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COVID-19 Vaccinators,

The Public Health Agency of Canada (PHAC) has issued a market withdrawal of all COVID-19 XBB vaccines in Canada, to take place on September 1, 2024.

The decision to withdraw all XBB vaccine products is part of the regulatory process to authorize the approval of Pfizer and Moderna's regulatory submission of KP.2 formulations to Health Canada for the upcoming fall 2024 respiratory illness campaign. As part of the authorization of the new formulation for the fall, Health Canada will remove the strain identifier (XBB / KP.2, etc.) from the naming convention of the COVID-19 vaccine products to enable the assignment of one drug identification number (DIN) for each presentation on an ongoing basis.

As a requirement of the regulator, Health Canada, the Ontario Ministry of Health is required to quarantine remaining supply of viable XBB vaccine starting on September 1, 2024, and follow local practices and process for the destruction of these vaccines. Vaccine sites are required to update COVaxON in a timely manner as part of the market withdrawal (please see Appendix 1 for guidance on inventory management).

For sites that do not have this product on hand, no action is required. Please continue to counsel and provide advice on COVID-19 vaccination, which is for individuals to be vaccinated with the new formulation per the National Advisory Committee on Immunization and the Ontario recommendations. The upcoming supply of the new formulation of KP.2 vaccine doses is expected to start distribution in late September. Specific details will be provided once confirmation of Health Canada authorization of KP.2 is received and manufacturer confirmation of delivery schedule following vaccine lot release.

As a result of this regulatory withdrawal process, XBB COVID-19 vaccine will not be available between the market withdrawal on September 1, 2024, to receipt of the new formulation of KP.2. Per the National Advisory Committee on Immunization and the Ontario program, it is recommended to wait for the new KP.2 formulation to provide greater protection against circulating COVID-19 strains compared to earlier vaccine formulations.

Thank you,

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Chief Medical Officer of Health and Assistant Deputy Minister, Public Health

c: Elizabeth Walker, Executive Lead, Public Health
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Appendix 1

Guidance on Inventory Management for the Withdrawal of XBB Vaccines

Required Actions after August 31, 2024:

- Discontinue use of all COVID-19 XBB vaccine products after August 31, 2024.
- Quarantine and label all COVID-19 XBB 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 XBB vaccines **does not** continue after the withdrawal date:

    1. Update the Vaccination Event Inventory status to 'Inactive' for **all** XBB vaccine lots.
    2. Update the Inventory Status to 'Suspended for Vaccines'.
    3. Upon destruction, clear all remaining XBB 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 XBB 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 XBB 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