REGISTRAR’S ADVISORY
Community Pharmacy Involvement in COVID-19 Immunization

Introduction
Over the last several years, pharmacies and pharmacy practitioners have become experts at administering vaccines and providing immunization clinics for their patients. This expertise is invaluable in positioning the profession to significantly contribute to the COVID-19 vaccine rollout that is underway and pharmacy professionals are now being called upon to do just that.

The COVID-19 immunization campaign is by far the largest and most aggressive ever undertaken worldwide. The vaccines being used are new, and it is anticipated that more will be approved by Health Canada throughout 2021 and beyond. For many of these vaccines, handling and storage requirements differ from most common vaccines, and clinical information and guidance about them is constantly evolving. The speed at which this campaign is unfolding is unprecedented, and the importance of it being successful is paramount.

While pharmacies and pharmacy managers have confidently operated many influenza vaccine clinics, it is important that they understand the unique issues specific to this significant immunization campaign that warrant special consideration. A pharmacy will need to adapt its standard approach for influenza immunization services to address these issues.

Similarly, pharmacy practitioners will need to stay current with evolving information as they prepare to become COVID-19 immunizers. They will need to closely monitor for new information about the vaccines and evolving updates from NS Public Health and adapt their immunization practice accordingly.

Purpose
It is critical to the public’s health and safety that community pharmacy’s involvement in the COVID-19 immunization is successful. This Registrar’s Advisory is aimed at supporting pharmacy owners, managers, and practitioners in identifying where adaptations to their standard immunization policies, procedures, and practices are needed so that they continue to meet legislated requirements and the NSCP standards of practice.

Legislative Requirements Applicable to Community Pharmacy COVID-19 Immunization Services

1. A pharmacy manager is required to develop, maintain, and enforce policies and procedures for the provision of COVID-19 immunization services that comply with the standards of practice. The Standards of Practice: Drug Administration s. 5.1 provides a preliminary list of topics that a pharmacy manager needs to consider
and address for immunization clinics generally. Pharmacy managers will need to consider what adaptations to the pharmacy's standard immunization policies and procedures are required for COVID-19 immunization services. Resources to support managers in meeting this requirement include:

- The Nova Scotia Department Health and Wellness (DHW) has prepared theNova Scotia COVID-19 Vaccine Program: Information for Health Care Professionalsdocument. This is acritical resource for pharmacy managers and pharmacy practitionersand is updated regularly as evidence on COVID-19 and COVID-19 vaccines evolves. It includes links to important references and provides answers to questions relevant to pharmacy practitioners and other healthcare providers in a Q&A format.

- The Public Health Agency of Canada (PHAC) has provided guidance on planning COVID-19 immunization clinics. The COVID-19 Vaccines – Planning for Immunization Clinics webinar walks through all stages of the immunization service, from the parking lot and greeting/screening through to post-administration observation, and is based on the Government of Canada document Planning for immunization clinics for COVID-19 vaccines.

- The Pharmacy Association of Nova Scotia (PANS) has prepared the PANS COVID-19 Program Implementation Guide. This contains detailed information about the program and information on clinic set up.

2. A pharmacy manager is required to establish a staffing plan commensurate with patient care requirements and take reasonable steps to implement it.

- It is anticipated that pharmacies will be managing large volumes of COVID-19 immunizations from April to October 2021, after which the annual influenza immunization campaign will launch. It is critical that the pharmacy’s owner and manager are diligent in complying with their requirement to establish a staffing plan that meets the human resource needs for all of the pharmacy’s services.

3. A pharmacy manager is required to implement policies that set out the practice roles and responsibilities of all non-registrant dispensary employees, consistent with the Pharmacy Act, regulations and the standards of practice.

- A pharmacy with a COVID-19 immunization clinic may need to hire additional non-registrant employees as support workers. Pharmacy managers must ensure that restricted activities are only undertaken by those with the licensed authority to do so.

- The NSCP and Nova Scotia College of Nursing (NSCN) have developed theJoint Statement on Nurses Employed in Community Pharmacies to Support the COVID-19 Pandemic Responseto support Nova Scotia’s COVID-19 immunization plan. A pharmacy may make use of the professional services of a nurse in accordance with this statement and upon the pharmacy manager being satisfied that the nurse has an active licence to practice. The pharmacy manager will need to collaborate with the nurse to determine the extent to which the nurse’s authorized scope enables them to undertake the various professional activities required by the NSCP standards of practice when a pharmacy provides immunization services. The pharmacy manager will need to make adaptations to the pharmacy’s immunization policy and procedures as needed. For clarity, required activities include:

- determining appropriateness to receive the immunization and supporting patients in providing informed consent (e.g., answering outstanding questions they may have about the immunization).
ensuring the patient’s consent for the immunization is informed (e.g., ensuring they have been made aware of the risk and benefits and responding to any questions the patient may have). For some patients whose underlying medical condition warrants a more detailed information and consent process, the nurse may need to involve a pharmacist or specialist (see the Nova Scotia COVID-19 Vaccine Program: Information for Health Care Professionals).

• preparing and administering the vaccine appropriately (set out in the Standards of Practice: Drug Administration).
• counselling the patient on anticipated effects and potential adverse effects.
• reporting adverse events following immunization (AEFI).

Guidance

The following guidance is provided to support pharmacy managers and practitioners in their involvement with the COVID-19 immunization campaign.

Coordination of the Vaccine Rollout in Pharmacies

The Pharmacy Association of Nova Scotia (PANS) is coordinating the vaccine rollout in pharmacies with the Department of Health and Wellness. Plans are evolving rapidly and will be communicated to pharmacies as they become available. Pharmacy managers and other PANS members need to pay close attention to the weekly email communication sent out by PANS and watch for specific communication that may be sent in between the weekly communication.

More information can be found on the Pharmacy Association of Nova Scotia COVID-19 Resource page.

Clinical Vaccine Information

While the concept of using vaccines to prevent illness is not new, the vaccines authorized for use against COVID-19 are new. The clinical information available about these vaccines is vast and is rapidly evolving. For pharmacists to be able to routinely answer patient questions and help guide patients in their decision to be vaccinated, they will need to undertake additional education specific to these vaccines. The Nova Scotia COVID-19 Vaccine Program: Information for Health Care Professionals is updated regularly and contains information specific to the Nova Scotia immunization campaign and links to many other sources of important information. Pharmacy practitioners need to read this critical resource in its entirety as a foundation to their self-learning.

Additional helpful information is available in the National Collaborating Center for Infectious Diseases (NCCID) and Public Health Agency of Canada (PHAC) webinars guidance documents including:

• COVID-19 Vaccines Foundational Webinar
• PHAC: Recommendations on the use of COVID-19 Vaccines
Vaccine Inventory Management

Given current vaccine supply issues, and the importance of having as many people as possible fully vaccinated, it is critical that vaccine inventory be managed properly and that no doses are wasted or rendered unusable. The vaccines being used, and in particular the mRNA vaccines, have specific handling, storage, and in the case of the Pfizer-BioNTech vaccine, dilution requirements.

Pharmacy practitioners need to ensure they are familiar with the specific requirements for each of the vaccines. Pharmacy managers need to review their recent refrigerator logs to ensure that they are operating in a manner that will support the storage requirements of these vaccines and ensure that all staff members are aware of the importance of the cold chain, including the process that must be followed should a cold chain break occur.

Information on the specific storage and handling requirements for the COVID-19 vaccines currently being used is available from the manufacturers:

- Pfizer-BioNTech: https://www.cvsvaccine.ca/
- Moderna: https://www.modernacovid19global.com/ca/

As new vaccines become available, pharmacy practitioners will need to consult the individual manufacturer’s product monograph for specific information.

Information on the use of low dead volume (LDV) syringes for the Pfizer-BioNTech vaccine can be found on the website, the NCCID/PHAC webinar COVID-19 Vaccines-Allergies and LDV Syringe Discussion, and the Pfizer-BioNTech website.

Vaccine Hesitancy

While many members of the public are incredibly eager to receive their vaccine, others are hesitant.

Healthcare providers are consistently ranked by patients as their most trusted source of information. As a healthcare provider that interacts frequently with the public, pharmacists are ideally suited to provide patients with easy-to-understand, accurate information. The public requires reassurance from pharmacists that the vaccines for COVID-19 are held to the same high safety, effectiveness, and quality standards as all other vaccines. Health Canada continually monitors vaccine safety and vaccine providers are required to report any unexpected adverse events to Health Canada.

Immunization Clinics

Pharmacies will provide COVID-19 vaccines to patients through an appointment-based, clinic style format as walk-in service is not an option in the early phases of the vaccine rollout. Some pharmacy owners/managers will use offsite locations for these clinics while others will run them in their retail pharmacy location. Regardless of
the format used, pharmacy managers need to consider the following to help them ensure a successful clinic while still being able to meet the needs of their regular patients:

- The quantity of vaccine expected to be administered over a period of time.
- The impact on the pharmacy’s regular workflow and how this will impact patient safety.
- The amount and type of staffing that will be needed to operate the clinic and the pharmacy.
- The space required (in consideration of physical distancing) for patients waiting to get their vaccines, those being vaccinated, those being monitored post-vaccination, and regular patients and customers of the pharmacy on the day of the clinic.

Information on planning for immunization clinics is available through the following resources:

- NCCID/PHAC webinar COVID-19 Vaccines – Planning for Immunization Clinics
- Government of Canada document Planning for immunization clinics for COVID-19 vaccines (PHAC)

Patient Monitoring and Preparation for Emergencies

As more and more people across the globe are immunized against COVID-19, confidence in the vaccine safety profile continues to grow. Despite this, these vaccines are new, and it is critical that patients are monitored for a minimum of 15 minutes post-vaccination and 30 minutes for specific populations. Although pharmacy practitioners always monitor patients after they have provided them with a vaccine, the rigor needed for monitoring for COVID-19 vaccines goes beyond what is generally needed for influenza. Pharmacy managers will need to plan how they will accomplish this monitoring while adhering to public health measures.

Although serious adverse effects such as anaphylaxis are rare, the general advice is that anaphylaxis should be anticipated in all patients and pharmacy practitioners must be prepared to handle this emergency, including knowing the requirements for reporting adverse events.

Less serious, and likely more common, are vasovagal type reactions. Although fainting in and of itself is generally not harmful, it can result in serious head injuries due to falling. Pharmacy practitioners must be prepared for this and ensure that necessary supplies are on hand.

Information on handling allergies and anaphylaxis can be found at:

- Information for Heath Care Providers on Allergies and Anaphylaxis following administration of COVID-19 vaccines
- Anaphylaxis and other Acute Reactions following Vaccination: Canadian Immunization Guide
- NCCID/PHAC webinar COVID-19 Vaccines-Allergies and LDV Syringe Discussion

Record Keeping and Patient Consent

Record keeping for the COVID-19 vaccine will not follow the same process as for other vaccines. Pharmacy practitioners are not required to record the record of the vaccine in their pharmacy software system or in the NS DIS Immunization Module. Instead, the Standards of Practice: Drug Administration require that “for vaccines
against SARS-CoV-2, the details of the immunization are submitted into CANImmunize Clinic Flow, a mobile app used by Public Health to record and track immunizations.

The Clinic Flow app will eliminate the use of paper-based consent forms and it may be possible for patients to indicate their consent at the time of booking their appointment. However, it is important for pharmacy practitioners to recognize that even if a patient indicates their consent at the time of booking, this does not eliminate the need for the pharmacist to review all health status and consent documentation within Clinic Flow to:

- ensure it is appropriate to provide the vaccine;
- provide the patient with an opportunity to have any of their questions answered; and
- counsel the patient on what to expect after they have been vaccinated and on the need and timing for a second dose.

More information on the Clinic Flow platform can be found on the Pharmacy Association of Nova Scotia COVID-19 Resource page and will be provided to pharmacies as the vaccine campaign continues to unfold.

Immunization of Special Populations

There are very few known absolute contraindications to receiving the COVID-19 vaccine. However, there are precautions for special population as the evidence of the safety and/or effectiveness of the COVID-19 vaccines is lacking – these population were either not studied or there were few trial participants that fell into these categories. These include:

- pregnancy, planning pregnancy, or breastfeeding
- patients who are immune compromised due to a drug or disease or an underlying autoimmune condition
- patients who have previously had COVID-19

The National Advisory Council on Immunization (NACI) recommends that COVID-19 vaccine series may be offered to these individuals if the benefits outweigh the potential risks for the individual (+/- fetus/infant) and if the patient has consented having had a discussion about the absence of evidence on the use of COVID-19 vaccines in this population.

Pharmacists have the expertise and skills necessary to ensure that the vast majority of people who can get a vaccine will get a vaccine, and they play a crucial role in providing education to patients to help inform their consent. The Nova Scotia Vaccine Expert Panel has developed guidance and a management pathway for healthcare professionals that can be found in Nova Scotia COVID-19 Vaccine Program: Information for Health Care Professionals. The information in this document can be used by pharmacists to help make decisions about when, and with whom they should consult about individuals that fall into these special populations.

Additional information can be found at:

- PHAC: Guidance on the use of COVID-19 vaccines
- The Pharmacy Association of Nova Scotia Webinar Nova Scotia Pharmacy’s Role in COVID-19 Vaccination (Dr. Tasha Ramsey provides a detailed discussion on special populations) (March 2021)