


Section 5.1

Medication and Vaccines

REFERENCED IN THIS SECTION:

Number/ Identifier	Name	Importance
 RECORD		
R-P	Medication and Vaccine Usage Plan	Mandatory
R-T	Treatment Record	
R-Y	Letter of Guarantee – Licensed Veterinarian	Mandatory, if applicable

SECTION 5.1

MEDICATION AND VACCINES

REQUIREMENTS

1. A valid veterinarian–client–patient relationship must exist and all prescription drugs used on-farm must be prescribed by a veterinarian licensed to practice in your province or territory with whom you have a valid veterinarian-client-patient relationship.
2. The PigSAFE Vaccine and Drug Use Policy must be respected and implemented, and the following elements must be available during the validation:
 - a. If applicable, copies of prescriptions must be available and indicate the withdrawal periods to be respected for all veterinary drugs labelled and extra labelled.
 - b. Written directions must be available for the use of all veterinary drugs.
 - c. All veterinary drugs used on-farm must be either labeled for pigs in Canada or labelled for another food producing animal in Canada.
 - d. All Active Pharmaceutical Ingredients (APIs) used on-farm must be compliant with Health Canada Regulations.
3. The Medication and Vaccine Usage Plan (R-P) must be completed, approved and signed by a licensed veterinarian and must be kept up to date. The Medication and Vaccine Usage Plan (R-P) must include:
 - a. all injectable, oral, topical and water-administered medications and vaccines used during the last 12 months
 - b. product names
 - c. identify if a drug identification numbers (DINs) is available
 - d. identify if it is a product that is prescribed
 - e. the reasons for product usage
 - f. the dosages
 - g. the methods of administration
 - h. cautions and warning
 - i. the storage location(s)
 - j. withdrawal periods.
4. The Treatment Record (R-T) must be completed and kept up to date. The Treatment Record must include the following information:
 - a. treatment start date
 - b. treatment end date
 - c. animal, pen, room numbers (IDs)
 - d. number of animals treated
 - e. weight of animals treated
 - f. product name
 - g. reason for product usage
 - h. dosage
 - i. injection site
 - j. method of administration
 - k. withdrawal period (days)
 - l. safe shipping date
 - m. whether any broken needles are present
 - n. the initials of designated personnel.

5. For each individual or group treatment of animals beyond weaning, all treatments (vaccines and drugs) must be recorded on the Treatment Record (R-T). This includes all products administered in the water, by injection, topically or orally.
6. If treatments are recorded on the sow cards, the following elements must be noted:
 - a. product name
 - b. dosage
 - c. date of injection
 - d. withdrawal date

For your convenience, templates have been created for each of the records listed above.

RATIONALE

- a. Health Canada is responsible for protecting human and animal health and the safety of Canada's food supply. Through the Veterinary Drugs Directorate, Health Canada evaluates and monitors drug safety, quality and effectiveness; sets standards; and promotes the prudent use of veterinary drugs administered to food-producing and companion animals.
- b. Drugs manufactured and sold in Canada are required by law to include specific information on their labels. Most manufacturers also include a product insert which provides information that does not fit on the label.
- c. The Medication and Vaccine Usage Plan and the Treatment Record allow the producer to demonstrate that medications and vaccines use on-farm are administered at approved dosages and respect the PigSAFE Drug Use Policy.

GUIDANCE

- a. A valid veterinarian–client–patient relationship (VCPR) exists when:
 - i. The licensed veterinarian assumes responsibility for making medical judgments regarding the health of a person's animal(s) and the need for treatment.
 - ii. The client agrees to follow the veterinarian's instructions.
 - iii. The veterinarian has sufficient knowledge of the person's animal(s) to start a general or preliminary diagnosis, at the very least. This may be done either by examination or by timely visits to the farm.
 - iv. The licensed veterinarian is readily available for follow-up care in case of adverse reactions or failure of the treatment regime.
 - v. Each province's legislation (acts and regulations) and the provincial veterinary association's by-laws specifically define the nature of the veterinary–client–patient relationships for that province.
- b. Definition of Extra-label drug use: Extra-label drug use refers to drugs administered for indications other than what are described on the label. Examples include deviations in terms of the following:
 - i. species of animal being treated
 - ii. age or stage of production
 - iii. dosage
 - iv. duration or frequency of treatment
 - v. purpose of treatment
 - vi. method of administration.

- c. The PigSAFE | PigCARE programs only permit extra-label drug use when:
 - i. a valid veterinarian–client–patient relationship exists
 - ii. a prescription issued by a licensed veterinarian exists with written directions, including a recommended withdrawal time, and the decision for extra-label drug use has been properly documented in that veterinarian’s medical records, and
 - iii. treatment records are maintained according to PigSAFE | PigCARE programs requirements.
- d. **A group treatment** is a treatment (e.g., vaccine, dewormer, hormonal treatment) given to a group of pigs or the entire herd at a specific time during any stage of production.
- e. **Contraindication:** Product contraindications and warnings should refer only to human or animal health concerns related to product usage.
- f. **Shelf life and expiry dates**
 - i. Medications and vaccines should be discarded if not used within the restricted time periods defined by your veterinarian
 - ii. Transport and store medication in a manner that protects shelf life to help maintain product quality on-farm.
 - iii. Always visually inspect medications prior to use. Bacteria can colonize in a bottle of antibiotics. Any change in colour, clarity or consistency may indicate a problem with the medication, in which case it should be discarded or returned to the supplier.
- g. **Compounding** is the combining of two or more ingredients, at least one of which is a drug or active ingredient, to create a product in a form appropriate for dosing. Compounding is regulated at the provincial level and only pharmacists and other practitioners (doctors, dentists, veterinarians) are permitted to compound products.
 - i. Mixing two or more medications in a syringe for delivery to animals is a form of compounding and is not permitted.
- h. A **Drug Identification Number (DIN)** is an eight-digit number assigned by Health Canada to a drug product prior to its being marketed in Canada. It uniquely identifies any drug product sold in a dosage form in this country. It is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada.
- i. The Canadian edition of the Compendium of Veterinary Products can be found at <https://cdmv.cvp-service.com>.
- j. The Health Canada Drug Product Database can be found at <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>
- k. For further information, consult the PigSAFE Canada Drug Use Policy.

AUDIT QUESTIONS

Q#	Audit Questions and Interpretations	Verification			
		Compliant	NC-Minor	NC-Major	N/A
Q5.1.1	To ensure that a valid veterinarian–client–patient relationship is in place, verify whether: <ul style="list-style-type: none"> a. the Medication and Vaccine Usage Plan is complete, approved, signed and dated by the licensed veterinarian with whom a valid Veterinarian Client Patient Relationship is established. OR b. that the letter of guarantee is signed by the licensed veterinarian with whom a valid Veterinarian Client Patient Relationship is established. 	Full and Partial Validation: <ul style="list-style-type: none"> ➤ R-P: Medication and Vaccine Usage Plan or a signed Letter of guarantee –Licensed veterinarian (R-Y) ➤ veterinary prescription 			
	a. Is a valid veterinarian–client–patient relationship established?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Are all prescription drugs that are used on-farm prescribed by a veterinarian licensed to practice in your province or territory with whom you have a valid veterinarian–client–patient relationship?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Q#	Audit Questions and Interpretations	Verification			
		Compliant	NC-Minor	NC-Major	N/A
Q5.1.2	Verify whether the PigSAFE Vaccine and Drug Use Policy is respected and the required elements are available during the validation.	Full and Partial Validation: > R-P: Medication and Vaccine Usage Plan > veterinary prescription > interview			
	Is the PigSAFE Vaccines and Drug Use Policy respected and implemented?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a. If applicable, are copies of prescriptions available and do they indicate the withdrawal periods to be respected for all veterinary drugs labelled and extra labelled?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Are written directions available for the use of all veterinary drugs?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. Are all veterinary drugs used on-farm either labeled for pigs in Canada or labelled for another food producing animal in Canada?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	d. Are all APIs used on-farm compliant with Health Canada Regulations?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q5.1.3	Verify that the Medication and Vaccine Usage Plan (R-P) includes all required elements. Also verify that it is complete, has been approved and signed by a licensed veterinarian, and is being kept up to date.	Full and Partial Validation: > R-P: Medication and Vaccine Usage Plan > veterinary prescription			
	Does the Medication and Vaccine Usage Plan include all PigSAFE-required elements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Q5.1.4	Verify that the Treatment Record (R-T) includes all required elements.	Full and Partial Validation: > R-P: Medication and Vaccine Usage Plan > R-T: Treatment Record > veterinary prescription			
	Does the Treatment Record (R-T) include all PigSAFE-required elements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Q#	Audit Questions and Interpretations	Verification			
		Compliant	NC-Minor	NC-Major	N/A
Q5.1.5	<p>Verify that each individual or group treatment of animals beyond weaning, including breeding stock, (vaccines and drugs) are recorded on the Treatment Record (R-T). This record must include each treatment administered in the water, by injection, topically or orally for a group of pigs or an individual pig.</p> <p>Verify that the record is completed on an ongoing basis and is being kept up to date.</p> <p>Cross-reference the information listed on the Treatment Record, the Medication and Vaccine Usage Plan and on prescriptions.</p> <p>If treatments are recorded on the sow cards, the following elements must be noted:</p> <ol style="list-style-type: none"> product name dosage date of injection withdrawal date 	<p>Full and Partial Validation:</p> <ul style="list-style-type: none"> ➤ R-T: Treatment Record ➤ R-P : Medication and Vaccine Usage Plan ➤ sow cards ➤ interview 			
	a. Are individual and group treatments for all animals beyond weaning (including breeding stock) recorded on the Treatment Record (R-T)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. If treatments are recorded on the sow cards, are the required elements recorded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

N/A = not applicable



LEVELS OF COMPLIANCE – EXAMPLES

COMPLIANT

- The Medication and Vaccine Usage Plan (R-P) is complete, approved and signed by a licensed veterinarian and corresponds with the given prescriptions.
- The Treatment Record (R-T) is complete and corresponds with the given prescriptions.

MINOR NON-COMPLIANCE **Timeline: 12 months**

- Some elements are missing from record R-P or R-T (i.e., not written down).

MAJOR NON-COMPLIANCE **Timeline: 60 days**

- There is evidence that no veterinarian–client–patient relationship exists, according to the definition in the program description.
- Record R-P or R-T is not available or is incomplete.
- Extra-label drug use is occurring without prescription.