



Health, Seniors and Active Living

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September 26, 2018

RE: Gardasil@9 Vaccine Problem Reporting

Dear Health Care Provider:

Manitoba Health, Seniors and Active Living (MHSAL) has been notified of a potential issue affecting the following two lots of Gardasil@9 vaccine:

Lot # N028718	Expiry Date: May 18, 2020	(Distributed by MHSAL in Jul/Aug 2018)
Lot # N025434	Expiry Date: May 18, 2020	(Distributed by MHSAL Apr-Present)

Issue Description: liquid contained inside the vial may appear murky and resemble a jelly-like or oily substance.

Corrective Action: The vaccine manufacturer has been contacted and should an immunization provider experience the issue described above, they have recommended vigorous agitation of the affected vial.

- If the vaccine returns to suspension, it is safe to use.
- If the vaccine does not return to suspension do not use the product, contact the Provincial Distribution Warehouse to arrange for the product to be picked up, and complete the MHSAL Vaccine and Biologics Product Problem Report Form that is attached and located on our website at:
<http://www.gov.mb.ca/health/publichealth/cdc/div/docs/vbpcpf.pdf>

To date, MHSAL has not been notified of any unusual Adverse Events Following Immunization (AEFI) with the Gardasil@9 lots specified above and Health Canada nor has the manufacturer issued a recall for these lot numbers. This is only for precautionary purposes. Please see the following for AEFI reporting requirements in Manitoba: http://www.gov.mb.ca/health/publichealth/cdc/docs/aeafi_reporting.pdf

Immunization providers are encouraged to fill out the MHSAL Vaccine and Biologics Product Problem Report Form any time they experience an issue with a publicly-funded vaccine. Reports are then collated by a pan-Canadian working group for review and may result in the identification of a larger widespread issue by the manufacturer. Do not dispose of the product. Any product that has a potential problem is to be returned for MHSAL to address with the manufacturer.

If you have any further questions regarding these matters, please contact Communicable Disease Control at 204-788-6737.

Thank you for your cooperation.

Sincerely,

Richard Baydack, PhD
Director
Communicable Disease Control
Health, Seniors & Active Living

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