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September 5, 2024

## **Dear Vaccination Stakeholder,**

The purpose of this letter is to inform Canadian vaccination distributors and stakeholders of updated storage conditions for SPIKEVAX® (COVID-19 mRNA vaccine), Drug Identification Number (DIN): 02541270.

Storage Conditions	SPIKEVAX Unpunctured vial	SPIKEVAX Punctured Vial
Refrigerated conditions: (2°C to 8°C)	50 days	Discard <b>24 hours</b> after first dose has been withdrawn
Room temperature conditions: (8°C to 25°C)	12 hours	Discard <b>12 hours</b> after first dose has been withdrawn



- The updated storage conditions are being shared in advance of Health Canada authorization of the 2024 strain update (KP.2 variant) to assist with distribution planning.
- Moderna confirms these storage conditions have been approved by Health Canada and will be reflected in the next update to the SPIKEVAX Product Monograph.
- There are no changes to the product presentation. SPIKEVAX will be available in one presentation: 0.1 mg/mL multidose vial (2.5 mL).

**Note:** These updates <u>do not apply</u> to the previous SPIKEVAX XBB.1.5 vaccine.

As a reminder, the transportation time for SPIKEVAX in refrigerated conditions (2° to 8°C) was updated in May 2024 as follows:

• If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials in liquid state for up to **36 hours at 2° to 8°C** when shipped using shipping containers which have been qualified to maintain 2° to 8°C and under routine road and air transport conditions with shaking and vibration minimized.

## **Additional Resources**

 For additional information including the Product Monograph and package leaflet, please visit <u>modernacovid19global.com/en-CA</u> or scan the QR code. Please check back often as the website will be updated with new information on SPIKEVAX as it becomes available.



Sincerely,

Leslie Madden BSc, MBA, LLM Senior Director, Head of Regulatory Science & Quality Assurance Moderna Biopharma Canada Corporation