Manitoba Health Vaccines and Biologics Product Complaint Procedure

DATE APPROVED: AUGUST 2022
APPLICABLE TO: ALL IMMUNIZATION PROVIDERS

PURPOSE: The purpose of this document is to outline the process in which immunization providers can report any vaccine or biologic product complaints to Manitoba Health.

POLICY: Manitoba Health reviews all complaints received and reports appropriate ones to the manufacturer and the Public Health Agency of Canada (PHAC) for potential investigation, product return for examination by the manufacturer, and potential cost recovery.

PROCEDURE:

1. Once an issue has been identified with a vaccine or biologic, determine if the issue affects more than one vial/syringe/pack. If so, put all affected product aside in the refrigerator and attach a note indicating DO NOT USE until further direction is provided by Manitoba Health.
2. If issue occurred affecting one vial/syringe and the product cannot be put aside (i.e. broken vial, needle separated, etc.) take note of the product information and discard into a designated Biologics container.

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3. Complete the Vaccine and Biologics Product Problem Report Form (second page) ensuring that all areas are completed and email to **vaccines@gov.mb.ca** or fax to Manitoba Health at 204-948-2040.
4. Manitoba Health will review the Vaccine and Biologics Problem Report and seek direction from the Manufacturer.
5. If required to return product to the manufacturer for investigation or potential cost recovery, Manitoba Health will advise the location to contact the Provincial Vaccine Warehouse to set up a return.
6. To prepare for the return to the Provincial Vaccine Warehouse, complete the Vaccine and Biologics Return Form located at: **http://www.gov.mb.ca/health/publichealth/cdc/div/manual/index.html** and include it with the product.
7. If the product is determined to be usable, Manitoba Health will advise the location and all quarantined product in the refrigerator can be returned back into regular supply for use.

Manitoba Health Vaccines and Biologics Problem Report Form

DATE OF REPORT (YEAR-MONTH-DAY):	REPORTED BY: NAME TITLE	
EMAIL ADDRESS:	REGIONAL HEALTH AUTHORITY:	
VACCINE AND BIOLOGIC DESCRIPTION (TYPE, BRAND NAME, FORMAT):		
LOT NUMBER / EXPIRY DATE:	MANUFACTURER:	NUMBER OF DOSES AFFECTED (VIALS, SYRINGES, ETC):

PROBLEM IDENTIFICATION (CHECK ALL THAT APPLY):

- ☐ DULL NEEDLE
- ☐ NEEDLE SEPARATES(ED) FROM SYRINGE
- ☐ OTHER (SPECIFY):
- ☐ CONTENTS CLOUDY OR CONTAINS PARTICLES
- ☐ LABEL CONCERNS (E.G. CAN'T READ LOT #)

DETAILS (PLEASE PROVIDE DETAILS OF THE PROBLEM EXPERIENCED INCLUDING DATE, TIME AND FREQUENCY/EXTENT OF THE PROBLEM:

ADDITIONAL COMMENTS:

CONFIDENTIAL WHEN COMPLETED

Email completed report to vaccines@gov.mb.ca (click Submit Form button) or print and fax to Manitoba Health at 204-948-2040. Manitoba Health will advise via email on the next steps required, if any.

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