2017-2018 Seasonal Influenza Immunization Handbook for Pharmacists

October 1, 2017

Government of Saskatchewan

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2017-2018 Publicly Funded Influenza Vaccine Eligibility

Government of Saskatchewan

Groups for whom influenza vaccination is particularly recommended

Publicly funded influenza vaccines may be administered to people who are six months of age and older who do not have vaccine contraindications. In particular, the following people are highly recommended to receive the influenza vaccine to reduce the incidence and burden of influenza disease and related health complications:

- All healthcare workers (HCWs), healthcare students, emergency response workers, visitors and volunteers who, through their activities, are capable of transmitting influenza to those at high-risk of influenza complications in independent practices, facilities, residences and community settings.
  - For the purposes of this statement, HCWs include any person, paid or unpaid, who provides direct or indirect health services, works, volunteers or trains in a health care setting.
- Adults (including pregnant women) and children ≥6 months with a chronic health condition including but not limited to:
  - cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis & asthma);
  - diabetes mellitus and other metabolic diseases;
  - cancer and other immune-compromising conditions (due to underlying disease, therapy or both);
  - renal disease;
  - anemia or hemoglobinopathies;
  - neurologic or neurodevelopment conditions including neuromuscular, neurovascular, neurodegenerative, neurodevelopmental disorders and seizure disorders (and for children includes febrile seizures and isolated developmental delay) but excluding migraine and psychiatric conditions without neurological conditions
  - morbid obesity (adult BMI ≥ 40, child BMI assessed as ≥ 95th percentile adjusted for sex and age)
- Children and adolescents with the following conditions:
  - Those undergoing treatment for long periods with acetylsalicylic acid, because of the potential increase of Reye syndrome associated with influenza.
- People of any age who are residents of nursing homes, long-term care facilities and other chronic care facilities.
- People ≥ 65 years of age.
- All children six to 59 months of age (younger than five years).
- All pregnant women.
- Aboriginal Peoples.
- Visitors to health care facilities and other patient care locations.
- Household and close contacts of individuals at high-risk of influenza-related complications whether or not the individual at high-risk has been immunized.
- Household and close contacts of infants less than six months of age.
- Members of households who are expecting a newborn during the influenza season.
- Those providing regular child care to children ≤ 59 months of age, whether in or out of the home.
- Those who provide services within closed or relatively closed settings to persons at high-risk.
- People who provide essential community services (e.g., provincial corrections staff who have direct contact with inmates).
- People in direct contact during culling operations with poultry infected with avian influenza.
- People working with live or dead poultry or swine.
- Health sciences students (human and animal health).
- Travellers – Influenza occurs year-round in the tropics. In temperate northern and southern countries, influenza activity peaks generally during the winter season (November to March in the Northern Hemisphere and April to October in the Southern Hemisphere).

Preamble

- This handbook includes the Saskatchewan Ministry of Health's ("*the Ministry*") recommendations for the 2017-18 seasonal influenza immunization campaign.
- The Ministry's Population Health Branch (PHB) supports Saskatchewan pharmacists by supplying publicly funded influenza vaccine and developing vaccine information sheets and client immunization record cards.
- The Ministry's Drug Plan and Extended Benefits Branch (DPEBB) supports Saskatchewan pharmacists by being the main contact for questions related to the DPEBB Influenza Immunization Program (IIP) policy, pharmacy billing requirements and processes, registering a pharmacy's participation in the IIP, and immunization data submission and collection from pharmacies. Pharmacies can contact Arlene Kuntz at the DPEBB at (306) 787-3306 or arlene.kuntz@health.gov.sk.ca . The DPEBB will work with Saskatchewan pharmacy wholesalers to provide vaccine ordering information and processes to pharmacies.
- Other questions from pharmacies including those related to the Ministry's Seasonal Influenza Immunization Program and delivery of vaccine from wholesalers **must** be submitted to the DPEBB. These questions will be directed to the appropriate resource for response.
- It is recommended that pharmacists print out this document for all staff to review.

The following principles may be considered to increase immunization rates, improve access to immunization services and enhance the overall client experience:

1. Immunization services should be accessible through pharmacy locations with flexible hours to ensure maximum opportunities for access.
2. Pharmacies should have specific strategies in place to mitigate fluctuations in demand or vaccine availability.

Influenza Program Dates

- The provincial publicly funded influenza program is scheduled to begin on Monday October 23, 2017 and end on March 31, 2018.
- Pharmacists and pharmacies are expected to be ready by the start date, but shall not administer publicly funded influenza vaccine before that date.

2017-18 Immunizer Parameters for Publicly Funded Influenza Vaccines

- Saskatchewan pharmacists can immunize persons 9 years of age and older with publicly funded multidose quadrivalent injectable influenza vaccines (QIVs).
    - Children younger than 9 years old are to be immunized at Public Health
    - Individuals without a valid Saskatchewan Health Card or who are not a Saskatchewan resident are to be immunized at Public Health
- Public Health Nurses, Physicians and Nurse Practitioners can immunize persons six months of age and older with publicly funded injectable QIVs.

Vaccine Information

- Fluzone® Quadrivalent (Sanofi Pasteur) and FluLaval® Tetra (GSK) quadrivalent injectable vaccines (QIVs) are inactive vaccines and contain the following viral strains:
  - A/Michigan/45/2015 (H1N1)pdm09-like virus;
  - A/Hong Kong/4801/2014 (H3N2)-like virus;
  - B/Brisbane/60/2008-like virus; and
  - B/Phuket/3073/2013-like virus.
- The National Advisory Committee on Immunization (NACI) 2017-18 influenza vaccine statement is posted at www.naci.gc.ca.
- Publicly funded QIVs are safe for use in persons with latex allergy.
- Publicly funded QIVs may be given concomitantly with or at any time before or after live attenuated vaccines or inactivated vaccines.
- The Ministry has purchased a supply of thimerosal-free Fluzone® Quadrivalent injectable vaccine for individuals who have an allergy to thimerosal confirmed and diagnosed by a physician. **Pharmacists and other non-public health immunizers must refer these individuals to Public Health for immunization.**
- The Ministry does not reimburse the cost of privately-purchased influenza vaccines.
- Refer to Appendix 2: *Characteristics of Influenza Vaccines Authorized in Canada, 2017-2018* for information on Canadian licensed influenza vaccines.

QIV by Age and Dosage

Age	Dosage (mL)	Number of doses required per season
9 years and older	0.5 mL IM	1

Precautions and Contraindications

- Previous anaphylaxis to influenza vaccine is a contraindication to receiving further influenza vaccine.
- Persons who had an anaphylactic reaction to a previous influenza vaccine dose or to any of the components in a specific vaccine (with the exception of egg), or who developed Guillain-Barré Syndrome (GBS) within six weeks of a live or inactivated influenza vaccination, should not receive further doses of any influenza vaccines.
- QIV administration should usually be postponed in persons with serious acute illnesses until their symptoms have abated. Immunization should not be delayed because of minor acute illness, with or without fever.
- As with all vaccine administration, immunizers must have the necessary equipment and medications to be prepared to respond to a vaccine emergency at all times.
- Egg-allergic individuals can receive a full dose of a QIV without prior influenza vaccine skin testing, as a routine practice that is supported by NACI.
- The Ministry of Health recommends that when a decision is made to re-immunize those who have suffered a past severe allergic reaction (not anaphylaxis as it is a contraindication) related to an influenza vaccine or its components, these individuals should be vaccinated in a setting where appropriate expertise, equipment and medications to manage respiratory or cardiovascular compromise is available (as discussed with MHO)and that they are observed post-immunization (e.g., minimum for 30 minutes).
- Oculo-respiratory syndrome (ORS) is defined as the presence of bilateral red eyes **plus** one or more respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that start within 24 hours of vaccination, with or without facial oedema. ORS **is not** considered to be an allergic response. Persons who experienced ORS with lower respiratory tract symptoms should have an expert review. Health care providers who are unsure whether an individual previously experienced ORS versus an IgE-mediated hypersensitivity immune response should seek

advice. Although the pathophysiologic mechanism underlying ORS remains unknown, it is considered distinct from an IgE-mediated allergic response.

- Persons who have a recurrence of ORS upon revaccination do not necessarily experience further **episodes** with future vaccinations. Data on clinically significant adverse events do not support the preference of one vaccine product over another when revaccinating those who have previously experienced ORS.

Consent for Immunization

- All immunizations in Saskatchewan are voluntary.
- Pharmacists are responsible to obtain informed consent from all clients before immunization with any publicly funded vaccine.
- All individuals must be screened by the pharmacist for contraindications prior to immunization.
- Influenza vaccine is safe and well-tolerated. The following counselling points should be emphasized by providers when discussing eligibility recommendations with clients:
  a. The risks and benefits of influenza vaccine should be discussed prior to vaccination, as well as the risks of not getting immunized.
  b. Vaccination is the most effective way to prevent influenza and the spread of influenza viruses.
  c. Each year there are new vaccine formulations to protect against the influenza virus strains that are expected in the coming influenza season. Even if the strains have not changed, getting influenza vaccine every year is necessary to maximize protection.
- The Ministry of Health 2017-2018 Influenza Vaccine fact sheet **must be provided by pharmacists to all clients** and is available to order free of charge from the Ministry's Publications Centre at: http://www.publications.gov.sk.ca/.
- Fact sheets can be viewed at: http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets. French versions are also available at this link.
- Post-immunization, it is recommended that clients receive a Ministry wallet card (available from the Publications Centre) bearing the client's name and date of immunization as proof they received the vaccine.

Government of Saskatchewan HealthLine 811 HEALTHLINEONLINE.CA **RECORD OF INFLUENZA IMMUNIZATION** **Name**: _____ **Immunization Date:** _____ **Vaccine type:** TIV QIV LAIV **Date of 2nd Dose for Child:*** _____ **HCW:** Yes No **Provider initials:** _____	***NOTE: 2 doses are required for children younger than 9 years old who are getting immunized with influenza vaccine for the first time.** **Dose #2 appointment date:** _____ YY/MM/DD • **Immunization Record App available at www.immunize.ca/en/app.aspx** • **For more information about Saskatchewan's immunization programs, go to: www.saskatchewan.ca/immunize** • **Pneumococcal 23 immunization date:** _____ YY/MM/DD

- Pharmacists are responsible to order these wallets cards free of charge through the Ministry's Publications Centre website at http://www.publications.gov.sk.ca/deplist.cfm?d=13&c=883.

Health Care Workers (HCWs)

- HCWs may present their wallet card to their employer indicating they have received influenza vaccine.
- HCWs, regardless of their employer, are strongly encouraged to receive their influenza immunization. Influenza vaccination provides benefits to health care workers and to the patients they care for.
- NACI considers the provision of influenza vaccination to be an essential component of the standard of care for all HCWs for the protection of their patients. **In the absence of contraindications, refusal of HCWs to be immunized against influenza implies failure in their duty of care to patients (NACI, 2015).**

By protecting themselves, HCWs also protect clients or patients who are unable to mount sufficient vaccine antibodies related to their health status or age.

- To protect vulnerable patients during influenza outbreaks, HCWs with confirmed or presumed influenza and unvaccinated HCWs who are not receiving antiviral prophylaxis should be excluded from direct patient contact
- Transmission of influenza between infected HCWs and their vulnerable patients results in significant morbidity and mortality. Randomized controlled trials conducted in geriatric long-term care settings have demonstrated that vaccination of HCWs is associated with substantial decreases in morbidity and mortality in the residents. Therefore, HCWs should consider it their responsibility to provide the highest standard of care, which includes annual influenza vaccination. In the absence of contraindications, refusal of HCWs to get immunized against influenza implies failure in their duty of care to patients.
- The 2017-18 NACI influenza statement can be accessed at https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2017-2018.html

Maternal and Infant Health

- The risk for complications and hospitalization related to influenza is greater among pregnant women who are in their second or third trimester.
- **QIVs are considered safe for pregnant women at all stages of pregnancy and they can be immunized by pharmacists if convenient to the client.**
- Immunizing pregnant and breastfeeding women may protect the baby through transplacental antibody passage or through breast milk.

Aboriginal People

- Aboriginal people are specifically mentioned due to increased risk based on higher prevalence of underlying health risk factors and social determinants of health including housing and living in remote communities.

Vaccine Delivery to Pharmacists

- Saskatchewan pharmacies will order publicly funded influenza vaccines directly from a Saskatchewan wholesaler (i.e., McKesson, Kohl & Frisch).
- The ordering process will be communicated directly to pharmacies by the DPEBB.

Vaccine Administration Issues

Occasionally, there may be an issue during vaccine administration to a client (e.g., a dose that is being injected into a client leaks out) resulting in less than a full 0.5 mL IM dose being administered. When this happens:

1) With the client's consent, re-immunize them with a full dose in another limb, **or** in the same limb at least 2.5 cm from the last injection site.
2) Report the first dose on the wastage report, so that the dose is accounted for (see next section below).

Note that only 1 claim for the Influenza Immunization fee can be submitted to the DPEBB in these situations.

Vaccine Wastage and Vaccine Problem Reporting

- Pharmacists must record wasted influenza vaccine **doses** on the *Vaccine Wastage Report* form noted in Appendix 7 and **submit by fax immediately after each event, or monthly at a minimum** to the **Saskatchewan Disease Control Laboratory (SDCL) at 306-798-0071.**
- Wasted vaccine doses means that the doses were not wholly administered to a client. Some examples are a multidose vial that has not been used up in the timeframe specified by the manufacturer; reconstituted

vaccine that has not been used; or a dose leaked out upon administration. If in doubt about whether a particular situation has resulted in a wasted vaccine dose, contact Arlene Kuntz at the DPEBB at (306) 787-3306 or arlene.kuntz@health.gov.sk.ca. **Wasted vaccine also includes all leftover vaccine (open and closed vials) at the end of the flu season.**

- Wasted influenza vaccines must be disposed of locally according to the *Saskatchewan Biomedical Waste Management Guidelines 2008* (http://www.environment.gov.sk.ca/adx/aspx/adxGetMedia.aspx?DocID=217,216,104,81,1,Documents&MediaID=1099&Filename=Biomedical+Waste+Management.pdf).
- Additional information on biomedical waste disposal can be found in the *Guidelines for Pharmaceutical Waste Disposal Services* in the Reference Manual for pharmacies from the Saskatchewan College of Pharmacy Professionals (https://scp.in1touch.org/uploaded/58/web/refmanual/Pharmaceutical%20Waste%20Disposal%20Program.pdf).
- Vaccine problem reports **and** implicated vaccines must be submitted immediately to the Ministry of Health immediately using the *Vaccine Problem Supply Report Form* (SPR-001) available in the SIM, chapter 9 (http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf).

Vaccine Cold Chain Interruption Reporting

- All cold chain interruptions/breaks and vaccine light exposures (beyond what is needed to administer a dose to a client) must be reported and faxed to the Ministry at 306-787-3237 immediately upon discovery using the *Pharmacy Cold Chain Break Report Form* available in the Saskatchewan Immunization Manual (SIM), chapter 9 section 5.2 available at (http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf) and in Appendix 6..
- Refer to Appendix 5: *How to Complete the Pharmacy Cold Chain Break Report Form* for information on how to complete the form.
- Pharmacists must fax these reports directly to the Ministry at 306-787-3237.

Adverse Events Following Immunization (AEFI)

- **To ensure the ongoing safety of influenza vaccines in Canada, reporting of all AEFIs is mandatory under the *Saskatchewan Public Health Act* (1994).**
- Electronic or paper Public Health Agency of Canada (PHAC) AEFI forms for publicly funded influenza vaccines MUST be completed by the healthcare provider to whom the client reported the event and submitted by fax to the RHA for review and MHO recommendation. **Pharmacists cannot make immunization recommendations for clients that have reported an AEFI.** Refer to Appendix 3: *Adverse Event Following Immunization Reporting Algorithm for Non-Public Health Healthcare Providers* and Appendix 4: *Regional Health Authority and First Nations Jurisdictions Public Health Contact Information for Non-Public Health Healthcare Providers.*
- If a client reports an AEFI to a healthcare provider who did not administer the vaccine, this healthcare provider is required to complete and submit an AEFI report to the RHA Public Health office AND to follow up with the client on the recommendations from the MHO. Note: The person reporting does not need to advise/contact the "injector" of the AEFI. However, the reporter should contact the "injector" if more details regarding the administration of the vaccine to that particular client are needed when completing the AEFI report form.
- Influenza vaccine AEFIs that meet **reporting criteria** in PHAC's *User Guide: Report of Adverse Events Following Immunization (AEFI)* available at http://www.phac-aspc.gc.ca/im/aefi-essi_guide/page1-eng.php must be recorded in the client's (electronic or paper) health record and in the provincial electronic immunization database. **Please ensure that you are familiar with this document.**

- RHAs are responsible for MHO recommendations and will enter the report information into the client's electronic immunization record in Panorama.
- The MHO recommendations must be reported to the original reporter of the AEFI who is obligated to follow up with the client. **Refer to Appendix 3: *Adverse Event Following Immunization Reporting Algorithm for Non-Public Health Healthcare Providers*.**
- Surveillance of all temporal influenza vaccine-related AEFIs is requested to help build on the reports from previous years.
- **To ensure patient safety, all immunizers shall immediately report any unusual, severe, serious or unexpected** adverse event assessed to be temporally related to vaccination to RHA public health officials. Refer to Appendix 4: *Regional Health Authority and First Nations Jurisdictions Public Health Contact Information for Non-Public Health Healthcare Providers*.
- RHA **public health officials** must immediately report **unusual, severe, serious or unexpected** AEFIs to the Ministry at 306-787-9576 in conjunction with a completed AEFI report for the client.
- An unexpected AEFI is an event that is not listed in available product information but may be due to the immunization, or a change in the frequency of a known AEFI. The following AEFIs are of particular interest for influenza vaccines:
  - ORS; and
  - GBS within 6 weeks following immunization.
- Regional MHO recommendations will be documented and will guide future recommendations which will be communicated to the patient by the reporter or other designate.
- Individuals reporting an AEFI of H1N1 vaccine or any past influenza vaccines may need consultation with the MHO and/or specialist prior to receiving a 2017-18 influenza vaccine.

Communications

- The Ministry's Communications Branch will coordinate with RHA communications staff regarding public messaging. The Ministry's Drug Plan and Extended Benefits branch are responsible to issue communication to provincial pharmacists.
- The Ministry, in cooperation with RHAs, has developed consistent public messaging to communicate eligibility criteria including risk groups to the public.
- For provincial media interviews, the provincial Chief/Deputy MHO and regional MHOs are the main spokespersons.
- HealthLine will link to RHA websites for clinic locations. RHAs will ensure clinic details are posted on regional websites.
- The 2017-18 Influenza Vaccine English and French fact sheets and related documents will be posted on the Ministry website by September 2017 at http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets

Vaccine Administration Statistics and Documentation

- Pharmacists will be responsible for submitting their billing information to the DPEBB on the same day the immunization is provided, in accordance with the DPEBB Influenza Immunization Program policy.
- DPEBB will be using demographic information from the pharmacy claim submission to provide data to the Population Health Branch to support collection of vaccine administered numbers for the 2017-2018 Influenza Vaccine Program. **Individual pharmacists/ pharmacies must not submit their administration data to the Population Health Branch.**
- For your information: Due dates for report submission are as follows (these are subject to change):

Calendar Week	Submission time period	Date of submission
Week 43	Oct 22– 28, 2017	Oct 31, 2017
Week 44	Oct 29 – Nov 4, 2017	Nov 7, 2017
Week 45	Nov 5 - 11, 2017	Nov 14, 2017
Week 46	Nov 12 - 18, 2017	Nov 21, 2017
Week 47	Nov 19 - 25, 2017	Nov 28, 2017
Week 48	Nov 26 – Dec 2, 2017	Dec 5, 2017
Week 49	Dec 3 – 9, 2017	Dec 12, 2017
Week 50	Dec 10 - 16, 2017	Dec 19, 2017
Week 51	Dec 17 - 23, 2017	Dec 26, 2017
Week 52	Dec 24 – 30, 2017	Jan 2, 2018
January 2017	Jan 1 – 31, 2018	Feb 7, 2018
February 2017	Feb 1-28, 2018	Mar 7, 2018
March 2017	Mar 1-31, 2018	Apr 11, 2018
Final submission	Oct 23, 2017 to March 31, 2018	May 7, 2018

- The DPEBB, along with the Saskatchewan College of Pharmacy Professionals and the Pharmacy Association of Saskatchewan, will provide information related to the provincial Seasonal Influenza Immunization Program to Saskatchewan pharmacists.

Appendix 1: Publicly Funded Quadrivalent Influenza Vaccines 2017-18

	FluLaval® Tetra (GSK) QIV split virion	**Fluzone® Quadrivalent** (SP) QIV split virion
Population	Everyone ≥ 6 months	Everyone ≥ 6 months
Dose	0.5 mL IM	0.5 mL IM
Components	Latex and antibiotic free and contains both influenza A strains and B viral strains, sodium chloride, potassium chloride, disodium hydrogen phosphate heptahydrate, potassium dihydrogen phosphate, α-tocopheryl hydrogen succinate, and polysorbate 80, and may contain traces of egg proteins (ovalbumin), sodium deoxycholate, ethanol, formaldehyde and sucrose. Thimerosal added as a preservative to multidose vials.	Latex, antibiotic and gelatin free and contains all surface antigens of this year's influenza A and B viral strains, formaldehyde, sodium phosphate-buffered, isotonic sodium chloride solution, and Triton® X-100, and may contain traces of egg protein and sucrose. Thimerosal is added as a preservative only to multidose vials.
Normal and Expected Reactions These reactions are mild to moderate and generally last 1-4 days.	• Soreness, warmth, redness, and swelling at the injection site. • Temporary limited movement of the immunized arm or leg. • Headache, fever, tiredness, muscle aches, and chills. • Loss of appetite.	• The most common reactions occurring after vaccine administration are injection site pain (11%-57%), erythema (7%-30%) and edema (6%-21%). • The most common systemic reactions observed after vaccine administration are asthenia (2%-18%), headache (2%-10%) and myalgia (2%-9%).
Presentation	• 5 mL multidose vial containing 10 doses of 0.5 mL	• 5 mL multidose vial containing 10 doses of 0.5 mL • 0.5 mL prefilled syringes (thimerosal free) - Public Health only
Contra-indications	• Persons with a history of a severe allergic or anaphylactic reaction to a previous influenza vaccine dose or any component of the influenza vaccine should discuss their situation with a public health nurse or their physician. • Persons who developed GBS within six weeks of a previous influenza vaccine.	• Persons with a history of a severe allergic or anaphylactic reaction to a previous influenza vaccine dose or any component of the influenza vaccine should discuss their situation with a public health nurse or their physician. • Persons who developed GBS within six weeks of a previous influenza vaccine.
Instructions for Administration	• Do not administer vaccine from a vial that has been opened for ≥28 days or has expired. • To get 10 doses out of a vials, GSK recommends that each 0.5 mL dose is withdrawn into a 1 mL syringe equipped with a needle gauge not larger than 23-G.	• Vaccine may be administered from a MDV that has been opened up to the expiry date indicated on the vial.
Special Instructions –	• Gently shake the vial before administration. • Date vials when opened. • Store 2°C-8°C. • Do not freeze or use if vaccine has been frozen. • Protect from light. • Pre-drawing is not recommended. • The Ministry recommends that vaccines be administered directly from the fridge or cooler and not warmed to room temperature prior to administration.	

Appendix 2: 2017-18 Licensed Influenza Vaccines

Product characteristics	Injectable								Intranasal
Manufacturer	BGP Pharma	GSK		Novartis			Sanofi Pasteur		AstraZeneca
Product name	**Influvac®**	**Fluviral®**	**FluLaval® Tetra**	**Agriflu®**	**Fluad®**	**Fluad Pediatric™**	**Fluzone® High-Dose**	**Fluzone® Quadrivalent**	**FluMist® Quadrivalent †**
Vaccine type	Trivalent inactivated - subunit	Trivalent inactivated - split virus	Quadrivalent inactivated - split virus	Trivalent inactivated - subunit	Trivalent inactivated - subunit	Trivalent inactivated - subunit	Trivalent inactivated - split virus	Quadrivalent inactivated - split virus	Quadrivalent Live attenuated
Route	IM	IM	IM	IM	IM	IM	IM	IM	IN
Authorized ages	≥ 3 years	≥ 6 months	≥ 6 months	≥ 6 months	≥ 65 years	6-23 months	≥ 65 years	≥ 6 months	2-59 years
Adjuvant	No	No	No	No	MF_{59}	MF_{59}	No	No	No
MDV Post-puncture shelf life	Refer to product monograph	Refer to product monograph	28 days	Refer to product monograph	Refer to product monograph	Refer to product monograph	Refer to product monograph	May be used up to the expiry date indicated on the vial	n/a
Thimerosal	Refer to product monograph	Refer to product monograph	Yes	Refer to product monograph	Refer to product monograph	Refer to product monograph	Refer to product monograph	Multidose vials only	No
Antibiotics	Refer to product monograph	Refer to product monograph	None	Refer to product monograph	Refer to product monograph	Refer to product monograph	Refer to product monograph	None	Gentamicin
Clinically non-relevant ingredients*	Refer to product monograph	Refer to product monograph	Appendix 1: 2017-18 Publicly Funded Influenza Vaccine Information	Refer to product monograph	Refer to product monograph	Refer to product monograph	Refer to product monograph	Appendix 1: 2017-18 Publicly Funded Influenza Vaccine Information	Refer to product monograph

Appendix 3: Adverse Event Following Immunization Reporting Algorithm for Pharmacists Who Administer Publicly Funded Influenza Vaccine

Pharmacist is informed of possible AEFI by patient and/or directly observes AEFI in patient and reviews AEFI user guide to assess reportable criteria.

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If event is reportable: Pharmacist completes AEFI Report Form sections 3; 4a; 4b if applicable; 5; 6; 7a; 7b; 7c; 7d; 8, 9a &/or 9b &/or 9c &/or 9d as applicable; and 10.

Pharmacists must report all AEFIs for publicly funded vaccines to the health regions. They cannot make recommendation and must not write anything in section 11. This section is only for the MHO to write in.

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Pharmacist faxes completed AEFI report form to the Regional Health Authority (RHA) and retains original report form for their records.

Refer to Appendix 4 for RHA contact information.

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Upon receiving the RHA Medical Health Officer's (MHO) *Recommendations for Further Immunization* (section 11 of AEFI), the Pharmacist who initiated the AEFI report form informs the client regarding the MHO's recommendations and refers the client to Public Health if they have further questions.

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The RHA must enter a client warning on the client's Panorama client record (until the AEFI module is supported in the future) as per Panorama bulletin 0024 Where Do I Document?

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RHA submits completed AEFI report to the Ministry of Health as per current practice.

Appendix 4: Regional Health Authority and First Nations Jurisdictions Public Health Contact Information for Non-Public Health Healthcare Providers

ATHABASCA HEALTH AUTHORITY
Box 124
BLACK LAKE SK S0J 0H0
Tel: 306-439-2200
Fax: 306-439-2212

CYPRESS HEALTH REGION
350 Cheadle Street West
SWIFT CURRENT SK S9H 4G3
Tel: 306-778-5280
Fax: 306-778-5408

FIRST NATIONS & INUIT HEALTH BRANCH
Health Protection Division
4th Floor, 2045 Broad Street
REGINA SK S4P 3T7
Tel: 306-780-3499
Fax: 306-780-8826

FIVE HILLS HEALTH REGION
107-110 Ominica Street West
MOOSE JAW SK S6H 6V2
Tel: 306-691-1500
Fax: 306-691-1539

HEARTLAND HEALTH REGION
Box 1300
ROSETOWN SK S0L 2V0
Tel: 306-882-2672 Extension 3, Option 3
Fax: 306-882-6474

KEEWATIN YATTHÉ HEALTH REGION
Box 40
BUFFALO NARROWS SK S0M 0J0
Tel: 306-235-2220
Fax: 306-235-4604

KELSEY TRAIL HEALTH REGION
Box 6500
MELFORT SK S0E 1A0
Tel: 306-752-6310
Fax: 306-752-6353

MAMAWETAN CHURCHILL RIVER HEALTH REGION
Box 6000
LA RONGE SK S0J 1L0
Tel: 306-425-8512
Fax: 306-425-8530

NORTHERN INTERTRIBAL HEALTH AUTHORITY
Box 787
PRINCE ALBERT SK S6V 5N6
Tel: 306-953-5000
Fax: 306-922-5020

PRAIRIE NORTH HEALTH REGION
11427 Railway Ave., Suite 101
NORTH BATTLEFORD SK S9A 1E9
Tel: 306-446-8617
Fax: 306-446-6432

PRINCE ALBERT PARKLAND HEALTH REGION
McIntosh Mall
800 Central Avenue
Box 3300
PRINCE ALBERT SK S6V 7V6
Tel: 306-765-6500 Option 0
Fax: 306-765-6495

REGINA QU'APPELLE HEALTH REGION
Population and Public Health Services
2110 Hamilton Street
REGINA SK S4P 2E3
Tel: 306-766-7777
Fax: 306-766-7607 Attention: Dr. Tania Diener

SASKATOON HEALTH REGION
Public Health Services
#101 - 310 Idylwyld Drive North
SASKATOON SK S7L 0Z2
Tel: 306-655-4620
Fax: 306-655-4723

SUN COUNTRY HEALTH REGION
900 Saskatchewan Drive
Box 2003
WEYBURN SK S4H 2Z9
Tel: 306-842-8618
Fax: 306-842-8638

SUNRISE HEALTH REGION
150 Independent Street
YORKTON SK S3N 0S7
Tel: 306-786-0600
Fax: 306-786-0620

Appendix 5: How to Complete the Pharmacy Cold Chain Break Report Form

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- The person discovering the cold chain break **or** the person reporting the cold chain break is the **Reporter.** Please include the reporter name, telephone number and fax number as questions or follow up information may be required. The email address is optional as most contact will be by telephone or fax.

- Answer all questions that are applicable to the **type** and **time** of the cold chain break:
  - Type of break: temperature or light excursion (most will be temperature excursions).
  - **Products must be quarantined regardless the type of break.**
  - Questions number 3 and 4: Fridge temperatures are required only if this is a fridge or thermometer malfunction including power outages.
  - Room temperature should always be included if data is available
  - Temperature logs are only required when there is a fridge or thermometer malfunction

- **Description of Break:** Describe how and why the break occurred; including **all** details.

- **Transportation:** If the cold chain break occurred during transportation, answer all questions in that box.

- **Refrigerator type/ Thermometer type:** Complete only if fridge **or** thermometer malfunction occurred.

- Indicate cause of cold chain break and corrective actions to prevent future situations.

- Indicate if the affected products have been administered to clients.

Page 2

- Print all vaccine information clearly using one line per lot number. Use appropriate vaccine abbreviations.

- Circle the appropriate answer for “multi-dose vial” and “previous cold chain break”

- Page 2 will be faxed back to the Pharmacist indicating if the vaccine is:
  - Viable – usable – maintain on cold chain and use as soon as possible.
  - Discard – not to be used and discarded as per organizational policy.

NOTE: The Ministry will fax recommendations directly to the reporting pharmacy.

Appendix 6: Pharmacy Cold Chain Break Report Form

Complete for all Saskatchewan Health publicly funded products. Do not assume that products must be wasted.

Date Break Discovered: *(yyyy-mm-dd)*	**Date of Report:** *(yyyy-mm-dd)*	**Reporter Name:**
Telephone Number:	**Fax Number:**	**Reporter Email Address:** *(optional)*
Location of Break (City / Town):	**Pharmacy Name**:	

Type of break: ☐ Temperature excursion (cooler than 2.0 °C and/or warmer than 8.0 °C) ☐ Light Exposure

1. **Vaccine found (mark if applicable):** ☐ in cooler with cold packs ☐ in cooler with no cold packs ☐ in box on counter ☐ not in box on counter
2. **Are products now quarantined, labeled do not use, and stored on cold chain?** ☐ Yes ☐ No *(attach explanation)*
   - Vaccine returned to storage between 2°C and 8°C on date _____ and time _____.
3. **Fridge temperature when break identified**: _____°C on date _____ and time _____.
   - **Max. temp** recorded during break interval: _____°C
   - **Min. temp** recorded during break interval: _____°C
   - **Time** out of cold chain (if different from above) _____ *(Provide description or attachments, e.g. chart tracing)*
4. **Last fridge temperature record before the break:** _____°C on date _____ and time _____.
5. **Room temperature before the break:** _____°C on date _____ and time _____.
6. **Is temperature log being submitted?** ☐ Yes ☐ No **If No, indicate why:** _____

Description of break:

Did break occur during transportation? ☐ **No** ☐ **Yes** **If yes,** then complete this section.

Vehicle type (e.g. car/courier) _____ Time delivery received: _____

Specify: ☐ Provincial Depot to Wholesaler ☐ Wholesaler to Pharmacy

Refrigerator type:

☐ Lab or Biological Fridge ☐ Domestic Fridge

☐ Bar Fridge ☐ Other _____

Date last serviced: _____

Thermometer/Monitor Type (Not Brand Name):

☐ Digital Min/Max ☐ Chart / Wheel Recorder

☐ Warm/Cold Mark ☐ No Monitor ☐ Other_____

Cause of cold chain break:

☐ Human error ☐ Thermometer malfunction

☐ Power outage ☐ Refrigerator malfunction

☐ Transportation ☐ Backup generator failed

☐ Other_____

Corrective action details and additional comments:

Have any affected products been administered to clients? ☐ No ☐ Yes

- **If yes**, indicate the date the Medical Health Officer was notified: _____
- **If yes,** identify these products using a separate page if necessary.

The pharmacy will be contacted by the Ministry after the break has been assessed with further instructions on use or disposal of the vaccine.

Adapted with permission from Alberta Health Services (August 2016)

Appendix 6: Pharmacy Cold Chain Break Report Form

Go to http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf for further instructions.

Vaccine Brand or Abbreviation	Manufacturer	# of Doses **– do not report as mL**	Lot Number	Expiry date	Open multidose vial?	Previous cold chain break?	SK Health USE ONLY	
							Viable	**Discard**
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		
					Yes No	**Yes No**		

Ministry of Health reviewer: _____ Date: _____ Total cost of wastage: $_____

Adapted with permission from Alberta Health Services (August 2016)

Appendix 7: Product Wastage Report Form

- **USE FOR: all vaccines, Tubersol™, TIg, Ig, RabIg, azithromycin, amoxicillin, benzathine penicillin (Bicillin® L-A), cefixime, ceftriaxone, ciprofloxacin, doxycycline, erythromycin, rifampin, epinephrine and lidocaine. Diluents for MMR, Var and MMRV do not need to be reported.**
- **DO NOT REPORT COLD CHAIN WASTAGE ON THIS FORM.**

Submit to: Saskatchewan Disease Control Laboratory
Provincial Vaccine Depot
5 Research Drive
Regina, SK, S4S 0A4
Fax: 306-798-0071
Phone: 306-787-7638

RHA site/FNJ site/Pharmacy/Wholesaler submitting report: _____

Reporter name: _____ Date: _____

Phone #:_____ Fax #: _____

					Indicate only 1 reason for wastage			
Product Name	Manu-facturer	Lot Number	Expiry date	Number of Doses	EXPIRED OPENED	EXPIRED UNOPENED	Dose not admini-stered	Defective or damaged (Note: Vaccine Problem Report must also be submitted)

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