Nova Scotia College of Pharmacists

PRACTICE POLICY

Refrigeration of Drugs, Vaccines, and Biologics

Effective Date: July 1, 2025

Introduction

Pharmacy practitioners are responsible for ensuring that drugs are stored in a manner that ensures their security and integrity. This responsibility requires diligence and rigor for drugs that have strict temperature requirements.

Maintaining the potency of drugs, vaccines and biologics is critical for several reasons:

- The harm to patients if they receive a product that has compromised or lost effectiveness
- These products are expensive and may be in limited supply.
- The need to re-vaccinate people who may have received an ineffective vaccine may cause a loss of public confidence in vaccines and/or the health care system.

Policy

Pharmacy managers and owners are responsible for ensuring that:

- policies and procedures are in place for the appropriate management of the cold chain, including an emergency management plan that addresses the steps to be taken when the temperature is out of range.
- policies and procedures are consistent with Nova Scotia Public Health and Health Canada requirements. (see resources below)
- appropriate storage equipment is used and maintained in good working order.

Refrigerators, freezers, or environments used to store drugs must be:

- unaffected by outside temperatures and able to maintain temperature within the recommended storage range without deviation (e.g., between 2°C and 8°C) even when surrounding temperatures change or after opening the door to remove a product.
- equipped with a thermometer or data logger that is calibrated to +/- 1ºC accuracy.
- equipped with a method to notify staff of temperature excursions in real time while the pharmacy is open.
- located in an area in the pharmacy* where access is restricted to authorized personnel.
- dedicated to the storage of drugs, vaccines, and biologics only.

Public Health Vaccines

Pharmacy practitioners play a critical role in the provision of publicly funded vaccines and have a responsibility to be good stewards of the public vaccine supply entrusted to their care. In addition to the requirements above, refrigerators, freezers, or environments used to store Public Health vaccines must:

- be located within the pharmacy*, and
- maintain the required temperature for the duration of the power interruption and do so without human intervention for at least the first 24 hours.

Note: Small, single door bar refrigerators must not be used, unless they are purpose built for vaccine storage

Consistent refrigerator, freezer, or environment temperature logging and reporting must take place by:

- Ensuring that the minimum and maximum temperatures are recorded, either manually or electronically, at least twice daily, once in the morning before the door is first opened and at the end of the day before the door is closed for the last time. Temperatures outside the accepted range must be reported to the pharmacy manager and action taken immediately.
- Reviewing the temperature log weekly to ensure proper temperature recording and to note trends in temperatures.

Report any breaks in the cold chain for publicly funded vaccines in accordance with local Public Health requirements. A copy of any *Vaccine Cold Chain Failure Incident Reports* submitted to Public Health must be forwarded to the NSCP at reports@nspharmacists.ca or by fax at (902) 444-7071.

Resources

- Nova Scotia Health: Immunization Manual (2019)
- Nova Scotia Health: Vaccine Toolkit
- Nova Scotia Health: Cold Chain Management
- Canadian Immunization Guide: Storage and Handling of Immunizing Agents
- Public Health Agency of Canada: National Vaccine Storage and Handling Guidelines for Immunization Providers (2015)

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* To clarify, "in the pharmacy" does not mean that it must be located within the dispensary, but it must be within the pharmacy, where access is restricted to authorized personnel.