Ministry of Health

Office of Chief Medical Officer of Health, Public Health

Box 12
Toronto, ON M7A 1N3

Fax.: 416 325-8412

Ministère de la Santé

Bureau du médecin hygiéniste en chef, santé publique

Boîte à lettres 12
Toronto, ON M7A 1N3

Téléc. :416 325-8412

September 18, 2026

RE: COVID-19 Vaccine Market Withdrawal

Dear Health Care Provider and Organizations,

This letter is to provide direction on the market withdrawal of Moderna Spikevax® and Pfizer-BioNTech Comirnaty® COVID-19 LP.8.1 vaccines in Canada.

The decision to withdraw all COVID-19 LP.8.1 vaccine products are part of Health Canada's regulatory process to support the authorization of the updated Spikevax® and Comirnaty® Omicron XFG formulation for the upcoming fall 2026/27 respiratory illness season. This market withdrawal is not related to product quality, safety or efficacy.

Effective immediately, the Ontario Ministry of Health is directing all custodians of Spikevax® and Comirnaty ® COVID-19 LP.8.1 vaccine to discontinue the distribution and administration of all lots of the product and place all remaining inventory in quarantine pending destruction. Vaccine custodians must follow their local policies, procedures and established processes for the destruction of vaccine inventory and the completion of associated documentation. Records of inventory destruction may be requested by the Ministry. **Effective immediately**, all remaining inventory must be either destroyed in accordance with local procedures or quarantined pending destruction. For sites that do not have these products on hand, no action is required.

The vaccine products and strain subject to this withdrawal are identified below:

Product names:

Spikevax® (COVID-19 mRNA vaccine) Omicron LP.8.1
Comirnaty® (COVID-19 mRNA vaccine) Omicron LP.8.1

Vaccine Strain: Omicron LP.8.1

DINs:

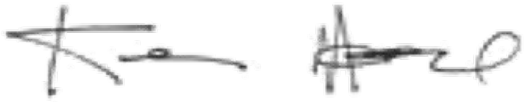
Spikevax®: 02541270 (Prefilled Syringe) / 02557770 (Multi-Dose Vial)

Comirnaty®: 02552035(Prefilled Syringe) / 02541823 (Multi-Dose Vial) / 02541858 (Single-Dose Vial)

As a result of regulatory withdrawal of existing formulations of COVID-19 vaccines, there will be a supply gap of COVID-19 vaccines until the new formulation of XFG is released. Please continue to counsel and provide advice to individuals seeking COVID-19 vaccines, that immunization with the new XFG formulation is recommended, once available, as per recommendations from the National Advisory Committee on Immunization (NACI). The new formulation provides greater protection against circulating COVID-19 strains compared to earlier vaccine formulations.

Initial supply of the updated COVID-19 XFG vaccine formulation is expected to be available in Ontario by late-September. Specific details will be provided when the new formulation is available in Ontario.

Sincerely,



Dr. Kieran Michael Moore, MD, CCFP(EM), FCFP, MPH, DTM&H, FRCPC, FCAHS
Chief Medical Officer of Health and Assistant Deputy Minister, Public Health

Appendix 1

GUIDANCE ON INVENTORY MANAGEMENT FOR THE WITHDRAWAL OF COVID-19 LP.8.1 VACCINES REQUIRED ACTIONS:

- Discontinue use of all COVID-19 LP.8.1 vaccine products.
- Quarantine and label all COVID-19 LP.8.1 vaccine products as “DO NOT USE” until physical destruction is completed.
- Please follow the steps below to ensure that administration of LP.8.1 vaccines **does not** continue after the withdrawal date:
    - Dispose of all COVID-19 LP.8.1 vaccines as per standard local procedures.
    - Custodians are required to maintain documentation of all vaccine disposals and make such records available to the Ministry upon request.
    - Routine cold chain monitoring for the above products will not be necessary.