COVID-19 Pfizer Adult/Adolescent Vaccine (Gray Cap; monovalent and bivalent)

Shipping, Storage, Thawing and Use Guidelines

A. Formulations:
- Monovalent – 30 mcg/0.3 ml - intended population: 12 years of age and older
- Bivalent – 30 mcg/0.3 ml - intended population: 12 years of age and older (booster dose only)

B. Shipping:
- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed in unpunctured vials at 2°C to 8°C.
- Single-dose preloaded syringes may be transported in exceptional circumstances
- Vials should be upright during transport, and tightly packed to reduce jostling of the vials.
- Validated containers must be used for transport.
- Temperature must be monitored continuously during transportation and documented

C. Storage:
-60°C to -90°C, Ultra-Low Temperature (ULT) Shipper (frozen):
  - Carton may arrive packaged in thermal packing designed for temporary storage. The shipper can be used for temporary frozen storage for up to 30 days.
  - If using the Pfizer-provided shipper upon receipt and after opening, dry ice should be replenished within 24 hours (maximum of 20-23 kg of dry ice pellets; recommended sizes: 9-16 mm). If transferring into a provincially/federally provided shipper, follow guidelines for dry ice replenishment to prepare shipper to store the vaccine.
  - With every re-icing, shipper can maintain ULT storage for 5 days with 2 openings per day of 3 minutes or less, i.e. dry ice must be replenished every five days. NOTE: Additional openings of shipper will require more frequent dry ice replenishment (see resource link below).
  - Temperature monitoring must be continually conducted while vaccine is stored in thermal shipper.

-60°C to -90°C, Ultra-Low Temperature (ULT) Freezer (frozen):
  - Monovalent: Can be stored at ULT for 18 months after manufacturing date printed on the vial/carton.
  - Bivalent: Can be stored at ULT for 12 months after manufacturing date printed on the vial/carton.
2°C to 8°C Refrigerator (thawed):
- Thawed vaccine can be stored for up to 10 weeks (70 days).
- Once placed in 2°C to 8°C environment, the carton should be updated with the expiry information.

2°C to 25°C Room Temperature (thawed):
- Vials may be stored for up to 24 hours at temperatures up to 25°C, with no more than 12 hours from the time of first puncture. After first puncture the vials should be stored at 2°C to 25°C
- Thawed vials can be handled in room light conditions.

D. Thawing:
Regular Use
- A carton of 10 vials may take up to 6 hours to thaw in the refrigerator (2°C - 8°C)

Immediate Use
- Thaw at room temperature (up to 25°C) for 30 minutes.

Handling Frozen Vials
- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to 5 minutes
- If carton is at room temperature for over 5 minutes, consider it to be thawing and do not place back in freezer. Vials must be stored and moved into a refrigerated (2°C-8°C) container.
- Individual vials removed from a carton and left at room temperature should not be returned to frozen or refrigerated storage and must be thawed for use.

Thawed vaccine cannot be refrozen.

E. Use
- Vials may be stored for up to 24 hours at temperatures up to 25°C with no more than 12 hours from the time of first puncture.
F. Vaccine Stability

<table>
<thead>
<tr>
<th>ULT</th>
<th>2°C to 8°C</th>
<th>Room temperature</th>
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<tbody>
<tr>
<td>-90°C to -60°C for 30 days (replenish dry ice q 5 days)</td>
<td>10 weeks (70 days)</td>
<td>Vials may be stored for up to 24 hours at temperatures up to 25°C with no more than 12 hours from the time of first puncture</td>
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<tr>
<td>-90°C to -60°C</td>
<td></td>
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<tr>
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<td></td>
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<td>Bivalent: 12 months from manufacturer date</td>
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G. Helpful Resources

While specific links have been identified below, it is highly recommended that health authorities and sites familiarize themselves with the resources provided by Pfizer at www.cvdvaccine.ca

- Pfizer Monovalent Product Monograph
- Pfizer Bivalent Product Monograph
- Pfizer COVID Vaccine Resources
- Pfizer Dry Ice Safety Data Sheet
- Pfizer Vaccine Shipping And Handling Guidelines
- Pfizer instructions on dry ice replenishment

Any questions or requests for revision of this document should be sent to IBCOC_Operations@phsa.ca
## List of Amendments

<table>
<thead>
<tr>
<th>Date</th>
<th>Section</th>
<th>Description</th>
<th>Author</th>
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<tbody>
<tr>
<td>July 22, 2022</td>
<td>A, B, C, D, E, F</td>
<td>SOP developed based on product monograph and information provided by Pfizer</td>
<td>Calvin Kaila</td>
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<tr>
<td>Oct 11, 2022</td>
<td>A</td>
<td>Information added about Bivalent formulation</td>
<td>Calvin Kaila</td>
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<tr>
<td>Dec 14, 2022</td>
<td>G</td>
<td>Link to bivalent monograph added and other hyperlinks updated</td>
<td>Calvin Kaila</td>
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<tr>
<td>Jan 11 2023</td>
<td>C, F</td>
<td>Expiry information updated</td>
<td>Calvin Kaila</td>
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