PROFESSIONAL PRACTICE POLICY

Refrigeration of Drugs, Vaccines, and Biologics

Introduction

Pharmacists have a responsibility to ensure that drugs are stored in a manner that ensures the integrity and security of the drugs. This responsibility requires particular diligence and rigour with drugs such as vaccines and biologics, which have strict temperature requirements that must be maintained as they become less effective or inactivated when exposed to temperatures outside the recommended range. Cold-sensitive vaccines experience an immediate loss of potency following freezing.

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

- There is a need to ensure that the product being used is effective.
- As immunizers, pharmacists will be entrusted with the storage of vaccines purchased by Nova Scotia taxpayers. Careful management of resources is important. Vaccines and biologics are expensive and may be in limited supply.
- The need to re-vaccinate people who have received an ineffective vaccine may cause a loss of public confidence in vaccines and/or the health care system.

Policy

Pharmacy managers have the responsibility to ensure appropriate storage equipment and policies are in place that are consistent with the Nova Scotia Immunization Manual, with the exception that other refrigerated drugs may be stored with vaccines and biologics. They must also read and be familiar with the information on storage and handling of immunizing agents in the Canadian Immunization Guide.

The requirements found in the NS Guidelines Immunization Manual include that small, single door refrigerators (e.g., regular bar fridges) must not be used to store vaccines or biologics. Any refrigerator used for vaccines or biologics storage 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. The thermometer shall be calibrated to +/- 1°C accuracy and shall provide minimum-maximum twice daily temperature monitoring and recording of the refrigerator (and freezer, if applicable) temperature;
- dedicated to the storage of drugs, vaccines, and biologics only; and
- located within the dispensary.
Note: There may be some commercial grade, counter height fridges purpose-built specifically to store drugs, vaccines, and biologics, but regular bar fridges should not be confused as being equivalent in terms of quality.

The following requirements apply to refrigerator temperature logging:

1. Record the minimum and maximum refrigerator (and freezer, if applicable) temperatures at least twice daily, once in the morning when fridge door is first opened and at the end of the day before the fridge is closed for the last time. Report temperatures outside the accepted range (2-8°C) to the pharmacy manager or designated vaccine coordinator and ensure that action is taken immediately.

2. The pharmacy manager or designated vaccine coordinator shall review the temperature log weekly to ensure proper temperature recording and to note trends in refrigerator/freezer temperatures. During periods when temperature is out of range, document any steps taken to address the temperature variances, including how drugs, vaccines and equipment are managed.