Ontario

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

August 27, 2025

Dear Health Care Provider,

This letter is to provide direction on the market withdrawal of all Pfizer COVID-19 KP.2 vaccines in Canada. All Moderna KP.2 products have reached expiry.

The decision to withdraw all KP.2 vaccine products is part of the Health Canada regulatory process to authorize the approval of Pfizer and Moderna's regulatory submission of LP.8.1 formulations for the upcoming fall 2025 respiratory illness season.

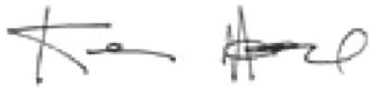
As required by Health Canada, the Ontario Ministry of Health is directing all custodians of Pfizer COVID-19 KP.2 vaccine to immediately quarantine and destroy the remaining supply of viable KP.2 vaccine and report their revised inventory on COVax$_{ON}$ by **September 2, 2025**. Local practices and processes for the destruction of these vaccines should be followed. For sites that do not have this product on hand, no action is required.

Vaccine sites are reminded of the requirement to update inventory in COVax$_{ON}$ promptly as part of the market withdrawal (please see Appendix 1 for guidance on inventory management).

As a result of this regulatory withdrawal of Pfizer KP.2 product and the expiration of the Moderna product, there will be no supply of COVID-19 vaccines until the new formulation of LP.8.1 is released. Please continue to counsel and provide advice to individuals seeking COVID-19 vaccines, that immunization with the new LP.8.1 formulation is recommended, once available, as per recommendations from the National Advisory Committee on Immunization (NACI). The updated formulation provides greater protection against circulating COVID-19 strains compared to earlier vaccine formulations.

The incoming supply of the new formulation of LP.8.1 vaccine is expected to be distributed in Ontario by late-September. Specific details will be provided when the new formulation is available in the province, along with full details on fall vaccination programs.

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 KP.2

VACCINES REQUIRED ACTIONS:

- Discontinue use of all COVID-19 KP.2 vaccine products.
- Quarantine and label all COVID-19 KP.2 vaccine products as “DO NOT USE” until physical destruction is completed.
- Ensure all vaccination records have been entered in COVax$_{ON}$ **prior to adjusting inventories. Entry of outstanding vaccination records must be completed ASAP.**
- Once all vaccination records have been updated, please follow the steps below to ensure that administration of KP.2 vaccines **does not** continue after the withdrawal date:

    1. Update the Vaccination Event Inventory status to ‘Inactive’ for **all** KP.2 vaccine lots.
    2. Update the Inventory Status to ‘Suspended for Vaccines’.
    3. Upon destruction, clear all remaining KP.2 inventory in COVax$_{ON}$ by entering wastage events referencing the appropriate wastage reason:

        - Wastage of **viable** vaccine doses (i.e., not yet expired, before beyond-use-date (BUD)) should be recorded using the wastage reason of **“Other”** accompanied with the following note: **“Doses wasted due to PHAC market withdrawal of all KP.2 vaccine products”**.
        - Wastage of **non-viable** vaccines (i.e., elapsed manufacturer’s expiry date or BUD) should be recorded using the appropriate wastage reasons (See Appendix 2 for list of wastage reasons).
        - Dispose of all COVID-19 KP.2 vaccines as per standard local procedures.
        - Routine cold chain monitoring for the above products will not be necessary.

Appendix 2: List of Wastage Reasons

Wastage Reasons
DP – OS -Damaged Product
DP – TAO – Damaged product during transport within PHU or between AOs
DE - Defective Product - Manufacturer
WR - ID - Insufficient Dose(s) From a Single/Multi-Dose Vial
WR - Dose(s) Remaining in a Multi-dose vial
WR – SVM – Suspected Vaccine Contamination - Manufacturer
WR - SV - Suspected Vaccine Contamination – Human error
WR - UN - Unused Pre-drawn Syringe
WR - VA - Vaccine Administration Issue
WR - VAS - Vaccine Ancillary Supply Issue Causing Vaccine Wastage
WR - RP – Vaccine vial punctured and not used before beyond use time
WR - RA – Vaccine vial left in room temperature conditions beyond use time
WR - RB – Fridge Stable (2 - 8 degrees C) Vaccine Vial Refrigerated beyond use time
WR - BE – Vaccine vial stored in ult/freezer/fridge temperatures beyond expiry date
WR – TT – Vaccine transported in thawed state beyond manufacturers recommendations