

Vaccine and Biologic Product Complaint Procedure and Form

Public Health

Date Approved: April 2014
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.
3. Complete the Vaccine and Biologics Problem Report (below) ensuring that all areas are completed and fax it 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.

Vaccine and Biologics Product Problem Report

❖ **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:** [number of vials, syringes, etc] _____

❖ **Problem Identification (check all those that apply):**

<input type="checkbox"/>	Dull needle
<input type="checkbox"/>	Needle separates(ed) from syringe
<input type="checkbox"/>	Contents cloudy or contains particles
<input type="checkbox"/>	Label concerns (e.g. can't read Lot #)
<input type="checkbox"/>	Other (Specify):

❖ **Details:** [Please provide details of the problem experienced; including date and time experienced and frequency/extent of problem. Attach additional page as necessary.]

❖ **Additional comments?** [Attach additional page as required]

Manitoba Health will advise via email on the next steps required, if any.

CONFIDENTIAL WHEN COMPLETED
Fax completed report to Manitoba Health at 204-948-2040