ANNEX 'A' – ATTACHMENT 11

Medical Directive for administration of:

- Tetanus & Diphtheria Toxoids Adsorbed Vaccine (Td); and
- Tetanus & Diphtheria Toxoids Adsorbed Combined with Acellular Pertussis Vaccine (Tdap)

Manual:	**Type:** Medical Directive
Section:	**Additional Sections:**
Developed by: AIM Health Group	**Original Effective Date:** June 1, 2012
Approved by:	**Date Revised:**
Cross Reference:	**Date Reviewed:** June 1, 2012

Order and/or Delegated Procedure: **Appendix Attached:** ☐ Yes ☐ No **Title:**

This medical directive governs the administration of Tetanus Diphtheria Adsorbed vaccine (Td) and Tetanus Diphtheria Adsorbed combined with component Pertussis vaccine (Tdap).

Recipient Patients: **Appendix Attached:** ☐ Yes ☐ No **Title:**

Recommended as a best practice for all CFIA employees who undergo health evaluations and/or medical
[illegible] ho by the nature of their work activities, could be at risk of exposure to bites, cuts, abrasions,
[illegible] nds and sharps/needlestick injuries.

Authorized Implementers: **Appendix Attached:** ☐ Yes ☐ No **Title:**

Health [illegible]re Professionals who possess the knowledge, skill and judgment to implement this medical directive. The [illegible]ter of this medical directive must be capable of the following:

1. [illegible]ent and document a medical directive.
2. To be [illegible]liar with and understand the Td and Tdap Protocol.
3. To fully explain the risks, benefits and alternatives to the procedure to the recipient.
4. To recognize and respond to a suspected allergic reaction post administration.

Indications: **Appendix Attached:** ☐ Yes ☐ No **Title:**

Pre-placement:

For adult employees who do not produce documentation of already receiving a pertussis booster vaccine dose at the time of employment, it is recommended that the tetanus-diphtheria (Td) booster dose be replaced by the combined Tdap vaccine as a single dose (On October 26, 2005 the Advisory Committee on Immunization Practices (ACIP) voted to recommend routine use of a single dose of Tdap for adults 19-64 years of age to replace the next booster dose of tetanus and diphtheria toxoids vaccine (Td).

The ACIP also recommended Tdap for adults who have close contact with infants younger than 12 months of age).

Td should be used for later booster doses or for individuals who have already had a pertussis booster.

Administration: The vaccine should be administered intramuscular (IM) into the deltoid muscle.

Non-immunized Adults:
Adults who have not previously received a primary tetanus toxoid series (given as Td) require three doses as part of an adult primary immunization regimen. The employee can receive the primary immunization series from the Service Provider or his/her family physician.

Primary Td immunization	Td	Tdap
Adults: none or uncertain of immunization series	3 doses* 0.5 ml IM: 1st dose: day 0 2nd dose: day 28-56 3rd dose: 6-12 months	One of 3 doses to be Tdap 0.5 ml IM
Adults: Booster	1 dose 0.5 ml IM every 10 years	Once only as adult dose

Periodic (during course of employment):
A booster dose of Td every ten years. If the employee has not received an adult booster dose of Tdap, it should be given once only as a booster dose.

Post-exposure Prevention of Tetanus in the Context of Wound Management:

- Appropriate cleansing and debridement of wounds is imperative, and use of antibiotics may be necessary.
- Establish Td/ Tdap vaccination history and administer booster dose of Td or Tdap as required. Some individuals with immune deficiency, including those with HIV infection, may not respond adequately to tetanus toxoid. Therefore, tetanus immune globulin (TIG) may be required in addition to tetanus toxoid in individuals with immune deficiency who have wounds that are not clean, regardless of the time elapsed since the last booster. In cases requiring TIG, referral to a facility that stocks this should be initiated.

History of tetanus immunization	Clean, minor wounds		All other wounds (i.e., major, unclean)	
	Td	TIG	Td	TIG
Uncertain or < 3 doses of an immunization series	Yes	No	Yes	Yes
≥ 3 doses received in an immunization series	No Yes, if > 10 year since last booster.	No	No Yes, if > 5 years since last booster. See * below	No Yes, if immune-deficient See ** below

* More frequent boosters are not required and can be associated with increased adverse events. The bivalent toxoid, Td, is not considered to be significantly more reactogenic than T alone and is recommended for use in this circumstance.

** Yes, if individuals are known to have a significant immune deficiency state e.g. HIV, since immune response to tetanus toxoid may be suboptimal.

Contraindications & Precautions	**Appendix Attached** ☐ **Yes** ☐ **No** **Title:**

This medical directive is contraindicated in adults who have:

- Known hypersensitivity to any of the vaccine components or signs of hypersensitivity after previous administration of diphtheria, tetanus, or pertussis vaccines.
- Employees who experience a major local reaction or high fever following a dose of tetanus toxoid should not be given another dose for at least 10 years.
- History of severe blistering reaction or anaphylaxis following a vaccine in the past.
- Avoid immunization of persons known to have developed Guillain-Barré Syndrome (GBS) within 8 weeks of a previous tetanus toxoid dose. Those who develop GBS outside this interval or have an alternative cause identified (e.g., Campylobacter jejuni infection) may receive subsequent tetanus vaccinations.
- Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause. Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy. Pertussis vaccine should not be administered to persons with such conditions until a treatment regimen has been established and the condition has stabilized.
- Should not be given to people who have experienced transient thrombocytopenia or neurological complications following an earlier immunization against diphtheria and /or tetanus.

PREGNANCY: There is no evidence that tetanus toxoid is teratogenic. In the event of a tetanus-prone wound during pregnancy, the employee should be advised to contact the Service Provider or her personal physician. Tetanus Immune Globulin should only be administered if clearly needed.

Adequate human data on the use of Tdap during pregnancy are not available. One does not expect vaccination to be harmful to the fetus however the vaccine should be used during pregnancy only when clearly needed and when the possible advantages outweigh the possible risks for the fetus. Adequate human data on the use during lactation and adequate animal reproductive studies are also not available

Precautions:

Postpone administration in people suffering from acute severe febrile illness. Presence of minor infection is not a contraindication.

Rubber stoppers in the pre-filled syringes contain latex so should be administered with caution to persons with known latex sensitivity or allergy.

The expected immunological response may not be obtained after vaccination for those receiving immunosuppressive therapy or are immune compromised as with conditions like AIDS.

Administer with caution to people with thrombocytopenia or a bleeding disorder since bleeding may occur following an IM injection. Firm pressure to be applied to injection site (without rubbing) for at least 2 minutes

Adverse reactions:

- Mild local reactions consisting of pain (84%), erythema (21%), and swelling (10%) at the injection site.
- Severe local reactions occur rarely and may be associated with high levels of circulating tetanus antitoxin. Mild transient fever, chills, headache (8%), and fatigue (5-8%).
- Generalized reactions may develop following injection and may take the form of allergic reactions including urticaria, itching and rash. Severe allergic reactions are very rare.

Consent:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title: Appendix 1: Vaccination Information and Consent**

Recipients of this medical directive must read, complete and sign before implementation can occur.
The implementer must then determine if the recipient is indicated for this medical directive.

This medical directive cannot be implemented until the recipient has provided informed consent for the proposed treatment by reading and signing CFIA's "Td and Tdap Vaccination Information and Consent"
To give informed consent, recipient must be provided information that includes:

- The nature of the treatment;
- Expected benefits of the treatment;
- Material risks and adverse effects of the treatment;
- Alternative courses of treatment; and
- Likely consequences of not having the treatment.

Guidelines for Implementing the Order / Procedure:	**Appendix Attached:** ☐ **Yes** ☐ **No** **Title:**

1. Review or be familiar with the protocol.
2. Screen recipient and assess indications and contraindications.
3. If potential recipient meets indications, obtain and document informed consent on the consent confirming that the recipient understands the benefits and has had the opportunity to ask questions and receive responses regarding the side effects.
4. If potential recipient is contraindicated, inform potential recipient and document.
5. Implement medical directive as per policy.
6. Administer.
7. Monitor recipient for adverse reaction for a minimum of 15 minutes post administration.
8. Complete all documentation as indicated.

Documentation and Communication:	**Appendix Attached:** ☒ **Yes** ☐ **No** **Title: Appendix 1 – Vaccination Information and Consent**

Document assessment findings and actions taken.

- Each document in the employee record must be clearly labeled with employee's full name in legible hand writing.
- Documentation shall include: time, date, medication, dose, route, site, lot number and signature.
- All of the above documents will be kept in the Service Provider's employee medical file for the duration specified by law.

Review and Quality Monitoring Guidelines: | **Appendix Attached:** ☒ **Yes** ☐ **No** **Title: Adverse Report Form**

Health Care Professional staff identifying any untoward or unintended outcomes arising from implementation of orders under this directive shall document and report these to the Service Provider as soon as possible for appropriate disposition. If required, an Adverse Report Form is to be completed.

Administrative Approvals (as applicable): | **Appendix Attached:** ☐ **Yes** ☐ **No** **Title:**

Jun 8/12

Approving Physician(s)/Authorizer(s): | **Appendix Attached:** ☐ **Yes** ☐ **No** **Title:**

Dr. Sol E. Sax, Medical Director, WHCS, AIM Health Group

Signature: Date: June 1, 2012

References: | **Appendix Attached:** ☐ **Yes** ☐ **No** **Title:**

1. Canadian Immunization Guide 7th Edition (2006).
2. Canadian Centre for Occupational Health & Safety (2010).
3. Compendium of Pharmaceuticals & Specialities (2010). Product monographs: Tdap (2006).
4. Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine. Morbidity & Mortality Weekly Report. December 15th, 55(RR17, 1-33).
5. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm?s_cid=rr5517a1_e
6. Katrina Kretsinger, MD, Karen R. Broder, MD, Margaret M. Cortese, MD et al. (2006). Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine. Morbidity & Mortality Weekly Report. December 15th, 55(RR17, 1-33).

Appendix 1
Vaccination Information and Consent

Tetanus & Diphtheria (Td) Vaccine and Tetanus & Diphtheria Combined with Pertussis Vaccine (Tdap)

Tetanus: Tetanus is an acute and often fatal disease caused by an extremely potent neurotoxin produced by Clostridium tetani. The organism is present in soil but has also been detected in the intestines of animals and humans. Wounds that are contaminated with soil or animal/human feces and that are associated with tissue injury are most frequently associated with tetanus. Cases related to injection drug use, animal bites and lacerations have been reported.

Diphtheria: Diphtheria is an acute, communicable disease caused by toxin-producing strains of the bacterium Corynebacterium diphtheriae. Symptoms result from local infection of the respiratory tract, which may lead to breathing difficulties, or infection of the skin or mucosal surfaces, or from dissemination of diphtheria toxin, which damages the heart and central nervous system. The fatality rate remains at about 5% to 10%, the highest death rates occurring among the very young and the elderly.

Pertussis: Pertussis is an acute, infectious cough illness that remains common in Canada despite longstanding routine childhood pertussis vaccination. Immunity to pertussis wanes approximately 5-10 years after completion of childhood vaccination, leaving adolescents and adults susceptible to pertussis (MMWR).

NACI (National Advisory Council for Immunization) recommends routine use of a single dose of Tdap for adults 19-64 years of age to replace the next booster dose of tetanus and diphtheria toxoids vaccine (Td).

Precautions and Contra-indications

The following people should not receive Td or Tdap vaccine:

- Known hypersensitivity to any of the vaccine components or signs of hypersensitivity after previous administration of diphtheria, tetanus, or pertussis vaccines.
- Employees who experienced a major local reaction or high fever following a dose of tetanus toxoid should not be given another dose for at least 10 years.
- History of severe blistering reaction or anaphylaxis following a vaccine in the past.
- Persons known to have developed Guillain-Barré Syndrome (GBS) within 8 weeks of a previous tetanus toxoid dose. Those who develop GBS outside this interval or have an alternative cause identified (e.g., Campylobacter jejuni infection) may receive subsequent tetanus vaccinations.
- Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy.
- Should not be given to people who have experienced severe bruising rash or neurological or brain complications following an earlier immunization against diphtheria and / or tetanus.

Pregnancy:

There is no evidence that Td can harm the fetus. In the event of a tetanus-prone wound during pregnancy, the employee should be advised to contact the Service Provider or her personal physician. Tetanus Immune Globulin should only be administered if clearly needed.

Adequate human data on the use of Tdap during pregnancy are not available. One does not expect vaccination to be harmful to the fetus however the vaccine should be used during pregnancy only when clearly needed and when the possible advantages outweigh the possible risks for the fetus. Adequate human data on the use during lactation and adequate animal reproductive studies are also not available

Precautions:

The following conditions should be noted to the provider giving the vaccine so a decision can be made on the advisability of administration.

- Acute severe febrile illness. Presence of minor infection is not a contraindication.
- Known latex sensitivity or allergy.
- Those receiving immunosuppressive therapy or are immune compromised as with conditions like AIDS.
- People with bruising or bleeding disorder since bleeding may occur following the injection.

Adverse Reactions:

- Mild local reactions consisting of pain (84%). erythema (21%), and swelling (10%) at the injection site.
- Mild transient fever, chills, headache (8%), and fatigue (5-8%).
- Generalized reactions may develop following injection and may take the form of allergic reactions including itching and rash. Severe allergic reactions are very rare.

Please read and respond to the following questions:

Do you have an acute illness, acute respiratory infections and/or fever today? If yes, please return when you are feeling better.	❑ Yes ❑ No
Have you had an allergic reaction to a previous vaccination?	❑ Yes ❑ No
Have you had severe blistering at the site of any previous vaccination?	❑ Yes ❑ No
Are you currently under treatment for HIV/AIDs, cancer or taking steroid or any immunosuppressant drugs?	❑ Yes ❑ No
Have you developed Guillain-Barré Syndrome (GBS)? If yes, when?	❑ Yes ❑ No
Have you had encephalopathy, seizures or any other neurological condition?	❑ Yes ❑ No
Are you taking anticoagulants or blood thinners or have a bleeding or bruising condition?	❑ Yes ❑ No

❑ Yes	I have read the above and understand the benefits, risks and possible complications of receiving tetanus, diphtheria toxoids adsorbed with component pertussis vaccine hereby consent to the administration of tetanus, diphtheria toxoids (Td) or tetanus and diphtheria combined with pertussis vaccine (Tdap) by the Health Care Professional. I agree to remain in the area for 15 minutes following the vaccine.
❑ No	I do not wish to receive tetanus, diphtheria toxoids adsorbed with component pertussis vaccine.

Employee Name (Print):	Employee Signature:
Date:	HCP Signature:

For HCP use:	Site:	Lot #:	Expiry Date:
HCP Name (print):		HCP Signature:	
Comments:			
Report of adverse reaction: ❑ Yes ❑ No If yes, complete adverse report form.			
Comments:		HCP signature:	

References:

1. Canadian Immunization Guide 7th Edition (2007).
2. Canadian Centre for Occupational Health & Safety (2010).
3. Compendium of Pharmaceuticals & Specialities (2010). Product monographs: Tdp (2006).
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Information Sheet

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