College of Registered Nurses of Prince Edward Island	INVESTIGATIONAL AND SPECIAL ACCESS PROGRAM MEDICATION PRACTICE DIRECTIVE
	Date Effective: April 2019
	Revised:
	Next Review Due: April 2022

Background

Registered Nurses may be expected to administer investigational drugs or medications accessed through the Special Access Program (SAP). Investigational drugs are used in clinical trials. The Special Access Program (SAP) allows prescribers to request access to drugs that are unavailable for sale in Canada. It is limited to clients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable.

Purpose

This practice directive provides guidance for registered nurses to administer investigational or special access program medications. SAP is supported by sections C.08.010 and C.08.011 of the *Food and Drug Regulations*.

Definitions

An investigational drug is a therapeutic agent that has been approved for human clinical trials by Health Canada and the practice setting. This may include drugs or chemicals used in a therapeutic manner that have not been approved for use in Canada, in an untried therapeutic manner to treat an entirely different disease, or where a new drug is introduced as a trial.

Special access program (SAP) medications refer to drugs that are not on a practice setting's formulary or approved for general use and require special authorization through the *Special Access Program of Health Canada*.

1.0 Policy

1.1 The use of all investigational or special access medications requires a prescription from a physician or nurse practitioner.

1.2 RNs administering investigational or special access program medication must have the necessary information (e.g. product monograph) to safely administer,

monitor and manage these medications and any potential side effects and adverse effects.

1.3 The physician/NP who is prescribing the drug is responsible to ensure that the registered nurse has access to the drug monograph/information sheet prior to administration of the drug (Note: the monograph/information sheet may come in the drug packaging or may need to be obtained separately).

1.4 The physician/NP prescriber is expected to provide education to the client/participant and relevant nursing staff with regard to the prescribed administration and possible side effects.

1.5 The RN administering special access program medication must have a signed and dated, client/participant consent form obtained by the prescriber prior to administration.

1.6 Investigational medications used in human clinical trials must be approved by the Health PEI Research Ethics Board and require an additional written consent, the process for which must be outlined in the research protocol.

1.7 The nurse is accountable for reviewing the product monograph prior to administration, correctly administering the medication, to intervene and hold the medication if severe side effects occur and to notify the physician/NP prescriber promptly.

1.8 The nurse is not accountable for any outcomes that the investigational medications or special access program medication themselves may produce.