GUIDELINE ON
GOOD DISTRIBUTION PRACTICE OF
VETERINARY VACCINES

VETERINARY PRODUCT MANAGEMENT SECTION
VETERINARY PUBLIC HEALTH DIVISION
DEPARTMENT OF VETERINARY SERVICES,
MINISTRY OF AGRICULTURE AND FOOD SECURITY,
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INTRODUCTION

This guidance outlines the key measures for Good Distribution Practice (GDP) specifically for veterinary vaccines, offering recommendations to wholesale distributors on best practices to ensure proper procurement, storage, transportation, and handling. The objective is to maintain control over the distribution chain, safeguard the quality and integrity of veterinary vaccines, and prevent falsified veterinary vaccines from entering the legal supply chain.

Compliance with GDP ensures that veterinary vaccines maintain their quality throughout distribution. Wholesale distribution encompasses all activities related to procuring, holding, supplying, or exporting veterinary vaccines, except for retail supply to the public. These activities are carried out by authorized holders of manufacturing or wholesale distribution authorizations for veterinary vaccines.

Anyone acting as a wholesale distributor must hold a wholesale distribution authorization and adhere to the GDP requirements of the Department of Veterinary Services. Manufacturers involved in distributing their veterinary vaccines must also comply with GDP. The definition of wholesale distribution applies regardless of the distributor's location or warehouses.

Definitions

Term	**Definition**
Authorities	Refer to government bodies or agencies such as the Department of Veterinary Services, local authorities or any relevant authorities.
Substandard and falsified	Substandard: Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or specifications, or both. Falsified: Veterinary vaccines that deliberately/fraudulently misrepresent their identity, composition or source.
Consignment	The delivery batch of veterinary vaccines is supplied at one time in response to a particular request or order.
Contamination	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter during manufacturing, sampling, packaging or repackaging, storage or transport.
Cross-contamination	Contamination of a veterinary vaccine with another veterinary vaccines

Good Distribution Practice (GDP)	The measures that need to be considered in the storage, transportation and distribution of any veterinary vaccines and such that the nature and quality intended are preserved when they reach the consumer.
Labelling	The term 'labelling' designates all labels and other written, printed or graphic matter upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. A shipping container, unless such container is also essentially the immediate container or the outside of the consumer package, is exempt from labelling requirements.
Manufacturer	Includes: a. the making or assembling of the veterinary vaccines; b. the enclosing or packing of the veterinary vaccines in any container in a form suitable for administration or application, and the labelling of the container; and c. the carrying out of any process in the course of any or the foregoing activities.
Marketing Authorization Holder	Representatives or companies acting as agents empowered by the manufacturer to sell or solicit sales for the manufacturer's products in a defined territory.
Packaging material	Any material employed in the packaging of veterinary vaccines, including any other packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
Printed packaging material	Packaging material which is imprinted with text or numbers or a combination of both.
Return veterinary vaccine	Veterinary vaccines are sent back from the end user to the supplier.

Storage	A term used to describe the safe keeping of veterinary vaccines such as starting materials and finished products received from suppliers, semi-finished products in process and finished products awaiting dispatch and products or cosmetics awaiting distribution to retailers and products or cosmetics (rejected, recalled and damaged) awaiting disposal.
Wholesale	A sale to any person who intends to sell again and any sale by a licensed wholesaler.
Wholesale distribution	Wholesale distribution of veterinary vaccines is all activities consisting of procuring, holding, supplying, importing or exporting veterinary vaccines, apart from supplying it to the public.
Veterinary Vaccine	A veterinary vaccine is a biological product, such as a suspension of live, attenuated, or inactivated microorganisms (or their components or products), that is administered to animals to induce active immunity against a specific disease or disease.

CHAPTER 1: QUALITY SYSTEM

PRINCIPLE

The organization shall establish and maintain a quality system to govern veterinary vaccine importation, exportation, procurement, storage, transportation and distribution activities. This system must define responsibilities, processes, and risk management, with procedures for all relevant activities undergoing systematic review. Justification and validation are required for critical process steps and significant changes. Management's leadership and personnel commitment are essential for effective quality system oversight and implementation.

QUALITY SYSTEM

1.1 The organization needs a comprehensive Quality System to ensure veterinary vaccines consistently meet quality requirements. This system must be fully documented, monitored for effectiveness, and include:

i. **Organization:** Clear structure, procedures, processes, and resources.
ii. **Actions:** Systematic steps to ensure confidence in product quality

1.2 The quality system must ensure that veterinary vaccines:

i. Comply with Good Distribution Practices (GDP) throughout procurement, storage, supply, import, export and distribution.
ii. Have clearly defined management responsibilities.
iii. Are delivered to the correct recipients on time.
iv. Have records made immediately.
v. Have documented deviations and investigated effectively.
vi. Have Corrective and Preventive Actions (CAPA) implemented to address and prevent issues, based on quality risk management.
vii. Have all quality-impacting changes documented and managed through a formal change control system.

1.3 **Traceability and Security:**

The Quality System must ensure a safe, transparent, and secure distribution system by establishing measures to track veterinary vaccines throughout the supply chain, from manufacturers to retailers.

Outsourced Activities:

The Quality System must control and review all outsourced activities related to product handling (procurement, storage, transport, etc.), including:

- Assessing the suitability and competence of contractors.
- Defining responsibilities and communication.
- Regularly monitoring and improving contractor performance.

Procurement and Release:

Authorized procedures must be in place for procurement and release, ensuring veterinary vaccines are sourced from approved suppliers and distributed by approved entities. A written procedure is needed to ensure and document the traceability of received and distributed veterinary vaccines.

Certification:

External quality system certification (e.g., ISO) is recommended but does not replace compliance with these guidelines.

CHAPTER 2: PERSONNEL PRINCIPLE

There must be enough competent personnel to carry out all assigned tasks. Individual responsibilities should be clearly understood by the personnel and documented.

GENERAL

2.1 The company must have an organization chart. Personnel in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies with an appropriate level of qualification. There should be no gaps or unexplained overlaps in the responsibilities of personnel involved in the application of GDP.

2.2 All personnel involved in handling vaccines, including drivers, should receive regular and appropriate training to maintain the quality of time and temperature. This training should encompass relevant legislation and regulations, operational procedures, safety protocols, and emergency response. Records of the training provided, along with checks on its effectiveness, should be available upon request.

2.3 Besides the basic training on the theory and practice of GDP, newly recruited personnel should undergo training that is specific and relevant to the duties they are assigned. Continuous training should also be given, and its practical effectiveness should be periodically assessed. Approved training programs should be available, and training records must be maintained.

2.4 Personnel should receive training specific to their tasks given (e.g. evaluation of Veterinary vaccines upon receiving, evaluation of complaints about damage during the process and return to the saleable stock of returned used Veterinary vaccines).

2.5 In addition, training should cover the identification of vaccines and the prevention of substandard and falsified Veterinary vaccines from entering the supply chain.

2.6 Proper procedures regarding personnel hygiene and the appropriate clothing for staff, based on the activities being performed, should be established and followed. Personnel should receive training on these procedures, and the clothing provided should be suitable for the tasks to be carried out.

CHAPTER 3: PREMISES AND EQUIPMENT

The premises and equipment must be appropriate and sufficient to ensure proper loading, unloading, storage, protection from contamination, and distribution of the vaccine. Specifically, the premises should be clean, dry, and kept within acceptable temperature ranges.

PREMISES

3.1 The premises should safeguard the veterinary vaccine from contamination and prevent deterioration caused by light, moisture, and temperature. Premises should have sufficient security to prevent unauthorized access and misappropriation of the veterinary vaccine. Visitors should be accompanied.

3.2 The premises should have adequate security measures to prevent unauthorized access and theft of the vaccine. Visitors must be accompanied at all times.

3.3 The premises must have a permanent address and be situated at a location approved by the local authority and/or comply with relevant Acts or Regulations, to which the licensee must adhere.

3.4 If the premises are not directly operated by the company, a written contract must be in place.

3.5 The receiving and dispatch areas should be properly designed to protect the vaccine from weather conditions. The receiving areas should be equipped and designed to allow for the cleaning of containers of incoming products/cosmetics, if needed, before storage.

3.6 Adequate storage areas should be available to ensure the orderly and segregated storage of different categories of vaccines, including those in quarantine, as well as rejected, returned, or recalled products. These storage areas should be clearly labelled, and access to the quarantine rejected, returned, or recalled areas must be restricted to authorized personnel only. Any system (e.g., computerized or barcoding system) used in place of physical separation must provide equivalent assurance of segregation and restricted access. Veterinary vaccines should be kept separate from non-biological substances.

3.7 The premises should be designed or modified to maintain the required storage conditions. They should be secure and large enough to ensure the safe storage and handling of veterinary vaccines. Storage areas must be equipped with adequate lighting and ventilation to support accurate and safe operations.

3.8 Storage facilities should be clean and free from accumulated waste and dust. A written sanitation program should be in place, outlining the cleaning frequency and methods for the premises and storage areas. Cleaning records must be maintained. There should also be clear procedures for cleaning up any spills to ensure the complete removal of contamination risks.

3.9 Veterinary vaccines should be stored off the floor and adequately spaced to allow for cleaning and inspection. Pallets should be well-maintained and kept clean.

3.10 The storage area should be designed and equipped to prevent the entry of insects, rodents, and other pests or animals. A written pest control program should be in place, and appropriate records should be maintained.

3.11 Appropriate storage conditions should be provided for hazardous, sensitive, and dangerous products, such as combustible liquids and solids, pressurized gases, highly toxic substances, and radioactive materials. These products should be stored in accordance with local regulations, with appropriate security and safety measures in place.

3.12 Printed packaging materials are considered critical to the conformity of veterinary vaccines, and special care should be taken to ensure their proper and secure storage.

3.13 Storage conditions for veterinary vaccines should align with the instructions on the label. The storage area must be equipped with devices or recorders that continuously monitor and record relevant conditions, such as maximum and minimum temperature and humidity. When storage conditions are not met, appropriate actions regarding the premises, equipment, or veterinary vaccines should be taken, and these actions must be documented.

3.14 The records and devices used for monitoring storage conditions should be placed in areas most likely to experience fluctuations, or at the hottest and coldest locations, as appropriate. The measuring equipment should be calibrated regularly to ensure it operates within the required range, and calibration records must be maintained.

3.15 An initial temperature mapping exercise should be conducted in the storage area before use, under representative conditions. Temperature monitoring equipment should be placed based on the results of the mapping exercise, ensuring that devices are positioned in areas prone to extreme fluctuations. The mapping exercise should be repeated if significant changes occur, based on the results of a risk assessment. Relevant documents and records must be retained, and retention periods should follow current regulations.

EQUIPMENT

3.16 All equipment involved in the storage and distribution of veterinary vaccines should be designed, located, maintained, and cleaned to meet the standards required for its intended purpose. Planned maintenance should be implemented for key equipment essential to the operation’s functionality.

3.17 Adequate procedures and records should be in place for operations, repairs, maintenance, and calibration activities of key equipment, including cleaning and safety precautions. Key equipment includes, for example, cold rooms/stores, monitored intruder alarms and access control systems, refrigerators, Thermohygrometers or other temperature and humidity recording devices, air handling units, and any equipment used in the onward supply chain.

3.18 Equipment used for distributing or transporting veterinary vaccines should be suitable for their intended use and properly equipped to protect the products from conditions that could impact their stability or packaging integrity, while also preventing any form of contamination.

3.19 When non-dedicated equipment is used, procedures must be established to ensure that the quality of the veterinary vaccines is not compromised.

3.20 Equipment used to monitor conditions within vehicles and containers, such as temperature and humidity, should be calibrated at regular intervals

3.21 Before a computerized system is put into use, it must be validated or verified to ensure it can consistently and accurately achieve the desired results. A written, detailed description of the system, including diagrams where appropriate, should be available and kept up to date. This documentation should cover the system's principles, objectives, security measures, scope, main features, how the system is used, and its interactions with other systems. Any changes to the system must be documented through a change control process.

3.22 Data should only be entered or amended in the computerized system by authorized personnel. It must be secured through physical or electronic means to prevent accidental or unauthorized modifications. Stored data should be periodically checked for accessibility, and regular backups should be performed to protect the data.

3.23 Procedures for handling system failures or breakdowns should be clearly defined. This should include processes for data restoration to ensure continuity and data integrity.

CHAPTER 4: VETERINARY VACCINES STORAGE

4. 1 List of veterinary vaccines including the cold chain storage temperature specifications should be provided for reference to personnel who handle the vaccines.

4.2 The net storage capacity of the facilities should be sufficient to accommodate peak veterinary vaccines stock levels, ensuring that the correct temperature conditions are maintained and enabling efficient stock management operations. Additionally, veterinary vaccines storage facilities must be qualified to confirm their ability to store the product following specified requirements. Qualification and validation records should be kept, and the facilities must consistently operate in compliance with the qualifying conditions at all times.

4.3 Household-style unit refrigerators are only acceptable if they have been independently tested and found to comply with the temperature control requirements of a recognized standard for pharmaceutical refrigerators.

4.4. Veterinary vaccines should be stored in dedicated, separated and securely locked facilities/areas that comply fully with all legislative and regulatory requirements.

4.5 The cold room and refrigerator must be fitted with an alarm system to alert personnel if any occurrence of temperature beyond specifications. Action and warning limits should be established. A periodic testing programs on the alarm system should be established to ensure the alarm system is functioning.

4.6 Alternative power systems should be established to ensure temperature remained and the temperature/humidity detector will continue functioning in the event of power failure. Periodic testing programs on alternative power systems should be established to ensure that it works. Alternative plan to provide alternative areas where storage temperature equivalent should be provided if no alternative power systems can be provided.

4.7 Calibration and temperature monitoring functions of all equipment, including alarms and other related equipment must be inspected at least annually.

4.8 Periodic maintenance programs for all temperature-controlled rooms, cold rooms, refrigerators must be established and implemented.

4.9 Verification upon receipt of veterinary vaccine should be done to ensure there are no signs of tampering and non-conformance (such as deviation of temperature profile from the manufacturer's recommendation as per the approved vaccine's label by the authority, physical damage to veterinary vaccines, packaging materials, etc.).

4.10 All veterinary vaccines (e.g. rejected, quarantined) must be stored under the storage conditions stated on the label other than the product which will be disposed of. If the storage temperature is found to have deviated from the storage specifications, manufacturers for the products should be contacted to confirm the suitability of the use of products and the decision recorded.

4.11 Maximum and minimum temperature and humidity (if needed) for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers must be monitored and recorded continuously using temperature and humidity monitoring devices.

4.12 Suitability of locations for placing temperature sensors in all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators, freezers and liquid nitrogen tanks used for storage of veterinary vaccines should be subjected to temperature mapping study. Mapping studies should be conducted in accordance with written procedures and storage conditions determined before the operation.

4.13 Container systems used for the transportation and distribution of veterinary vaccines must undergo full qualification to ensure they are suitable for their intended purpose. These systems should be capable of maintaining the specific temperature profile required for each vaccine, minimizing any vaccine degradation caused by temperature sensitivity, and meeting the stability criteria set by the veterinary vaccines manufacturer. Additionally, documented proof of compliance and assurance of system functionality should be readily available for review upon request.

4.14 Packaging operations for veterinary vaccines should be verified according to written procedures, with the packaging being mapped and continuously monitored. A system must be in place to control the reuse of temperature protection components (e.g., ice/water blankets, water/gel packs, phase change materials, insulated packaging) to prevent the accidental use of incomplete components. Necessary precautions should also be implemented when using dry ice during transportation to avoid direct contact with the veterinary vaccines, preventing potential coagulation of the veterinary vaccines.

4.15 Veterinary vaccines should be clearly labelled and easily distinguishable from other veterinary vaccines in the same shipment. If veterinary vaccines are being air freighted, the package(s) should be labelled according to International Air Transport Association (IATA) regulations.

4.16 Procedures must be implemented to handle the returned veterinary vaccines and also the veterinary vaccines that have been stored under out of the specified storage condition during the reception, storage and distribution of products.

4.17 Veterinary vaccines should be transported under validated conditions to ensure that the relevant temperature range is maintained according to the directions on the label of the veterinary vaccines. In addition, simulation studies can be conducted to validate the delivery conditions, taking into account the possibility of the worst situation.

4.18 Refrigerated vehicles or containers to transport veterinary vaccines should be mapped and continuously monitored.

CHAPTER 5: STOCK HANDLING AND STOCK CONTROL PRINCIPLE

The goal is to ensure that veterinary vaccines retain their identity and are distributed according to their packaging details. Efforts should be made to minimize the risk of substandard or counterfeit products entering the legal supply chain. Veterinary vaccines must only be sourced from approved, authorized suppliers. If obtained from another wholesaler, the receiving party must verify that the supplier follows good distribution practices. Veterinary vaccines must be properly authorized by the relevant authority before distribution, and key operations should be documented in the quality system.

RECEIVING

5.1 Upon receipt of veterinary vaccine deliveries, each shipment should be verified against the purchase order, Certificate of Analysis (CoA), and Material Safety Data Sheet (MSDS) (if applicable). The vaccine's label, type, and quantity must be checked for accuracy. If the consignment includes multiple batches, it should be divided according to the supplier's lot numbers for proper handling and tracking

5.2 All veterinary vaccine containers must be inspected for tampering, contamination, and damage. If any issues are found, the affected container or entire delivery should be quarantined for further investigation. Proper records should be maintained for each delivery.

5.3 The delivery order or equivalent document should include product descriptions, quality (if applicable), quantity, supplier details, supplier's batch number, date of receipt, assigned batch number, and transport/storage conditions. Records should be retained according to current regulations.

5.4 All veterinary vaccines must stay in quarantine until authorized personnel issue a written statement either releasing or rejecting them.

STOCK ROTATION AND CONTROL

5.5 Regular checks should be made to compare actual and recorded quantities of veterinary vaccines. Any significant discrepancies should be investigated for potential mix-ups or incorrect stock issues.

5.6 The principle of stock rotation (FIFO)- should be followed, and veterinary vaccines with expiry dates.

5.7 Veterinary vaccines with broken seals, damaged packaging, or suspected contamination should not be sold or supplied.

5.8 Regular checks should be made to identify expired veterinary vaccines. Precautions should be in place to prevent the issuance of expired items.

5.9 Labels and containers of veterinary vaccines must not be altered or tampered with. Compliance with relevant regulations regarding labels and containers is required.

5.10 Cartons or bulk containers should be labelled with at least the product name, batch number, and, if necessary, expiry or retest date.

RETURNED AND REJECTED

5.11 All returned or rejected veterinary vaccines should be placed in quarantine, clearly marked, and stored separately in a restricted area.

5.12 Returned veterinary vaccines should follow a written, risk-based process, considering the product type, specific storage needs, and the time since dispatch. Returns must comply with contractual agreements. A record of return must be maintained.

5.13 The fate of returned and rejected veterinary vaccines should be determined after proper evaluation by a trained and authorized person.

5.14 Arrangements should be made for the safe transport and storage of returned/rejected veterinary vaccines, adhering to relevant storage requirements.

5.15 Returned veterinary vaccines approved for sale should be integrated into the stock rotation system to ensure FIFO procedures.

5.16 Recovered stolen veterinary vaccines cannot be returned to saleable stock.

5.17 All actions related to returned products should be approved and recorded.

5.18 Substandard or falsified products found in the distribution network should be segregated from other products and clearly labelled as "Not For Sale" or similar. The regulatory authority and the marketing authorization holder should be informed immediately.

5.19 Records for each return should include:

- Name and address of the consignee returning the products
- Product name/designation, batch number, and quantity
- Reason for return
- Use or disposal of the returned products and assessment record.

DISTRIBUTION

5.20 There should be controls in place to ensure the correct veterinary vaccine is picked, and it must have an appropriate remaining shelf life at the time of picking.

5.21 Shipping materials should only be allocated after receiving a sales order. Distribution procedures should be defined based on the nature of the veterinary vaccines and any specific precautions required.

5.22 Import and export activities should follow national laws and international guidelines, especially when dealing with veterinary vaccines in free trade zones. Measures should be taken to prevent unauthorized products meant for export from entering the internal market.

5.23 Deliveries should only be made to authorized distributors to distribute the veterinary vaccines.

5.24 A written procedure for delivering veterinary vaccines to recipients should be in place.

5.25 A system should be established to trace and identify the distribution of each batch of veterinary vaccines, allowing for an effective recall if needed.

5.26 For all suppliers, a delivery document (e.g., Delivery Order) should include the date, product name, batch number, and quantity supplied. Supplier's name and address, consignee's name, delivery address, and storage location (if different), transport and storage conditions. Records should be maintained to track the location of the veterinary vaccines.

DISPOSAL

5.27 Veterinary vaccines intended for destruction should be clearly identified and segregated according to procedures.

5.28 The destruction of veterinary vaccines should follow national laws and regulations, with consideration for environmental protection.

5.29 Records of disposal should be kept for a defined period to ensure proper documentation.

CHAPTER 6: TRANSPORTATION

PRINCIPLE

Manufacturers, importers, and wholesalers must protect veterinary vaccines from damage, contamination, theft, and temperature fluctuations during transport. Regardless of the transportation method, it must be proven that product quality and integrity remain intact, using a risk-based approach for planning.

GENERAL REQUIREMENT

6.1 Vehicles used for transportation must be suitable and properly equipped to protect product stability, and packaging integrity, and prevent contamination.

6.2 Dedicated vehicles should be used where possible. If shared vehicles are used, cleaning procedures must be followed, documented, and verified.

6.3 All vehicles involved in distribution must have operational and maintenance procedures, including pest control programs. Cleaning agents must not harm product veterinary vaccine quality.

6.4 Risk assessments should be determined when temperature controls are necessary. Monitoring equipment (e.g., temperature and humidity sensors) must be regularly calibrated.

6.5 Vehicles and containers should be spacious enough for proper storage of different product categories.

SECURITY AND DOCUMENTATION

6.6 Measures must be in place to prevent unauthorized access, tampering, and theft during transportation.

6.7 Shipments must include proper documentation for identification and regulatory compliance at ports, borders, and warehouses.

6.8 Veterinary vaccines must be transported in a way that:

- Maintains product identity
- Prevents contamination
- Reduces risk of spillage, breakage, and theft
- Controls temperature and humidity as required

6.9 The veterinary vaccines must have documentation to ensure **traceability** throughout the supply chain.

6.10 Transportation must comply with international agreements and national regulations for dangerous goods.

PACKAGING AND LABELLING

6.11 Packaging materials and containers must be designed to prevent damage during transport.

6.12 If seal controls are in place, seals must be properly tracked, verified, and remain intact.

6.13 Containers must have clear labels indicating handling, storage requirements, and contents.

6.14 Any damage or issues during transit must be recorded and reported.

HANDLING OF REJECTED, RECALLED & RETURNED PRODUCTS

6.15 Mechanisms should allow for the segregation of rejected, recalled, or substandard products during transit.

6.16 These products must be securely packaged, labelled, and documented.

THIRD-PARTY TRANSPORTATION

6.18 When using third-party transport providers, a contract must be in place outlining the required conditions.

6.19 Transportation providers must be informed of specific transport requirements.

6.20 If the route includes unloading, reloading, or transit storage, additional attention must be given to temperature control, cleanliness, and security.

6.21 Companies must ensure that transportation providers are competent and report any incidents or deviations during transit.

CHAPTER 7: VETERINARY VACCINES COMPLAINTS

All complaints must be **documented and handled properly** following established procedures. Records should be accessible to authorities, and **returned products must be assessed** by authorized personnel before resale approval.

COMPLAINT HANDLING PROCESS

7.1 Companies must have procedures for managing both written and verbal complaints regarding product defects.

7.2 Each complaint must be documented separately.

7.3 Investigations should address:

- The cause of the complaint
- Distribution conditions
- How the product was used

7.4 Corrective actions must be implemented to prevent recurrence.

7.5 Complainants should receive a response within a defined timeframe after the investigation is completed.

RESPONSIBILITY & INVESTIGATION

7.6 A designated person must handle complaints, with the authority to initiate investigations and decide on necessary actions.

7.7 Contact details of the responsible person should be included in the complaint procedure.

7.8 If a defect is found in one batch, other batches should be assessed to determine if they are also affected.

CHAPTER 8: VETERINARY VACCINE RECALLS

8.1 A veterinary vaccines recall is a process initiated by manufacturers, importers, and wholesalers to remove a specific product from all distribution channels. This action is taken when significant quality defects or serious adverse reactions are reported, posing a potential health risk to consumers.

8.2 Decision for recall

Unless the Director has already specified the extent of a recall, the company's Product Recall Committee will decide the recall's degree and level, based on the severity of the risk

8.3 A veterinary vaccine recall is initiated if there is a potential health risk to users due to;

- Faulty production
- Adverse reactions

8.4 The decision for recall shall be made by;

- The manufacturers and distributors, who may voluntarily initiate a recall
- The Director of Veterinary Services Malaysia, who can direct a recall

8.5 The Product Recall Committee, responsible for executing and coordinating recalls, must:

- Include personnel responsible for the recall process.
- Handle all aspects of the recall urgently and efficiently.

DEGREE AND LEVEL OF RECALL

The criteria below are used to classify the recall.

8.6 DEGREE OF RECALL

Veterinary vaccines recalls are categorized based on the severity of the quality defect or adverse reaction:

- **Degree I (Critical):** Products posing major health risks that could cause serious injury or death. **Embargo required within 24 hours.**
- **Degree II (Significant):** Products posing minor health risks or those failing to meet quality standards. **Embargo required within 72 hours.**
- **Degree III (Minor):** Products recalled for other reasons (e.g., labelling issues). **Embargo required within 30 days or as specified**

- The degree of recall is classified according to the severity of quality defects and adverse reactions of the veterinary medicine.

8.7 LEVEL OF RECALL

The scope of a veterinary vaccines recall depends on the nature of the problem, the vaccine's distribution range, and the level of risk involved. The recall will target:

- Level A: All consumers (end users)
- Level B: All points of sales (e.g. Hospitals, Pharmacies, Clinics, Specialists Centers)
- Level C: All sub-distributors (wholesalers)

GENERAL

8.8 A designated person or committee is responsible for coordinating and executing all veterinary vaccine recalls. Contact details for this point of contact must be included in the recall procedure.

8.9 Recall Notification

When a veterinary vaccine recall is initiated, all relevant parties (based on the recall level) must be informed with appropriate urgency. The notification should include:

- Product name, strength (if applicable), and pack size.
- Batch number and nature of the defect.
- Recall level: consumer (end-user), points of sale, or sub-distributors (wholesalers).
- Specific actions to be taken.
- Urgency of action and reasons, including any health risk information

8.10 The local regulatory authority must be informed of all veterinary vaccine recalls. For imported/exported veterinary vaccines, Country of origin regulatory counterparts must also be notified.

8.11 When a recall affects a specific batch, assess whether other batches may also be impacted.

8.12 Veterinary vaccines under recall must be stored and transported under appropriate conditions until a final decision is made.

8.13 The recall process must be documented, including reconciliation of recalled veterinary vaccines. A final report must be submitted to the local regulatory authority

CHAPTER 9: SUBSTANDARD AND FALSIFIED VETERINARY VACCINE

Any substandard and falsified Veterinary vaccines must immediately be separated from all other products to prevent confusion. These vaccines must be clearly labelled as “Substandard” or “Falsified”. All activities related to the handling of these vaccines must be documented and the sale and distribution be stopped immediately. A consistent approach across the entire supply chain is crucial to effectively combat substandard and falsified veterinary vaccines.

GENERAL

9.1 A designated person or committee must manage and coordinate all veterinary vaccine recalls. Their contact information should be included in the recall procedure.

9.2 Once a veterinary vaccine is confirmed to be substandard or falsified;

- Remove immediately from the market.
- Ensure the vaccine cannot re-enter the supply chain.
- Keep any samples needed for public health, regulatory, or legal reasons
- Arrange for the safe and appropriate disposal of the vaccine
- Record all decisions and actions taken.

CHAPTER 10: OUTSOURCED ACTIVITIES PRINCIPLE

Any activities referenced in the GDP guidelines and delegated to another party should be clearly defined, agreed upon, and controlled to prevent misunderstandings that could compromise the integrity of the Veterinary vaccines. A written contract must be in place between the Contract Giver and the Contract Acceptor, clearly outlining the responsibilities of each party.

GENERAL

10.1 The Contract Giver is responsible for evaluating the Contract Acceptor's competency to effectively carry out the required work. They must ensure, through the contract and audits, that the principles and guidelines of GDP are followed. Audits of the Contract Acceptor by the Contract Giver should be allowed at any time.

10.2 The Contract Acceptor should have suitable premises, equipment, procedures, knowledge, experience, and competent personnel to effectively carry out the work assigned by the Contract Giver.

10.3 The Contract Acceptor should not delegate any of the work assigned under the contract to a third party without the prior evaluation and approval of the Contract Giver. Additionally, the Contract Giver or the Contract Acceptor should audit the third party. Any arrangements made between the Contract Acceptor and a third party should ensure that wholesale distribution information is shared in the same manner as between the original Contract Giver and Contract Acceptor.

10.4 Depending on the nature of the activities performed, the Contract Acceptor should understand that they may be subject to inspection by the regulatory authority.

CHAPTER 11: SELF-INSPECTION

PRINCIPLE

The quality system should include regular self-inspections to assess the implementation and adherence to the principles of GDP. These inspections are essential for ensuring that the processes are being followed correctly and that the required standards are met. Additionally, they help identify areas where corrective and preventive actions may be necessary to maintain the integrity of the system and prevent potential issues.

GENERAL

11.1 Self-inspections should be carried out to cover all aspects of GDP, ensuring compliance with the relevant regulations, guidelines and procedures within a defined time frame. These inspections should be performed in an independent and detailed way by a designated, competent person, according to an approved written procedure.

11.2 The results of all self-inspections must be documented, with reports detailing all observations made during the inspection. Where applicable, these reports should include proposals for corrective actions. An effective follow-up program should be placed to monitor the implementation of corrective measures. Management should review the inspection reports, assess the corrective actions taken, and ensure that they are properly recorded.

CHAPTER 12: MANAGEMENT OF DOCUMENTATION AND RECORDS

PRINCIPLE

Policies and procedures should be implemented to ensure:

- All records are maintained in compliance with legislative requirements.
- All records are kept in line with the general requirements of this guideline and other relevant guidelines set by the national regulatory authority.
- Errors from verbal communication are prevented, and the tracking of relevant operations during the receipt, storage, and distribution of veterinary vaccines is enabled.

Management of Documentation

12.1 Documentation includes all written procedures, instructions, contracts, records, and data, whether in electronic or paper form. All documents must be approved, signed, and dated by the appropriate authorized individuals and should not be altered without proper authorization.

12.2 Documents should be:

- Clear, concise, comprehensible, and easily accessible to those who need them.
- Numbered, dated, and include a title, along with the name and position of the person responsible for the document.
- Contain detailed instructions on the subject matter and include a review date.

Management of Records

12.3 Any alterations made to the documentation should be signed and dated. The alteration should allow the original information to remain legible. If applicable, the reason for the alteration should be documented.

12.4 An accurate record of all receipts and sales transactions must be maintained.

12.5 Records should be made at the time each operation is performed, ensuring that all significant activities or events are traceable. The records must be clear and easily accessible. The retention of documentation related to the distribution of veterinary vaccines should comply with national requirements.

12.6 If records are computerized, only authorized personnel should be allowed to enter or modify data. Access should be controlled using passwords or other security measures. Each user should have a unique identifier (User ID) for personal use, ensuring that activities can be traced back to the responsible individual.

12.7 Electronically stored records should be protected through regular backup transfers, either on paper or by other means. It is essential that the data, including the audit trail, remain easily accessible throughout the retention period. Back-up data should be stored securely at a separate location for as long as necessary.

12.8 All relevant records and documentation should comply with the current requirements by the Department of Veterinary Services.

12.9 Distributor Records

Records of transactions should include accurate and detailed information regarding the receipt, handling, storage, and distribution of products. These records must be maintained in compliance with regulatory requirements and should be readily accessible for auditing and traceability purposes. They should document the date, quantity, and any other relevant details, and should be kept securely to prevent unauthorized access or alterations.

12.10 Importation Records

Importation records should include detailed information about the imported products, such as the quantity, description, origin, supplier, shipping details, and any relevant documentation such as invoices, customs declarations, and import permits. These records must be maintained accurately and in compliance with regulatory requirements to ensure traceability, accountability, and the proper handling of imported goods. Importation records should be securely stored and readily available for inspection by regulatory authorities.

ANNEX 1: CHECKLIST FOR INSPECTION OF GDP ON VETERINARY VACCINES

1.0 Personnel

- ☐ Organization chart is available and updated
- ☐ Clear job descriptions are defined for each role
- ☐ Training programs are conducted and documented
- ☐ Procedures are in place and accessible
- ☐ Records of personnel activities and qualifications are maintained
- ☐ Evaluation processes for personnel performance are conducted
- ☐ Hygiene and clothing standards are defined and followed
- ☐ Relevant procedures are in place and followed

2.0 Premises and Equipment

- ☐ Storage areas are adequate and segregated appropriately
- ☐ Premises are suitable for the type of products stored
- ☐ Lighting and ventilation are adequate
- ☐ Cleaning procedures are established and documented
- ☐ Cleaning records are maintained
- ☐ Licensed by local authority
- ☐ Pest control procedures are in place and records kept
- ☐ Sanitation procedures are implemented
- ☐ Temperature and humidity are monitored
- ☐ Calibrated devices are used and documented
- ☐ Environmental conditions are suitable for stored products
- ☐ Maintenance procedures for facilities/utilities are implemented
- ☐ Contract warehouses, if any, are approved for use

3.0 Stock Handling and Stock Control

- ☐ FIFO/FEFO principles are followed
- ☐ Proper checks are conducted on stocks
- ☐ Controls are in place for rejected, returned, and expired stocks
- ☐ Records and documents ensure traceability
- ☐ Receiving procedures are documented and followed
- ☐ Stock rotation and control are implemented
- ☐ Procedures for returned and rejected items are established
- ☐ Distribution and disposal procedures are documented
- ☐ Inventory records are updated regularly
- ☐ Expiry dates are recorded and controlled
- ☐ Certificate of Analysis (CoA) available for imported products

4.0 Transportation

- ☐ Transportation documents are available
- ☐ Vehicles used are suitable for the products
- ☐ Temperature mapping is conducted
- ☐ Monitoring of storage conditions during transportation is performed
- ☐ Operational and maintenance procedures for transport are in place
- ☐ Pest control during transport is addressed

5.0 Veterinary Vaccine Complaints

- ☐ Procedures for handling complaints are in place

- ☐ Records of investigation and follow-up are maintained

6.0 Product/Cosmetic Recalls

- ☐ Procedures for product recalls are documented
- ☐ Recall records are maintained

7.0 Substandard and Falsified Products

- ☐ Procedures for handling are in place
- ☐ Records are maintained

8.0 Outsourced Activities

- ☐ Contract Giver and Acceptor responsibilities are clearly defined
- ☐ Contracts are established and available

9.0 Self-Inspection

- ☐ Self-inspection procedures include plan, frequency, and scope
- ☐ Records of self-inspection are maintained
- ☐ Cold chain management training is provided and documented for relevant personnel
- ☐ Backup power supply is available and functional for cold storage units
- ☐ Continuous temperature monitoring systems are used for vaccine storage
- ☐ Vaccine storage areas are equipped with validated cold chain equipment
- ☐ Refrigerators/freezers used for vaccine storage are regularly serviced and calibrated
- ☐ Strict adherence to vaccine expiry dates is ensured
- ☐ Vaccines are stored according to manufacturer-specified conditions
- ☐ Temperature loggers accompany vaccine shipments
- ☐ Insulated containers or cold boxes are used during transportation
- ☐ Vaccines are transported using validated cold chain procedures
- ☐ Vaccine batch numbers are recorded and traceable for all complaints
- ☐ Adverse event reports related to vaccines are promptly investigated
- ☐ Vaccines from affected batches are quarantined immediately
- ☐ Recall procedures include notification to veterinary clients and authorities
- ☐ Reporting system for suspected falsified veterinary vaccines is in place

REFERENCES

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4. Guidelines for Storage of Essential Medicines and other Health Commodities. USAID in collaboration with the World Health Organization (WHO).
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