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REPUBLIC OF KENYA

VETERINARY MEDICINES DIRECTORATE

GUIDELINES FOR GOOD DISTRIBUTION PRACTICE (GDP) FOR VETERINARY MEDICINAL PRODUCTS

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Abbreviations

CAPA Corrective action preventive action
GPS Global positioning system
FEFO First expiry first out

Introduction

This advice provides stand-alone measures on Good Distribution Practice (GDP) for veterinary medicinal products as well as recommendations on appropriate tools to assist wholesale distributors in conducting their activities and to guarantee that veterinary medicinal products are appropriately manufactured, imported, stored, transported and handled as well as to ensure control of the distribution chain and consequently maintain the quality and the integrity of veterinary medicinal products while preventing falsified medicines from entering the legal supply chain. Compliance with good distribution practices for veterinary medicinal products will ensure control of the distribution chain and consequently maintain the quality and the integrity of veterinary medicinal products.

wholesale distribution means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products in bulk. Any person acting as a wholesale distributor of veterinary medicinal products has to hold a wholesale dealers permit and comply with the good distribution practice for veterinary medicinal products.

Possession of a manufacturing permit includes authorization to distribute the veterinary medicinal products covered by the permit. Manufacturers performing any distribution activities with their own veterinary medicinal products must therefore also comply with good distribution practice for veterinary medicinal products.

Definition

‘Good distribution practice for veterinary medicinal products’ means the part of the quality assurance which ensures that the quality of veterinary medicinal products is maintained throughout all stages of the supply chain from the site of manufacturer to the pharmacy or person authorized or entitled to supply veterinary medicinal products to the public and other persons or entities in accordance with Veterinary Medicines Directorate Regulations.

Quality management

Principle

Wholesale dealers must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities5. All distribution activities should be clearly defined and systematically reviewed. All critical steps of distribution processes and significant

changes should be justified and where relevant validated. The quality system is the responsibility of the organization's management and requires their leadership and active participation and should be supported by staff commitment.

Quality system

The system for managing quality should encompass the organizational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the product delivered maintains its quality and integrity and remains within the legal supply chain during storage and/or transportation. The quality system should be fully documented and its effectiveness monitored. All quality system-related activities should be defined and documented.

A quality manual or equivalent documentation approach should be established and should include a description of any differences in the quality system regarding handling of products of different types. A responsible person should be appointed by the management, who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained. The management of the distributor should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

The size, structure and complexity of distributor's activities should be taken into consideration when developing or modifying the quality system. A change control system should be in place. This system should incorporate quality risk management principles and be proportionate and effective. The quality system should ensure that:

a) medicinal products are manufactured, imported, held, distributed or exported in a way that is compliant with the requirements of GDP;
b) management responsibilities are clearly specified;
c) products are delivered to the right recipients within a satisfactory time period;
d) records are made simultaneously;
e) deviations from established procedures are documented and investigated;
f) appropriate corrective and preventive actions ('CAPA') are taken to correct deviations and prevent them in line with the principles of quality risk management.
g) the operations do not pose a risk to the environment or risk of development of antimicrobial resistance.

Management of outsourced activities

The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply or export of medicinal products. These processes should incorporate quality risk management and include:

a) assessing the suitability and competence of the contract acceptor to carry out the activity and checking authorization status, if required;
b) defining the responsibilities and communication processes for the quality-related activities of the parties involved;

c) monitoring and review of the performance of the contract acceptor, and the identification and implementation of any required improvements on a regular basis.

Management review and monitoring

The management should have a formal process for reviewing the quality system on a periodic basis. The review should include:

a) measurement of achievement of quality system objectives;
b) assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, deviations, CAPA, changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments and audits; and external assessments such as inspections, findings and customer audits;
c) emerging regulations, guidance and quality issues that can impact the quality management system;
d) innovations that might enhance the quality system;
e) changes in business environment and objectives.

The outcome of each management review of the quality system should be documented in a timely manner and effectively communicated internally.

Quality risk management

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively. Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the treated animal or animal group, the persons responsible for the animal and the treatment, the consumer of a food producing animal or the environment. The level of effort, formality and documentation of the process should be commensurate with the level of risk.

Personnel

Principles

The correct distribution of veterinary medicinal products relies upon people. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the wholesale dealer is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

Responsible person

The wholesale dealer must designate a person as responsible person for good distribution practices compliance. The responsible person should meet the qualifications and all conditions provided for by the VMD regulations. The responsible person should have appropriate competence and experience as well as knowledge of and training in good distribution practices compliance. The responsible person should fulfil their responsibilities personally and should be

continuously contactable. The responsible person may delegate duties but not responsibilities. The written job description of the responsible person should define their authority to take decisions with regard to their responsibilities. The wholesale dealer should give the responsible person the defined authority, resources and responsibility needed to fulfil their duties. The responsible person should carry out their duties in such a way as to ensure that the wholesale dealer can demonstrate good distribution practices compliance and that public service obligations are met. The responsibilities of the responsible person include:

a. ensuring that a quality management system is implemented and maintained;
b. focusing on the management of authorized activities and the accuracy and quality of records;
c. ensuring that initial and continuous training programmes are implemented and maintained;
d. coordinating and promptly performing any recall operations for veterinary medicinal products;
e. ensuring that relevant customer complaints are dealt with effectively;
f. ensuring that suppliers and customers are approved;
g. approving any subcontracted activities which may impact on good distribution practices;
h. ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
i. keeping appropriate records of any delegated duties;
j. deciding on the final disposition of returned, rejected, recalled or falsified products;
k. approving any returns to saleable stock;
l. ensuring that any additional requirements imposed on certain products by directorate are adhered to.

Other personnel

There should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities of veterinary medicinal products. The number of personnel required will depend on the volume and scope of activities. The organizational structure of the wholesale distributor should be set out in an organization chart. The role, responsibilities, and interrelationships of all personnel should be clearly indicated. The role and responsibilities of employees working in key positions should be set out in written job descriptions, along with any arrangements for deputizing.

Training

All personnel involved in wholesale distribution activities should be trained on the requirements of good distribution practices. They should have the appropriate competence and experience prior to commencing their tasks. Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training program. The

responsible person should also maintain their competence in good distribution practices through regular training. In addition, training should include aspects of product identification and avoidance of falsified medicines entering the supply chain. Personnel dealing with any products which require more stringent handling conditions should receive specific training. Examples of such products include hazardous products, radio active materials, products presenting special risks of abuse (including narcotic and psychotropic substances), and temperature-sensitive products. A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

Hygiene

Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.

Premises and Equipment

Principles

Wholesale distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of veterinary medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.

Premises

The premises should be designed or adapted to ensure that the required storage conditions are maintained. They should be suitably secure, structurally sound and of sufficient capacity to allow safe storage and handling of the veterinary medicinal products. Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

Veterinary medicinal products should be stored suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair. Where premises are not directly operated by the wholesale distributor, a contract should be in place. The contracted premises should be covered by a separate wholesale distribution authorization. Veterinary medicinal products should be stored in segregated areas which are clearly marked and have access restricted to authorized personnel. Any system replacing physical segregation, such as electronic segregation based on a computerized system, should provide equivalent security and should be validated.

Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated physically and electronically, if an electronic system is available. This includes, for example returned products. Any product suspected of falsification and falsified veterinary medicinal products found in the supply chain, expired products, recalled products and rejected products should be immediately physically and electronically separated, if an electronic system is available and stored in a dedicated area away from all other veterinary medicinal products. The appropriate degree of security should be applied in these areas to ensure

that such items remain separate from saleable stock. These areas should be clearly identified. Special attention should be paid to the storage of products with specific handling instructions as specified in the regulations, such as narcotics and psychotropic substances. Special storage conditions (and special authorizations) may be required for such products.

Hazardous products, as well as products presenting special safety risks of fire or explosion, such as medicinal gases, combustibles, flammable liquids and solids, should be stored in one or more dedicated areas subject to local legislation and appropriate safety and security measures.

Receiving and dispatch bays should protect products from prevailing weather conditions. There should be adequate separation between the receipt and dispatch and storage areas. Procedures should be in place to maintain control of inbound/ outbound goods. Reception areas where deliveries are examined following receipt should be designated and suitably equipped.

Unauthorized access to all areas of the authorized premises should be prevented. Prevention measures would usually include a monitored intruder alarm system and appropriate access control. Visitors should be accompanied.

Premises and storage facilities should be clean and free from litter and dust. Cleaning programmes, instructions and records should be in place. Appropriate cleaning equipment and cleaning agents should be chosen and used so as not to present a source of contamination. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination. Vehicles should be cleaned regularly. Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination.

Premises should be designed and equipped so as to afford protection against the entry of insects, rodents or other animals. A preventive pest control programme should be in place.

Rest, wash and refreshment rooms for employees should be adequately separated from the storage areas. The presence of food, drink, smoking material or medicinal products for personal use should be prohibited in the storage areas.

Temperature and environmental control

Suitable equipment and procedures should be in place to check the environment where veterinary medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises. An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions.

Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise should be repeated according to the results of a

risk assessment exercise or whenever significant modifications are made to the facility or the temperature controlling equipment.

For small premises of a few square meters which are at room temperature, an assessment of potential risks, such as heaters, should be conducted and temperature monitors placed accordingly.

Equipment

All equipment impacting on storage and distribution of veterinary medicinal products should be designed, located and maintained to a standard which suits its intended purpose. Planned maintenance should be in place for key equipment vital to the functionality of the operation.

Equipment used to control or to monitor the environment where the veterinary medicinal products are stored should be calibrated at defined intervals based on a risk and reliability assessment. Calibration of equipment should be traceable to a national or international measurement standard.

Appropriate alarm systems should be in place to provide alerts when there are excursions from pre-defined storage conditions. Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality.

Equipment repair, maintenance and calibration operations should be carried out in such a way that the integrity of the veterinary medicinal products is not compromised. Defective vehicles and equipment should not be used and should either be labelled as such or removed from service.

Equipment not relevant for the wholesale activities should not be stored in the medicines storage area. Adequate records of repair, maintenance and calibration activities for key equipment should be made and the results should be retained.

Key equipment would include for example cold stores, monitored intruder alarm and access control systems, refrigerators, thermohygrometers, or other temperature and humidity recording devices, air handling units and any equipment used in conjunction with the onward supply chain.

Computerized systems

Before a computerized system is brought into use, it should be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

A written, detailed description of the system should be available (including diagrams where appropriate). This should be kept up to date. The document should describe principles, objectives, security measures, system scope and main features, how the computerized system is

used and the way it interacts with other systems. Data should only be entered into the computerized system or amended by persons authorized to do so.

Data should be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals. Back up data should be retained for the period stated in national legislation but at least five years at a separate and secure location. Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.

Qualification and validation

Wholesale distributors should identify what key equipment qualification and/or key process validation is necessary to ensure correct installation and operation. The scope and extent of such qualification and/or validation activities such as storage, pick and pack processes, should be determined using a documented risk assessment approach. Equipment and processes should be respectively qualified and/or validated before commencing use and after any significant changes, such as repair or maintenance.

Validation and qualification reports should be prepared summarizing the results obtained and commenting on any observed deviations. Deviations from established procedures should be documented and further actions decided to correct deviations and avoid their reoccurrence (corrective and preventive actions). The principles of CAPA should be applied where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel.

Documentation

Principles

Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of veterinary medicinal products. All types of document should be defined and adhered to.

General

Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available and retrievable. Written procedures should describe the distribution activities which affect the quality of veterinary medicinal products. These include but are not limited to: receipt and checking of deliveries, suppliers and customers control, storage, cleaning and maintenance of the premises and equipment, including pest control, checking and recording of the storage conditions, protection of veterinary medicinal products during transportation, security of stock on site and of consignments in transit, withdrawal from saleable stock, handling of returned products, recall plans, validation and qualification, procedures and measures for the disposal of unusable

veterinary medicinal products, procedures for investigating and resolving complaints, procedures identifying veterinary medicinal products suspected of falsification.

Documentation should be sufficiently comprehensive with respect to the scope of the wholesale distributor's activities and in a language understood by personnel. It should be written in clear, unambiguous language and be free from errors. Procedures should be approved signed and dated by the responsible person. Documentation should be approved, signed and dated by appropriate authorized persons, as required. It should not be hand-written; although, where it is necessary, sufficient space should be provided for such entries. Any alteration made in the documentation should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.

Documents should be retained for the period stated in national legislation but at least five years. Personal data should be deleted or anonymized as soon as their storage is no longer than necessary for the purpose of distribution activities. Each employee should have ready access to all necessary documentation for the tasks executed. Valid and approved procedures should be used.

Documents should have not unambiguous content; title, nature and purpose should be clearly stated. Documents should be reviewed regularly and kept up to date. Version control should be applied to procedures. After revision of a document, a system should exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures should be removed from workstations and archived.

Relationships and control measures for original documents and official copies, data handling and records need to be stated for all paper based, electronic and hybrid systems. Records must be kept either in the form of purchase/sales invoices, delivery slips, or on computer or any other form, for any transaction in veterinary medicinal products received, supplied. Records must include at least the following information: date of the transaction; name of the veterinary medicinal product including as appropriate, pharmaceutical form and strength; quantity received, supplied, stating pack size and number of packs; name and address of the supplier, customer or consignee, as appropriate; batch number, expiry date of the veterinary medicinal products8 and additional requirements specified by national legislation.

Records should be made at the time each operation is undertaken, if handwritten, in clear, legible and indelible handwriting.

Operations

Principles

All actions taken by wholesale distributors should ensure that the identity of the veterinary medicinal product is not lost and that the wholesale distribution of veterinary medicinal products

is performed according to the information on the outer packaging. The wholesale distributor should use all means available to minimize the risk of falsified veterinary medicinal products entering the legal supply chain. All key operations described below should be fully described in the quality system in appropriate documentation.

Qualification of suppliers

Wholesale distributors must obtain their supplies of veterinary medicinal products only from persons who are themselves in possession of a manufacturing permit which covers the product in question. Where veterinary medicinal products are obtained from another wholesale distributor, the receiving wholesale distributor, must verify that the supplier complies with the principles and guidelines of good distribution practices and that they hold an authorisation.

Appropriate qualification and approval of suppliers should be performed prior to any procurement of medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked based on quality risk management principles.

When entering into a new contract with new suppliers, the wholesale dealer should carry out 'due diligence' checks in order to assess the suitability, competence and reliability of the other party. Attention should be paid to:

a) the reputation or reliability of the supplier;
b) offers of veterinary medicinal products more likely to be falsified;
c) large offers of veterinary medicinal products which are generally only available in limited quantities;
d) diversity of products handled by supplier; and
e) out-of-range prices.

Qualification of customers

Wholesale distributors must ensure they supply veterinary medicinal products only to persons who are authorized or entitled to supply veterinary medicinal products to the public or otherwise authorized to procure veterinary medicinal products from a distributor in accordance with national law.

Checks and periodic rechecks may include requesting copies of customer's authorizations according to national law, verifying status on an authority website, requesting evidence of qualifications or entitlement according to national legislation. Wholesale dealers should monitor their transactions and investigate any irregularity in the sales patterns of narcotics, psychotropic substances or other dangerous substances. Unusual sales patterns that may constitute diversion or misuse of veterinary medicinal product should be investigated and reported to competent authorities where necessary. Steps should be taken to ensure fulfilment of any public service obligation imposed upon them.

Receipt of veterinary medicinal products

The purpose of the receiving function is to ensure that the arriving consignment is correct, that the veterinary medicinal products originate from approved suppliers and that they have not been visibly or not visibly damaged during transport.

Veterinary medicinal products requiring special storage or security measures should be prioritized and once appropriate checks have been conducted they should be immediately transferred to appropriate storage facilities.

Storage

Veterinary medicinal products should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention should be paid to products requiring specific storage conditions.

Incoming containers of veterinary medicinal products should be cleaned, if necessary, before storage. Any activities performed on the incoming goods (e.g. fumigation) should not impact on the quality of the veterinary medicinal products.

Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks. Stock should be rotated according to the 'first expiry, first out' (FEFO) principle. Exceptions should be documented.

Veterinary medicinal products should be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Medicinal products should not be stored directly on the floor unless the package is designed to allow such storage (such as for some medicinal gas cylinders). Veterinary medicinal products that are nearing their expiry date/shelf life should be separated immediately from saleable stock physically and electronically, if an electronic system is available. Stock inventories should be performed regularly taking into account national legislation requirements. Stock irregularities should be investigated and documented.

Destruction of obsolete goods

Veterinary medicinal products intended for destruction should be appropriately identified, held physically and electronically separated, if an electronic system is available and handled in accordance with a written procedure. Destruction of veterinary medicinal products should be in accordance with national or international requirements for handling, transport and disposal of such products. Records of all destroyed veterinary medicinal products should be retained for a defined period.

Picking

Controls should be in place to ensure the correct product is picked. The product should have an appropriate remaining shelf life when it is picked.

Supply

For all supplies, a document (e.g. delivery note) must be enclosed stating the date, name, pharmaceutical form of the veterinary medicinal product, strength, batch number, expiry date, quantity supplied stating pack size and number of packs, name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different), unique number to allow identification of the delivery order, applicable transport and storage conditions and additional requirement specified by national legislation.

For traceability purpose, records should be kept so that the actual location of the product can be known. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of counterfeit or potentially counterfeit pharmaceutical products.

Complaints, returns, suspected falsified veterinary medicinal products and veterinary medicinal product recalls

Principles

All complaints, returns, suspected falsified veterinary medicinal products and recalls must be recorded and handled carefully according to written procedures. Records should be made available to the competent authorities. An assessment of returned veterinary medicinal products should be performed before any approval for resale. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified veterinary medicinal products.

Complaints

Complaints should be recorded with all the original details. A distinction should be made between complaints related to the quality of a veterinary medicinal product and those related to distribution. In the event of a complaint about the quality of a veterinary medicinal product and a potential product defect, the manufacturer and/or marketing authorization holder should be informed without delay. Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint. A person should be appointed to handle complaints and allocated sufficient support personnel. If necessary, appropriate follow-up actions (including CAPA) should be taken after investigation and evaluation of the complaint, including where required notification to the national competent authorities.

Returned veterinary medicinal products

Returned products must be handled according to a written, risk-based process taking into account the product concerned, any specific storage requirements and the time elapsed since the veterinary medicinal product was originally dispatched. Returns should be conducted in accordance with national law and contractual arrangements between the parties. Veterinary

medicinal products which have left the premises of the distributor should only be returned to saleable stock if all of the following are confirmed:

a. the veterinary medicinal products are in their unopened and undamaged secondary packaging and are in good condition; have not expired and have not been recalled;
b. veterinary medicinal products returned from a customer not holding a wholesale distribution authorization or from pharmacies

Products returned to saleable stock should be placed such that the 'first expired first out' (FEFO) system operates effectively. Stolen products that have been recovered cannot be returned to saleable stock and sold to customers.

Falsified veterinary medicinal products

Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any veterinary medicinal products they identify as falsified or suspect to be falsified, stop the distribution and act on the instructions as specified by the competent authorities.

A procedure should be in place to this effect. It should be recorded with all the original details and investigated. Any falsified or suspected to be falsified veterinary medicinal products found in the supply chain should immediately be segregated physically and electronically, if an electronic system is available, and stored in a dedicated area away from all other veterinary medicinal products and be appropriately labelled. All relevant activities in relation to such products should be documented and records retained.

Veterinary medicinal products recalls

There should be documentation and procedures in place to ensure traceability of products received and distributed, to facilitate product recall. In the event of a product recall, all affected customers to whom the product has been distributed shall be informed with the appropriate degree of urgency and clear actionable instructions. The national regulatory authority should be informed of all product recalls. The effectiveness of the arrangements for product recall should be evaluated regularly and at least annually.

Recall operations should be capable of being initiated promptly and at any time. The distributor must follow the instructions of a recall message, which should be approved, if required, by the competent authorities. Any recall operation should be recorded at the time it is carried out. Records should be made readily available to the competent authorities. The distribution records should be readily accessible to the person(s) responsible for the recall, and should contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batch numbers as required by national legislation and quantities delivered), including those for exported products and veterinary medicinal product samples. The progress of the recall process should be recorded for a final report including reconciliation of the recalled product.

Outsourced activities

Principles

Any activity covered by the good distribution practice for veterinary medicinal products that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the veterinary medicinal product. There must be a written contract between the contract giver and the contract acceptor which clearly establishes the duties of each party. Inspections of the contract acceptor can be carried out by representatives of the competent authority.

Contract giver

The contract giver is responsible for the activities contracted out. The contract giver is responsible for assessing the competence of the contract acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles of good distribution practice for veterinary medicinal products are followed.

An audit of the contract acceptor should be performed before commencement of, and whenever there has been a change to, the outsourced activities. The frequency of audit should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time. The contract giver should provide the contract acceptor with all the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.

Contract acceptor

The contract acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the contract giver. The contract acceptor should not pass to a third party any of the work entrusted to him under the contract without the contract giver's prior evaluation and approval of the arrangements and an audit of the third party by the contract giver or the contract acceptor.

Arrangements made between the contract acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original contract giver and contract acceptor. The contract acceptor should refrain from any activity which may adversely affect the quality of the veterinary medicinal product(s) handled for the contract giver.

The contract acceptor must forward any information that can influence the quality of the veterinary medicinal product(s) to the contract giver in accordance with the requirement of the contract.

Self-Inspections

Principles

Self-inspections should be conducted in order to monitor implementation and compliance with good distribution practice for veterinary medicinal products principles and to propose necessary corrective measures.

Self-inspections

A self-inspection programme should be implemented covering all aspects of good distribution practice for veterinary medicinal products and compliance with the regulations, guidelines and procedures within a defined time frame. Self-inspections may be divided into several individual self- inspections of limited scope.

Self-inspections should be conducted in an impartial and detailed way by designated competent company personnel. Audits by independent external experts may also be useful but may not be used as a substitute for self-inspection. All self-inspections should be recorded. Reports should contain all the observations made during the inspection. A copy of the report should be provided to the management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their cause should be determined and the corrective and preventive actions (CAPA) should be documented and followed up. The effectiveness of the CAPAs should be reviewed.

Transportation

Principles

It is the responsibility of the wholesale distributor to protect veterinary medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport and whenever possible monitor these conditions. Regardless of the mode of transport, it should be possible to demonstrate that the veterinary medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilized when planning transportation.

Transportation

The required storage conditions for veterinary medicinal products should be maintained during transportation within the defined limits as described on the outer packaging by the manufacturers and by the marketing authorization holder. If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported to the distributor and recipient of the affected veterinary medicinal products to assess the potential impact on the quality of the veterinary medicinal product. A procedure should also be in place for investigating and handling temperature excursions.

It is the responsibility of the wholesale distributor to ensure that vehicles and equipment used to distribute, store or handle veterinary medicinal products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their

quality and packaging integrity. Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) or other systems, electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security of veterinary medicinal products while in the vehicle.

There should be written procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions. Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Risk assessment of delivery routes should be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles and/or containers should be maintained and calibrated at regular intervals at least once a year.

Dedicated vehicles and equipment should be used, where possible, when handling human and veterinary medicinal products. Where non- dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the medicinal products will not be compromised. Deliveries should be made to the address stated on the delivery note and into the care or the premises of the consignee.

Veterinary Medicinal products should never be left on alternative premises. For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available. Where transportation is performed by a third party, the contract in place should encompass the requirements of Outsourced activities.
Transportation providers should be made aware by the wholesale distributor of the relevant transport conditions applicable to the consignment. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to the temperature monitoring, cleanliness and the security of any intermediate storage facilities. Provision should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route.

Containers, packaging and labelling
Veterinary medicinal products should be transported in containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination. Selection of a container and packaging should be based on the storage and transportation requirements of the veterinary medicinal products; the space required for the amount of medicines; the pharmaceutical forms, also including medicated premixes; the anticipated external temperature extremes; the estimated maximum time for transportation including transit storage at customs; the qualification status of the packaging and the validation status of the shipping containers.
Containers should bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all

times. The containers should enable identification of the contents of the containers and the source.

Products requiring special conditions

In relation to deliveries containing veterinary medicinal products requiring special conditions such as narcotics or psychotropic substances, the wholesale distributor should maintain a safe and secure supply chain for these products in accordance with requirements laid down. There should be additional control systems in place for delivery of these products. There should be a protocol to address the occurrence of any theft.

Veterinary medicinal products comprising highly active materials should be transported in safe, dedicated and secure containers and vehicles. The relevant safety measures should be in accordance with international agreements and national legislation.

For temperature-sensitive veterinary medicinal products, qualified equipment, such as thermal packaging, temperature-controlled containers or temperature-controlled vehicles, should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and customer. If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals.

Temperature mapping under representative conditions should be carried out and should take into account seasonal variations. If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions. If cool-packs are used in insulated boxes, they need to be located such that the product does not come in direct contact with the cool-pack.

Staff must be trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool-packs. There should be a system in place to control the re-use of cool- packs to ensure that incompletely cooled packs are not used in error. There should be adequate physical segregation between frozen and chilled ice packs. The process for delivery of sensitive products and control of seasonal temperature variations should be described in a written procedure

Summary for Good Distribution Practice for Wholesale dealers

Principle	**Specification**	**Requirement**
Premises and equipment	Location with respect to fire hazards	Should away from Petrol station, Gas cylinders,

	Identification of hazard areas	Hazardous products, as well as products presenting special safety risks of fire or explosion, such as medicinal gases, combustibles, flammable liquids and solids, should be stored in dedicated areas and should be well identified and labelled with a skull and 2 crossbones.
	Emergency protocols displayed	Emergency pictograms should be well displayed to provide guidance in case of an emergency.
	Labelling of sections	The various sections of the complementary business should be well labelled
	Labelling of veterinary medicines designated areas	All veterinary medicines should be labelled broadly in the specific classes as they are arranged in the premise eg dewormers, injectable, Multivitamins. There should be a clear distinction between the veterinary medicines and veterinary pest control products
	Storage conditions	Environmental factors to be considered include temperature, light, humidity, air circulation and cleanliness of the premises. An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Thermometers and hydrometers to monitor the temperature and humidity of the rooms, refrigerators and freezers should be in place. Accompanying temperature logs for each should be provided. Equipment used should be calibrated at defined intervals based on a risk and reliability assessment. There should be restricted access of category I and category II products
	Vermin and insect proofing	Pests control methods eg fly catcher, fluorescent light, rat traps should be provided. Only Mechanical methods for rat traps is recommended.

	Descriptions of floors and the walls of the building	The floor should be easy to clean with minimal seams and no grout lines, helping to prevent mold, germ and pest infestation. The walls should be smooth and without seams.
	Emergency lighting, firefighting equipment and first aid kit(s	Fully serviced firefighting equipment should be available, Well equipped first aid kit that is ready accessible to the personnel, emergency lighting may be necessary depending on the size of operation
	Description of size and space for operations	The space provided should be sufficient for the size of operation of the business. Should be secure, structurally sound and of sufficient capacity to allow safe storage and handling of the products. Storage areas should be provided with adequate lighting. Pallets should be kept in a good state of cleanliness and repair
Personnel	Personnel protection equipment used in premises	Personal protective equipment, should be provide and used to minimize exposure to hazards that cause serious workplace injuries and illnesses.
	Competency of staff	The staff should have relevant training in reference to veterinary medicines, good distribution practices, stores and warehouse keeping
	Sanitary facilities	Sanitary facilities separate for each gender should be available, with soap and clean running water.
Documentation	Standard operating procedures displayed	The standard operating procedure for receiving and dispatch of products to/from the warehouse should be available and displayed at point of use
	Records of movement of all veterinary medicines	Documentation should be readily available and retrievable. All records of movement of product into and from the warehouse should be available for inspection at least five years from the date of issue.

	Description of disposal system for expired veterinary medicines	A standard operating procedure for disposal system of the expired, damaged unused, spilt, and contaminated veterinary medicinal products should be available.
Self- Inspections	Self- Inspections	Self-inspections should be conducted in an independent and detailed way by a designated, competent person, according to an approved written procedure.
Product complaints	Returned veterinary medicinal products	Returned products must be handled according to a written, risk-based process taking into account the product concerned, any specific storage requirements and the time elapsed since the veterinary medicinal product was originally dispatched
	Falsified veterinary medicinal products	Inform the competent authority and the marketing authorisation holder of any veterinary medicinal products they identify as falsified or suspect to be falsified, stop the distribution and act on the instructions as specified by VMD
	Recalls	Should have documentation and procedures in place to ensure traceability of products received and distributed, to facilitate product recall
Outsourced services	Contract giver	responsible for assessing the competence of the contract acceptor
	Contract acceptor	should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the contract giver
Transportation		The required storage conditions for veterinary medicinal products should be maintained during transportation within the defined limits as described on the outer packaging by the manufacturers.

OUTLINE OF THE REQUIREMENTS OF A RETAIL VETERINARY PHARMACY

1. Retail Veterinary pharmacy and premise permit - Mandatory
2. Suitable design, layout construction with adequate ventilation must be provided.
3. Sufficient space for storage of veterinary products. Space should allow proper display of products, allow proper stacking and allow free air circulation
4. All sections e.g. veterinary section, crops section and the veterinary medicines should be labelled broadly in the specific classes as they are arranged in the premise e.g. dewormers, injectable, Multivitamins. There should be a clear distinct partition between other veterinary medicines; veterinary pest control products; and the other complementary business. Mandatory
5. All prescription only medicines should be kept under lock and key. Only the professional in charge should have access to this medicines. Mandatory
6. The pharmacy attendants must wear adequate protective dust coats. Mandatory
7. First aid facilities should be available e.g. adequately equipped First aid kit, fire extinguishers)
8. Attendant in charge of the premises stocking veterinary products should be trained veterinary professionals, registered and retained by Kenya Veterinary Board. Mandatory
9. All products requiring cold chain should be stored in a refrigerator/cold room. The refrigerator should be exclusively used for storage of veterinary products. Temperature logs for refrigerators should be maintained on a daily basis. Provision of standby generator or alternative power supply to supply the refrigerator/cold room in case of power outages. Mandatory.
10. Adequate water within the premises should be available to facilitate hand washing.
11. Floors should be made of suitable material that is easy to clean.
12. All veterinary medicinal products should be sold in their primary pack sizes as supplied by the manufacturer. Avoid decanting or/and aliquoting
13. Maintain records of movement of product into and from the premise. They should be maintained for a minimum of 5 years.
14. A standard operating procedure for disposal system of the expired, damaged unused, spilt, and contaminated veterinary medicinal products should be available
15. General cleanliness of the premises should be maintained at all time.
16. Sanitary facilities should be available, with soap and clean running water.
17. Pests control methods e.g. rat traps should be provided. Mechanical methods for rodents control are recommended.

Reference

Advice on implementing measures for Good Distribution Practice (GDP) for veterinary medicinal products EMA/158452/2020

Frequently asked questions

What is seen as regular training in GDP; once per two years or a shorter timeframe?
Answer: Regulators expect annual GDP refreshed training for staff. It is up to the company to define how this is achieved and be able to justify their approach. Staff should demonstrate competence for the tasks they perform and the responsibilities they hold. The training frequencies could for example be determined by the complexity of the task and the experience of the staff.

How should I review the training effectiveness? Qualitatively or quantitatively? Or by any other means?
Answer: Staff should demonstrate competence for the task performed and for the responsibilities they hold. Review will therefore depend on the subject of the training, all of these are relevant, some training needs formal assessment, others may require observing the trainee to ensure he is capable of performing the task. This should be defined in your training programme, records should be kept.

What are the pre-requisites for the area for physical segregation?
A dedicated and clearly identified area is needed. Access to these areas must be managed with restriction to authorised personnel only. An appropriate degree of security should be applied in these areas to ensure that products remain separate from saleable stock. Storage areas for controlled substances must be segregated and physically secure in accordance with national legislation.

How can receiving and dispatch bays be designed to protect products from prevailing weather conditions?
Protection from adverse environmental conditions can be achieved via a combination of an external canopy, vehicle tunnels, appropriate doors and procedures during receipt and dispatch.

For premises and storage facilities, adequate cleaning programmes should be in place. How can this be realised?
The cleaning regime should be systematic, covering all areas, including racking, on an appropriate frequency to maintain cleanliness. The respective process should be defined in writing based on a risk assessment evaluating all relevant factors and conditions. Checklists may be useful. Cleaning procedures should also cover the handling of spillages.

What is an adequate preventive pest control programme?
Pest control agents should be selected to avoid the risk of contaminating products. Many companies use licensed pest-control experts or a pest control service. A contract should be in place to cover such work.

Where should we put temperature monitoring equipment?
Warehouse temperature monitoring should be based on a mapping exercise which has identified the worst case positions.

What needs to be considered when importing medicinal product from outside the Kenya?
If products are to be sourced from outside the Kenya, then the importer must have a Whole sale dealers permit and market authorization for the products obtained from the VMD before commencing any importation of medicines.

What is the meaning of FIFO and FEFO?
FIFO = “first in, first out”; it means that products stored first are to be retrieved first.

FEFO = “first expiry, first out”; this is to ensure that product with shortest expiry date is placed into the market first. It also helps to ensure that products reaching end users have sufficient remaining shelf life.

Why is it not allowed storing product directly on the floor?

Products stored on the floor are more likely to become damaged or contaminated by spillages, water, dirt and or pests.

Why do I need to document the destruction of obsolete drugs?

This ensures that these products do not inadvertently (re-)enter the supply chain or become diverted.