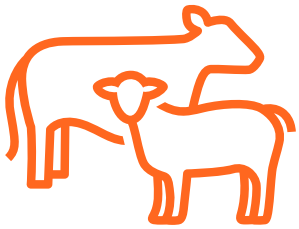
TECHNICAL INFORMATION UPDATE



Zoetis Livestock Vaccine Handling Guide

INTRODUCTION

Why vaccine handling is important

Vaccination programs should look beyond the scheduling of vaccination events and **ensure that the animals are immunised and not merely vaccinated.** No vaccine is 100% effective.

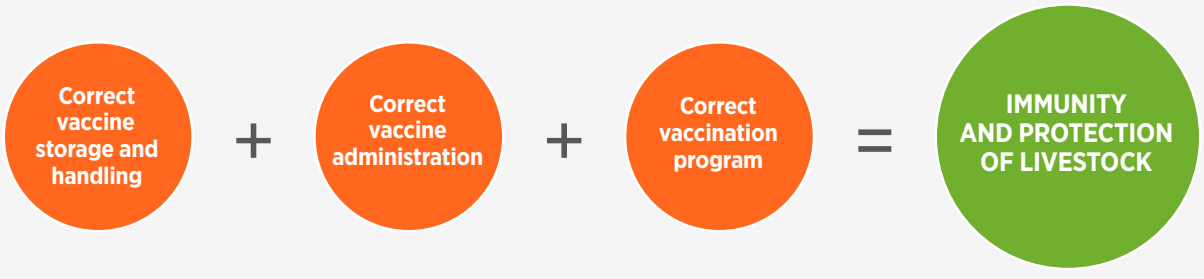
The purpose of this guide is to summarise how veterinarians, resellers and farmers can maximise the chances of immunising livestock through careful handling of vaccines. **Inadequate vaccine handling can not only reduce vaccine efficacy, but also cause direct harm to animals or people.**

Vaccine handling fast facts:

1. Read and follow vaccine label directions
2. Store vaccines at **2-8°C** unless otherwise stated on the label
3. Maintain hygienic vaccination equipment and vaccine packs
4. Plan vaccinations in advance to avoid;
   - vaccine expiring,
   - missing the right time to vaccinate and ability to administer a booster dose, and
   - clashes with other activities
5. Avoid vaccinating stressed or unwell animals
6. Dispose of needles and vaccine packaging responsibly

This guide approaches vaccine handling in three parts:

- **A:** Before vaccination
- **B:** During vaccination
- **C:** After vaccination



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A: BEFORE VACCINATION

i. Read and follow the vaccine label

Always become familiar with vaccine labels before vaccination.

Reading the label prior to use helps to avoid errors associated with:

- Vaccination timing and course required for protection
- Vaccination of appropriate ages and classes of stock
- Correct vaccination location on the animal
- Correct quantity of vaccine required for the job
- Special requirements such as unique vaccinators

Product labels can change over time. Some products have very specific and critical vaccination intervals, usage conditions or contraindications.

ii. Maintain cold chain during storage and transport

Unless otherwise stated, livestock vaccines must be stored at 2-8°C.

Vaccine components may degrade prematurely if stored or transported inappropriately. Freezing can reduce efficacy as it causes changes to the chemical structure of the vaccine. In the case of live vaccines, deviation from the recommended temperature directly affects the viability of the live organisms responsible for stimulating immunity.

The most common causes of cold chain failure are:

- Vaccines left outside the refrigerator on delivery
- Vaccines transported in cars from store without consideration of temperature
- Power cuts
- Refrigerator failure (especially in hot weather)
- Accidental alteration of the thermostat setting on the refrigerator
- Door seal failure (the refrigerator works harder and the resulting temperature gradient within the refrigerator creates warm vaccine near the door and frozen vaccine at the back)
- Overloading the refrigerator with vaccine packs stored too close together (inadequate cool air circulation)
- Cooling large masses of warm objects in the same space (e.g. colostrum)

Zoetis recommendations for maintaining correct storage temperatures:

- Unless otherwise stated, vaccines must be stored and transported at 2-8°C
- Ensure vaccine shipments are planned so that delivery occurs during work hours and a staff member can unpack and refrigerate the vaccine on arrival. This is especially important near weekends and during holiday periods
- Place a digital thermometer inside the refrigerator and monitor the temperature regularly
- Store vaccines in the refrigerator so there is space between them to allow the air to circulate and better maintain target temperature
- Ensure that vaccine is packed inside the fridge so as not to inhibit airflow (i.e. not pushed up against the back and sides of the fridge, but ideally with about a 3-5 cm gap between the product and walls of the unit). If airflow is not adequate and the fridge struggles to maintain appropriate temperatures, you may run the risk of vaccine freezing and the product being spoiled
- Secure the thermostat so it is not accidentally adjusted
- Ensure that you regularly check your vaccine fridges each day to check that they are maintaining adequate temperature (between 2° and 8°C). Ideally, your vaccine fridge should be sitting at about 3-4°C. Note: At the end of this document (Appendix 1.1) you will find a simple template that you can use to track the daily temperature of your fridge so you can identify issues quickly
- Examine and clean the condenser unit of your refrigerator regularly. You can use a vacuum cleaner, dust broom or air-compressor to do this job. You can search for instructional videos on-line or view them on YouTube; e.g. search for 'clean fridge condenser' & your brand of fridge

Note: The package insert may be used as proof of vaccine storage requirements for insurance claims on vaccine which has to be discarded due to extended power cuts, fridge failures etc, which are covered by insurance policies.

Zoetis fridges enquiries

For any questions regarding Zoetis fridge breakdowns there are several contact options:

- Your local Zoetis Sales Representative, OR
- Zoetis Product Support: 1800 814 833, productsupport.au@zoetis.com

IF YOUR ZOETIS VACCINES GETS TOO HOT OR FREEZES —
Contact the Zoetis product support team:
1800 814 883
productsupport.au@zoetis.com

iii. Protect vaccines from light

Ultraviolet light accelerates the degradation of vaccines.

Zoetis recommendation:

- Keep livestock vaccines in the original carton when not in use

iv. Scheduling/planning of vaccination programs

Vaccination events should always be planned

Plan all vaccination days to ensure vaccinations are administered at the right time according to the label i.e. pre-joining. Planning also helps you to avoid administering too many products simultaneously, especially to sick or stressed animals and during hot weather. Administering multiple vaccines at the one time, especially in hot weather, can increase the risk of post-vaccination adverse drug events. Vaccination when the animal is wet or muddy should be avoided, therefore it is best to plan your vaccination program around wet weather.

Zoetis recommendations:

- Each farm should have a herd health program that ensures all animals are immunised at the correct time and avoids the application of excessive numbers of products concurrently
- Avoid administering multiple vaccines at any one time whenever possible, especially in hot weather. Check with your local Zoetis sales representative if you have any questions
- Mineralised vaccines should be used with caution where alternative mineral supplements are already being provided

v. Check equipment and vaccine prior to day of vaccination

Use the correct vaccinator and always calibrate prior to use

Some vaccines use specific vaccinators (e.g. the Scabigard applicator for Scabigard, the Gudair Sekurus 1mL Safety vaccinator for Gudair). Specialised vaccinators usually require practice. Inaccurate equipment may result in overdosing (resulting in not enough vaccine on hand) or underdosing (meaning the entire group should be re-vaccinated) therefore always calibrate vaccinators prior to use.

Zoetis recommendations:

- Use the correct vaccinator and practice using it prior to use on the day
- Use a shrouded vaccinator for best vaccine placement and increased user safety
- Read the vaccine leaflet or label for information on vaccinator handling
- Calibrate vaccinators before use with a measuring flask or syringe
- Inspect equipment prior to use to ensure it is clean (see “After vaccination” for cleaning advice)
- Check the vaccine is within its expiry date and its in-use life (if opened). Vaccines that are expired or have exceeded their in-use life should be discarded (see “After Vaccination”)

FOR MORE INFORMATION ON VACCINE STORAGE AND CALIBRATION OF THE ZOETIS APPLICATORS

Please visit the **Best Practice Instructional Videos** on the Zoetis website Livestock Solutions **https://www.zoetis.com.au/livestock-solutions**

B: DURING VACCINATION

i. Maintain cold chain when in the field

Unless otherwise stated, keep vaccines at 2-8°C when in the field.

Take steps to minimise the time vaccine packs are warmed to room temperature and exposed to light during use. A range of vaccine pouches are on the market to assist with this. These pouches are generally manufactured from special insulating materials designed to keep vaccines cool and protected from light. If working over a whole day, place vaccines into a cooler with an ice brick if not being used during a break. It may be necessary to replace ice bricks during the day or otherwise use a portable refrigerator to keep the vaccine cool.

Zoetis recommendations:

- Use insulated bags/cooler with ice packs during transport to the yards or a car fridge
- Ice packs should be chilled in the freezer for at least 24 hours before use
- Be careful not to freeze vaccines in cooler with ice packs (this is more likely to happen if the vaccine is removed from its packaging while in the cooler). Avoid placing open packs of vaccine directly against ice bricks
- Use vaccine pouches during use to slow the heating of vaccine and protect it from light
- Place vaccines in a cooler when not in use whilst in the yards

ii. Maintain hygiene during use

Poor hygiene during use can result in adverse events.

The risk of a hygiene breakdown resulting in an adverse event, i.e. a vaccination site abscesses or a generalised infection, is a function of the type, extent, and duration of contamination. If the vaccine or vaccination equipment i.e. vaccinator and draw-off tube, is stored or used in a contaminated state, bacteria will multiply.

Do not sterilise needles with chemicals during use as this can impact the efficacy of vaccines and cause irritation at the vaccination site. It is not recommended to attempt to disinfect skin before vaccination with live vaccines as the disinfectant may also destroy the vaccine. Vaccines should be handled aseptically with clean hands and contact with unsterile surfaces must be avoided.

See “After Vaccination” for information on cleaning vaccinators.

Zoetis recommendations:

- Avoid vaccination when animals are wet
- Do not administer vaccine through visibly contaminated skin
- Change the needle, draw-off tube and vaccinator if they become contaminated
- Do not contaminate vaccine pack stoppers before perforating them (e.g. dirty hands)
- Disinfect stoppers with an appropriate disinfectant before perforation, e.g. methylated spirits
- Use a new draw-off tube with each new vaccine pack. Some draw off tubes can be boiled to sterilise them and then reused. Frequent attachment of the draw off tube may cause the stopper to leak. Therefore, the tube should ideally not be attached more than twice
- Do not perforate vaccine pack bungs with used needles, including the needle on the vaccinator
- Do not inject unused vaccine in the vaccinator or draw-off tube back into the vaccine pack This could contaminate the vaccine pack, especially if it will be stored before next use
- Do not attempt to sterilise needles with chemicals (e.g. methylated spirits) during use

iii. Connect vaccinators correctly

Take care when connecting draw-off tubes to avoid contaminating or damaging vaccine packs and applicators.

Used draw-off tubes may contain bacteria or organisms that could contaminate the vaccine pack.
Also, blunt draw off tube spikes increase the risk of leakage or pushing the bung into the vaccine pack.

Follow the same instructions when withdrawing single doses into a disposable syringe. **Zoetis has no data on the stability of Zoetis vaccines when removed from the original vaccine pack therefore vaccine needs to be used as soon as possible.**

Zoetis recommendations:

- Ensure the draw-off tube spike is sharp before connecting
- Use a new draw-off tube for each pack

iv. Select the appropriate needle size and replace regularly

Use the appropriate needle.

The tables below provide suggested needle sizes for cattle and sheep.

Zoetis recommendations:

- Carefully select the appropriate needle size based on the site of injection and the age and condition of the animal
- Use a new needle at the start of each vaccination session
- Never straighten or reuse a damaged needle
- Change needles every 50-100 animals (or more frequently), or sooner if it is contaminated, bent, burred or blunted
- For subcutaneous vaccines, use the shortest needle possible

a) Sheep — Suggested needle sizes

Class of Stock	Needle Gauge	Needle Length	Needle Angle to Skin
Lambs	18G	¼ inch	45°
Adults off-shears/short wool/ low body condition score	18G	¼ inch	45°
Adults with wool growth	18G	¼ inch	90°

b) Cattle — Suggested needle sizes

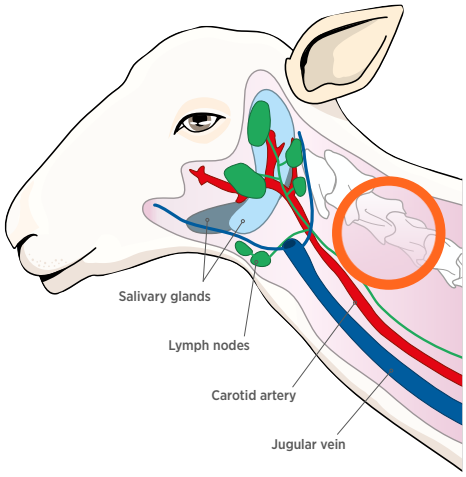
Class of Stock	Needle Gauge	Needle Length	Needle Angle to Skin
Subcutaneous	16-18G	3/8 – ½ inch	45°
Intramuscular	16-18G	1-1½ inch	90°

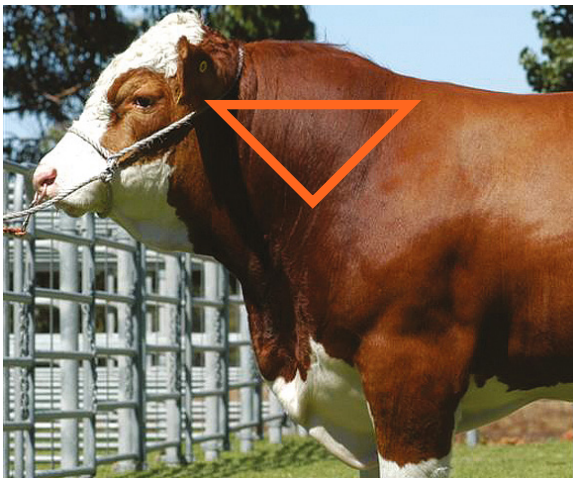
v. Administer the correct dose to the correct site

Always administer vaccines at the site recommended on the label.

Prior to vaccinating check whether the vaccine is to be administered subcutaneously (under the skin) or intramuscularly (into the muscle). When administering multiple vaccines concurrently, ideally choose injection sites that enable each vaccine to be processed by a different draining lymph node. E.g. when two vaccines are used, administer each vaccine on different sides of the neck. If you do need to administer two vaccines on the same side of the neck, separate the injection sites so the vaccines do not mix (minimum of 10 cm apart e.g. approx. one hand width). Follow a consistent pattern and record the site of each vaccine so that in the event of injection site lesions, it is evident which vaccine is responsible.

Refer to Sheep and Cattle image below for correct vaccination site:





#Scabigard is administered inside the front leg or brisket.

Zoetis recommendations:

- Administer vaccines to the side of the neck unless stated otherwise
- When multiple vaccines are used:
  - Choose sites on opposite sides of the neck where possible
  - If site close by, space injections so the vaccines do not mix in the animal (e.g. 10cm between injections).
  - Never mix different vaccines in the same container (or vaccines with other products) unless specifically stated on the vaccine label
  - Keep the injection sites consistent for each vaccine and document which vaccine was injected where in case of subsequent injection site lesions
- Ensure animals are adequately restrained to facilitate correct placement of injections
- Take your time when administering vaccines to ensure best results — safety and efficacy
- Keep a record of the batch number and expiry date with the details of which animals were treated for your records

vi. Shake vaccine packs regularly and gently before use and when in use

Vaccine components can settle and separate therefore gently agitate prior to use and during use.

Excessive shaking can create foam.

Zoetis recommendations:

- Agitate vaccine packs before use and regularly when in use (e.g. every race of animals)
- Use a gentle swirling motion or gently invert the pack several times

vii. Avoid vaccinating stressed or compromised animals

Late pregnancy, heat stress and poor health can reduce the immune response to vaccination and increase the risk of adverse events.

Zoetis recommendations:

- Avoid vaccinating pregnant livestock too close to calving/lambing
- Avoid vaccinating cattle (and sheep) if the temperature is over 30°C with over 40% humidity, or at lower temperatures with a higher humidity
- Sick, malnourished or stressed animals should not be expected to develop the same immunity as healthy animals

viii. Accidental exposure or self-injection

Always take care when administering vaccines to avoid accidental self-injection of yourself or others.

Accidental human injection may have negative outcomes due to:

- Local trauma or infection from the needle
- Local or systemic effects from the vaccine, if injected.

Injection of a vaccine may cause an allergic or inflammatory reaction. Some vaccines, such as live scabby mouth vaccines and endocrine vaccines, may also be active in humans. Consult the specific vaccine instructions and manufacturer for advice if a vaccine is accidentally injected.

General information in the case of human exposure or injection:

- Seek medical attention if you are concerned or if vaccine is injected and show the package leaflet or the label to the Medical Practitioner
- Advice and Safety Data Sheets (SDS) for Zoetis products are available from **http://www.zoetis.com.au** or call the **Zoetis Product Support team on Ph: 1800 814 883**
- If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 131126
- If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water If splashed in eyes, wash out immediately with water
- Prompt medical attention must be sought in the case of self-injection with oil-based vaccines (e.g. Gudair, Silirum, Vibrovax), even in the absence of clinical signs. In the case of exposure to Gudair or Silirum, please contact the **Zoetis Product Support team** as we can assist you with further information for your Medical Practitioner
- Human exposure to any livestock vaccine should be reported to Zoetis and/or the APVMA

Zoetis recommendations:

- Use specialised vaccinators according to vaccine label instructions
- Read and follow label instructions on vaccine handling
- Take care when changing needles or during maintenance — this is a common time for needle stick injuries to occur
- In particular, wear gloves and eye protection when administering scabby mouth vaccines Other people handling animals immediately after they have been vaccinated against scabby mouth should wear gloves if they will be in direct contact with the vaccination area
- Wear gloves when cleaning equipment that has contained Scabigard, Gudair or Silirum
- Absorb spills and dispose of it in medical waste containers. Wash the area and dispose of the material. Surfaces or materials contaminated by live vaccines should be cleaned and disinfected with suitable disinfectants or boiling for 10 minutes

FOR MORE INFORMATION ON VACCINATION TECHNIQUE FOR THE ZOETIS VACCINE RANGE AND WHAT TO DO IN CASE OF THE ADVERSE EVENT
Please visit the **Best Practice Instructional Videos** on the Zoetis website Livestock Solutions
https://www.zoetis.com.au/livestock-solutions

IF YOU OR SOMEONE YOU KNOW, HAS HAD A SUSPECTED ADVERSE EVENT, INCLUDING HUMAN EXPOSURE OR AN ANIMAL REACTION WITH ANY ZOETIS PRODUCT, PLEASE CONTACT OUR PRODUCT SUPPORT TEAM IMMEDIATELY ON PH: 1800 814 883

C: AFTER VACCINATION

i. Clean vaccinators

Always clean your vaccinators.

Vaccine residue is a food source for organisms i.e. bacteria. Storage of equipment and packs containing vaccine may enable a microbial colony to establish. Furthermore, the residue of one vaccine can interfere with a different vaccine, e.g. components of inactivated vaccines can destroy live vaccines. Vaccine residues or vaccine left in a vaccinator, even overnight, may also damage seals making the plunger hard to push and slow to refill or result in blocked valves, all resulting in inaccurate dosing.

Operators should wear gloves when dismantling and cleaning Scabigard applicators to prevent self infection. Scrubbing brushes should be avoided as they can scratch the skin and inoculate live virus.

Zoetis recommendations:

- Follow vaccinator manufacturer instructions on applicator cleaning and maintenance
- Vaccination applicators should be dismantled, cleaned and rinsed with clean water as soon as possible after use
- Use mild dishwashing liquid to clean equipment, especially after using oily vaccines like Gudair or Vibrovax, and rinse thoroughly as detergent residues may interfere with vaccines
- Some applicators can be boiled for 10 minutes to sterilise them (e.g., Scabigard applicator) — check the manufacturer's instructions first
- Discard the draw-off tube and use a new draw-off tube with each new vaccine pack. Some vaccines state that draw-off tubes can be boiled to sterilise them and then be reused
- Boiled applicators and tubes must be allowed to cool to room temperature before use
- Lubricate vaccinators after cleaning as required according to the applicator manufacturer's instructions
- Some vaccinators should be discarded at the end of each season's use, to minimise the risk of contamination e.g., Scabigard applicator

FOR MORE INFORMATION ON HOW TO CLEAN YOUR ZOETIS VACCINATORS
Please visit the **Best Practice Instructional Videos** on the Zoetis website Livestock Solutions
https://www.zoetis.com.au/livestock-solutions

ii. Dispose of needles in sharps containers

Carefully disposal of all used needles

Zoetis recommendations:

- Veterinarians and farmers should dispose of needles in designated and appropriately labelled sharps containers. These containers should be disposed of appropriately

iii. Dispose of vaccine packs and unused vaccine responsibly

Some products are harmful to the environment so follow the disposal directions on the label.

Zoetis recommendations:

- Disposal instructions are provided on product labels or package insert (also part of the registered label). Generally, dispose of empty containers by wrapping with paper and putting in garbage or in approved medical waste containers
- Vaccine packs containing unused vaccine can generally be disposed of in land fill

iv. Store part used packs according to label instructions

Check the recommended in-use storage life of opened vaccine packs and follow the label directions.

Zoetis recommendations:

- Most packs of inactivated veterinary vaccines contain a preservative that takes care of minor contamination during use. However, the added preservative can be overcome by gross contamination. The suitability of a vaccine as a growth media for bacteria will also vary depending on how the vaccine is formulated
- Extended vaccine broaching claims has been a relatively recent addition to product labels to allow re-use of opened packs of vaccine for longer than the day after broaching
- It is important that label instructions be followed when re-using broached packs of vaccine
- Do not inject unused vaccine in the vaccinator or draw-off tube back into the vaccine pack. This could contaminate the entire vaccine pack
- **Clearly record the date the pack was opened on the packaging. Many vaccines have a space provided on the carton**
- **Unscrew the draw off tube from the vaccine pack during storage**
- Disinfect the stopper with a suitable antiseptic, e.g. methylated spirits
- Unless otherwise stated, place the vaccine pack in the original outer packaging and store upright in the refrigerator at 2-8°C, protected from sunlight
- Use a new draw-off tube with each new vaccine pack. Some draw off tubes can be boiled to sterilise them and then reused. Frequent re-attachment of the connecting tube may cause the stopper to leak. Therefore, the draw-off tube should not be re-attached more than twice

v. Post-vaccination reactions

Reactions post vaccinations can occur. Always seek veterinary advice and contact the manufacturer.

Be aware of the possibility of post-vaccination reactions, such as local tissue lumps and abscesses. Local reactions are more likely with some vaccines. Adherence to aseptic technique (appropriate handling and storage) and correct placement of vaccines will minimise the risk of post-vaccination reactions.

Some vaccines carry the risk of allergic reactions. Where a product has a history of allergic reactions, a warning will be present on the product label. There will always be the risk of anaphylactic reactions. Some animals will recover without treatment; however, severely affected animals may require veterinary treatment.

Vaccine registrations are carried out under standardised conditions in healthy animals. It is impossible to conduct registration studies under every condition that is encountered when products are used in the field. Likewise, different combinations of products, including vitamins and minerals, drenches and other vaccines may also interact resulting in adverse outcomes.

Any suspected adverse drug events should be reported to the registrant and/or the APVMA. This allows valuable information to be gathered post registration when products are used under field conditions, in different breeds of animals and in conjunction with, or after, other animal health products which may result in further refinements to product labels and warning statements.

FOR ANY SUSPECTED ADVERSE EVENT, INCLUDING HUMAN EXPOSURE OR AN ANIMAL REACTION WITH ANY ZOETIS PRODUCT, PLEASE CONTACT OUR PRODUCT SUPPORT TEAM IMMEDIATELY ON PH: 1800 814 883

APPENDICES

Appendix 1.1 Zoetis Fridge Monitoring Template

Date and Time	Temperature	Signature