

STANDARD OPERATING PROCEDURE

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| Chapter: Science System and Performance (SSP) | SOP#: |
| Section: Vaccine Storage and Handling | |
| Subject: NSHA: Ordering and Receiving Products from Suppliers or PSPC | |
| Approved by: | Approval Date: |
| Applies To: Public Health Staff | |

INTRODUCTION

The Department of Health and Wellness determines the annual vaccine quantity needs and the monthly ordering schedule (for the fiscal year April 1 to March 31) in conjunction with Biological Depot Immunization Coordinator. Only the Bio Depot can order vaccines/biologicals from suppliers or manufacturers. All invoices from Suppliers will be sent to the Provincial Biodepot.

The purpose of this standard operating procedure is to outline the process for ordering and receiving vaccines/biologicals that support the proper storage and handling of vaccines using current evidence based information, and provincial and national guidelines.

1.0 Process for Ordering Products from Suppliers or Public Service Procurement Canada (PSPC) for the Biological Depot

- 1.1 On a monthly basis the Biological Depot Pharmacy Practicing Assistant reviews current inventory on hand (refer to view inventory user guide). The Biological Depot Pharmacy Practicing Assistant compares the inventory on hand to the contracts and the allotted monthly amounts (The Biodepot Spread Sheet) and forecasts the vaccine orders necessary for the upcoming month.

- 1.2 The Biological Depot Pharmacy Practicing Assistant decides if an adjustment is required for the monthly ordering schedule.

2.0 Process for Adjustment to Monthly Ordering Schedule

- 2.1 The Biological Depot Pharmacy Practicing Assistant summarizes the request for an adjustment and submits this to the Immunization Coordinator by e-mail.
- 2.2 The Immunization Coordinator will review the request and submit a request to the Department of Health and Wellness (DHW) Consultant, Communicable Disease Prevention and Control (CDPC) for approval of an adjustment to the monthly ordering schedule.
- 2.3 DHW Consultant (CDPC) will approve adjustment with confirmation by e-mail to the Immunization Coordinator.

3.0 Process for Vaccine Ordering from Suppliers or PSPC for the Biological Depot

3.1 The Biological Depot

- 3.1.1 The product delivery request functionality is restricted to users with the Inventory Provincial role. The PDR process is completed by the Biological Depot Pharmacy Practicing Assistant, Immunization Coordinator, or the Central Zone Biological Coordinator.
- 3.1.2 The NSHA Biological Depot Pharmacy Practicing Assistant for the Biological Depot will verify the invoice from the Supplier and verifies information on invoice against the PDR ([hyperlink to user guide reference sheet](#)).
- 3.1.3 The Biological Depot Pharmacy Practicing Assistant will email the PDR to the Supplier or PSPC.
- 3.1.4 The Biological Depot Pharmacy Practicing Assistant will receive an email confirmation from the supplier of PSPC that the order has been processed.

- 3.1.5 If a supplier does not have the amount of vaccine requested and cannot meet the needs of the order, the Immunization Coordinator will consult with the CDPC Consultant. The CDPC Consultant will be informed of rationale for not meeting needs (shortage or limitations of vaccine that veer from an allocation). If necessary, the CDPC Consultant will consult with PSPC regarding supply for remaining vaccine in the request.
- 3.1.6 The Biological Depot Pharmacy Practicing Assistant will specify a date for delivery. In the event the supplier must change the date a confirmation email is sent stating the date the order will arrive.
- 3.1.7 The Biological Depot Pharmacy Practicing Assistant will receive the vaccine order, verifying storage and handling during transit. On receipt of the vaccine the temperature recording device (TT4-Temp Tale) are stopped and read immediately upon arrival. The temp Tale will indicate if the temperature has been out of range (+2°C and +8 Celsius). The devices are checked for a CCB and put in the fridge before the vaccine is accepted into the biodepot inventory in Panorama.
- 3.1.8 The Biological Depot Pharmacy Practicing Assistant will read and record the temp tale recordings (decision point).
- 3.1.9 Biological Depot Pharmacy Practicing Assistant will verify the invoice from the Supplier against the PDR including price and quantity received to retrieve/update the PDR in Panorama.
- 3.0 Process for Temp Tale recordings if outside the Correct Range**
- 4.1 If the temp tale recording in the shipment is outside the correct range (+2°C and +8 Celsius), the Biological Depot Pharmacy Practicing Assistant will mark the products outside the correct range as quarantined for CCB investigation.
- 4.2 The products are placed in Quarantine HPL by the Biological Depot Pharmacy Practicing Assistant and marked as exposed do not use until

investigated by Biological Depot Pharmacy Practicing Assistant and supplier ([hyperlink to user guide reference sheet](#)).

4.3 The Biological Depot Pharmacy Practicing Assistant will record the shipment in Panorama and place in the fridge (quarantine) until direction from Supplier. Upon receipt of the suppliers confirmatory email to release the product, the product will be placed in the Operational HPL and recorded in Panorama ([hyperlink to user guide reference sheet](#)).

5.0 Process for Temp Tale recordings within the Correct Range

5.1 If the temp tale log is within the correct range (+2°C and +°8 Celsius) and the products are placed in the Operational HPL by the Biological Depot Pharmacy Practicing Assistant.

5.2 All shipments from suppliers (Merck, Pfizer) request that they read the temp tale log and provide confirmation to release the product. These products will be placed in the Quarantine HPL ([hyperlink to CCB policy](#)) until the Biological Depot Pharmacy Practicing Assistant has received a confirmatory email from the supplier to release the product ([hyperlink to user guide reference sheet](#)).

5.3 The Biological Depot Pharmacy Practicing Assistant will do a physical count verifying the packing slip and Supplier invoice matches completely with the PDR.

5.4 The Biological Depot Pharmacy Practicing Assistant will mark “Approved for Payment” in Panorama ([hyperlink to user guide reference sheet](#)).

5.5 Upon completion of “Approved for payment” the Provincial Biological Pharmacy Practicing Assistant will send the verified invoice and backup documentation to the CDPC Administrative Assistant.

6.0 Process if the physical count does not have a full match to the PDR and packing slip

6.1 When the Biological Depot Pharmacy Practicing Assistant completes the physical count and there is at least one product line that does not match with the PDR then the Biological Depot Pharmacy Practicing

Assistant/designate will record denied quantity on Receive PDR Screen ([hyperlink to user guide reference sheet](#)).

- 6.2 The Biological Depot Pharmacy Practicing Assistant will follow up with the supplier or PSPC regarding error in shipment (missing vaccine, incorrect vaccine in shipment compared to PDR).
- 6.3 If the shipment does not have the correct amount ordered on the PDR the Biological Depot Pharmacy Practicing Assistant will receive the quantity shipped in Panorama. The Supplier will then arrange to fill a backorder for the remaining vaccine and communicate this by e-mail with the Biological Depot Pharmacy Practicing Assistant.
- 6.4 The Biological Depot Pharmacy Practicing Assistant notifies the Immunization Coordinator and DHW CDPC Consultant by e-mail summarizing the discrepancy and the request for back order from the Supplier.
- 6.5 If the shipment has the wrong vaccine compared to the PDR then the Biological Depot Pharmacy Practicing Assistant will return the shipment to the supplier and would then receive the order at a later date when it is sent to the Biological Depot.
- 7.0 **Process if the physical count does match the PDR and packing slip (decision point)**
 - 7.1 The Biological Depot Pharmacy Practicing Assistant will confirm that the product lot exists in panorama ([hyperlink to user guide reference sheet](#)).
 - 7.2 If the product lot does not exist the Biological Depot Pharmacy Practicing Assistant will create a new product lot ([hyperlink to user guide reference sheet](#)).
 - 7.3 If the product lot does exist the Biological Depot Pharmacy Practicing Assistant will receive accepted quantity in appropriate HPL.
 - 7.4 The Biological Depot Pharmacy Practicing Assistant will send back the TT4 and any documentation required by the specific supplier.

8.0 Biological Depot Pharmacy Practicing Assistant /designate Waiting for Supplier Release (decision point)

- 8.1 All shipments from suppliers (Merck, Pfizer) request that they read the temp tale log and provide confirmation to release the product. These products will be placed in the Quarantine HPL until the Biological Depot Pharmacy Practicing Assistant has received a confirmatory email from the supplier to release the product.
- 8.2 If the Biological Depot Pharmacy Practicing Assistant receives approval to release the product from the supplier then he/she will physically move the product to Operational HPL. The Biological Depot Pharmacy Practicing Assistant will record move to Operational HPL ([hyperlink to user guide reference sheet](#)).
- 8.3 The Biological Depot Pharmacy Practicing Assistant will approve PDR for payment.
- 8.4 If the Biological Depot Pharmacy Practicing Assistant is informed the product is not approved for release it will be returned to the supplier.

9.0 Biological Depot Pharmacy Practicing Assistant not waiting for supplier release

- 10.0 If the Biological Depot Pharmacy Practicing Assistant does not have to wait for the supplier to release the vaccine and there has not been a CCB then the Biological Depot Pharmacy Practicing Assistant /designate will approve PDR for payment ([hyperlink to user guide reference sheet](#)).
- 9.2 If the shipment is not approved for release by the supplier then the Biological Depot Pharmacy Practicing Assistant will return the shipment to the supplier and receive new product at a later date when it arrives to the biological depot.
- 9.2 If the Biological Depot Pharmacy Practicing Assistant is notified by the supplier of a CCB the product will be marked as having a CCB and the adverse storage event will be documented ([hyperlink to user guide reference sheet](#)) and followed as a CCB by the Biological Depot Pharmacy Practicing Assistant/Immunization Coordinator.

- 9.2 If the Biological Depot Pharmacy Practicing Assistant is notified there has not been a CCB then the product will be physically moved to the Operational HPL. The Biological Depot Pharmacy Practicing Assistant/designate will record the move to the Operational HPL in panorama.
- 9.2 The Biological Depot Pharmacy Practicing Assistant will mark “Approved for Payment” in Panorama ([hyperlink to user guide reference sheet](#)).
- 9.6 Upon completion of “Approved for payment” the Provincial Biological Coordinator will send the verified invoice and backup documentation to the CDPC Administrative Assistant.

DEFINITIONS

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| Biological Depot | The vaccine storage facility located 7 Mellor Avenue Public Health (PH), housing vaccines for district and provincial distribution. |
| Cold chain break (CCB) | Several events can occur during transportation or storage that may compromise the cold chain, thus exposing the vaccine to adverse conditions (temperatures outside the recommended range or adverse light exposure, delays during shipping, storage unit malfunctions, vaccines mistakenly stored at inappropriate temperatures. When a cold chain break is suspected the Biological Depot Pharmacy Practicing Assistant/Immunization Coordinator will follow up the investigation to determine if vaccine remains safe to use. |
| PDR | A product request to an external Supplier to replenish the inventory at a holding point. Panorama functionality for a PDR is a provincial role. |
| Correct Range | The optimum temperature for refrigerated vaccines is between +2° Celsius and +8° Celsius (PHAC, 2015) |

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| Holding Point Location | A discrete location where product is kept in inventory. Holding Point Locations (HPLs) can be arranged into a hierarchy (e.g., warehouse, aisle, shelf, bin or fridge, shelf, bin). Product must be received into, and issued from a specific HPL. |
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REFERENCES

Public Health Agency of Canada (2015). National Vaccine Storage and Handling Guidelines for Immunization Providers 2015. PHAC, Ottawa, ON.

APPENDICES

HISTORY

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| CURRENT VERSION |
| Prepared by: Stacey Dunphy Reviewed by: Jana Vickers, The Biological Depot Pharmacy Practicing Assistant Savia Pye, CDPC Consultant, DHW Teri Cole, CDPC Consultant, DHW Version #: October 9, 2017 |

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| RESCINDED VERSIONS |
| SOP #: Version #: SOP Subject: Approved by: Date approved: |

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