support of continuity of patient care and collaborative care, the pharmacist shall complete the appropriate communication regarding the prescribing activities for a patient to

- other professional staff in the pharmacy,
- the patient's primary health care provider,
- the original prescriber (if different from the primary health care provider), and/or
- the appropriate health care professionals.

The pharmacist shall communicate, in writing, the required information using the established procedural framework and form within hours or as

soon as possible thereafter (refer to Appendix E – Communication Process and Notification Forms).

- 3.8.3 The pharmacist shall conduct prescribing related communications with a patient or other health care professionals regarding assessment, follow-up, patient counselling and personal/sensitive information or other matters in accordance with the patient’s wishes, in a manner that respects patient confidentiality.
- 3.8.4 The pharmacist must ensure that communications with patients or their agents cannot be observed or overheard.
- The pharmacist must offer the patient a private counselling room. Pharmacies will have two years from the approval of these standards to comply. Any renovations to existing pharmacies, or new pharmacies, must be able to offer this private counselling area upon inspection for a Permit.

3.9 COMPLETE DOCUMENTATION

- 3.9.1 The pharmacist shall document the prescribing process in order to maintain an accurate record of the circumstances and prescription details including:
- New written prescription with all required details and signed by the prescribing pharmacist. Details will include a reference to the original prescription, where applicable (i.e. prescription adaptation, therapeutic substitution and prescription renewal).
 - Patient’s presenting health condition or drug related problem, patient assessment details/findings (the extent to which it is applicable and pertinent to the prescribing circumstances. Note that the format for documenting this information may follow SOAP (subjective, objective, assessment, plan), DARP (data, action, response, plan) or similar approach. Where applicable, file any supporting information (e.g. laboratory report, previous prescription label, written documentation of diagnosis from health care professional requesting pharmacist to select and prescribe appropriate drug therapy, etc.) with the prescribing documentation.

- Follow-up plan that is sufficiently detailed for other health care professionals or care givers to monitor the patient's progress.
- Date and method of notifying original prescriber and/or any other health care professionals, as appropriate.
- Acknowledgement of informed and voluntary consent in accordance with applicable legislative requirements (refer to Appendix D for Patient Consent and Disclosure Requirements).
- Where applicable, clear reference to the original prescription including the prescriber name and contact details on both the patient's record and the new prescription.
- Identification of prescribing pharmacist.
- Details of subsequent monitoring and follow-up, where appropriate.

3.9.2 The pharmacist shall create and maintain documentation of the prescribing process that is:

- Completed in a timely manner concurrent with the process.
- Recorded using an electronic and/or paper based system. If both are being used, the electronic record shall identify and reference the paper record.
- Recorded, as required, in the provincial DIS.
- Retained for ten years.

For further details regarding documentation, refer to Appendix F – Documentation Requirements.

4 PRESCRIPTION RENEWAL

In addition to the General Standards of Practice for Pharmacist Prescribing (detailed in Section 3 of this document), the following standards apply to pharmacist prescribing to renew a prescription.

4.1 A pharmacist shall only undertake prescribing to renew a prescription that is:

- an original prescription from their pharmacy that has not been previously renewed by a pharmacist or transferred to another pharmacy;
- for a drug listed in Schedule I, II or III, pursuant to the Drug Schedules Regulations of the PEI Pharmacy Act, and is not listed in the Controlled Drugs and Substances Act and its Regulations, i.e. pharmacists cannot prescribe narcotics, controlled drugs, exempted codeine products (e.g. Tylenol #1), or targeted substances (except benzodiazepines prescribed for a convulsive disorder or where discontinuation presents a risk of seizure);
- providing drug therapy for a chronic or long-term condition, which is stabilized; and
- prescribed for an intended use that reflects an indication approved by Health Canada. Otherwise, prescribed for an intended use which is:
 - widely accepted as best practice in Canada and supported by extensive medical literature demonstrating safety and efficacy, or
 - consistent with a research protocol in which the patient is enrolled.

4.2 A pharmacist who undertakes prescribing to renew a prescription shall be satisfied that:

- the renewal is for the same drug, dosage, formulation and regimen (a pharmacist shall not adapt the dose, formulation or regimen or complete therapeutic substitution when prescribing to renew a prescription unless, at that time, the manufacturer cannot supply the drug to be renewed),

- continued drug therapy is warranted to maintain or enhance patient care and can be extended without the patient seeing the original prescriber,
- the prior assessment of the patient's condition supporting the drug therapy is still relevant,
- there is no indication that the original prescriber would not renew the prescription,
- the patient is expected to obtain therapeutic benefit from renewing the drug and the therapeutic benefit is expected to outweigh the risks of renewing the drug,
- the patient has a stable history on the medication and the drug dosage, formulation and regimen are appropriate and unchanged,
- there are no existing known problems with the drug to be renewed (e.g. drug interactions, adverse effects or contraindications),
- the patient's condition and treatment with the drug are being monitored appropriately, and
- the prescription renewal, is estimated to provide a duration of no more than 90 days and no more than what was authorized per refill under the original prescription.

5 PRESCRIPTION ADAPTATION– ADDITIONAL STANDARDS

In addition to the General Standards of Practice for Pharmacist Prescribing (detailed in Section 3 of this document), the following standards apply to adaptation of a prescription by a pharmacist.

5.1 When prescribing to adapt a prescription from another prescriber, a pharmacist may modify:

- the dose of the drug,
- the formulation of the drug,
- the regimen of the drug, and/or
- the duration of the drug therapy.

5.2 A pharmacist shall only adapt a prescription that is:

- current
- authentic, and
- for a drug listed in Schedule I, II or III, pursuant to the Drug Schedules Regulations of the Prince Edward Island Pharmacy Act, and is not listed in the Controlled Drugs and Substances Act and its Regulations.

5.3 A pharmacist who adapts a prescription shall assess the patient and specific circumstances, as appropriate, to be satisfied that:

- the drug in the adapted prescription is being prescribed for an intended use that reflects an indication approved by Health Canada. Otherwise, the drug is being prescribed for an intended use which is:
 - accepted as best practice and supported by medical literature and
 - the adapted prescription will maintain or enhance the effectiveness of the drug therapy or improve adherence and is not expected to introduce any problems or additional risks to the patient.

5.3.1 A pharmacist may adapt a prescription's **dose of the drug** when:

- the drug strength prescribed is not commercially available,

- the dose of the drug is missing from the prescription and sufficient information about the drug therapy can be obtained from the patient, patient record or other sources to determine the appropriate dose,
- a patient-specific factor (e.g. age, weight, organ function, other medical conditions/medications, etc.) requires the dose to be adjusted, or
- in the pharmacist's professional judgment, the circumstances indicate a different dose will be clinically beneficial to the patient.

5.3.2 A pharmacist may adapt a prescription's **formulation or regimen** when:

- the formulation prescribed is not commercially available,
- the formulation or regimen is missing from the prescription and sufficient information about the drug therapy can be obtained from the patient, patient record or other sources to determine the appropriate formulation or regimen,
- an adjustment in the formulation or regimen will enhance the ability of the patient to take the medication more effectively, or
- in the pharmacist's professional judgment, the circumstances indicate a different formulation or regimen will be clinically beneficial to the patient.

5.3.3 A pharmacist may adapt a prescription's **duration of drug therapy** when:

- the duration of therapy is missing from the prescription and sufficient information about the drug therapy can be obtained from the patient, patient record or other sources to determine the appropriate duration, or
- in the pharmacist's professional judgment, the circumstances indicate a different duration of therapy will be clinically beneficial to the patient.

5.3.4 In accordance with general standard 3.8 regarding effective communication, a pharmacist shall advise the original prescriber about the prescription adaptation except when the formulation of the prescribed drug is changed, unless:

- the formulation change necessitates a modification to the drug dose or regimen; or
- the pharmacist determines, based on his/her professional judgment, that communication of the formulation change is warranted.

6 THERAPEUTIC SUBSTITUTION – ADDITIONAL STANDARDS

In addition to the General Standards of Practice for Pharmacist Prescribing (detailed in Section 3 of this document), the following standards apply to pharmacist prescribing when substituting the prescribed drug with a different drug that has an equivalent therapeutic effect.

6.1 A pharmacist shall only undertake prescribing for therapeutic substitution to replace a prescription that is:

- current (i.e. prescription is not over one year old and has not been dispensed, has refills remaining or has an unused portion of a dispensed prescription remaining), authentic, and
- for a drug listed in Schedule I, II or III, pursuant to the Drug Schedules Regulations of the Prince Edward Island Pharmacy Act, and is not listed in the Controlled Drugs and Substances Act and its Regulations.

6.2 A pharmacist who undertakes prescribing to substitute a prescribed drug with a different drug that has an equivalent therapeutic effect shall assess the patient and specific circumstances, as appropriate, to be satisfied that:

- the substituted drug, dose and regimen will have an equivalent therapeutic effect based on indications approved by Health Canada or based on an intended use which is:
 - from the same Therapeutic Class
 - is the intended use either widely accepted as best practice in Canada and supported by extensive medical literature demonstrating safety and efficacy, or
 - consistent with a research protocol in which the patient is enrolled;
- sufficient knowledge and understanding have been obtained regarding the patient (e.g. his/her symptoms, medical history, health status, allergies/intolerances and safety considerations; and, where applicable, consider his/her personal circumstances, practical needs, values and preferences), condition being treated, patient specific circumstances and drug selection criteria in order that the therapeutic substitution supports the original therapeutic goal;

- the therapeutic substitution will maintain/enhance the effectiveness of the drug therapy or improve adherence and is not expected to introduce any problems or additional risks to the patient; and
- the therapeutic substitution drug selection supports the patient's best interest with respect to financial, formulary or payer considerations.

6.3 When prescribing for the purposes of therapeutic substitution, a pharmacist shall not extend the prescription beyond the period when the original prescription and any refills would have finished or beyond one year from the original prescription date, whichever is sooner.

APPENDIX A –PRESCRIBING DECISION FRAMEWORK

The following framework provides a decision-making tool representing the key elements of the Standards of Practice – Prescribing of Drugs by Pharmacists. This framework can be used by the pharmacist to help determine whether or not to proceed with prescribing a drug for a patient. It includes general considerations, which apply to all pharmacists prescribing, as well as considerations for each specific category of pharmacist prescribing. The framework provides an overall guideline for pharmacists but does not attempt to represent all aspects of the standards.

<p style="text-align: center;">Section 3 General Standards of Practice Decision to Prescribe Considerations</p>	<p style="text-align: center;">Standard Reference #</p>
<p>Is the decision to prescribe what is in the best interest of the patient’s health and safety, evidence informed and focused on optimizing health outcomes for the patient?</p>	<p>3.1.1</p>
<p>Do I have sufficient information, knowledge and understanding about the patient to undertake prescribing, including his/her:</p> <ul style="list-style-type: none"> • symptoms, • medical history, • health status, • allergies/intolerances, and • safety considerations? <p>In addition, are there other factors to consider, where applicable, including his/her:</p> <ul style="list-style-type: none"> • personal circumstances, • practical needs, • values, and • preferences 	<p>3.1.2</p>
<p>Am I willing to accept legal accountability for my prescribing decision in this instance and for the benefits and risks to the patient resulting from the prescribed drug?</p>	<p>3.2.1</p>
<p>Is the prescribing to be undertaken in this instance within my scope of practice, knowledge, skills, competencies and experience?</p>	<p>3.3.2</p>
<p>Do I have sufficient knowledge and understanding of the condition being treated to undertake prescribing in this instance?</p>	<p>3.3.3</p>

Section 3 General Standards of Practice Decision to Prescribe Considerations	Standard Reference #
Do I have sufficient knowledge and understanding of the drug being prescribed to undertake prescribing in this instance? Does the intended use of the drug reflect an indication approved by Health Canada? Or is the intended use either widely accepted as best practice in Canada and supported by extensive medical literature demonstrating safety and efficacy or consistent with a research protocol in which the patient is enrolled?	3.3.3
Have I obtained information from and consulted with others when practical and in the best interest of the patient (e.g. primary health care provider, original prescriber, other health care professionals)?	3.4.1
Is my prescribing decision free from situations, arrangements or associations that create a conflict of interest or compromise my professional independence, judgment or integrity?	3.5.1
Is my decision to prescribe and choice of drug based on clinical suitability, cost effectiveness and what is in the best interest of the patient?	3.5.4
Have I provided sufficient information to the patient or their agent and involved them in the prescribing process and decision making?	3.6.2
Do I have informed and voluntary consent to prescribe a drug for the patient and complete the associated communication?	3.6.3
Am I willing to complete the necessary monitoring / follow-up, communication and documentation associated with providing a prescription?	3.7, 3.8, 3.9

Section 4 Prescription Renewal Decision to Prescribe Considerations	Standard Reference #
<p>Does the prescription renewal meet the following criteria:</p> <ul style="list-style-type: none"> • Being prescribed to renew an original prescription from my pharmacy that has not been previously renewed by a pharmacist or transferred to another pharmacy? • For a drug not listed in the Controlled Drugs and Substances Act and its Regulations, i.e. not a narcotic, controlled drug, exempted codeine product (e.g. Tylenol #1), or other targeted substance? • Providing drug therapy for a chronic or long-term condition, which is 	4.1

stabilized?	
<p>With respect to the prescription renewal, am I satisfied that:</p> <ul style="list-style-type: none"> • The renewal is for the same drug, dosage, formulation and regimen? (Unless I need to adapt the dose, formulation or regimen or complete therapeutic substitution because the manufacturer cannot supply the drug to be renewed at this time.) • Continued drug therapy is warranted to maintain or enhance patient care and can be extended without the patient seeing the original prescriber? • The prior assessment of the patient’s condition supporting the drug therapy is still relevant? • There is no indication that the original prescriber would not renew the prescription? • The patient is expected to obtain therapeutic benefit from renewing the drug and the therapeutic benefit is expected to outweigh the risks of renewing the drug? • The patient has a stable history on the medication and the drug dosage, formulation and regimen are appropriate and unchanged? • There are no existing known problems with the drug to be renewed (e.g. drug interactions, adverse effects or contraindications)? • The patient’s condition and treatment with the drug are being monitored appropriately? • The prescription renewal, including any assigned refills, is estimated to provide a duration of therapy of no more than 90 days and does not exceed the amount authorized per refill under the original prescription? 	4.2

Section 5 Prescription Adaptation Decision to Prescribe Considerations	Reference #
Am I adapting a prescription to modify the dose, formulation, regimen and/or duration of the drug therapy?	5.1
<p>Is the prescription being adapted meet the following criteria:</p> <ul style="list-style-type: none"> • For a current (i.e. prescription is not over one year old and has not been dispensed, has refills remaining or has an unused portion of a dispensed prescription remaining) and authentic prescription? • For a drug not listed in the Controlled Drugs and Substances Act and its Regulations, i.e. not a narcotic, controlled drug, exempted codeine product (e.g. Tylenol #1), benzodiazepine or other targeted substance? 	5.2

<p>With respect to the prescription adaptation, am I satisfied that:</p> <ul style="list-style-type: none"> • The adapted prescription will maintain / enhance the effectiveness of the drug therapy or improve adherence and not introduce any problems or additional risks to the patient? 	5.3
<p>Am I adapting a prescription's dose for one of the following reasons?</p> <ul style="list-style-type: none"> • The drug strength prescribed is not commercially available, • The dose of the drug is missing from the prescription and sufficient information about the drug therapy can be obtained from the patient, patient record or other sources to determine the appropriate dose, • A patient-specific factor (e.g. age, weight, organ function, other medical conditions / medications, etc.) requires the dose to be adjusted, or • In the pharmacist's professional judgment, the circumstances indicate a different dose will be clinically beneficial to the patient. 	5.3.1
<p>Am I adapting a prescription's formulation or regimen for one of the following reasons?</p> <ul style="list-style-type: none"> • The formulation prescribed is not commercially available. • The formulation or regimen is missing from the prescription and sufficient information about the drug therapy has been obtained from the patient, patient record or other sources to determine the appropriate formulation or regimen. • An adjustment to the formulation or regimen will enhance the ability of the patient to take the medication more effectively. • In my professional judgment, the circumstances indicate that a different formulation or regimen will be clinically beneficial to the patient. 	5.3.2
<p>Am I adapting a prescription's duration of therapy for one of the following reasons?</p> <ul style="list-style-type: none"> • The duration or therapy / quantity is missing from the prescription and sufficient information about the drug therapy has been obtained from the patient, patient record or other sources to determine the appropriate duration/ quantity. • In my professional judgment, the circumstances indicate that a different duration or therapy / quantity will be clinically beneficial to the patient. 	5.3.3

Section 6 Therapeutic Substitution Decision to Prescribe Considerations	Reference #
<p>Is the prescribing for therapeutic substitution being undertaken for a prescription that meets the following criteria:</p>	6.1

<ul style="list-style-type: none"> • For a current (i.e. prescription is not over one year old and has not been dispensed, has refills remaining or has an unused portion of a dispensed prescription remaining) and authentic prescription? • For a drug not listed in the Controlled Drugs and Substances Act and its Regulations, i.e. not a narcotic, controlled drug, exempted codeine product (e.g. Tylenol #1), benzodiazepine or other targeted substance? 	
<p>With respect to the therapeutic substitution, am I satisfied that:</p> <ul style="list-style-type: none"> • The substituted drug, dose and regimen will have an equivalent therapeutic effect based on indications approved by Health Canada or an intended use which is widely accepted as best practice in Canada and supported by extensive medical literature demonstrating safety and efficacy or consistent with a research protocol in which the patient is enrolled? • I have sufficient knowledge and understanding of the patient (e.g. his/her symptoms, medical history, health status, allergies/intolerances and safety considerations; and, where applicable, his/her personal circumstances, practical needs, values and preferences), condition being treated, patient-specific circumstances and drug selection criteria in order that the therapeutic substitution supports the original therapeutic goal? • The therapeutic substitution will maintain / enhance the effectiveness of the drug therapy or improve adherence and is not expected to introduce any problems or additional risks to the patient? • The therapeutic substitution drug selection supports the patient’s best interests with respect to financial, formulary or payer considerations? 	6.2
<p>Does the therapeutic substitution prescription not extend the prescription beyond the period when the original prescription and any refills would have finished or for more than one year from the original prescription date, whichever is sooner?</p>	6.3

APPENDIX B – REFERENCE DOCUMENTS

Pharmacists shall carry out the prescribing of drugs in accordance with the Standards of Practice – Prescribing of Drugs by Pharmacists as well as the following legislation, regulations, the Code of Ethics, agreements, other standards of practice and policy directives relevant to pharmacy practice in Prince Edward Island, including:

- Prince Edward Island Pharmacy Act,
- PEI Authorization and Standards Regulations
- Adaptation and Therapeutic Substitution Regulations
- Continued Care Prescribing Regulations
- Pharmaceutical Informatics Act and Regulations
- Drug Schedules Regulations,
- Controlled Drugs and Substances Act & its Regulations,
- Food and Drugs Act & Regulations,
- PEIPB Code of Ethics,
- Model Standards of Practice for Canadian Pharmacists,
- Supplemental Standards of Practice for Schedule II and III Drugs, and
- PEIPB Standards of Practice, Policy Directives and Guidelines (where applicable).
- Provincial Formulary (PEI)
- Provincial Interchangeable Drug List

APPENDIX C – FIRST AID and CPR CERTIFICATION REQUIREMENTS

A pharmacist shall maintain current certification in First Aid and Cardiopulmonary Resuscitation (CPR) as required qualifications for prescribing drugs as specified in Standard 3.3.7 in the Standards of Practice: Pharmacist Prescribing. The certification requirements established by Council for First Aid and CPR are outlined below. Certifications for First Aid and CPR are to be obtained through the Canadian Red Cross, St. John Ambulance Canada or other organization recognized by Council.

FIRST AID

Certification in First Aid

CARDIOPULMONARY RESUSCITATION (CPR) CERTIFICATION

Minimum Certification Requirements - all of the following skills are required for CPR certification (CPR Level C*):

- Adult/Child/Baby CPR – one rescuer
- Adult/Child/Baby choking
- Automated External Defibrillator (AED) Operator Certification

In addition to fulfilling the minimum requirement, pharmacists are encouraged to obtain the following preferred/non-mandatory additional CPR skills (these skills are offered in CPR Level HCP*):

- Adult/Child/Baby 2-rescuer CPR
- Rescue breathing
- Bag-Valve-Masks (BVMs) use

Recertification Requirements:

- Recertification to be in accordance with the certifying organization (such as, for example, the Canadian Red Cross, St. John Ambulance Canada, etc.).

* At time of printing, the specified CPR levels were reflective of national listings by the Canadian Red Cross and St. John Ambulance Canada.

APPENDIX D – PATIENT CONSENT and DISCLOSURE REQUIREMENTS

A pharmacist shall obtain informed and voluntary consent for the pharmacist prescribing service and disclosure of information related to pharmacist prescribing in accordance with applicable legislative and regulatory requirements.

For reference, the following overview provides a general understanding of who can provide consent (i.e. Consent Authorities) as well as documentation and information disclosure requirements. For further details and specifics beyond those provided in this appendix, refer directly to the applicable legislation/regulations.

CONSENT AUTHORITIES

Adult Patients

A pharmacist shall obtain informed and voluntary consent from an adult patient, provided that the patient has the capacity to consent.

A pharmacist can assume that an adult patient has the capacity to consent and make his/her own treatment and prescription decisions, unless the pharmacist has reason to doubt a patient's capacity. Through communicating with the patient and obtaining required information to support the prescribing process (conducted in person if practicable), a pharmacist can confirm a patient's capacity to consent by determining that the patient has the ability to:

- understand information that is relevant to making a treatment decision, and
- appreciate the reasonably foreseeable consequences of a decision.

Mature Minors

A pharmacist can obtain informed and voluntary consent from a mature minor. A mature minor is one who is capable of understanding the nature and consequences of the treatment and has, therefore, legal capacity to consent to his/her treatment.

A pharmacist shall rely on their own judgment to ascertain whether a minor is sufficiently mature to make treatment decisions. The following factors can assist the pharmacist in assessing the maturity of a minor:

- What is the nature, purpose and utility of the recommended medical treatment? What are the risks and benefits?
- Does the minor demonstrate the intellectual capacity and sophistication to understand the information relevant to making the decision and to appreciate the potential consequences?
- Is there reason to believe that the minor's views are stable and a true reflection of his or her core values and beliefs?
- What is the potential impact of the minor's lifestyle, family relationships and broader social affiliations on his or her ability to exercise independent judgment?
- Are there any existing emotional or psychiatric vulnerabilities?
- Does the minor's illness or condition have an impact on his or her decision making ability?
- Is there any relevant information from adults who know the minor (e.g. physicians)?

In situations where a pharmacist determines that a minor has the necessary maturity to make his or her own treatment decisions, all rights in relation to giving or withholding consent will belong to the minor. The parent or guardian will no longer have any overriding right to give or withhold consent.

Patient Agents

When prescribing for an adult or mature minor patient who is not available to provide consent and another individual indicates by direction or implication that he/she is the patient's agent, the pharmacist shall take reasonable steps to confirm the identity of the individual who is acting as the patient's agent and to confirm that the individual has the patient's authorization to act on their behalf. The pharmacist shall consider the nature, purpose and process of the activity requiring consent, including the associated benefits and risks, when using

professional judgment to accept consent from the patient's agent in this situation.

Non-Mature Minors

For non-mature minors, a pharmacist shall obtain informed and voluntary consent from the patient's agent. The patient's agent shall be determined in accordance with the considerations and ranked order outlined in the Patients Lacking Capacity to Consent section.

Patients Lacking Capacity to Consent

For patients who lack the capacity to consent, a pharmacist shall obtain informed and voluntary consent from the patient's agent. The pharmacist shall deal with the patient's agent as represented by a substitute decision maker appointed by the patient through the Personal Directives Act or the Medical Consent Act to make personal care decisions (including health care decisions) should the patient become incapable of making decisions.

In situations where a personal directive or medical consent appointment exists, the pharmacist shall request a copy of it, follow the instructions and general principles regarding personal care decisions set out in the directive and file it in the pharmacy records for the patient.

In situations where a personal directive or medical consent appointment does not exist (and for non-mature minors as referenced above), the pharmacist shall deal with the patient's agent as represented by a substitute decision maker in the following ranked order:

- Legal guardian (appointed by the court)
- Nearest relative (as applicable), in this order:
 - Spouse – includes married, common-law (partners living together for one year or more) and registered domestic partners
 - Child
 - Parent
 - Person standing in loco parentis
 - Sibling
 - Grandparent

- Grandchild
- Aunt or uncle
- Niece or nephew
- Other relative
- Public trustee

There is a limitation on the determination of the nearest relative by the ranked order. In order to be a substitute decision maker, the patient's nearest relative shall meet the following criteria:

- has been in personal contact with the patient over the preceding 12 months or has been granted a court order to waive the 12 month period (note that spouses are exempt from this 12 month personal contact requirement);
- is willing to assume decision-making responsibility;
- knows of no person of a higher rank in priority who is able and willing to assume decision-making responsibility; and
- makes a statement in writing to certify the relationship with the patient, that they are willing to act as the substitute decision maker, and know of no person ranked higher in priority.

In addition, the pharmacist shall be satisfied through direct or telephone discussions with the individual and using their professional judgment that the nearest relative can act as the patient's agent given the nature and purpose of the treatment, the intellectual capacity of the individual and the impact on the patient.

DOCUMENTATION REQUIREMENTS

Documentation of Informed Consent

A pharmacist shall include documentation in the pharmacy records for the patient that informed and voluntary consent was obtained and from whom. Written consent from the patient or patient's agent is not required. Documentation of consent in the pharmacy records for the patient shall include:

- the name of the person who provided consent,
- confirmation of consent (can be satisfied by checking a “consent obtained” box) for the pharmacist prescribing service and for disclosure of prescribing decision details and information to the patient’s primary health care provider, the original prescriber (if different from the primary health care provider and/or other appropriate health care professionals, and
- where applicable, confirmation of consent directly on the prescription record for the pharmacist to dispense a drug which he/she prescribed.

Documentation for Patients Lacking Capacity to Consent

For a patient who lacks the capacity to consent and a personal directive or medical consent appointment exists, a pharmacist shall obtain a copy of the Personal Directive or Medical Consent and file it in the pharmacy records for the patient.

For a patient who lacks the capacity to consent / non-mature minors where the patient’s agent is the “nearest relative”, a pharmacist shall obtain and file written confirmation from the agent that he/she is the nearest relative (supported by a birth certificate or other identification), that he or she has been in personal contact with the patient over the preceding 12 months, is willing to assume decision-making responsibility with respect to the pharmacist prescribing, and knows of no one who ranks higher in the hierarchy of relatives who is able and willing to assume decision making responsibility.

For a patient who lacks the capacity to consent / non-mature minors where the patient’s agent is a legal guardian or public trustee, a pharmacist shall review the court issued order to confirm applicability and retain a copy of the documentation.

INFORMATION DISCLOSURE REQUIREMENTS

In accordance with the Pharmacist Drug Prescribing Regulations and section 3.8 of these standards, a pharmacist shall communicate all actions taken in prescribing to the patient’s primary health care provider, the original prescriber (if different from the primary health care provider) and/or other appropriate health care professionals.

There can be other circumstances that require or justify a pharmacist to disclose information regarding actions taken in prescribing without the patient's informed and voluntary consent, including:

- reporting an adult in need of protection in accordance with the Adult Protection Act,
- reporting child abuse in accordance with the Children Protection Act, and
- reporting notifiable diseases in accordance with the Notifiable and Communicable Diseases Regulations.

Refer to the cited legislation for additional information regarding the disclosure of information in the above circumstances.

APPENDIX E – COMMUNICATION PROCESS AND NOTIFICATION

INTRODUCTION

The Standards of Practice – Prescribing of Drugs by Pharmacists specifies the importance of effective communication and inter-professional collaboration in support of patient health and safety in a patient-centred and collaborative model of care. An established process is required for timely and appropriate communication and collaboration among pharmacists, other health care professionals and the patient regarding the pharmacist prescribing process and decisions. A communication process framework and notification forms for pharmacist prescribing are provided in the following sections.

PROCESS FRAMEWORK

Communication Roles and Responsibilities	
Prescribing Process - supporting the patient's health, safety and best interest:	
Prescribing Pharmacist	To support the prescribing process, communicates with and obtains input and information from the following, as appropriate: <ul style="list-style-type: none">• patient or patient's agent,• primary health care provider,• original prescriber (if applicable and different from primary health care provider), and/or• other pharmacists / health care professionals.
Patient or Patient's Agent	Provides information to the prescribing pharmacist to support the prescribing process
Primary Health Care Provider, Original Prescriber & Other Pharmacists / Health Care Professionals	Provides information and input to the prescribing pharmacist to support the prescribing process.

Prescribing Decision - providing information on the pharmacist prescription for changed or renewed drug therapy to support continuity of patient care and collaborative care:	
Prescribing Pharmacist	<p>For communication with patient or patient's agent:</p> <ul style="list-style-type: none"> • Communicates the patient assessment details / findings, prescribing decision, associated rationale, follow-up plan and any notification to other health care professionals. • Uses communication method which maintains confidentiality. <p>For communication with primary health care provider, original prescriber (if applicable and different from primary health care provider) and other applicable pharmacists / health care professionals:</p> <ul style="list-style-type: none"> • Communicates patient's presenting health condition or drug related problem, patient assessment details / findings, prescribing decision, associated details and rationale, supporting information (e.g. instructions to patient) and follow-up plan / responsibilities. • Provides written communication using the standard Pharmacist Prescribing Notification form (provided in the Notification Forms section of Appendix E). • Uses communication method which maintains confidentiality. • Completes communication within 24 hours of writing the prescription or as soon as possible thereafter
Patient or Patient's Agent	Listens to information from the prescribing pharmacist and asks questions, if required, to fully understand what the drug is for, how to take it, the possible side effects and follow-up plan.
Primary Health Care Provider, Original Prescriber & Other Pharmacists / Health Care Professionals	<p>Reviews Pharmacist Prescribing Notification form and adds it to the patient record.</p> <p>Considers the new prescription in future care and treatment of the patient.</p> <p>Takes appropriate action, if warranted by the new prescription (e.g. risk to the patient).</p>

Follow-up Results - providing information on subsequent patient monitoring to support continuity of patient care and collaborative care:	
Prescribing Pharmacist	<p>For communication with patient or patient's agent:</p> <ul style="list-style-type: none"> Obtains information on the response to the new prescription and provides additional information, as required. <p>For communication with primary health care provider, original prescriber (if applicable and different from primary health care provider) and other applicable pharmacists / health care professionals:</p> <ul style="list-style-type: none"> Communicates the results of subsequent monitoring of the patient regarding the pharmacist prescribing. Provides written communication using the standard Monitoring Results Notification form (provided in the Notification Forms section of Appendix E). Uses communication method which maintains confidentiality. Completes communication within 24 hours of follow-up with patient or as soon as possible thereafter.
Patient or Patient's Agent	Provides information to the pharmacist and asks questions, if applicable, regarding the response to the new prescription.
Primary Health Care Provider, Original Prescriber & Other Pharmacists / Health Care Professionals	<p>Reviews Monitoring Results Notification form and adds it to the patient record.</p> <p>Considers the monitoring results in future care and treatment of the patient.</p> <p>Takes appropriate action (e.g. intervention, monitoring, etc.), if warranted by the monitoring results.</p>

Pharmacist Prescribing Notification- For Your Records

Notification Information

Original Prescriber:	Date:
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Original Prescription Information

Prescription Details:

Pharmacist Prescribing Category

Adaptation
 Dose
 Formulation
 Regimen

 Renewal
 Therapeutic Substitution

Rationale for Prescribing:

Prescription Information

Affix Rx Label	Health Card Number:
	Informed Consent : <input type="checkbox"/> Patient <input type="checkbox"/> Patient's Agent

Follow-up Plan

Therapeutic Goal	Communication to Patients	Follow-up Date	Pharmacist

Pharmacist's Signature:	Lic#
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APPENDIX F- DOCUMENTATION REQUIREMENTS

The following information regarding prescribing by a pharmacist shall be documented, filed and retained in the pharmacy records:

General Patient Information	Name
	Contact information
	Date of birth
	Gender
	Weight and height, if applicable
	Any known contraindications or allergies/ intolerances to drugs, excipients or other substances related to drug therapy.
	Medical conditions
	Pregnancy and lactation status, if applicable
	Other relevant information
Prescription Order (written or printed copy)	Patient name and address
	Date of prescription
	Drug name, strength and dosage form
	Quantity
	Directions for use and route of administration
	Number of refills and interval between each refill, if applicable
	Name of prescribing pharmacist
	Reference to the original prescription and prescriber name / contact information, where applicable (i.e. prescription adaptation, therapeutic substitution and prescription renewal).
	File the original and new prescriptions together in cases where the original prescription from another prescriber is adapted or

	substituted with a therapeutic equivalent.
Prescribing Details	Date of prescribing decision
	Presenting health condition or drug related problem including symptoms, signs, history and any treatment.
	<p>Patient assessment details / findings, including:</p> <ul style="list-style-type: none"> • date of assessment • physical characteristics, condition and measurements (e.g. weight, height, etc) • date, extent and results of last assessment of the condition, if applicable • laboratory or other diagnostic test results • subjective and objective findings • diagnosis (if available) • medical history, as applicable • family medical history, as applicable • current medical conditions, medications, non-medication therapies, health care products / devices and treatments • risk factors • other health care professionals and caregivers involved in providing treatment/care • personal circumstances, practical needs, values and preferences, where applicable • other information relevant to the assessment
	Description of prescribing decision, its rationale and any supporting information / documents (e.g. laboratory report, previous prescription label, written documentation of diagnosis from health care professional requesting pharmacist to select and prescribe appropriate drug therapy, etc.)
	Instructions to patient
Follow-up plan details to allow other health care professionals or	

	caregivers to monitor patient's progress.
	Name of prescribing pharmacist
	Information to allow other professional staff in the pharmacy to provide continuity of care.
	Date and method of notifying original prescriber
	Date and method of notifying other health care professionals, if applicable
	Reference to the original prescription and prescriber name / contact information, when applicable (i.e. prescription adaptation, therapeutic substitution and prescription renewal).
	Patient informed and voluntary consent (refer to Appendix D for Patient Consent and Disclosure Requirements).
	Details of subsequent monitoring and follow-up regarding the pharmacist prescribing, where applicable.

