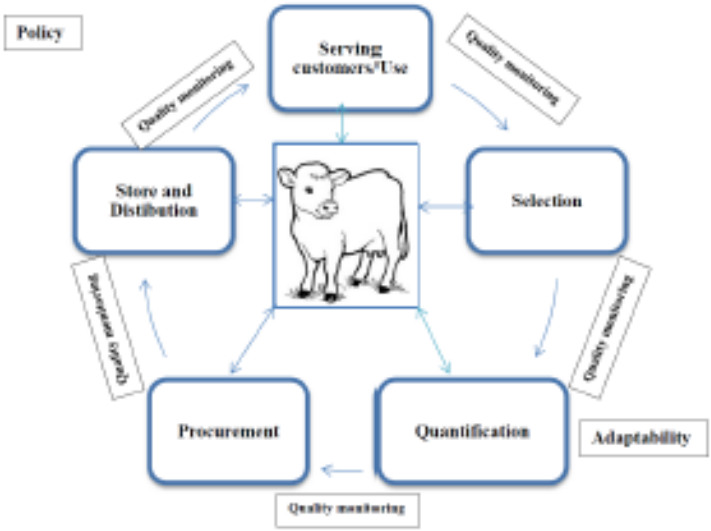
VETERINARY PHARMACEUTICALS MANAGEMENT MANUAL FOR ETHIOPIA



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Veterinary Drug and Animal Feed Administration and Control Authority

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Preface

The Veterinary Drug and Feed Administration and Control Authority (VDFACA) was establish in 2011, to administer and control veterinary drugs and feed in Ethiopia. The Authority had developed many guidelines and manuals aimed at strengthening regulatory capacity of the authority and to promote rational use of veterinary medicines in the country. This Veterinary Pharmaceutical Management Manual (VPMM) is one of the most important and the first of its kind manual. Veterinary drugs are not only key inputs in the animal health services but also one of the biggest expenditure in terms of resources. Moreover, effective and efficient pharmaceutical management of these essential resources require that animal health workers have the right skills, knowledge, attitude, and practice. Wastage through wrong selection, quantification, procurement, and distribution, overstocking, expiry, and inappropriate use should be minimized and their use prioritized as vital, essential, none or less essential (VEN/L) classification.

The Manual contains information on how the selection, quantification and procurement, distribution, use, and quality assurance of veterinary pharmaceuticals should be done. Veterinary pharmaceuticals management information system (VPMIS) and alternative or complementary veterinary medicines are also included.

This manual is expected to help animal health and veterinary drug professionals in enhancing the quality of veterinary pharmaceutical services in efforts to decrease

the economic loss and public health hazard due to zoonotic diseases. The VAFACA encourages professionals to use the manual in their practice.

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List of Abbreviations

AMR	Antimicrobial resistance
AMU	Antimicrobial use
CAM	Complementary or alternative medicines
DD	Daily demand
DRA	Drug regulatory authority
DTC	Drugs and Therapeutics Committees
FGDs	Focus group discussions
GMP	Good manufacturing practice
GPP	Good prescription practice
LT	Lead time
LMIC	Lower and middle income countries
LMIS	Logistics management information system
OIE	International organization for animal health
OUTLs	Order up to level
PPM	Planned preventive maintenance
ROPs	Reorder point
RFID	Radiofrequency identification device
SDP	Supply and demand planning
SOP	Standard operating procedure
SPC	Summary of product characteristics
VSTG	Veterinary Standard Treatment Guidelines
VDFACA	Veterinary Drug and Feed Administration and Control Authority
VEN	Vital, essential and non-essential
VMP	Veterinary medicinal products
WHO	World Health Organization

Operational Definitions

ABC analysis: classification system based on Prieto principle which means:

A-items are pharmaceuticals with annual consumption value are the highest. The top 70-80 percent of the annual consumption value of the company typically accounts for only 10-20percent of total inventory items.

B-items are the interclass items, with a medium consumption value. 15-25 percent of annual consumption value typically accounts for 30 percent of total inventory items.

C-items are, on the contrary, items with the lowest consumption value. The lower five percent of the annual consumption value typically accounts for 50 percent of total inventory items.

Bin card: Card that records receipts, issues, and balances held in the stores. The bin card is kept in the warehouse with the physical stock.

Cold chain: A system of freezers, refrigerators, cold boxes, and other devices needed to maintain the proper temperature for vaccines (and other perishable supplies) from the point of manufacture to the point of administration.

Dispensed-to-user data: Data on the quantity of pharmaceuticals given to or used by customer.

First-expiry/first-out procedure (FEFO): A method of inventory management in which products with the earliest expiry date are the first products issued, regardless of the order in which they are received. This method is more demanding than *FIFO* but should be used for short-dated products such as vaccines.

First-in/first-out procedure (FIFO): A method of inventory management in which the first products received are the first products issued. This method generally minimizes the chance of drug expiration.

Health commodity security: Commodity security exists when every person is able to obtain and use quality essential Pharmaceutical whenever s/he needs them.

Holding costs: The costs of carrying inventory, usually expressed as a percentage of the average inventory. These costs include both the capital costs and the storage costs

Inventory control: The function of supply management that aims to provide sufficient stocks of medicines at the lowest costs possible.

Issue: To distribute a specific amount of an item to an intermediary stocking facility or a health facility.

Issues data: Data about the quantity of pharmaceuticals moved from one level of the system to another or from department to another in the same facility.

Lead time: The time interval between when new stock is ordered and when it is received and available for use.

Logistics Management Information System (LMIS): A logistics management information system collects, organizes and reports data that enables people to make logistics system decisions.

Maximum stock level: In most reordering formulas, this level is the target stock level, which is the stock needed to satisfy demand until the next order after the current one is received.

Pipeline: The entire chain of physical storage facilities and transportation links through which supplies move from the manufacturer to the end user, including port facilities, central warehouse, regional warehouse, district warehouse, all service delivery points (SDPs), and transport vehicles, including community based distribution networks.

Pull (requisition) system: The person who receives the supplies calculates the quantities of supplies required

Push (allocation) system: The person who issues the supplies calculates the quantities of supplies required.

Reorder level: The reorder level is the quantity of remaining stock that should trigger a reorder of the item. In the minimum-maximum ordering system, this level is called the minimum stock level.

Safety stock: The buffer, cushion, or reserve stock kept on hand to protect against stockoutsstock outs caused by delayed deliveries or markedly increased demand.

Service level: Most commonly defined as the percentage of items requested that are supplied, in the quantity requested, by a supplier or warehouse in one delivery. This term is sometimes used to describe the percentage of demand that is met from stock on hand.

Stock: Goods and materials stored for future use.

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1. INTRODUCTION

1.1 Preliminary

Agriculture is the basis of Ethiopia's economy and is most important in terms of generation of foreign currency. The sector is the primary source of livelihood for more than 85 percent of Ethiopian households who practice subsistence crop and livestock production. The livestock sector in Ethiopia contributes 12 percent and 33 percent of the total and agricultural Gross Domestic Product (GDP), respectively, and provides livelihood for 65 percent of the population. The sector also accounts for 12-15 percent of total export earnings, the second in order of importance.

Animals provide highly nutritious foods, as well as draught power; transport; manure; and hides and skins. To ameliorate the development constraints and realize the benefits from the huge but untapped resource, efforts have been made in various aspects to develop the livestock sector in Ethiopia. These efforts include the provision of inputs and services such as veterinary services, breed improvement, feed resources development, research, extension services and development, finance and marketing. Animal diseases are one of the major bottlenecks of animal productivity in Ethiopia. Many of the diseases affecting livestock are transboundary in nature and can have a devastating impact on animal productivity and production; trade in live animals, meat and other animal products; human health; and, consequently, on the overall process of health and economic development.

1.2 Veterinary Pharmaceuticals and their Importance

Veterinary pharmaceuticals (VP) are natural or synthetic chemical substances that are used in the prevention, diagnosis, and treatment of infectious and non-infectious

diseases in animals. Veterinary drugs and feed administration and control proclamation no. 728/2011 also defined them as "Any substance or mixture of substances used in the diagnosis, treatment or prevention of animal disease, and includes products used to treat against internal and external parasites and disease transmitting vectors, biological products, sanitary items and veterinary instruments". The products are grouped under antimicrobial agents, anthelmintics, anti-inflammatory drugs, appetite stimulants/tonics, calcium/magnesium or other mineral or vitamin or nutrient supplements, drugs for external parasites, hormones, sedatives and anaesthetics, vaccines and blood products. The VPs kill or inhibit the growth of pathogenic microorganisms and parasites such as bacteria, viruses, fungi, helminthes, ticks and fleas.

The animal health industry provides value to society by protecting animals and as a consequence, humans, from diseases. Veterinary pharmaceuticals help keep pets and food-producing animals healthy. The public health benefits include safer and more secure food supplies, more efficient production for increased food supply, improved sustainability, and prevention of the transmission of zoonotic diseases. To ensure effective and sustainable animal disease control while minimizing risks to humans and animals, governments are expected to provide appropriate regulations on the manufacturing, authorization, distribution and use of veterinary products through their veterinary legislations. The current (2019) National Veterinary Drug List (NVDL) of veterinary drugs for Ethiopia provides more details.

1.3 Rational Use of Veterinary Pharmaceuticals

Drugs should be used only when required at the required amount and combination. Improper use of drugs may result in ineffective treatment, unnecessary wastage of resources, and may harm the user patient. In using veterinary drugs, certain steps have to be followed before deciding on what procedures to be used. The primary purpose of animal health management has to be in prevention of diseases through improving biosecurity, infection control, good production and husbandry practices and reducing in unnecessary use of antimicrobials. As much as possible, narrow spectrum antimicrobials have to be prescribed and used, following clinical examination at targeted infectious diseases treatment and based on evidences and on microbiological susceptibility tests.

Rational approach to therapeutics requires careful evaluation of the health problem in each species of animal and selecting appropriate therapeutic strategies. Proper diagnosis of animal diseases requires extensive discussions with owners and clinical examinations and confirmed by appropriate laboratory procedures. The efficacy of treatment largely relies on correct diagnosis. Whenever the alternatives exist, non-pharmacological treatment should be given priority to chemical treatment. In veterinary medicine, preventive measures are preferred than treatment. Thus possible preventive measures should be given attention to check the spread of animal diseases.

The selection of treatment requires risk-benefit-cost analysis, particularly in food animals. Uneconomical and high-risk treatments are avoided unless and otherwise the animals have special attachment with the owner (e.g. dogs and cats) or the genetic makeup of the animal should be conserved. Apart from the cost of a particular drug, its

efficacy and safety with minimal adverse effects and minimal residues in food animals should be given due attention. Drug choice depends on individual patient and prescription; whenever written it should clearly indicate the species of animal, the age, sometimes breed, the dose of the drug in the formulations available locally and the duration of treatment. In food animals, consideration should be given to the withdrawal period of drugs in case an emergency slaughter is recommended (included in prescription writing).

1.4 Antimicrobials Prudent Use and Stewardship

The extensive use of antimicrobial agents in livestock production systems has for decades supported the commercialization and intensification of food-animal production by facilitating early weaning, increased milk, egg and meat production and promotion of animal welfare. However, the notable gains derived from VMP use have come with a heavy cost to public health and the economy. The overuse and misuse of antimicrobial agents in humans, animals and plants has now been linked to the acceleration of the natural evolutionary processes by which microbes become resistant to antimicrobial treatments. Antimicrobial Resistance (AMR) occurs when microorganisms such as bacteria, viruses, fungi and parasites change in ways that make treatment ineffective. The transfer of resistant microorganisms to animals, food, environment and humans occurs through a variety of routes. A one health approach and Ethiopian strategy has therefore been drafted to combat the global public health and economic threat arising from AMR. Prudent use of antimicrobials should lead to more rational and targeted use, thereby maximizing the therapeutic effect and minimizing the development of AMR.

Antimicrobial resistance refers when microorganisms, bacteria, fungi, viruses, and parasites, evolve resistance to antimicrobials. As a result of AMR, medicines that were once effective treatments for diseases become less effective or even useless, leading to a reduced ability to successfully treat infections, increased mortality; more severe or prolonged illnesses; production losses in agriculture; and reduced livelihoods and food security. AMR microorganisms can develop in our food chains and the environment, and move between animals and humans by direct exposure, consumption, or contact with the environment.

However, antimicrobials are often misused for therapeutic and non-therapeutic uses. The antimicrobials use in humans and animals; and around 75-90 percent of antimicrobials used by humans and animals are excreted unchanged. Release of waste from health care facilities and farms and effluent from pharmaceutical plants enter into the environment all of which contributed to selection pressure, reservoir to AMR and have health and economic consequences.

Globally, farmers use a bulk of antimicrobials for their animals to treat disease in sick animals; prophylactically to avoid disease in animals at high risk; and most controversially as growth promoters to 'meeting' the increasing global demand for safe meat, milk, fish and eggs, and other products of animal origin. In addition to their use in animal husbandry, antimicrobials are used in companion animals, agriculture, and contaminate the environment.

Antimicrobial resistance is a major global animal and human health threat. The health consequences and

economic costs of AMR are estimated at 10 million human fatalities a year, a decrease of around 11percent in livestock and production and productivity, and a 2 to 3.5 percent decrease in global Gross Domestic Product (GDP), amounting to US$ 100 trillion by 2050. However, the full impact remains hard to estimate.

Before prescribing antimicrobials, it is essential to take into consideration cross- and co-resistance, which any exposure to antimicrobials can increase the chances of AMR. Veterinary Standard Treatment Guideline (VSTG) has a number of benefits; some of these can be mentioned as follows:

- Provides standardized guidance to practitioners and options for the future;
- Enables providers to concentrate on making the correct diagnosis;
- Promotes high quality of care by directing practitioners to the most appropriate drugs for specific conditions;
- Provides best quality of care since patients are receiving optimal therapy;
- Provides information for forecasting and ordering according to the morbidity;
- Provides information for purchase of pre-packed drugs; fixed dose combinations, and of various relevant formulations;
- Enables consistent and predictable treatment from all levels of providers and at all locations; and
- Are designed to improve the quality of animal health care and decrease the use of unnecessary or harmful interventions.

In order to rationalize the use of antimicrobials, the following principles should be taken into account:

- The Antimicrobial should be prescribed by a licensed veterinarian;
- The continued need for antimicrobial should be reassessed on a regular basis to avoid unnecessary use;
- Perioperative prophylaxis antimicrobials use should be minimized through using aseptic techniques; if so should be administered prior to surgery and not for more than 24 hours.
- Other alternative options for controlling disease (e.g. vaccines) have to be considered over antimicrobials;
- As much as possible antimicrobial susceptibility tests have to be used in zoonotic and commensal microorganisms and target pathogens should be established.
- Antimicrobials categorized as critically important and reserve should not be used in animals since they are also used in treating life-threatening infections in humans and only under strict supervision and minimize the development of resistance;
- Antimicrobial metaphylaxis (mass administration of antimicrobials to a group of animals to eliminate or minimize disease outbreak) should never be used in place of good management practices;
- Routine antimicrobials use for prophylaxis must be avoided and reserved for exceptional case-specific indications;
- Administering antimicrobials to an entire herd or flock should be avoided whenever possible;
- the cause and the nature of the infection in animals and the range of available antimicrobial options

should be taken into account when making decision regarding antimicrobial treatment;

- Sick animals should be isolated and treated individually;
- Narrow-spectrum antimicrobial should always be the first choice unless prior susceptibility testing;
- As much as possible use of broad-spectrum antimicrobials and antimicrobial combinations should be avoided with few exceptions of combinations;
- In case of recurrent infection(s) in animals requiring antimicrobials, efforts should be made to identify and eradicate the strains of the microorganisms and changing the production conditions, animal husbandry and/ or management;
- Antimicrobials should not be used for the treatment of self-limiting infections in immunocompetent animals.

1.5 Veterinary Pharmaceuticals Logistics Cycle

Logistics activities as the operational component of supply chain management include quantification, procurement, inventory management, transportation and fleet management, and data collection and reporting. Supply chain management includes the logistics activities plus the coordination and collaboration of staff, levels, and functions. The supply chain includes global manufacturers and supply and demand dynamics, but logistics tends to focus more on specific tasks within a particular program animal health system.

The goal of veterinary pharmaceuticals logistics system is much wider than simply making sure a product gets where it needs to go. Ultimately, the goal of every

veterinary pharmaceutical logistics system is to help obtain and use quality essential veterinary pharmaceuticals whenever they need them, in the necessary quality supplies at the required time and place and at all times.

1.5.1 Review of key Logistics Terms and Concepts

There are different logistics terms that are used in the veterinary pharmaceuticals supply chain management system. The major terms with their definition are listed in operational definitions.

1.5.2 Purpose of Logistics System

The purposes of logistics system are:

- To ensure the six "RIGHTS":
  - **RIGHT** Product in the
  - **RIGHT** Quantity of the
  - **RIGHT** Quality at the
  - **RIGHT** place at the
  - **RIGHT** time for the
  - **RIGHT** cost
- To serve customers
- To ensure animal health commodity security exists for each client

1.5.3 Highlights of Veterinary Pharmaceuticals Logistics Cycle

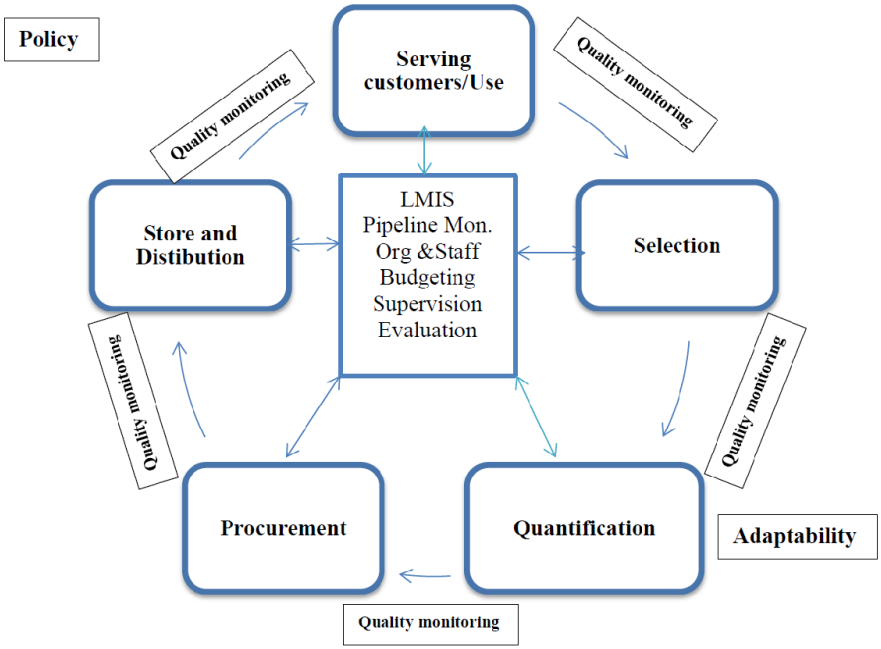

Figure 1: The Veterinary Pharmaceuticals Logistics Cycle

The major activities of the logistics cycle are product selection, quantification, procurement, storage and distribution. All the activities are performed by focusing on use.

1.5.4 Serving Customers/Use

There are two perspectives regarding the customers in the logistics cycle. From suppliers' perspective, it focuses on serving customers, whereas from customers' point of view it is related to rational use of veterinary pharmaceuticals. Serving Customers is shown at the top of the cycle to show

its importance: we do all of our work in logistics in order to serve the customer. If we can achieve the Six Rights, then we are serving the customers. Everyone who works in logistics must remember that they select, procure, store, or distribute products to meet customer needs. In addition to serving the needs of the end customer, the customer seeking animal health services, each person in the process is also serving the needs of more immediate customers. For example, storekeepers provide customer service when they issue medicines to the veterinary health facility and the facility to the farmer. The logistics system ensures customer service by fulfilling the six rights. Each activity in the logistics cycle, therefore, has to contribute to customer services and satisfaction and to ensuring commodity security. You can look at the respective chapters on selection, quantification, procurement, inventory management, distribution, and veterinary pharmaceuticals management information.

1.5.5 Organization and Staffing

A logistics system can only work if well-trained and efficient staff monitor stock levels, place orders, and provide products to clients. The animal health system assigns the appropriate resources to staff to complete logistics activities. In fact, some countries have established national logistics management units that analyze logistics data and provide feedback throughout the system. Organization and staffing, therefore, are important parts of the cycle. For a logistics system to work correctly, staff must make the six rights a top priority.

1.5.6 Budget

The allocation and management of finances directly affect all parts of the logistics cycle, including the quantities of

products that can be procured, the amount of storage space that may be available, the number of vehicles that can be maintained, and the number of staff working in logistics. Mobilizing resources and securing a budget line item for veterinary pharmaceuticals and logistics activities is extremely important to ensure that products are available and that the logistics system operates effectively. To determine the resources needed to scale up, supply chain managers first need to assess what the expected costs are at different levels of the logistics system. When determining supply chains costs, managers should consider the cost of storage, transportation, and management; and determine what share of these costs each stakeholder will cover.

1.5.7 Supervision

Supervising the staff who works within the logistics system keeps it running smoothly and helps to anticipate changes. Routine, effective supervision, coupled with on-the-job training in logistics, helps to both prevent and resolve supply problems and human resource constraints.

1.5.8 Monitoring and Evaluation

Routine monitoring and periodic evaluation of the pipeline and logistics system activities help demonstrate how well the system is performing, the areas that can be improved, as well as the system's impact on service provision.

1.5.9 Quality Monitoring

It is important to understand the role of quality monitoring in ensuring an efficient and effective logistics system. In the logistics cycle, notice how quality monitoring appears between each activity of the logistics cycle. Quality

monitoring refers not only to the quality of the product, but also to the quality of the work.

1.6 Governance of Veterinary Medicinal Products in Ethiopia

1.6.1 Veterinary Drug and Feed Administration and Control Authority (VDFACA)

Veterinary Drug and Animal Feed Administration and Control Authority is established under the regulation number 272/2012 to execute proclamation number 728/2011. The authority started working in June 2013.

The Authority is responsible and mandated to:

- Prepare and submit to the competent organ standards for the safety, efficacy and quality of veterinary drugs and the safety and quality of feed and feed additives and, upon approval, follow up the implementation and observance of same;
- Set standards of competence for persons to engage in veterinary drug or feed trade; issue certificates of competence to those referred to in sub-article(2)(b) of Article 3 of this proclamation; and renew, suspend or revoke certificates in accordance with this proclamation and regulations and directives issued hereunder;
- Evaluate and register veterinary drugs and feed additives to be produced in the country or imported; and renew, suspend or revoke a registration in accordance with this proclamation and regulations and directives issued hereunder;
- Prepare lists of and structure veterinary drugs and feed additives for the country;

- Formulate policies and legislation governing veterinary drugs and feed and, upon approval by the government, follow up their implementation.
- Promote and strength the veterinary drug and animal feed sector by monitoring domestic and foreign new scientific inventions and adapting them to the country's specific conditions;
- Evaluate laboratory and clinical studies in order to ensure the safety, efficacy and quality of traditional veterinary drugs; and authorize the use of traditional veterinary drugs in the veterinary service;
- Serve as veterinary drug and feed information center; disseminate veterinary drug and feed information center; disseminate veterinary drug and feed information to professionals and the public; ensure the accuracy and relevance of information disseminate by others; and prohibit dissemination of ambiguous or erroneous information;
- Authorize the conducting of clinical trials of veterinary drugs and monitor the process;
- Monitor and regulate narcotic and psychotropic drugs used in veterinary practice, and report the same to the Ethiopian Food and Drug Authority:
- Organize quality control laboratories required to carry out its duties;
- Provide training for the appropriate organs in handling and utilization of veterinary drugs and feed;
- Register and regulate substances and mixtures used, in accordance with Article 2(2) of this Proclamation, for treatment of animal external parasites and controlling animal disease transmitting vectors; and report the same to the organ empowered under Proclamation No. 674/2010; the detail implementation shall be in accordance with the regulation to be issued.

Under the current Ethiopian Federal system, the VDFACA, established under the Ministry of Agriculture is mandated, under the jurisdiction of the Federal government to control and regulate VMPs but the Regional Agricultural Bureaus or their equivalents have to regulate the veterinary medicinal products within their administrative territory. These institutions should work in harmony with the federal institutions to best regulate the veterinary medicinal products.

1.6.2 The Veterinary Medicinal Products Supply System

There are two sectors in VP supply system in Ethiopia i.e. the government system and the private sector. Regional Agricultural or livestock and fishery bureaus and private sectors involved in animal health services are responsible for the selection, quantification, procurement, inventory management and distribution of veterinary pharmaceuticals that are utilized in the veterinary service system. Generally, there is no government organization in the country established and specialized for veterinary medicinal products selection, procurement, and supply chain system unlike the human health supply chain system managed by Ministry of Health. Such a gap may be one critical factors hindering the operationalization of an efficient VP supply chain system in the country.

2. SELECTION OF VETERINARY PHARAMCEUTICALS

2.1 Introduction to Selection of Veterinary Pharmaceuticals

To serve customers and fulfill their expectations, it is important to select the right veterinary pharmaceuticals. Studies have shown that governments of developing countries are allocating 40 to 60 percent of their health budget to pharmaceuticals. However, sometimes, even the most essential medicines are not accessible in the market.

Globally, there are so many different veterinary pharmaceutical products available; prescribers often find it impossible to keep the knowledge up-to-date and to compare alternatives and these may contribute to inconsistent prescribing within the same animal health care system or evening the animal health facility. It also lowers the purchasing power due to the large number of duplicative and non-essential veterinary pharmaceuticals in the market. also in addition to that, it makes monitoring and maintaining stock levels of all products throughout the system very difficult and the supply chain system unmanageable. Therefore, it is essential to limit the number of veterinary pharmaceuticals that are appropriate to disease burden and are available in a given veterinary health facility. To provide the best and most reliable animal health care for the animal population, the smallest number of veterinary medicines needed to treat 90percent of the problems should be selected.

2.2 Who Should Select the Required Pharmaceuticals at Different Levels?

In the above section, we have seen the potential advantages of selecting a limited number of products to the prescriber, supplier and the patient. Who and how products are

selected determine the acceptability and usability of national veterinary drug list. Ethiopia has, the NVDL, which should be available in the country. Each veterinary service based on the type of services can select veterinary pharmaceuticals from NVDL, under carefully set criteria, considering many aspects including demand, and disease prevalence, cost etc. The treatment guidelines which are carefully prepared and updated play a significant role in such selection procedures. It is recommended that the selection of veterinary pharmaceuticals be done by a committee and informed by evidenced based data and information for guiding the use of those medicines.

Members of the committee should be selected with reference to their positions and responsibilities. Appropriate people can include:

- a veterinarian
- a veterinary pharmacist/pharmacologist
- at least one veterinary drug store keeper
- a drug information specialist
- a laboratory technician
- an animal health assistant
- An administrator representing finance and purchasing department, as needed.

A dedicated and committed chairperson and secretary are critical to the success and efficiency of the committee. In most settings, a senior veterinary doctor, ideally well-known and respected, is appointed as the chair and a senior veterinary pharmacist as the secretary.

2.3 Criteria for Selection of Veterinary Pharmaceuticals

2.3.1 Criteria for the Selection of Medicines

The choice of essential veterinary medicines depends on many factors. These include:

- Relevance to the pattern of prevalent diseases
- Proven efficacy and safety
- Adequate scientific data and evidence of performance in a variety of settings
- Relatively easy to establish adequate quality
- Favorable cost-benefit-risk ratio
- Desirable pharmacokinetic properties
- Possibilities for local manufacture
- Availability as single compound

Valid scientific evidence should always serve as a base for the selection of essential medicines. Only those medicines for which sound and adequate data on efficacy and safety are available from clinical studies should be selected. Each selected medicines must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established. Where two or more medicines appear to be similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability.

In cost comparisons between medicines, the cost of the total treatment, and not only the unit cost of the medicines, must be considered. The cost-benefit-risk ratio is a major consideration in the choice of some medicines. In some cases the choice may also be influenced by other

factors, such as comparative pharmacokinetic properties, or by local considerations such as the availability of facilities for manufacture or storage.

The selection criteria must be developed with the participation and thorough discussion of multidisciplinary committee and publishing these defined criteria to ensuring transparency of the procedure. All veterinary pharmaceuticals have to be registered (undergone prior evaluation and proven to be effective, safe, and of good quality) by the regulatory authority VDFACA not only to avoid delay but also wastes time and money, and risks of spoilage or expiry of products while at customs.

If there is adherence to VSTG by prescribers, selecting veterinary medicine based on VSTGs make the supply chain management relatively easier Each time VSTGs or products change, the supply chain must adapt to it. Service providers should also be trained in prescribing and dispensing new treatment regimens and products. New products must be incorporated into logistics management procedures for ordering, stock monitoring, and reporting on consumption and stock levels.

2.3.2 Criteria for the Selection of Laboratory Reagents

The selection criteria for laboratory reagents include:

- Inclusion of the product in protocols and standards
- The status of registration of the product with local regulatory bodies
- Technical criteria of test sensitivity and specificity.
- Cost and available financing.
- Storage requirements, such as cold chain, and capacity to maintain the products.
- Skill level of personnel (or training requirements).

- Ease of use of the product.
- Packaging of the products to facilitate distribution.
- Shelf-life.
- Compatibility with existing instrumentation (durables).
- Closed- or open-system (for equipment's) - Closed system equipment's require specific brands of reagents, while open systems do not.

However, lack of standards, rapid technology changes, closed-system instruments and uncoordinated donation of equipment and reagents are some of the major challenges in selecting laboratory products. Some of the remedies to these challenges include: using standard testing protocols which help to develop a product list for each level in the laboratory supply system; choosing open systems for test instrumentation; and preparing for changes in test technology are highly recommended.

2.3.3 Criteria for Selecting Veterinary Equipments

Selecting veterinary equipment is not an easy task, because of the wide range of products available. Need, appropriateness, quality, safety and performance standards, cost, source, use, maintenance and material are some of the criteria considered in deciding what to include in a standard list and what to procure.

A) Need

Think about why you are planning to purchase the equipment. Issues to consider are:

- Animal health
- Technical
- Economic
- Clinical

There may be animal health or epidemiological reasons for needing the supplies or equipment. For example, you may need them to prevent, diagnose or treat a new animal health problem or to improve existing services. Whether you are adding something new to your facility or replacing an existing item, use the VEN system to help you decide whether a new or replacement item is 'vital', 'essential', or 'not so essential' for your services.

An equipment should not be replaced just because it is old or when a newer model is available. Only buy replacements for items that have reached the end of their useful life, those are: not economical to repair or technically obsolete where the manufacturer is no longer producing spare parts, consumables and accessories. Sometimes an item of equipment becomes clinically obsolete, because the technology or technique is no longer considered appropriate, or a more cost-effective or more clinically effective model becomes available. Different types of equipment last for different lengths of time, although this depends on how often they are used and how well they are maintained.

B) Appropriateness

Equipment should be appropriate for the setting in which they will be used. Issues to consider include:

- Local conditions;
- Compatibility; and
- Acceptability.

Avoid buying items that are too technically sophisticated for local conditions. The latest model often requires more expertise to use and maintain, and complicated items tend to break down more frequently. If you are thinking about procuring a particular item, it can be useful to talk to someone in a facility that has experience of using that

model. You also need to check the reliability and durability under local conditions. For example, it may be important to find out if the equipment functions well in an environment that is hot, humid, dry or dusty, and if special storage conditions are required. Some supplies and equipment are particularly sensitive to certain conditions, for example, microscopes are sensitive to humidity.

Equipment should be compatible with existing equipment and appropriate for the level of service provided by your facility. You also need to check that supplies and equipment will be familiar to staff.

C) Quality

Equipment must be of sufficiently high quality in terms of:

- Performance;
- Safety;
- Materials and design; and
- Labelling and packaging.

The quality of performance you need depends on how often an item will be used and how long you are expecting it to last. Buy the quality that is best suited to your needs. It is worth buying better quality supplies and equipment if they are going to be used frequently or are expected to last a long time. However, it is not always necessary to buy the very best quality. For example, good 'mid-range' quality stainless steel instruments are probably the best buy. It is not cost-effective to buy the most expensive because instruments are easily misplaced, or the cheapest because these are more likely to rust or fall apart. Patient care and safety should never be compromised by poor quality. Supplies and equipment must meet safety standards. Safety also depends on the quality of installation, correct use and regular maintenance.

D) Safety and performance standards
All medical equipment should meet international, regional or national safety and performance standards. The most important standards include:

IEC: are international standards for the electrical safety of electrical and electromechanical equipments. IEC 601 is the international standard specifically for electrical and mechanically safe medical equipment for use by practitioners and with patient animals.

ISO: are international standards for quality management and systems. ISO 9000–9004 is a series of standards covering the quality of manufacturing processes, design and development, construction, installation and service. ISO standards do not currently exist for all medical supplies and equipment, but do apply to syringes, needles, gloves, instruments and scales, for example.

CE mark: indicates that a product meets European Union directives, standards, and applies to sterile medical supplies for.

Pharmacopoeia specifications: which establish quality specifications for the most commonly used drugs and some medical supplies, such as bandages, tape and swabs. Important pharmacopoeias include the British (BP), European (EP), United States (USP) and WHO International Pharmacopoeia (IP).

Quality certificates or export certificates: which are issued under various national and regional standards such as ISO 9000 or the equivalent EN 29000. If possible, before purchasing, check the quality of the labeling and the packaging. Labeling should include information about country of origin, date of manufacture and, if appropriate,

expiry date and storage instructions. Packaging should protect supplies and equipment from damage or deterioration during transit and storage.

The labeling or packaging also includes information that manufacturers are required to provide to users. This information is sometimes presented as symbols, which are intended to be understood by any user irrespective of their languages.

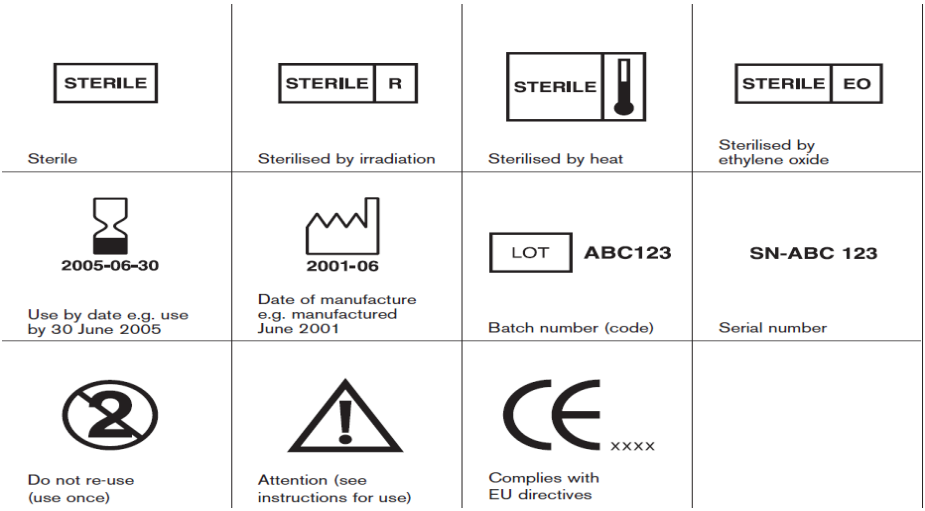

Figure 2: Information provided by manufacturers

E) Costs

Better quality equipments are more expensive, but cheaper ones are often of poor quality. Buying the cheapest items can be a false economy, because they may need repairing or replacing more frequently. It may be more cost-effective to spend more on a higher quality item that is more reliable and that lasts longer. Equipment that are close to their expiry date are sometimes offered for sale at low prices. Be careful not to buy more than you can use before the expiry

date, otherwise you will waste resources. Packaging also adds to the cost of supplies and equipment, but it is usually worthwhile purchasing goods that are well packaged. Poorly packaged goods are more likely to be damaged in transit.

In addition to the purchase cost, other initial costs to consider include:

- Import tax and customs duty;
- Transportation and insurance;
- Installation; and
- Staff training.

You also need to check that your budget will cover operational (running) costs throughout the lifespan of the equipment, including:

- Consumables and accessories – allow for continuity of these supplies; and
- Maintenance and servicing – allow 5-7percent of capital cost

F) Source

Another important factor is the source of supplies and equipment. There are issues to consider related to:

- Manufacturers and suppliers;
- Imported supplies; and
- Used supplies

The quality of manufacturing standards differs from country to country. Only procure supplies and equipment from a licensed, reputable and reliable source. Before buying, ask the supplier which safety and performance standards an item complies with. Be wary of copies, items made to look like a well-known brand, as these are often of poor quality and do not conform to international standards.

If you are thinking about importing supplies and equipment, you will need foreign exchange. Find out if the supplier will provide all the necessary documentation for customs clearance and decide whether you can deal with import procedures, transport, insurance and other arrangements.

Buying second hand, refurbished or reconditioned equipment requires particular care. Asking the following questions can help:

- What condition is the equipment in? How much longer will it last?
- If it has been reconditioned, what is its new lifetime?
- Will it be supplied with installation and use instructions, service and repair manuals?
- Has it been fully tested and calibrated? Are all the essential parts, and at least two year's supply of accessories and working materials (including all the consumables and spare parts needed to use the equipment) included?
- Will the supplier be able to continue to provide accessories, consumables and spare parts, technical support and maintenance for the future life of the item?
- What after sales support will the supplier provide?
- How long will it take from placing the order to receiving the item?
- Will staff have to be trained to use the equipment or are they already familiar with it?

Sometimes it is more cost-effective to buy new rather than used equipment, which only has a limited life. Obtaining accessories, consumables and spare parts can also be difficult for older models that are no longer made. Find out

the cost of a new model of the same or a similar item of equipment and compare this with the cost of a used model.

G) Use and maintenance

It is essential that your facility can use and maintain the supplies and equipment you procure. There is no point in obtaining items if your staff does not have the expertise or information to use them effectively or if you cannot access maintenance support and technical back up. Issues to consider include:

- Utilities
- Skills and training
- Technical back up
- Consumables, accessories and spare parts

Check that your facility has the utilities needed to use an item of equipment. For example, some equipment requires a reliable power supply, adequate quantities and quality of water, and an effective waste disposal system. If your facility has an unreliable or fluctuating power supply, choose equipment that can be operated with kerosene, gas or battery power, or consider whether you can afford to purchase a voltage stabilizer for electronic equipment.

Consider how easy it will be for your staff to use, clean and maintain the equipment. Do all the staff that will use it already have the skills required or will they receive training? Find out if the manufacturer or supplier provides training and other support services. Check that the equipment is supplied with simple, easy to use instructions, user, repair and service manuals, and a list of spare parts.

If maintenance requires the services of a skilled technician, find out whether you have access to technicians locally or

nationally who can service and repair the equipment, and who can provide planned preventive maintenance. Planned preventive maintenance is the regular maintenance service recommended by manufacturers, which should supplement maintenance carried out by health facility staff using the equipment. Manufacturers and suppliers do not have service agents in all countries. If there is no authorized agent in your country, find out if there are other organizations that offer this service.

Check whether the supplier provides a guarantee or warranty for the equipment and parts. Guarantees can last for a year or more, although the length of time depends on the type of equipment or product. While an item of equipment is under guarantee or warranty, the manufacturer should replace or repair it (either directly or through a distributor or local agent), or provide a refund if the equipment is found to be defective due to faulty materials or workmanship, either on arrival or during use. However, if there is no authorized agent in a country, the user may be responsible for the cost of sending the item back to the manufacturer. A guarantee does not cover defects arising from items not used correctly, misuse, neglect, accidents or repairs carried out by other companies.

Finally, consider the availability of consumables, accessories and spare parts. Find out what you will need to operate and maintain the equipment, how much these items cost, where they can be obtained and how easy it is to get hold of them, and for how long they will continue to be available in future.

H) Material

Another important consideration is the material from which the item is made. Instruments made from tungsten carbide last longer but are the most expensive. Instruments made from good quality stainless steel last longer than plastic instruments but are more expensive. Items made of aluminum are lightweight but bend and buckle more easily than items made of iron or stainless steel. Metal items that rust easily are difficult to clean. Make sure metal items that need to be cleaned and sterilized or disinfected regularly have a polymerized finish, polyester coating, epoxy coating or are made from good quality stainless steel. Polyester or epoxy coating also provides additional protection from scratches and abrasions.

Glass items are fragile and break easily. Not all glass items can be re-used. Many glass items are also manufactured in plastic. Plastic does not break easily and weighs less than glass, making it safer to use and easier and cheaper to transport. Some plastic items can be re-sterilized, others cannot. Although most supplies are quite durable, some spoil if left unused for too long, for example, rubber tubing and latex items. Plastic wrapping helps to protect such items against high humidity and is more robust than paper wrapping.

I) Disposable or reusable

Some supplies and equipment, such as gloves and syringes, are available as disposable and as reusable products, and you may need to decide which type to procure.

- *Disposables:* are items designed for single use. Disposables should only be used once and should not be re-used.
- *Reusable:* are items designed to be used more than once. Reusable should only be re-used after proper cleaning and sterilization and/or disinfection.

Both types have advantages and disadvantages in terms of convenience and cost. Disposables are more convenient than reusable. However, using disposables cost more than reusable as they need to be replaced more often. When comparing costs you also need to include the cost of sterilizing reusable equipment. To help you to decide what type is most suitable for your animal health facility, consider the following issues:

- Is there a national or local policy regarding the use of disposable or reusable?
- Does your facility have the equipment required for sterilization?
- Can you obtain regular and reliable supplies?

2.4 Approach for Selection of Veterinary Pharmaceuticals List

It is very important that an explicit and previously agreed process and selection criteria is followed at each step, in order to increase diseases treatment coverage and veterinarian's confidence and usefulness of the list. Here are the approaches to be followed to select veterinary medicines list.

Step 1: Prioritize a list of common health problems or diseases being treated in the animal health service

Collect and collate the causes of morbidity and mortality in the area. The diseases may be ranked to identify the most

common diseases being treated and reviewing the previous mortality and morbidity records.

Step 2: Determine the first choice of treatment for each diseases

For each disease, an appropriate first choice of treatment should be identified using the VSTGs. Alternatively, an expert committee can be brought together to identify the appropriate treatment for each of the common animal health problems.

Step 3: Draft, circulate for comment, and finalize the list

A draft of the selected list must be reviewed by the appropriate body. It is useful to identify:

- The most important veterinary medicines (which are absolutely essential) and those that are less essential;
- The most expensive medicines; and
- Whether all the medicines that are prescribed in large volumes, or are expensive, are essential (analyzed based on ABC-VEN matrix).

The committee must agree and disseminate on their comments and provide feedback. All information to be discussed and deliberated upon, such as disease profile and VSTGs, must be available during the discussions, together with evidence-based reviews where possible.

Step 4: Develop policies and guidelines for implementation

The formulary list will never be useful unless there are documented policies and guidelines on how it should be used. These should include:

- Who should use the list
- How the list should be reviewed and updated

- A clear mechanism for adding and deleting veterinary medicines from the list
- How clinical staff can request medicines that are not included on the list in exceptional or emergency situations.

Step 5: Educate staff about the selected list and monitor implementation

All the staff in the veterinary service must be educated about the list. A common problem is that prescribers continue to request and use medicines not on the list. There should be a clear system of implementation, accountability and enforcement including reprimands and sanctions. End users and opinion leaders can be involved in evaluating and enforcing the implementation.

3. VETERINARY PHARMACEUTICALS QUANTIFICATION

3.1 Introduction to Quantification

Quantification is the process of estimating the total quantities of veterinary pharmaceuticals and total costs of the products required for a specific program during a specific period and determining when shipments of the products should be delivered to ensure optimal and uninterrupted supply. Quantification has to be reconciled with the resources at hand. Quantification has to inform supply chain decisions on veterinary pharmaceuticals selection, distribution, procurement, use, financing, and delivery. Quantification does not end when the final quantities and costs have been determined. Instead, it is an ongoing process of monitoring, reviewing and updating the forecasting data and assumptions and recalculating the total pharmaceuticals requirement and costs as needed. It is important to compare the actual quantities consumed with the forecasted quantities, to assess the accuracy of the forecast and improve the quality of quantifications. Good quantification contributes to the Six Rights of the supply chain: Right- products, quantities, condition, place/customer, time and cost. Quantification, a critical supply chain management activity links information on services and commodities from the facility level with program policies and plans at the national level to estimate the quantities and costs of the commodities required for a health program. Therefore, a good quantification should ensure consistent product availability, minimal wastage and no overstocking and easy management of the whole supply chain to reduce morbidity and mortality and save livestock resources, minimize cost and satisfy customers. On the other hand, poor quantification is a reason for widespread shortages/stock-outs, expiries, distortion of

demand, irrational use of veterinary medicines and wastage of scarce resources.

3.2 Importance of Quantification

The result of the quantification should be formally presented to stakeholders. This helps the quantification team to receive feedback about the assumptions made during forecasting and the supply planning steps, as well as the data sources used. Presenting the results of the quantification is also an opportunity for the team to describe the national stock status of veterinary pharmaceuticals to all stakeholders and to outline the supply chain actions required to maintain adequate stock levels.

During the presentation/planning of the key outputs from a national veterinary pharmaceuticals quantification exercise, the team should:

- Review all data sources used and include a discussion of challenges in data collection and data quality.
- Summarize the forecasting assumptions and description of data sources and key informant inputs used to inform the assumptions.
- Summarize the supply planning assumptions (especially if assumptions about the amount and timing of funding commitments will affect procurement and delivery of commodities).
- List the total quantities and cost of each product required, for each year of the quantification.
- Determine the national stock status (months of stock on hand) for each product (Pipeline Stock Status Graphs are very useful to convey this information); highlight products close to expiry; stocked out; or

overstocked, based on the national stock status analysis.
- Summarize the shipment delivery schedules by funder and by supplier.
- List the total funding gaps for the next 24 months.
- List the specific actions required to address any critical stock imbalances and to maintain stocks at the established levels.

These quantification outputs enable program managers, funders, buyers, and suppliers to plan and schedule their inputs, to coordinate available resources, and to advocate for additional resources when funding gaps are identified. Presentation of the quantification results to policymakers, program managers, procurement managers, funders, and commodity managers facilitates the following activities:
- Program planning and budgeting
- Mobilization and allocation of funding for commodity procurement
- Coordination of multiple sources of funding for procurement
- Procurement decision making about which products to procure, how much to procure, and when to procure
- Adjustment of timing of procurements and shipment delivery schedules to ensure continuous supply while avoiding stock outs and overstocking.

In addition, conducting a quantification exercise typically reveals supply chain management needs, including strengthening data collection and reporting systems and inventory management procedures, and improving dissemination and training of providers in standard treatment guidelines. The quantification exercise is also an

opportunity to identify and advocate for other supply chain improvements.

3.3 Key Steps in Quantification

No matter which veterinary drug a program distributes, a quantification exercise follows the same key steps. These steps, outlined in figure below, include preparation, forecasting, and supply planning.

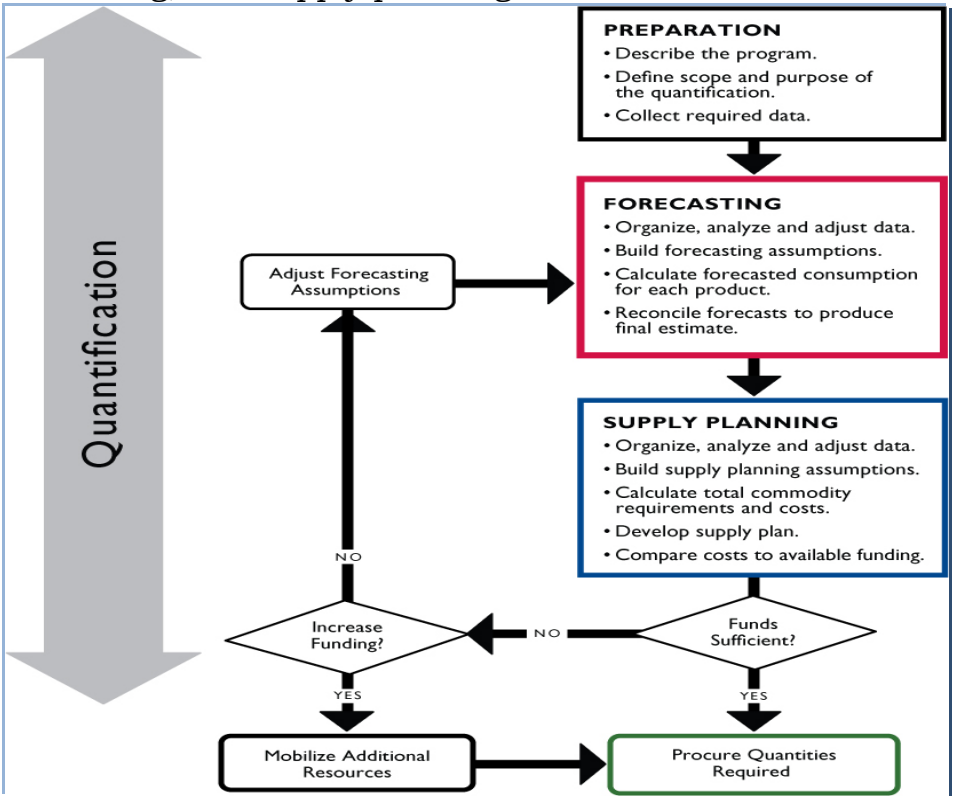

Figure 3: Steps in Quantification of Pharmaceuticals

3.3.1 Preparation

Prior to collecting data, the following initial steps should be taken: (1) describe the program and (2) define the scope,

purpose, and timeframe of the quantification and (3) Collect required data.

A) Describe the program

- Summarize the background, status, and performance of the program for which the pharmaceuticals/commodities are being quantified.
- This summary should include a review of program goals, strategies, and priorities, and any expansion plans or change in policies that may significantly influence uptake of services and demand for commodities.
- It should note any challenges the program has encountered in ensuring the supply of pharmaceuticals for the program and availability of products at service delivery points.
- The pharmaceuticals that will be quantified should also be identified and agreed.

B) Purpose of the Quantification

It is important to identify the purpose of the quantification and how it will address the program's needs. Examples of the purpose of quantification include the following:

- To provide data on specific commodity requirements and costs for the government's annual budget allocations
- To inform donors about funding requirements and advocate for resource mobilization for commodity procurement
- To estimate commodity needs and assess stock status of the in-country supply pipeline to identify and correct supply imbalances

C) Time frame of the Quantification

- For maximum effectiveness and usefulness for procurement purposes, it is recommended to conduct a quantification of commodity requirements for one full year to minimize seasonal fluctuations.
- This should include not only the actual quantities of each product to be procured and when, but also a shipment delivery schedule based on funding available and established program stock levels that account for procurement and supplier lead times and buffer stock.
- Quantifying veterinary pharmaceuticals requirements and costs for a year period facilitates timely procurement and identification of funding gaps to mobilize needed resources before stock outs occur, or to adjust shipment schedules to avoid overstocking.

D) Collect the required data

The importance of available and quality services and logistics data for informing the quantification cannot be underestimated. A well-functioning animal health management information (AHMIS) and veterinary pharmaceuticals logistics management information system (LMIS) are central to improving the accuracy and usefulness of health commodity quantifications. In addition, morbidity data, demographic data, national program policies, strategies, and expansion plans should be used.

Different types of data and information will be required at each step, in the quantification process. The data and information may be collected through:

- ✓ Interviews
- ✓ Consultative meetings with key stakeholders
- ✓ Through existing reports (AHMIS and LMIS) and

- ✓ Direct data collection at animal health facilities.
- ✓ Reviewing of different documents to collect demographic and morbidity data

3.3.2 Forecasting

Forecasting, the second step in the quantification process, uses the data collected during the preparation step to estimate the quantity of each product that will be dispensed or used during each year of the quantification. These quantities are the basis for calculating the total commodity requirements in the supply planning step. The forecasting step in a quantification exercise is a four-part process

- ✓ Organize, analyze, and adjust the data.
- ✓ Build and obtain consensus on the forecasting assumptions.
- ✓ Calculate the forecasted consumption for each product.
- ✓ Compare and reconcile results of different forecasts

3.3.2.1. Types of Data for Forecasting

There are five major types and sources of data for forecasting (Table 1).

- *Consumption:* Quantity dispensed to users/ issues and stock out period
- *Morbidity:* Prevalence and incidence of diseases
- *Demographic/population data:* number of livestock population and growth trend, population disaggregated by species, age, sex, weight etc.
- *Service data:* service capacity and coverage, number of cases diagnosed and treated
- *Program targets:* national annual program targets or service and not based on realistic program coverage rates set as goals for the program.

Table 1: Types and sources of data for forecasting

SN	Type of Data	Data	Data Sources
1	Demographic	• Total livestock population • Proportion of livestock population disaggregated by: ✓ age groups ✓ Pregnant animal population ✓ Incidence ✓ Number of households	• National Agricultural census e.g. CSA 2007 • Livestock DHS e.g. 2000, 2005, 2011 • Livestock Population growth projections e.g CSA 2015
2	Morbidity	• Prevalence • Incidence	• Epidemiological surveillance data e.g. DOVAR and ADINIS • Health Indicator Reports • Researches
3	Services	• Number of Mastitis cases treated e.g. ✓ Number of Mastitis cases treated by age group, pregnancy, severity level ✓ Formulations and dosages of pharmaceuticals used to treat/ diagnose • Total number of cases	• Animal health reports, program M&E reports, facility surveys of service records, daily registers • reported number of services provided, e.g., number of cases of disease condition treated,
4	Consumption	• Quantity of each	• Veterinary

		commodity dispensed at the facilities • Quantity of each commodity distributed from National, regions, Zones and Woredas stores • Days out of stock at each level	reports, facility surveys of stock records and consumption records • Reported quantities of products dispensed or quantities of products used
5	Program Targets	• Targets on coverage of service • Targets on diagnosis • Targets for elimination	• National policy and strategic planning documents • National annual program targets or service coverage rates set as goals for the program

3.3.2.2. Forecasting Methods

There are different methods of forecasting methods. Their applicability is dependent on the time frame of the forecast (i.e., how far in the future we are forecasting), the existence of patterns in the forecast (i.e., seasonal trends, peak periods), the availability of data and the number of variables to which the forecast is related.

In general, forecasts can be classified according to three time frames: short range, medium range, and long range. Short-range forecasts typically encompass the immediate future and are concerned with the daily operations, such as daily demand or resource requirements. A short-range forecast rarely goes beyond a couple of months into the

future. A medium-range forecast typically encompasses anywhere to 1 year. A forecast of this length is generally more closely related to a yearly plan and will reflect such items as peaks and valleys in demand and the necessity to secure additional resources for the upcoming year. A long-range forecast typically encompasses a period longer than 1 or 2 years. Long-range forecasts are related to management's attempt to plan new products for changing markets, build new facilities, or secure long-term financing. In general, the further into the future one seeks to predict, the more difficult forecasting it becomes. The line of demarcation between medium- and long-range forecasts is often quite arbitrary and not always distinct.

A. *Consumption Method*: uses records of past consumption of individual veterinary pharmaceuticals (adjusted for stock outs and projected changes in pharmaceuticals use) to project future need.
B. *Morbidity Method:* estimates the need for specific veterinary pharmaceuticals based on the expected number of attendances, the incidence of common diseases, and standard treatment patterns for the diseases considered.
C. Proxy Consumption Method: uses data on disease incidence, medicine consumption, demand, or use, and/or pharmaceutical expenditures from a “standard” supply system or country and extrapolates the consumption or use rates to the target supply system, based on animal population coverage or veterinary service level to be provided. Generally used if neither the consumption-based nor the morbidity-based method is feasible. The proxy consumption method is also useful for crosschecking projections made with the other methods. The proxy consumption method is flexible enough to apply to various situations and can be either veterinary population or

service based. This method starts from two sets of data: the number of episodes of each animal health problem and average standard treatment schedules.

D. *Service-Level Projection of Budget Requirements:* Uses the average veterinary medicine cost per attendance or veterinary clinic stay for different types of services in a standard system to project veterinary pharmaceuticals costs in similar types of facilities in the target system. This method does not estimate quantities of individual medicines, rather produces a rough estimate of financial needs for pharmaceutical procurement and not the quantity of products. The method relies on two assumptions: that the "standard" system (used for comparison) and the target system are comparable in terms of animal patient attendance and veterinary clinic stay per type of facility. This method can be useful in predicting medicine costs in a new system or in a system in which no data are readily available. Although those methods can be used the most common methods of forecasting veterinary pharmaceuticals are consumption and morbidity methods which are discussed below in more detail

Steps in Consumption-Based Method Calculation

Step 1: Select list of veterinary pharmaceutical products to be quantified

Step 2: Determine the historical consumption period (preferably 1 year)

Step 3: Enter data on historical consumption and stock-outs for each product for the consumption review period

Step 4: Adjust for incomplete reporting.

Step 5: Substitute the consumption data from previous year and adjust for stock outs

Step 6: Calculate the average monthly consumption adjusted for stock-outs

$$\mathbf{C_A = C_T \div [R_M - (D_{OS} \div 30.5)]}$$

Where C_A = Average monthly consumption, adjusted for stock-outs

C_T = Total consumption during the review period

R_M = Total consumption review period in months

D_{OS} = Number of days an item was out of stock during the review period

30.5 = Average number of days per month

An alternative method which is simpler but less precise is dividing the total consumption by the difference of review period in months and estimated stock out period in months i.e.

$$\mathbf{C_A = C_T \div [R_M - Mos]}$$

Where Mos= estimated number of months an item was out of stock during the review period.

For instance, if medicine "X" and "Y" were out of stock for 5 days and 25 days, respectively, Months of out of stock for these medicines can be estimated by converting days to closest month. In this case, while five days of out for medicine X is rounded to 0 month of stock, 25 days of out stock for medicine Y rounded to 1 month. Accordingly, calculate the adjusted average monthly consumption for Albendazole 2500 mg.

- For Albendazole 2500 mg of 60 bolus total consumption in 12 months was 18,000 pks with 34 days out of stock
- The adjusted average monthly consumption (C_A)in packs:
    - $C_A = C_T \div [R_M - (D_{OS} \div 30.5)]$
    - $C_A = 18{,}000 \div [12 \text{ months} - (34 \text{ days} \div 30.5)]$

- C_A = 18,000 ÷ [12 months – 1.1148 months]
- C_A = 18,000 ÷ 10.8852
- C_A = 1,654 packs of 1,000 tabs

Alternatively, 34 days can be rounded to 1 month only. Then, C_A computed as follows:

$C_A = C_T \div [R_M – Mos]$

- C_A = 18,000 ÷ [12 months – 1 month]
- C_A = 18,000 ÷ [12 months – (34 days ÷ 30.5)]
- 1636. Packs ~1636 packs

Step 7: Calculate the projected average monthly consumption

$C_P = C_A+(C_A \times A_U)$

C_P = Projected average monthly consumption

C_A = Average monthly consumption, adjusted for stock-outs

A_U = Utilization adjustment

- Example: For albendazole 2500 mg of 60 bolus, the projected average monthly consumption based on a 5% increase is:
  - $C_P = C_A+(C_A \times A_U)$
  - C_P = 1,654 +(1,654 x 5% increase)
  - C_P = 1,654 +83 = 1,737 packs of 1000 tabs

Step 8: Calculate the projected yearly consumption

$C_Y = C_P \times 12$

C_Y = Projected yearly consumption

C_P = Projected average monthly consumption

- Example: For albendazole 2500 mg of 60 bolus, what is the projected yearly consumption?

$C_Y = C_P \times 12$

C_Y = 1,737 packs / mx 12 m

C_Y = 20,844packs of 60 bolus

Step 9: Calculate the projected cost of consumption requirements for the forecast year

Cost of each product $_Y$ = C_Y x unit cost

- Example: For albendazole 2500 mg of 60 bolus with pack price of $10 what is the projected cost for the forecast year?

  Cost of each product $_Y$ = C_Y x Unit cost
  Cost of each product $_Y$ =20,844 packs x $10
  = $208,440

A very good source of data for this method are the stock records cards and bin cards. Example of a stock card is shown below.

1) Example on how to calculate recorded consumption from stock record cards

Example 1.1: Drug: Oxytetracycline 10% injection (100 ml vial) (stock Card)

Date	Description	Quantity Received	Quantity Issued	Balance stock
1 Jan.	Opening stock	-	-	50,000
10 Feb.	To dispensary	-	20,000	30,000
15 Mar.	To outreach services	-	20,000	10,000
1 Apr.	Procurement from CMS	80,000	-	90,000
2 Apr.	To dispensary	-	10,000	80,000
10 May	To dispensary	-	20,000	60,000
20 June	To outreach services	-	20,000	40,000
15 July	To outreach services	-	10,000	30,000
2 Aug.	Procurement from CMS	100,000	-	130,000
10 Aug.	To dispensary	-	20,000	110,000
20 Sept.	To dispensary	-	20,000	90,000
10 Oct.	Procurement from CMS	70,000	-	160,000
15 Oct.	To outreach services	-	20,000	140,000
10 Dec.	To dispensary	-	20,000	120,000
31 Dec.	Closing stock	-	-	120,000

Recorded Consumption = (Quantity Received Plus Opening Stock) minus Closing Stock
Recorded Consumption = (250,000 + 50,000) - 120,000 = 180,000
Therefore, the recorded consumption for Oxytetracycline 10% injection (100 ml vial) from the stock Card is 180,000 vials.

2) Consumption adjustment for avoidable wastage & losses (reduce the recorded consumption by 5 to 10percent or as shown in the stock card in italics, reduce from the recorded consumption.

Example 1.2: Procaine Penicillin and Dihydrostreptomycin Sulphate 200,000 IU+ 200mg

Date 1985	Description	Quantity Received	Quantity Issued	Balance stock
1 July	Opening Stock	-	-	1,800
14 July	To dispensary	-	600	1,200
2 Aug.	Procurement from CMS	1,500	-	2,700
10 Oct.	To dispensary	-	600	2,100
15 Nov.	To outreach services	-	600	1,500
10 Dec.	Procurement from CMS	1,500	-	3,000
12 Jan.	To dispensary	-	600	2,400
14 Feb.	*Expired/destroyed*	-	*800*	*1,600*
10 Mar.	To outreach services	-	600	1,000
1 Apr.	*Broken /crushed/ S.*	-	*300*	*700*
1 Apr.	Procurement from CMS	1,500		2200
18 May	To dispensary	-	600	1,600
15 June	To outreach services	-	600	1,000
30 June	Closing stock	-	-	1,000
30 June	*Unaccounted*	-	*500*	*500*

Consumption adjusted for avoidable wastage = Recorded consumption - avoidable wastages

Consumption Adjusted for avoidable wastage =
[(1800+4500-500) - (800+300+500)] = 4200 vials
Therefore consumption adjusted for avoidable wastage and losses for Procaine Penicillin and Dihydrostreptomycin Sulphate 200,000 IU + 200mg is 4200 vials.

3) Consumption Adjusted for Stock Outs (this is an upward adjustment)

Example 1.3: Procaine penicillin G 200000IU + Dihydrostreptomycine 200mg/ml, 100 ml vial

Date 1985	Description	Quantity Received	Quantity Issued	Balance stock	Remark
1 Sep.	Opening	-	-	10,000	
20 Sep.	To dispensary	-	10,000	0	Can be ignored because it is less than a month
1 Oct.	Procurement from CMS	20,000	-	20,000	
2 Oct.	To outreach services	-	10,000	10,000	
2 Nov.	To dispensary	-	10,000	0	3 months stock out
1 Feb.	Procurement from CMS	50,000	-	50,000	
21 Mar.	To dispensary	-	10,000	40,000	
1 April	To outreach services	-	10,000	30,000	
20 Jun.	To outreach services	-	10,000	20,000	
30 Jun.	Closing	-	-	20,000	

Consumption Adjusted for Stock Outs = Recorded Consumption (reduced by avoidable wastage and losses) multiplied by Period in calculation (usually 12 months) divided by product in stock (months)
Consumption adjusted for stock outs = [(10000 +20000+50000)-20000] X 12/9 = 80000
Therefore, the consumption of Procaine penicillin G

200000IU + Dihydrostreptomycine 200mg/ml, 100 ml vial adjusted for stock out is 80000.

These calculations done above can be performed in the format below for all the veterinary medicines. And the rest of the calculations can continue. Summary for Consumption Based Method of Quantification (MS Excel will be used here)

#	Drug & Dosage Form	Strength	Recorded Consumption	Avoidable Wastage (15 to 0%)	Stock in (Months/ days)	Adjusted Consumption G = [D-E] +[D* 12/ F]	# of patients in a year	Average drug Consumption /1000 patients/year I=G/H	Adjusted Quantity	Order pack (unit)	Order pack rounded L= J/ K	Current Order pack price	Total Price N= L* M	Reconciled Quantity (ABC & VEN) O= +/- L	Reconciled value P= M* 0	% of the total by value Q=(P/ P Total)* 100
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I = G/H**	**J**	**K**	**L**	**M**	**N**	**O**	**P**	**Q**
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Morbidity-Based Method: Summary of Steps

Morbidity method uses veterinary standard treatment guidelines (VSTGs), treatment algorithms and projected number of patients/ cases expected to receive treatment or services as shown in Figure 4.

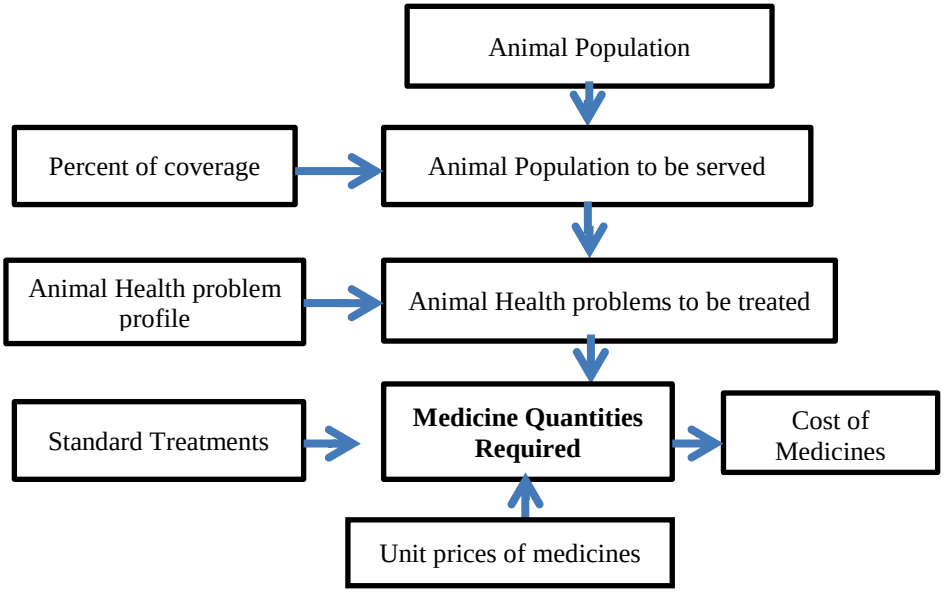

Figure 4. Schematic presentation of the morbidity method of quantification

Step 1: List the specific animal health conditions to be addressed with the forecast

Step 2: Determine the list of veterinary pharmaceuticals to be quantified

Step 3: Collect data on each animal health condition treated

Step 4: Calculate the estimated number of veterinary drug treatment episodes

$$E_T = N_C \times F$$

E_T= Total number of projected veterinary drug treatment episodes for each health condition

N_C = Projected total number of animal health contacts

F = Frequency of occurrence of animal health condition

Note: Services data (number of visits, services provided, treatment) adjusted as needed can be used to calculate E_T

Step 5: Calculate quantities of individual veterinary pharmaceuticals required for each standard treatment episode

$$\mathbf{Q_E = D_{BU} \times N_D \times L_D}$$

Q_E= Quantity of each medicine needed for each treatment episode

D_{BU} = Basic units per dose

N_D= Number of doses per day

L_D= Length of treatment in days

Example: Oxytetracycline 10% injection once daily for 3 days (Dose = 25ml once a day, for 3 days), the quantity of the drug needed for each 250kg cattle per treatment is:

$Q_E = D_{BU} \times N_D \times L_D$

$Q_E = 1 \times 25ml \times 3$

Q_E = 75ml per treatment episode

Step 6. Calculate the quantity of medicine needed for each health problem.

$$\mathbf{Q_T = E_T \times Q_E \times P_T}$$

Q_T = Total quantity of each medicine needed in basic units

E_T = Number of projected treatment episodes for each health condition

Q_E = Quantity of each medicine needed for each treatment episode

P_T = Percentage of cases expected to be treated with that regimen/ product

Example: Of 5,000,000 total cattle patients in a year, 65% are expected to be treated with 2500mg Albendazole 1 bolus dosage per treatment episode.

- The total quantity of 2500mg Albendazole needed per year for these patients is:
  $Q_T = E_T \times Q_E \times P_T$
  $Q_T = 5{,}000{,}000 \times 1 \text{ bolus} \times 65\%$
  $Q_T = 19,\ 500\ 000$ bolus per year
  $Q_T = 325{,}000$ packs of 60 per year

Step 7. Calculate the total projected quantity of requirements for all animal health conditions

- **T_p** = Total quantity of projected requirements for all program areas
- **T_p = Uncomplicated$_p$ + Severe$_p$**
- **Uncomplicated$_p$** = Projected total quantity for uncomplicated helemtheiasis
- **Severe$_p$** = Projected total quantity for Severe Helementhiasis

Step 8. Calculate the projected cost of vet morbidity requirements for the forecast year

Cost of each product $_Y$ = C_Y x unit cost

- Example: For ACT 6x4, what is the projected cost for the forecast year?

Cost of each product $_Y$ = C_Y x unit cost/ pack
Cost of each product $_Y$ = 19500 packs x $1.75/ pack
Cost of each product $_Y$ = $ 34, 125

Summary of Morbidity-Standard Treatment Method of Quantification Step one (MS Excel will be used here)

#	Cause of Morbidity	Average Standard Treatment Schedule: Drug, Dosage, Duration (use more than one line if more than one medicine)	% Rxed of Standard treatment (for 1st line 60%; 2nd 30%; 3rd 10%)	Quantity per Rx for full course	Total # of treatment episodes, in one year (records are counting # of patients rather than episodes)	Total quantity for all episodes F=D*E
	A	**B**	**C**	**D**	**E**	**F**
	African Horse Sickness					
	African Swine Fever					
	Anaplasmosis					
	Anthrax					
	Babesiosis					
	Blackquarter					
	Camel Pox					
	CBPP					
	Contagious Caprine Pleuro-Pneumonia					
	Equine Herpes Virus					
	FMD					
	Fowl Cholera					
	Gumboro					
	Haemo-Septicemia					
	Lumpy Skin Disease					
	Newcastle Disease					
	Pest Des Petits Ruminants					
	Rabies					
	Sheep And Goat Pox					

#	Cause of Morbidity	Average Standard Treatment Schedule: Drug, Dosage, Duration (use more than one line if more than one medicine)	% Rxed of Standard treatment (for 1st line 60%; 2nd 30%; 3rd 10%)	Quantity per Rx for full course	Total # of treatment episodes, in one year (records are counting # of patients rather than episodes)	Total quantity for all episodes F=D* E
	A	**B**	**C**	**D**	**E**	**F**
	Tuberculosis					
	Contageous Echtyma					
	Black leg					
	Malignant catarrhal fever					
	Pasteurellosis					
	Infectious Bursal Disease					
	Infectious Bovine Rhinotracheitis					
	Unknown Camel Disease					
	Camel Pox					
	Fowl Typhoid					
	Equine Herpes Virus					
	Peste des Petit Ruminants					
	Fowl Pox					
	Trypanosomosis					
	Mastitis					
	Internal parasites (need to be detailed)					
	External parasites					
	Pneumonia					
	Urinary tract infection					
	Milk fever					

#	Cause of Morbidity	Average Standard Treatment Schedule: Drug, Dosage, Duration (use more than one line if more than one medicine)	% Rxed of Standard treatment (for 1st line 60%; 2nd 30%; 3rd 10%)	Quantity per Rx for full course	Total # of treatment episodes, in one year (records are counting # of patients rather than episodes)	Total quantity for all episodes F=D* E
	A	**B**	**C**	**D**	**E**	**F**
	Newcastle disease					
	Infectious bursa disease					
	Mareks disease					
	Fowl Pox					
	Salmonellosis-Pullorum Disease					
	Salmonellosis-Fowl Typhoid					
	Fowl Cholera					
	Colibacillosis					
	Mycoplasmosis					
	Coryza					
	Coccidiosis					

Selection of the appropriate Forecasting Method depends on:

- The availability, completeness, and accuracy of data
- New programs vs. mature programs
- Changes in program policies, testing and treatment guidelines and protocols, and product/formulations.

*Whenever possible and data is available, using the combination of consumption and morbidity methods and comparing the results of the forecast is recommended, to minimize forecast error and associated risks.

3.3.3 Supply Planning

Supply planning steps are used to estimate the total veterinary pharmaceuticals requirements and costs for the program. To calculate this estimate the following data and information are required:

- start with the forecasted consumption for each product;
- the existing stock on hand;
- any quantities of product already on order, but not yet received;
- the established maximum and minimum stock levels;
- procurement and supplier lead times;
- a buffer stock for unexpected delays;
- Estimations of wastage (losses caused by expiry, pilferage, damage);
- Shelf life of the products;
- Minimum and maximum stock levels;
- Estimations of safety stock levels;
- Projected unit costs of products;
- Freight, logistics, procurement and other costs;
- Available funds for the quantification period; and
- Estimating storage capacities.

Data for supply planning is different from the data for the forecasting. However, you can collect data for both the forecasting and the supply planning steps at the same time.

Product-related data: specific veterinary product characteristics (formulations, dosages, shelf life, temperature requirements, number of units per pack size, unit cost, and others)

Supplier-related data: supplier prices, supplier packaging, information supplier lead times, current shipping and handling costs by supplier.

Funding: funding sources for procurement of commodities, amount and timing of funding commitments by funder funding disbursement schedule.
Procurement: Procurement lead time for each procurement mechanism.
Distribution: Customs clearance, fees in-country storage and distribution cost (if applicable).
Stock status: Current stock on hand of each product at program level (preferably from physical inventory), program maximum and minimum stock levels, product consumption and expiration dates to assess months of stock on hand for each product
Estimate the Total Commodity Requirements and Costs: involves determining the total quantity for each product by considering the above data and information, multiply by prices, and adding additional costs of the procurement. Reconcile the total cost with the available finance: if there is sufficient finance to cover all the costs then the final forecasted quantity to be procured will be the same. However, if the finance available is not sufficient to procure the total quantity the next step will be to reduce the amount using VEN/L principle.

3.4 Process for Initiating, Reviewing and Updating Quantification

Quantification is an ongoing process of monitoring, reviewing, updating, forecasting data and assumptions. For mature programs, reviewing and updating the quantification every six months is sufficient. For new or expanding programs, more frequent updates are suggested quarterly reviews are recommended so updates can be made as new data become available.

Example: Quarterly Updates and Pipeline Monitoring

What to do?

- Obtain current consumption data for commodities from all levels of the animal health system.
- Update stock on hand for each product.
- Review assumptions and revise them if better information is available.
- Review and update shipment delivery schedules.
- Update amounts and timing of funding commitments.
- Recalculate product requirements and costs over time.
- Estimate and update funding needs and gaps.

Who should do it?

Ideally, the same people who participated in the initial quantification should conduct routine updates.

Where should data come from? The data can come from the reverse process of the supply chain. The following are some of those:

- LMIS from the service delivery level (stock or bin cards).
- Reports submitted by animal health facilities to higher levels.
- Data from partners on products provided to animal health facilities and procurement plans.
- Issues data for products used for animal health facilities from higher levels.
- National, regional, and facility stock-on-hand data for veterinary products used for the program.
- Procurement plans, including orders placed and expected arrival dates of planned shipments of

3.5 Application of Quantification

Quantification applications include

- Calculating estimated order quantities, costs and delivery dates for procurement.
- Planning financial requirements, mobilizing, and securing financial resources.
- Facilitating coordination with donors, procurement agents, health facilities and other stakeholders
- Estimating storage needs.
- Informing manufacturers on future demand of commodities for manufacturing decisions and preparation.
- Assessing rational use of commodities.

4. VETERINARY PHARAMCEUTICALS PROCUREMENT

Procurement is the process of purchasing to obtain the necessary items that can be used to accomplish services. Typically, the word "purchasing" should not be used interchangeably with the word "*procurement*", since procurement includes expediting, supplier quality, and transportation and logistics in addition to purchasing.

Resources are almost always limited. Hence, it is crucial to use the limited resource wisely. It is a good practice to make use of economic analysis methods such as cost-benefit analysis or cost-utility analysis during procurement. Procurement aims at getting the best quality items by the lowest possible cost. Whichever procurement procedures are used, the items must satisfy the quality requirements of customers.

4.1 Make or Buy Analysis

The make-or-buy analysis is the action of deciding between manufacturing an item internally (or in-house) or buying it from an external supplier (also known as outsourcing). The outcome of this analysis should be a decision that maximizes the long-term financial outcome. It might initially appear that a make or buy analysis is a quantitative one that involves a simple comparison of internal production costs to a supplier's quoted price. However, it needs a number of qualitative information and decisions that may override a numerical analysis of production costs. For example, in Ethiopia, most of the veterinary equipment and merchandise are mainly imported and there are often complaints about quality. Hence, the government may decide or encourage the local production of these products to enhance quantity and

quality of products. Also, disinfectants, antiseptics and other working solutions can be manufactured locally.

4.2 Good Veterinary Procurement Practices

Some of the good procurement practices are:

- Order quantities based on reliable estimate of actual need;
- Procure the right veterinary pharmaceuticals in the right quantities at the lowest possible cost;
- Select reliable suppliers of quality products;
- Product quality assurance methods;
- Ensure timely delivery and notification;
- Reliable payment and good financial management;
- Annual audit with published results;
- Transparency and written procedures; and
- Regular reporting on performance

The four pillars of procurement (*quality, cost, speed* and *ethics)* have to be fulfilled during purchasing. In addition, the procurement should be in compliance with basic principles (*integrity, transparency, fair competition, equal treatment* and *best value for money*) and suppliers are required to provide documentation or evidence to support the quality.

4.3 Procurement Methods

Procurement methods are related to the procedures a purchaser uses to select a supplier. In the public sector, procurement methods are often specified by government regulations or by an agreement with an outside funder and applied in accordance with financial thresholds.

It is necessary to know and follow federal and/or regional laws. There are permissions and restrictions on the quantity to purchase and to make international, national or local

biddings. Organizations may set standards in the purchasing process. The procurement methods used by public-sector include:

A. Competitive Bid or Tender

In systems that have adopted principles of good public-sector procurement, bidding documents provide product specifications and performance expectations as well as rules and instructions about how to submit offers and information about in what way a winning bid will be chosen. Submissions are held until a specified closing date, and then opened publicly. Each offer is evaluated on its technical, commercial, contractual, and financial merit, and a winning bid is chosen in accordance with pre-established criteria described in the bidding documents. No negotiation is allowed except with regard to minor contractual points. There are two types of bids: open and restricted.

Open bid: Sealed bids are solicited by means of a widely advertised invitation open to all suppliers that are interested to participate in the competition.

B. Restricted Bid or Tender

Restricted bid: procedures and documentation are similar to open bidding. Restricted bid can be selective or prequalified. Selective: Sealed bids are solicited only from certain suppliers selected by the procuring entity.

Prequalified*:* Sealed bids are solicited only from suppliers selected through a process of prequalification carried out by the procuring entity that examines financial, business, and technical qualifications. Procedures and documentation are similar to open bidding.

C. Request for Quotation (Competitive Negotiation)

Quotations are solicited from a limited number of manufacturers and suppliers. Offers are opened as they arrive, and price and content are considered on a case-by-case basis and may be negotiated. A contract is awarded based on the lowest price and what is considered to be the most advantageous offer.

D. Sole-Source (direct) Procurement

Price and terms are negotiated with one chosen supplier without benefit of competition. Sole-source procurement is an exception and is typically used when an item is available from only one single supplier. Other reasons are: delivery dates or delays resulting from competitive solicitation are not acceptable; an emergency has occurred; or due to user acceptability of an ongoing product usage.

E. Shopping (Performa)

Selection is based on comparison of prices published or otherwise communicated by at least three suppliers. Performa is the quick and simplest ways of purchasing. However, it is the least preferred way in terms of purchasing laws and rules as it doesn't allow the free and fair competition among suppliers. It is inappropriate particularly for high-quantity/high-value purchases.

F. Pooled Procurement

Some regional states in Ethiopia purchase veterinary drugs and items at region level in a pooled procurement system. Pooled procurement has its own merits and demerits. Some of the advantages of pooled procurement are:

- Reducing costs due to bulk purchasing
- Helpful to implement rules, regulations and guidelines in the region

- Important to prepare essential veterinary drugs list for the level
- Improving quality assurance systems
- Improving supplier performance

Some of the disadvantages of the process are

- The need of individual districts or clinics may be overlooked and they may not be satisfied
- There may be storage, inventory control, distribution problems in kind or quantity

Table 2: Characteristics of purchasing practices

Method	**Effect on Price**	**Lead Time**	**Work Load**
Open Tender	Usually lowest prices	Moderate to long	High
Restricted Tender	Favourable	Moderate to long	High
Competitive Negotiation	Can be favourable	Short to moderate	Moderate
Direct Procurement	Usually highest prices	Short to moderate	Low

4.4 Factors affecting price

The factors affecting pricing decisions varied and multiple. The prices of products and services are determined by the interplay of five factors, which are demand and supply conditions, production and associated costs, competition, buyer's bargaining power and the perceived value.

4.5 Procurement cycle

A procurement cycle is the repeating sequence of steps in a procurement process, generally starting at the initial planning phase and ending at possession of the goods, documentation and evaluation of the process. Steps and

timing vary by situation and procurement method. A complete procurement cycle using competitive bidding, may take months, depending on complexity, value, and number of approvals required. Procurement is a cyclic process that involves preparation, tendering biding, purchasing, activities before, during and after purchasing (Fig. 5).

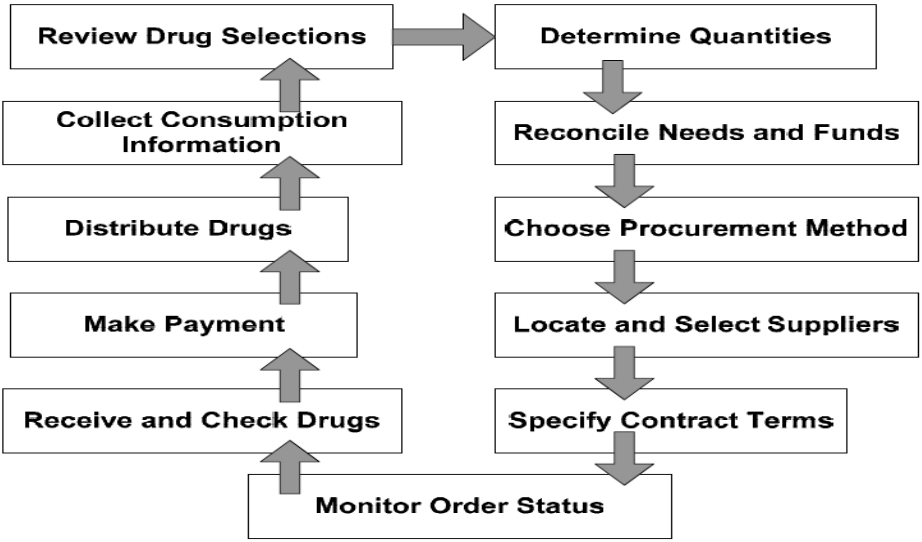

Figure 5: Procurement cycle

Purchasing and Receiving of Items

- Check quality of items whether the items satisfy the specification or not
- Check the preparation whether it is for treatment or laboratory use. For example, activated charcoal can be prepared either for laboratory or treatment purposes
- There should not be any damage or leakage for drugs, chemicals, reagents or equipment

- Check appropriate labelling or the expire date
- For permanent equipment, there should be clear instruction on how to use or repair it (users' manual). Demonstration or testing by the company may be needed.
- Check the quantity of secondary or tertiary containers and compare it with the label.
- Make sure that you receive legally acceptable receipts (VAT payer, TIN number) that match with the bidding document.

Transportation

The purchased items should be transported carefully to avoid damage. It is necessary to follow veterinary items transportation guidelines or regulatory requirements.

- Temperature sensitive items should be transported separately in a condition which is recommended by manufacturer
- Direct sunlight is dangerous for many chemicals; so it should always be avoided
- Moisture may damage some items; hence, items should be protected from rain or any sort of moisture. Liquid and solid items should be separated or the liquid should always be at the bottom.
- Separation may also be needed based on the nature of the items. For example, acaricides or insecticides should be handled separately.

Storage

- Items should be stored appropriately in a well-constructed and ventilated house

- Follow the manufacturer's recommendations for storage. Air conditioning is always needed if the room temperature of the storage area exceeds 30^{o}c.
- Avoid any mechanical damage (for example rodents should not damage drugs or their containers).
- Follow first- in first out (FIFO) and first expire first use (FEFU) principles

Evaluation, Communication and Documentation

These are very important, but usually missed. Evaluation of the overall process of procurement is helpful to acquire experience for improvement. Proper evaluation and documentation are essential to avoid mistakes or errors happening again and again. It is also helpful to identify unethical suppliers and take different level of measures against them based on the evidences and severity of the incident.

An assessment has to be conducted in terms of time taken by the process, voluntariness of companies to deliver particularly in remote places. Hence, alternative methods have to be designed.

4.6 Common Procurement Challenges

- Absence of a comprehensive procurement policy
- Inadequate rules, regulations, and structures
- Insufficient experience and training to respond to market situations
- Government funding that is insufficient and/or released at irregular intervals
- Fragmented veterinary drug procurement at provincial or district level
- Lack of unbiased market information
- Corruption and lack of transparency

5. VETERINARY PHARAMCEUTICAL DISTRIBUTION

5.1 Managing Distribution

5.1.1 Goals of distribution management

The primary distribution management goal is to maintain a steady supply of veterinary pharmaceuticals and supplies to facilities where they are needed while ensuring that resources are used in the most effective way. Distribution costs, including storage and transportation costs, are a significant expense of running an animal health supply system, often second only to personnel costs. Transportation costs alone may exceed the value of the medicines distributed to some locations, especially which cover large geographical areas. Reducing these costs can mean that more money is available for medicine purchases and clinical care.

In planning distribution systems to maximize service while minimizing total cost, it is important not to fall into the trap of improving one part of the system to the detriment of the overall system. Often times, health programs are frequently managed by well-qualified health personnel who lack logistics experience. Warehouse and transport managers, storekeepers, and drivers may possess these skills but may have little influence on decision making. The best way to use their knowledge and skills is to make them part of a logistics team that manages the system design process.
A well-run distribution system should:-

- Maintain a constant supply of veterinary medicines
- Keep veterinary medicines in good condition
- Minimize veterinary medicine losses caused by spoilage and expiry
- Rationalize veterinary pharmaceutical storage points

- Use available transport as efficiently as possible
- Reduce veterinary pharmaceutical theft and fraud
- Provide information for forecasting veterinary pharmaceutical needs
- Incorporate veterinary pharmaceuticals quality assurance program

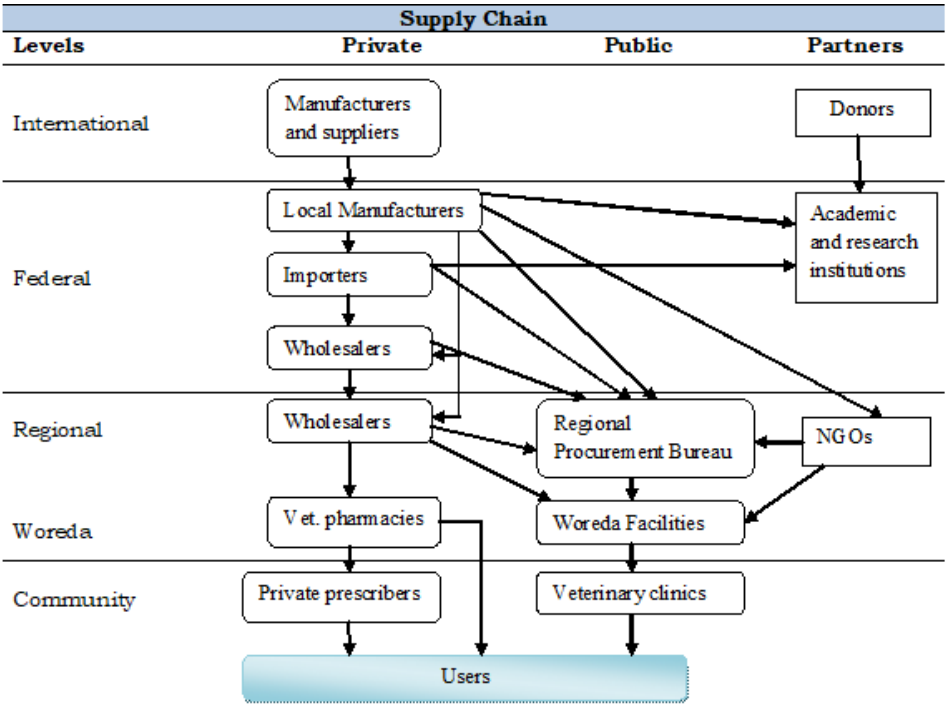

Figure 6: Veterinary drug supply chain

5.1.2. Veterinary Pharmaceuticals Distribution Cycle

The distribution cycle begins when pharmaceuticals are dispatched by the manufacturer or supplier. It ends when

medicine consumption information is reported back to the procurement unit.

The major activities of the distribution cycle include:

Pharmaceutical procurement: The distribution sequence intersects the procurement process at the point which medicines and commodities are available for delivery to the animal health facilities.

Port clearing: Unless the medicines are acquired locally or the international supplier takes responsibility for port clearing, it is the purchaser's first step in making medicines available for distribution. Port clearing involves identifying shipments as soon as they arrive in a port, processing all importation documents, completing any customs requirements, storing medicines properly until they leave the port, surveying the shipment for losses and signs of damage, and collecting the medicines as soon as they have been cleared. Port clearing may be managed directly or through a separate contract with a port-clearing agent.

Receipt and inspection: Central stores staff must carry out a complete inspection of every shipment as soon as it is received from the port or local supplier. The shipment must be kept separate from other stock until this inspection has been completed. Inspectors should check for damaged and missing items and for compliance with the contract conditions concerning type, quantity, presentation, packaging, labeling, and any special requirements. Prompt and accurate inspection of all shipments is essential to ensure that suppliers fulfill their contracts.

Inventory control: Establishing and maintaining effective inventory records and procedures are the basis for coordinating the flow of veterinary pharmaceuticals through the distribution system and the primary protection against theft and corruption. The inventory control system is used for requisitioning and issuing veterinary medicines, for financial accounting, and for preparing the consumption and stock balance reports necessary for procurement. Record keeping must be sufficiently detailed to provide audit that accurately traces the flow of medicines and funds through the system. This audit must be designed to satisfy the requirements of government auditors as well as program managers. An appropriate inventory management system should be adapted to suit the capacity and needs of personnel at all levels in the animal health program. Inventory records must be monitored regularly by supervisors to ensure accuracy and to avoid or detect losses. Careful inventory control is a key to providing a cost-effective and responsive distribution system.
Storage: Storage facilities may range from large mechanized warehouses at the national level to small wooden boxes sitting in animal health centers or carried by animal health professionals. Proper location, construction, organization, and maintenance of storage facilities help to maintain veterinary medicines quality, minimize theft and loss through damage, and maintain regular supply to animal health facilities.

Requisition of supplies: veterinary pharmaceutical supply systems may operate under a push or a pull system. The forms and procedures for requisition are a key part of the inventory control system. The requisition system may be manual or computerized or a combination of both, but it should always be designed to simplify distribution by

facilitating inventory control, providing an audit for tracing the flow of veterinary medicines, assisting in financial accounting, and listing medicines issued.

Delivery: veterinary medicines may be delivered by warehouse staff or collected by animal health facility staff. Transport may involve air, water, railway, or on- and off-road vehicles, porters, or a combination of means. Cost-effective choices between public- and private sector carriers need to be made. Transport managers should select methods of transportation carefully and schedule deliveries realistically and systematically to provide punctual and economic service. Vehicle breakdowns; availability of fuel, lubricants, and spare parts; seasonal variations in access routes; safety along specific supply lines; the availability of private-sector services; and other local factors must all be considered in transport planning.

Dispensing to patients: The distribution process achieves its purpose when veterinary medicines reach the veterinary clinics, properly prescribed, dispensed with adequate information and administered at the right dose and route to the animal patient.

Consumption reporting: Reporting is the link in the distribution cycle is the flow of information on consumption (which takes into account actual demand—that is, what would have been consumed if not stocked out) and stock balances back through the distribution system, to the procurement Office, for use in quantifying procurement needs. When adequate inventory and requisition records are kept, compiling consumption reports is straightforward.

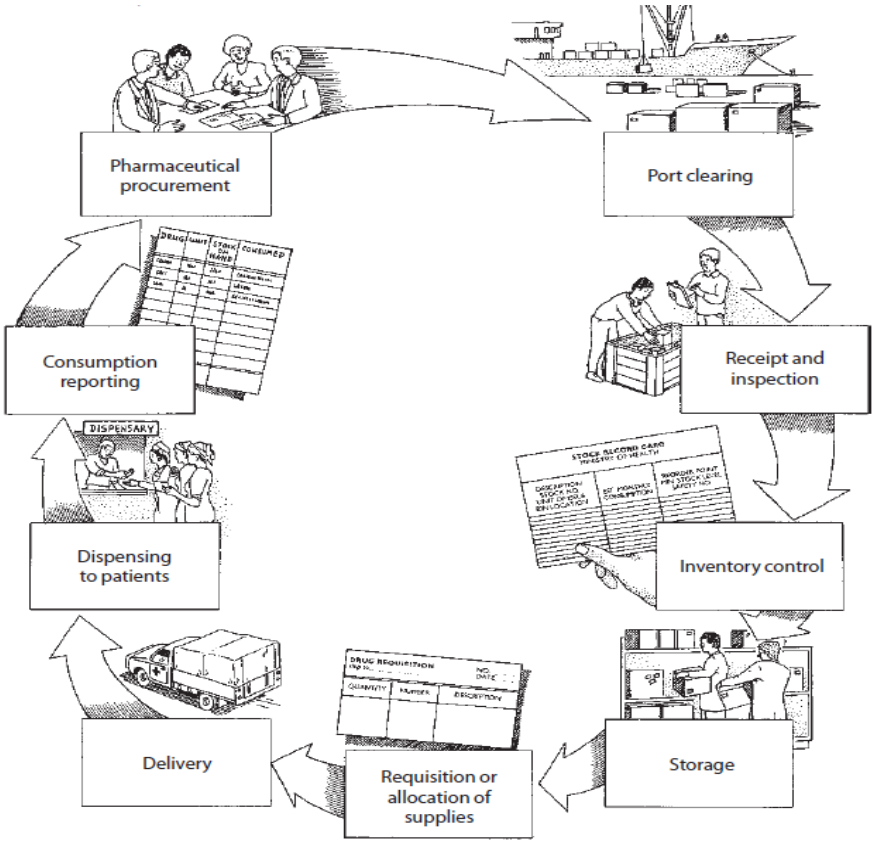

Figure 7: The distribution cycle

5.1.3. Distribution Network

A veterinary pharmaceutical distribution system may require several layers of stores, each with distinct functions. In a typical three-level distribution system, purchases from a supplier are received *central or federal stores,* which generally serve a whole country or region and may or may not supply animal health facilities directly. The physical size of the primary central stores is determined by national or

regional demand for medicines and by the supply frequency. In some cases, this level can be eliminated, with direct delivery from suppliers to regional stores. The size of the regional stores is determined by the demand for veterinary medicines and number of animal health facilities to be served and the frequency of supply by the central stores. Regional stores distribute veterinary medicines to individual animal health facility stores. The number and level of stores from suppliers to health facilities can vary or change to decrease the opportunity for losses, and enhances control. Additional factors to consider in determining the number of storage levels are: geography, livestock population, availability of storage space, staff, availability and cost of transport, political and other resource constraints

Push and pull systems

Distribution schemes can be defined by which levels of the system order veterinary medicines and which, passively receive the medicines. The two basic alternatives are:

- **Pull system:** Each level of the system determines what types and quantities of medicines are needed and places orders for supply. This type of system is sometimes called an independent demand or a requisition system. When using a pull system, managers of operational units are expected to estimate their own demand and submit requisitions to central stores indicating their requirements. Pull systems are preferred whenever the capacity exists to manage them effectively.
- **Push system:** Supply sources at some level in the system determine what types and quantities of medicines will be delivered to lower levels. A delivery plan is made at the beginning of a planning period, usually a year, and supplies are delivered according to the plan. This type of

system is also known as an allocation or a ration system. In a push system, operational units are expected to supply certain stock and consumption information to the supply source so that issuing officers can plan allocations. A push system on the other hand, can be useful in certain situations, such as for disaster relief and when the supply pipeline does not function at all levels of the system.

Conditions favoring a pull system

- Lower-level staff members are competent in assessing needs and managing inventory.
- Sufficient supplies are available at supply sources to meet all program needs.
- A large range of products is being handled.
- Field staff members are regularly supervised, and performance is monitored.
- Good data are available to decision makers.

Conditions favoring a push system

- Lower-level staff members are not competent in inventory control.
- Demand greatly exceeds supply, making rationing necessary.
- A limited number of products is being handled.
- Disaster relief is needed, or the situation calls for short-term supply through prepacked kits

5.1.4. Resupply Interval

The re-supply interval determines whether deliveries are made to user units quarterly, monthly, weekly, or at any other time. If deliveries are made weekly, average stock levels will be low and the likelihood of stock outs will decrease, but transport costs will be very high. If deliveries

are made only once a year, transport costs will be low, but the average stocks and storage costs will be high. The optimum resupply interval should be worked out to suit individual program needs. Most public programs use intervals of one to three months. The following are helpful factors to consider before making a decision—

- Storage capacity at each level of the system
- Availability, order size, carrying capacity, and cost of transport
- Seasonal factors that influence transport reliability
- Staffing levels and competence of staff at each level of the system
- Other factors, such as expiration dates, security against pilferage, cash flow, and other locally relevant concerns

5.2 Inventory Management

Inventory management is key in veterinary pharmaceutical supply system. Without a healthy inventory management system, the veterinary pharmaceutical supply system as a whole will not be viable. Inventory management for veterinary pharmaceutical supply sounds easy where all that must be done is to order, receive, store, issue, and then reorder a limited list of items. In reality, the task is difficult, veterinary pharmaceutical supply system leads to waste of financial resources, shortages of medicines resulting in services interruption or overstocks of veterinary medicines resulting in expiration. .

Seven basic issues must be considered for effective and efficient inventory management.

1. The inventory's purpose and the type of distribution system

2. The records and reports that will provide the foundation for inventory management
3. The selection of items to be stocked
4. The balance between service levels, including stock out costs, ordering costs, and stock-holding costs
5. The frequency and when to order
6. The policy on how much to order and methods for determining reorder quantities or reorder interval
7. The control of costs associated with inventory management (ordering, stock out, and stock holding costs)

Accurate and current stock records are essential for good inventory management. They are the source of information used to calculate needs, and inaccurate records produce inaccurate needs estimations (and problems with stock outs and expiry). Each inventory system should monitor performance with indicators and produce regular reports on inventory and order status, operating costs, and consumption patterns. The primary reason for holding stock in a veterinary pharmaceutical supply system is to ensure availability of essential items almost all the time. The selection of items to stock should be based on their value to animal health and on the regularity and volume of consumption. The VEN/L (vital, essential, and none- or less-essential) and ABC value analyses are useful tools for defining which veterinary pharmaceuticals must be held in stock. Although ABC value analyses are often based on the value of the medicines, for inventory management, ABC analyses based on order frequency and volume are also important.

Key issues in inventory management are service level and safety stocks. The service level is the measurement of service from a warehouse with the goal of never having

stock outs. The principal determinant of service level is safety stock, the higher the level of safety stock in the warehouse, the higher the service level. However, excessive safety stocks cause excessive inventory-holding costs which may also lead expiry. The basic method for setting safety stock is multiplying the lead time by the average monthly consumption, but adjustments may be needed to cope with variations in consumption and lead-time patterns. The other key determinant is the turnaround time with the supplier or the warehouse, that is, the time taken to fill and deliver an order once it is received by the supplier or the warehouse. The ideal inventory model is the optimal stock movement pattern, in which inventory levels are as low as possible (without risking stock outs) and optimized, consumption patterns are consistent, and suppliers always deliver on time, but this model is rarely achieved in practice. The three common inventory models used in pharmaceutical supply systems are defined by how often regular orders are placed with suppliers:-

1. Annual purchasing (one regular order per year)
2. Scheduled purchasing (periodic orders at set times during the year)
3. Perpetual purchasing (orders are placed whenever stock becomes low, or when stock levels reach predetermined reorder levels)

Average inventory levels (and holding costs) are expected to decrease with more frequent orders. The basic formulas for calculating order quantity are relatively simple; two useful formulae are minimum- maximum and consumption based. Both incorporate several essential factors:-

- Average monthly consumption
- Supplier/warehouse lead time
- Safety stock

- Stock on order
- Stock in inventory
- Stock back-ordered to lower levels

The formula used for order quantity should be adjusted to take into account factors such as seasonal demand, expiry dates, expected changes in use or prices, currency fluctuation, and availability of storage space.

Key ways of minimizing total costs include:

- Lowering order processing, purchase, or delivery costs through efficient procurement
- Lowering stock-holding costs through good storekeeping practices
- Controlling stock levels and minimizing stock outs by using effective inventory control techniques
- Minimizing financial costs through use of attractive financing methods

Primary considerations in promoting efficiency are the costs of purchasing and holding stock in inventory. A regular and accurate stock count and standard methods for valuing the inventory are needed to determine the base inventory value. Other relevant costs are the operating costs associated with procurement and withholding inventory. The objective of good inventory management is to maintain a steady supply to operating units (and patients) while minimizing the costs of holding inventory and managing procurement. Compiling information on the total costs of inventory management (pharmaceutical acquisition costs, inventory-holding costs, purchasing operations costs, and shortage costs) allows managers to evaluate strategies for reducing costs.

5.3 Transport Management

Unreliable transport for veterinary pharmaceutical supplies is a major problem in many animal health care programs.

Good transport practice demands reliability, efficiency, safety, accountability, timeliness, affordability, and sustainability. Policy makers and administrators need to appreciate that effective and responsive animal health service depends on always having veterinary medicines available when and where they are needed.

Transport can be provided for veterinary pharmaceuticals and related supplies either by the center/region or facility, by the supplier, or by an outsourced transport service. The type, volume, frequency, and duration of transport services required are determined by the nature of the animal health service. For practical purposes, the main stores or central stores require major transport when moving veterinary pharmaceuticals from port to warehouse and then to facility. If the store has branches in different parts of the country, it will need to transport the supplies to the branches.

When planning transport system improvements, managers must:

- Thoroughly review and understand the existing transport system
- Select suitable vehicles
- Ensure adherence to standard operating procedures
- Ensure that vehicles are used for their intended purpose
- Maintain vehicles properly
- Replace vehicles before they wear out or become too expensive to operate
- Provide funds for vehicle maintenance and replacement
- Consider the formation of a vehicle pool system

- Consider alternatives, such as third-party and private-sector contracts

Effective quality assurance procedures are needed to ensure that pharmaceuticals are correctly handled before, during, and after transit, to avoid damage.

5.3.1. Select Appropriate Vehicles

Vehicle type, fuel, spare parts, temperature control, and need for refrigeration are critical issues for selection. Determining the size and mix of the transport fleet must be done based primarily on the weight of the shipments that the fleet must carry for each established route, as well as the basic characteristics of those routes, including the number of days needed to complete a route and any restrictions, such as the working hours at animal health facilities.

Vehicle type: Choose vehicles that are simple in design, robust, easy to maintain, available spare parts, and suited to local road conditions. Choose vehicles that have interchangeable components, particularly items such as tires, batteries, engines, and transmissions.
Fuel: Diesel-powered vehicles are usually more cost effective than gasoline-powered vehicles. They are more expensive to buy and maintain, but they are more fuel-efficient and may be more reliable and longer lasting.

Accessories and spare parts: Every vehicle should carry a tool kit, first-aid kit, fire extinguisher, and spare tires.

Temperature control: Choose vehicles painted white to reduce internal temperatures during hot weather. They may also need to be fitted with ventilator units. Most veterinary

pharmaceuticals should not be stored for prolonged periods at temperatures above 30°C. Even in temperate climates, this temperature can exceeded when a vehicle parked in the sun. Some medicines, vaccines, and blood products may be damaged by exposure to temperatures even below 30°C. These items transported in cold boxes or refrigerated vehicles. In very cold climates, blood products and some pharmaceuticals and vaccines need protection against freezing during transport. Goods compartments may need to be heated; alternatively, products can be transported for limited distances using vaccine cold boxes fitted with "warm packs."

Refrigerated vehicles: Refrigerated vehicles are more difficult to maintain than conventional vehicles and should be used only in countries with a good maintenance infrastructure. Rather, it may be best to choose vehicles that have independent body units. The refrigerated body lasts longer than the vehicle to which it is attached and may be transferred to a new chassis. Refrigeration units that can be powered by an independent engine will continue to operate even if the vehicle itself breaks down. All units should have electrical backup power units for use during overnight stops, and suitable power outlets should be provided at the stopping points. When refrigerated vehicles break down, the shipment can be exposed to unacceptable temperatures within a few hours. It is important to ensure that adequate contingency plans (such as extra cold boxes) exist for this hazard.

Ensure vehicle security: Vehicles are stolen for resale or for spare parts, and pharmaceuticals may be stolen in transit. Precautions to take include—

- Employing security guards.

- Planning delivery routes so that vehicles can be securely parked during overnight stops.
- Never to leave vehicles unattended during transit.
- Avoiding driving at night. Security problems are often worse after dark.
- Installing burglar alarms, immobilization devices, or both. Fit security dead bolts on cab doors and goods compartments. Where security is extremely difficult, it may be necessary to fit grilles around the cab interior.
- Buying vehicles with sleeping compartments for drivers if long delivery trips are required.
- Vehicle is fitted with a fire extinguisher.
- Tools and spare parts should be carried so that the driver can make simple repairs without having to leave the vehicle unattended.
- Installing a mobile communication radio for communication with the base.

5.3.2. Maintaining Veterinary Pharmaceutical Quality

Transport managers are responsible for ensuring that veterinary pharmaceuticals are not damaged during transit.

- The pharmaceutical manufacturer's original outer packing should withstand normal handling preferred palletized handling exists throughout the system. At the intermediate stores, this outer packing often must be removed to allow the assembly of small consignments; these must be repacked for transport in strong cartons or reusable crates. Empty spaces in partly filled cartons or crates should be filled with newspaper, straw, wood shavings, or other loose material to stop the contents from rattling about and prevent cartons from being crushed.

- If mechanical handling equipment is available, loads may then be assembled onto pallets. Pallets, cartons, or crates should be carefully and systematically loaded into vehicles on a first-in/last-out basis. They must then be held secure by straps, nets, or other means.
- The vibration caused by travel over rough roads can damage tablets and other breakable products; long journeys over rough roads should be avoided whenever possible.
- Delivery journeys in very hot or cold weather may damage temperature-sensitive products. Appropriate precautions must be taken, as discussed earlier in this chapter.
- Water damage during heavy rain can be avoided by ensuring that pharmaceuticals are unloaded directly into a building and not left standing outside. Make sure that vehicles have the necessary materials to protect loads from direct sun, dust, rain, and pilferage. Canvas covers and straps are as essential as spare tires and need to be carried at all times.

5.4 Storage of Veterinary Pharmaceuticals

5.4.1 Premises

A veterinary pharmaceuticals premises must be a permanent building or part of a permanent building, be clean, well maintained and vermin proof. Premises where medicines are held should be capable of being secured to deter intruders. Controlled drugs and injection equipment are attractive not only to drug mis-users but also to criminals.

Areas of the practice used for the storage or supply of medicines must not be residential, and public access should be denied or controlled to areas medicines are held (they should be 'staff only areas'). There should be no smoking, no food consumption or storage of food in areas where medicines are stored or supplied, with notices in place informing staff and clients accordingly. Particular attention should be taken with fridges; the storage of medicines alongside food or laboratory samples must be avoided.

5.4.2 The Dispensary

Take care to ensure the safe storage of all medicinal products. Medicines must be stored in accordance with the manufacturer's summary of product characteristics (SPC) or datasheet.

- Medicines should be protected from environmental conditions that may damage or degrade them such as light, temperature and humidity.
- Storing products in their original packaging will give the best protection against environmental damage.
- The dispensary should also be fitted with blinds on any windows to protect against bright light, and light sensitive products should be kept in their outer packaging.
- Ventilation must be adequate, and hot water sterilizers and autoclaves should not be used in the dispensary because they may adversely affect the humidity of the room.
- To avoid contamination, medicines should not be stored in toilet or washing areas, or laboratories.
- Flammable products must be stored in an appropriate flammables cabinet specifically designed for this purpose, preferably on the floor to prevent breakages.

- Shelving should be of sturdy construction and well designed to reduce the possibility of breakage and spillage. It should be designed in such a way to ensure medicines are easy to locate with areas suitable for small and bulk storage.

5.4.3 Temperature Monitoring

Ensure that medicines are stored at the correct temperature in accordance with the SPC.

- Products to be stored at ambient room temperature do not require refrigeration and should be kept between 8°C and 25°C. Storage of products at ambient temperatures should be monitored if the temperature is outside this range or remains unusually high or low for any significant period of time.
- Products that require refrigeration such as vaccines, antisera and some reconstituted antibiotics must be stored in a fridge between 2°C and 8°C. These products should be removed from the delivery cool chain as soon as possible and stored in a fridge. They should only be removed from the refrigerator for immediate use. Care should be taken to ensure the refrigerator maintains a temperature between 2°C and 8°C.

Temperatures should be monitored at least daily, and this should ideally be the responsibility of the storekeeper. Maximum/minimum thermometers and a registration logbook can be used for this purpose. The use of continuous data loggers to monitor the temperature can be convenient, but these should only be used if an audible alarm alerts the user to temperatures deviating from the required range.

Monthly or quarterly downloading of the temperatures into graph format is useful to determine trends in temperature fluctuations, but notice of temperatures outside the required range comes too late to prevent the product being used if an audible alarm is not present. Generally, data loggers should be downloaded at least weekly.

A written plan should be in place detailing the actions to be taken if temperatures in the dispensary or refrigerator fluctuate outside the recommended temperatures. For example, this may include the direction to dispose if the temperature drops below 2°C or that further information should be sought from the medicine manufacturer if the temperature of the fridge was maintained above 8°C for longer than a few minutes. Regular cleaning, servicing and stock control in refrigerators should be performed as for other storage areas. Practice cars should be fitted with refrigeration units and monitored in the same way as the practice fridge.

5.4.4 Stock Control

Efficient stock control allows you to have the right product in the right place at the right time. It ensures that capital is not tied up unnecessarily and protects against problems arising in the supply chain. It is good practice to:

- Set stock levels to allow accurate stock holding
- The store keeper is responsible for stock control
- Store products in original packaging, in a logical order
- Supply a product leaflet or SPC with all products dispensed

- Dispense products with the shortest expiry date first
- Store products with different batch numbers together.

Dates of deliveries and items delivered from manufacturers or wholesalers should be recorded unless this information is on the retained invoice or delivery note. Packs with damaged or defaced packaging and out-of-date stock should be stored separately while awaiting disposal. Once stock has been dispensed and taken from the premises, it should not be accepted back into the dispensary unless correct storage during this time can be guaranteed. The batch number of products dispensed for administration to food-producing animals should be recorded on the case file for batch tracking purposes.

5.4.5 Stocking Levels

In order to perform stock control effectively, stock order levels (maximum and minimum) must be set for every product. This could be done using a bin-cards placed on the products at the correct place, a sticker on the shelf or a fully automated system. Any system will require information such as product description, order up to level (OUTL), reorder point (ROP), supplier, item code etc.

The amount of stock to be kept can be calculated using this basic equation: **OUTL = D x L** (D = daily demand; L = lead time).

In practice, however, average daily demand is very difficult to calculate accurately and does not take weekends, public holidays or periods of exceptional use into account. It may

be better to work on a principle of two or even four weeks' cover so the average daily demand becomes the average demand for two or four weeks. This will allow sufficient stock to cover for any emergencies. It may be wise to keep four weeks' cover of any medicines used in emergencies but only two weeks of routine products where the consequences of not having in stock are not so high. If the item is seasonal, extra consideration needed to set an OUTL, which may be different for specific seasons.

Repeat orders can be a cost-effective way of ordering stock for frequently used products. Products subject to intermittent use will not fit into the calculation of OUTL. For example, some emergency medicines used infrequently but when required, large volumes may be used. This needs to be factored in when OUTLs are set. Stock control is an ongoing process. Stock levels should be altered as new products are brought to the market or preferences change.

5.4.6 Stock Rotation

Products with the shortest expiry should be dispensed first to reduce the number of products going out of date. This can be achieved by ensuring that all new stock from deliveries is placed at the bottom or back of current stock, but it is useful to double check that the expiry dates of the newly delivered stock are longer than current stock, particularly if orders are placed with different companies.

5.4.7 Stock Loss and Annual Stock Take

There are a number of reasons for stock loss within a veterinary practice. These include:

- Products going out of date

- Broken or damaged stock
- Items mistakenly not charged
- Theft
- Items charged for by wholesalers but not received
- Wholesaler credit for goods returned or missing not received
- Consumable wastage.

Products going out of date means money lost to the practice. Setting appropriate ROPs and OUTLs will reduce stockholding and lead to fewer products going out of date. Monthly date checking should be performed to ensure products are used before they expire.

There is always the need to perform an annual stock take where incoming and outgoing veterinary pharmaceuticals are reconciled. Any missing items must be accounted for.

- Out-of-date products are considered 'stock' until they are removed from the stock file or they will be assumed to be missing.
- Broken or damaged stock should be recorded for stocktaking purposes.
- To prevent the theft of medicines, ensure clients do not have access to medicine cupboards when left alone in the consulting room. Regular stock takes of vulnerable items should be performed to check for discrepancies.
- Medicines received from wholesalers should always be checked against delivery notes and any missing or damaged goods claimed for at the time of receipt. Once a claim has been made, ensure the credit is received by reconciling credit notes against returns books.

- This can help identify where medicines are being wasted and also help with reconciling stock during audits.

5.4.8 Medicine Returns

Because correct storage conditions (and therefore safety and effectiveness) of medicines returned by owners cannot be guaranteed, such products should be disposed of and not accepted back into stock unless the guarantee that the product has been stored according to its SPC.

Products dispensed for animals on the premises that have not left the practice can be accepted back into stock provided the storage conditions are known to be acceptable and they are not contaminated in any way (e.g. by using the same syringe to withdraw multiple oral doses from a bottle of liquid medicine). Unwanted or mistakenly ordered medicines should be returned to wholesalers as soon as possible.

5.4.9 Expiry Dates and In-Use Shelf Life

It is illegal to supply or administer a medicine after the expiry date detailed on the pack or to obscure the expiry date on the packaging of any medicine. Requirements in national legislation to ensure the stability and safety of the product mean that some products such as injectable have an in-use shelf life. In-use shelf life is the length of time after which the product must be disposed of upon opening. For most multi-dose injectable, the in-use shelf life is 28 days, thus making it an offence to administer the product after 28 days of opening (unless the original expiry date is shorter).

Multi-dose vials should be marked with the date of first opening and the date of expiry. Bright stickers can be useful to draw attention, but all multi-dose vials with an in-use shelf life now have a space to write this information. Any medicine left in the vial after the specified time must be discarded. For single-use ampoules, the required dose should be withdrawn immediately and the remainder disposed of. Oral liquids should generally be disposed of six months after opening. Care should also be taken with some medicines that are sensitive to humidity as these may have an in-use shelf life stated on the SPC. Short-dated stock should be marked as such and brought to the front of the shelf to be used first. Any stock that has gone out of date should be separated and recorded before destruction.

5.4.10 Dispensary Management

One person should be responsible for ensuring the legal requirements, safety assessments and best practice procedures. This person should be responsible for ensuring:

- The layout of the dispensary is efficient and appropriate shelving is used
- The dispensary is always clean and tidy
- Date checking is performed and recorded regularly
- Staff are suitably trained
- Standard operating procedures (SOPs) are written and implemented
- Stock control is efficient to reduce stock loss
- Storage conditions (particularly temperature) are monitored in the dispensary.

- Dispensary manual containing SOPs and forms should be available and read by all involved in the dispensary.
- Staff should be trained to prevent contamination of the medicine and the staff itself, personal cleanliness, hand washing and cover open wounds at all times, how to avoid direct contact with medicines, use of tablet-counting triangle and spatula.

6. USE OF VETERINARY PHARMACEUTICALS

Veterinary pharmaceuticals are applied or administered to the animals by veterinary professionals or sometimes, the owner or the attendant him/herself. The medicine should be used to achieve a well-defined target or objectives of treatment i.e. should not be used randomly. The medicines should have appropriate quality, desirable action, a few or no side effects, and completely removed from the body of an animal when it is no longer needed. Complete removal helps to avoid unacceptable drug residues in animal products. The medicines used should improve animals' health, and be safe for consumers and the environment as well as legally registered by the regulatory authority.

6.1 Rational Use of Veterinary Medicines

The rational use of medicines requires that the animal patient receives appropriate medicines to their clinical needs, in doses that meet the individual requirements for an adequate period of time, and at the lowest cost to the owner and the society. Rational use of medicines should meet the following criteria:

- *Appropriate indication*: The decision to give the medicine(s) based on medical rationale and that therapy is an effective and safe treatment for the right diagnosis.
- *Appropriate medicine*: The selection of drugs based on safety, efficacy, suitability and cost considerations.
- *Appropriate dosage, administration and time of treatment.*
- *Appropriate animal patient:* No contra-indications exist and the likelihood of adverse reactions is minimal, and the drug is acceptable to the owner.

- *Correct dispensing*: appropriate information for owners about the prescribed drug and animal condition in an appropriate packaging that maintains its stability.
- *Adherence of animal patient to treatment*

6.2 Factors Influencing Rational Medicines Use

There are several factors that affect the rational use of medicines. However, the most important factors are:

- Lack of up to date and unbiased information or awareness on consequences of irrational medicines use.
- Inadequate training and education on proper diagnosis and pharmacology of the medicines.
- Poor communication between clinician and animal owner: Treatments or instructions that do not consider the owners' belief, environment, or culture.
- Lack of diagnostic facilities
- Demand from the owner*:* to satisfy the owner expectations and demand of quick relief, veterinarians prescribe medicines for every single complaint.
- Defective pharmaceutical supply system and ineffective drug regulation
- Inappropriate promotional activities of pharmaceutical companies
- Unethical practices by animal health professionals

6.3 Interventions in Promoting the Rational Use of Drugs

Even through drugs are playing a key role in prevention and control of several diseases, many of them are not absolutely safe: they may damage vital organs like kidney, liver, heart and lungs. The use of antimicrobials promotes the development of antimicrobial resistance (AMR). Therefore, care should be taken while applying or administering drugs

on/in animals. Steps to solve problems related to drug use include:

Step 1: Identify drug use problems: first it needs to describe common drug use practices and assess to what extent these are rational, and to describe what people in the communities and animal health workers consider to be drug use problems. It is possible to use existing secondary data, and if resources are available new data on drug use by consumers can also be collected.
Step 2: Prioritize drug use problems: The overview of problems identified in step 1 forms the basis to prioritize and select as the focus of the intervention.

Step 3: Analyse drug use problems and identify possible solutions: it is necessary to analyse the factors that contribute to and cause to the identified problem and propose possible solutions. In conducting such analyses, you may need to consider the various layers of influences: the family, the community, the health institution, the state, and the global environment. Such analysis helps to develop an appropriate intervention aimed at changing the inappropriate use practices. The analyses are done in consultation with key stakeholders. They also help to identify possible solutions.

Step 4: Select and develop interventions: to change individual behaviours at the identified targets.

Step 5: Pre-test interventions: Pretesting involves trying out the intervention in a small group of the target audience. The target's feedback and the results are used to fine tune further intervention, evaluation and monitoring activities.

Step 6: Implement interventions: Pretesting can lead to changes in the way the selected intervention is implemented. Once the intervention has been optimized, it can be implemented.

Step 7: Monitor and evaluate interventions: monitoring and serve to improve an intervention, and help in sharing successes and failures with others.

6.4 Irrational Use of Veterinary Medicines

Irrational medicines use includes:

- Use of drugs when no drug therapy is indicated (e.g., antibiotics for viral infections)
- Use of more medicines than are clinically necessary
- Use of the wrong medicine for a correct indication or vice versa
- Use of medicine with doubtful or unproven efficacy
- Use of correct medicine with incorrect route of administration, dosages, and duration
- Failure to prescribe and dispense in accordance with standard treatment clinical guidelines
- Inappropriate medication by owners.

6.4.1 Magnitude of Irrational Use of Medicines

Although information on prescribing and dispensing of veterinary medicines is scanty, more than 50% of human medicines are prescribed, dispensed or sold inappropriately, and another 50% of human patients fail to take them correctly. The problem is expected to be so severe in veterinary medicine, hence the need to study these in detail to have meaning interventions.

6.4.2 Impacts of Irrational Use of Medicines

Irrational use of medicines leads to:

a) Emergence of resistant organisms, thereby rendering treatment ineffective. These will exacerbate or prolong illness leading to increased morbidity and mortality. AMR leads to search for alternative antimicrobials, which may be more toxic and higher in price. Massive quantities of antimicrobials are used in animals for therapeutic and non-therapeutic purposes and are excreted mostly unchanged to the environment thus increasing the selection of the antimicrobial resistant micro-organisms that can spread from animals and the environment to humans and vice versa.
b) Increase risk of unwanted effects such as adverse drug reaction
c) Masking or confusing or delaying of the correct diagnosis
d) Wastage of resources
e) Increase cost of treatment
f) False sense of security (owners)
g) Loss of faith or confidence on the profession
h) Public health hazard

6.4.3 Measures to Improve Irrational Medicines Use

The irrational use of medicines can be improved through proper diagnosis and selection of the right medicine which is safe, effective, and convenient to administer, and cost effective to the owner and the society at large. These can be carried out by accurate and complete prescription and dispensing of the medicines. Informing owners on the side effects, adverse drug reactions, dosage schedule and risk of withdrawing the therapy are also essential. These can be facilitated through:

- Use of standard treatment guidelines (STG)

- Implement problem-based and evidenced-based training in clinical pharmacotherapy in undergraduate and post graduate medical and paramedical education and training and based on national STGs
- Train pharmacists and drug sellers to be active members of the healthcare team and to offer useful advice to consumers about the rational use of veterinary medicines
- Engage consumers in the rational use of veterinary medicines educations
- Develop a strategic approach to improve prescribing in the private sector through appropriate regulation and long - term collaborations with professional associations
- Establish systems or indicators to monitor rational use

6.5 Processes of Veterinary Pharmaceutical Prescribing Practices

6.5.1 Principles of Rational Prescribing

Good Prescribing Practice (GPP) is prescribing the right veterinary medicines for the right animal patient, in the right dosage of the right formulation and for the right length of time. The GPP also includes not prescribing any veterinary medicines at all if not needed. It requires detailed knowledge of the patho-physiology of the diseases and clinical pharmacology of the veterinary medicines.

The use of International Non Proprietary Names (INN) or generic names of veterinary medicines in prescribing is an essential component of good prescribing practice. This is because generic veterinary medicines are less costly, and for a generic prescription, any suitable product can be

dispensed hence avoiding delay while looking for a specific brand.

6.5.2 Prescription process

There are six major steps to be followed in the prescribing process.

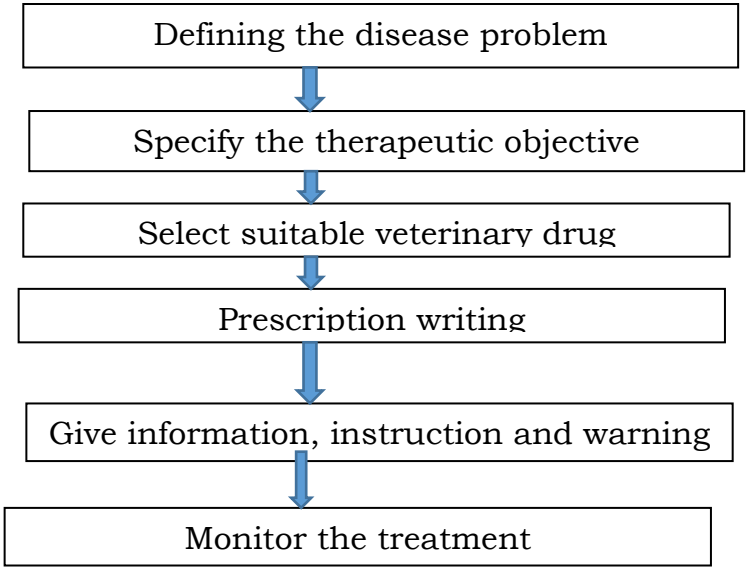

Figure 8: major steps in prescription process

6.6 Process of Veterinary Pharmaceuticals Dispensing Practices

6.6.1 Principles of Good Dispensing Practices

Dispensing practice plays a central role in the provision of rational veterinary medicines. The dispensing of veterinary medicines refers to the process of preparing veterinary medicines and distributing to users with provision of appropriate information, counselling and follow up. It may

be based on a prescription or an oral request of the owner, depending on the type of veterinary medicines to be dispensed.

Good dispensing practices ensure that the correct veterinary medicine is delivered to the right animal patient owner, in the required dosage and quantities, with clear advice and information on the application and/or administration. Dispensing veterinary medicines includes all the activities that occur between the time the prescription or oral request of the owner is presented and the veterinary medicines with appropriate packaging and information are issued to them. This process may take place in the animal health institutions and/or community veterinary pharmacy retail outlets. No matter where dispensing takes place or who does it, any error or failure in the dispensing process can seriously affect the care of the animal patient in medical, economical, and public health consequences. Therefore, the dispenser plays a crucial role in the therapeutic process and in minimizing the hazards.

The quality of dispensing may be determined by the training and supervision in which the dispenser has received and the veterinary medicines information available to the dispenser. Veterinary pharmaceutical dispensers must have knowledge about the veterinary medicines being dispensed. They should have knowledge on the indications and use; correct one time dose frequency and duration; precautions about the method of use; common side effects; common interaction with other medicines or feed; storage requirement; good calculation and arithmetic skills; the ability to explain information clearly by the language the owner can understand and check whether the information is being understood.

6.6.2 Dispensing procedures

The development and use of written standard operating procedures for dispensing process will improve consistency and quality of health care. The framework for such SOP may be based on the five major steps to be performed in the dispensing cycle during the dispensing process.

There are five major steps to be followed in the dispensing process.

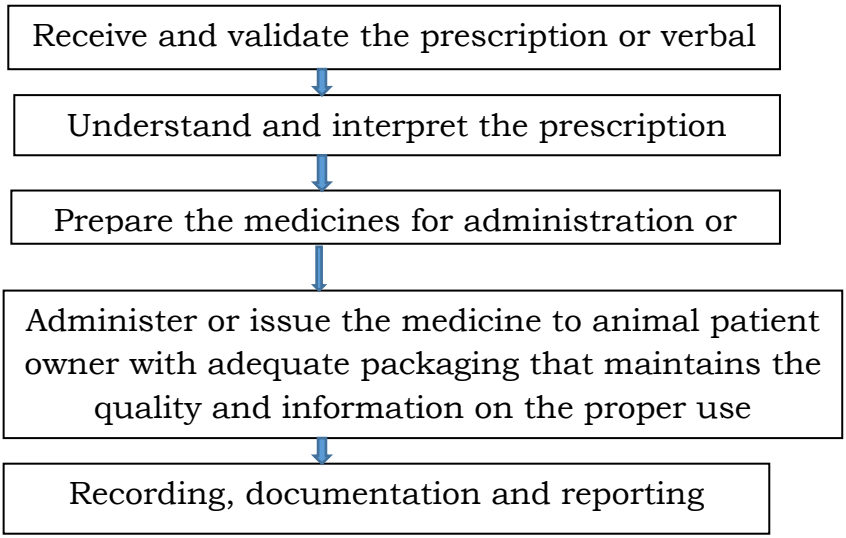

Figure 9: Steps of dispensing practice

6.7 Pharmacovigilance

Pharmacovigilance of veterinary drugs can be defined as the detection and investigation of the effects of the use of these products, mainly aimed at safety and efficacy in animals and safety in people exposed to the products. It is important to guarantee the continued safety and efficacy of veterinary drugs in use thus help to increase public and animal health. It is important to detect the nature and frequency of

adverse drug events (ADEs) including periodic re-evaluation of the benefit-risk ratio of drugs in order to assist the regulatory bodies, professionals and owners take appropriate action to minimize risks of AEs to animals. Adverse drug event (ADE) reporting and monitoring system facilitates the collection of unbiased and timely safety data observed during veterinary clinical practice in 'real life' circumstances. It is also important in detection of lack of efficacy, detection and prevention of counterfeit and substandard products in veterinary practice.

All adverse events should be considered reportable and key players in this activity are all stakeholders, including market authorization holders (MAHs), animal health professionals and owners of animals. Early detection and reporting of safety and efficacy problems in animals is helpful to reduce the harmful effects resulting from use of these veterinary drugs, to assess the risk and benefit of the product, and improve the selection and rational use of drugs through provision of timely warning to animal healthcare professionals.

Rationale for Pharmacovigilance

Information on the safety and efficacy of a veterinary drug once marketed is limited to premarketing evaluation, clinical trials and other factors in the product development process. Therefore, premarketing safety evaluation of veterinary drugs at the time of registration is inherently limited due to the following three reasons:

1. The animal population in clinical trials is very selective and limited. Many types of animals with different characteristics are often excluded from studies, such as those in certain age groups and sex, animals with

diseases other than the one being treated and those using other drugs concurrently. This often prevents the identification of side effects caused by interaction of more than one drug given at the same time.

2. The duration of a clinical trial is too short. Such studies do not allow the detection of adverse effects that appear after long periods of use or exposure, especially with chronic medication.
3. Differences between countries which lead to variation in patient factors, variation in drug utilization among animal health professionals, variation in drug manufacturing processes used which influence pharmaceutical quality and composition of locally produced products and those imported outside the country.

For these reasons, it is obvious that safety and efficacy monitoring of a drug is carried out through the life cycle of each veterinary drug. The VDFACA, Marketing authorization holders and animal health professionals are responsible to monitor these products.

Reporting of Adverse Drug Events (ADEs)

The collection of reports from several reporters in different parts of the country assists in making associations (strengthening of signal) between a particular drug and the adverse event. Therefore, it is better to ensure that all necessary information for reporting of AE reports are obtained and reported through the reporting form. Reporters should report the adverse event immediately after it occurs, as delay in reporting will make reporting inaccurate and unreliable. If possible, a decision should be taken to report whilst the patient animal is still with reporter's hand, which gives a chance to the reporter to

clear any ambiguity by re-questioning owner or examining the patient animal, so that the details can be filled in at once on the reporting form. Any other factors, which may contribute to causing the event such as other prescribed drugs, self-medication, herbal products, feed, chemicals, ask the owners particularly about other drugs taken need to be considered. One animal or one human being, or a medically appropriate group exhibiting similar clinical signs should be included in a single report.

Components of an ADE Report

An ADE report should include at least the following components;

I. *Animal information* (Number of animals treated, number of animals showing signs, number of animals dead (if available), characteristics of animals showing reactions (Species/breed, sex, age and weight) and physiological condition of the animal).

II. *Adverse event description*
   a. Brief description of the AE(s): Preferably, the nature of the adverse event being reported but as clearly as possible, including the signs and severity should be briefly described.
   b. Time or date of onset of the adverse event: time of onset or the occurrence of the adverse event in relation to the administration of the drug. The date of onset in the following order; day, month and year should be indicated. Better to describe also whether the adverse event appears immediately following drug administration or not and the duration of symptoms.
   c. Describe whether the ADE disappears or continue when complete withdrawal of the treatment or reducing dose of the drug.

d. Other relevant information such as treatment history of the animal, laboratory tests done and postmortem findings to confirm the case.

III. Information related to the suspected drug(s)

- Name of the suspected veterinary drug (s): trade name and generic name of the drug including its manufacturer, batch number and expiry date should preferably be reported.
- Administered dose, frequency and route of administration should be clearly filled on the reporting format.
- The dates of beginning and termination of the administration of each drug should be stated, and preferably recorded as follows: date/month/year. If drug administration has not been terminated at the time of reporting, state 'Continuing'.
- Reason for use: indication or condition for which the drug(s) was given for should be stated.
- Particulars of other veterinary drug(s) administered to the animal concurrently with the suspected drug, including drug administration for at least one month back with dosage, route of administration, duration of administration and indications.
- Better to mention if any treatment given to the patient animal after experiencing the AE.

IV. Information about the reporter

Writing the name and contact address of the reporter will help the regulatory body to get in touch if more information is needed. It will also help to send feedback to the reporter. Personal particulars such as name, address of the animal health facility (vet hospital, institution, vet clinic, animal

health post or others), e-mail address (optional), signature, telephone number and date of reporting the reaction (indicating date/month/year) are required. The contact details will be kept confidential and will not be passed on to anyone outside without the reporters' permission. While the VDFACA publishes information derived from these reports, it never includes the personal details of the people who made the reports.

Who Should Report

All animal health professionals and animal health institutions using veterinary drugs (government and private veterinary clinics, veterinary pharmacies, and research and education institutions), should report any case of suspected AEs when encountered to the patient animal or human in contact as part of their responsibility. Marketing Authorization Holders (MAHs) (manufacturers and/or local agents) should have safety data reporting system to the regulatory authority, which are reported to them from users of their products. It is mandatory for veterinary drug MAHs to monitor their products in the market and report any suspected undesirable effects to the authority. Animal owners can report to nearby animal health professionals and/or animal health clinic to be reported through.

What to Report

Any undesirable adverse event suspected to be associated with use of veterinary drug, biologicals, herbal drugs, and medical devices should be reported. Any of the following events should be reported: serious adverse events; unexpected adverse events; an observed increase in frequency of a known adverse event; all suspected AEs associated with drug-drug; and drug-feed or drug-feed supplements interactions. Others are: AEs in special field of

interest such as drug abuse and drug use in pregnancy and during lactation; AEs observed after off-label use of drugs; and an adverse event to veterinary drugs, which occurs in humans.

How to Report

The ADEs can be reported either directly to the regulatory body, VDFACA or to the MAH. The regulatory body is responsible for establishing a system of reporting. The VDFACA is currently using a standardized yellow form to receive reports, by which the reporters can send ADE reports through free postage. So, individuals/organizations can send their report in a standardized self-adhesive postage paid "yellow form", which can find it from VDFACA offices and regional and/or Woreda animal health coordination offices and veterinary clinics, it can also be found in VDFACA website (http://www.vdfaca.gov.et).

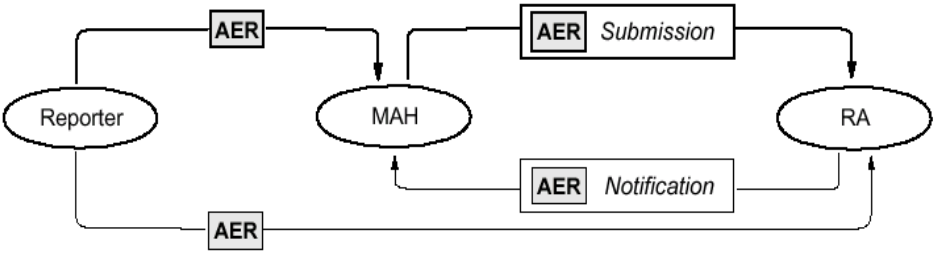

Figure 10: ADE reporting cycle

As shown on the above figure adverse events should be reported either directly to the market authorization holder (MAH) or to VDFACA. The MAH shall then submit the AEs to VDFACA. VDFACA will also notify the MAH all AEs reported about his product(s).

Management of ADE Reports and Regulatory Actions

The regulatory Authority should securely and properly handle the reports. The Authority may also initiate an active surveillance to collect the suspected product(s) from the market and analyze them to support the scientific causality assessment. The Authority is also authorized to communicate all stakeholders to stop using the suspected product(s) until regulatory decision is given after causality assessment. The outcome of the report, together with any important or relevant information relating to the reaction reported, will be communicated to the reporters and other parties as appropriate. After a significant AE is detected and a decision on the course of action determined, the information shall be communicated rapidly and systematically to animal health professionals, MAHs, livestock and fishery offices, other public and private animal health institutions, the media and the public.

If an adverse event is confirmed, based on the causality assessment of the reports and/or active surveillance of the suspected products the following regulatory measures may be decided based on the severity of the AEs the veterinary medicine imposes.

- Suspension or revoke of market authorization;
- Inclusion of additional label warning statements;
- Product recalls;
- Formulation or manufacturing process changes; or
- Education of product users through the media or other appropriate forums.

6.8 Investigating the Use of Veterinary Pharmaceutials

6.8.1 Data Sources

The source of data to assess the use of veterinary medcines can be import, local manufacture, import permits and

distribiution records, the community, community leaders, healers, farmers or animal owners/handlers, veterinary pharmacies and pharmacists , animal health professionals and records, prescriptions and animal health services records .

Appropriate and pretested questionnaires have to be used to collect data from the community, famers and professionals. It is preferable to use separate questionnaire for farmers, professionals and the general community. The data collector should follow proper ethical conditions that are required in the collection of such type of sensitive information. The data collector should explain the objectives of the study. The particpinats of the study should provide informed consent.. The data collector should be assured the anonymity of the informant that his/her name will not appear in the summary document which will displayed to the public latter.

Recorded data in drug import, distribution, veterinary medcines retail at pharmacies, and animal health service can serve as the sources of information. Despite different drawbacks of the data in such areas , valuable information can be extracted based on the evidences from recorded data. The rules, regulations and guidelines should advocate FOR the importance of keeping appropriate records in both private and public institutions. Fragmented and scarce records are available especially in private practitioners, pharmacies and even in importers and distributors.

The information about drug use and distribution can also be obtained from secondary data sources. These include: published studies, reports of agencies involved in the implementation of health care (baseline surveys, health

surveys, monitoring reports and evaluations) sales and consumption figures prescriptions.

All these data sources can be used to:

- Get the overview of drug consumption, distribution, prescription and end use
- Get specific information on drug use in commonly occurring diseases
- Identify drug use problems
- Look into trends on use of veterinary medicines

6.8.2 Sampling

Sampling involves the selection of a number of study units from a defined study population. When drawing a sample, a researcher first needs to decide which population (s)he intends to study. This depends on the research objectives and questions. Sampling is needed since the researcher cannot reach each individual in the population. The sample to be taken for the study should be the representative of the population using random techniques (simple random sampling, systematic sampling, stratified sampling, cluster sampling, multi-stage sampling). This is done to ensure that everybody in the population has about the same chance to be included in the study. The researcher should reduce any sort of bias. Appropriate statistical tools or principles must be followed to determine the amount of sample (sample size) for the study. In reality, sample size is determined based on the availability of resources (time, human resources, transport and money). A Very small sample lead to incorrect interpretation and decision. Therefore, enough sample has to be collected. Once can also consult pharmaco-epidemiology books to determine appropriate sample size for both qualitative and quantitative study.

6.8.3 Methods of Investigating Veterinary Medicines Uses

The data collection tool developed to investigate veterinary medicines use should have at least questions for extracting general and specific information as well as solutions that are important to solve problems by already available or locally derived mechanism. Some of the methods are described below:

a. Document review

Strengths and weaknesses of document reviews

The strengths of using document reviews are:

- They are a cost-efficient way of doing research
- They avoid duplication of efforts

The weaknesses of document reviews are:

- Consent is often needed from the "owner" of data
- It is sometimes difficult to assess the reliability and accuracy of the data
- Data are often outdated and/or data may be costly

b. Semi-structured interviews

Semi-structured interviews are based on the use of interview guideline. This is a written list of questions or topics that need to be covered during the interview. These interviews can help you to collect information on:

- local terms for common animal health problems and types of vetetrinary medcines used.
- sources of veterinary medcines: where do people go to obtain drugs, and what are the advantages and disadvantages of the various sources, in their view?
- sources of advice: where do people commonly go for advice on day-to-day health care problems?

- perceived veterinary medcines use problems: what do people and health workers consider to be drug use problems in their communities?
- why people use drugs irrationally?

How to conduct semi-structured interviews:
Semi-structured interviews follow an open and informal interview style. They allow for a listing of health problems using local illness terms and a listing of drugs commonly used, as well as an exploration of problems, the reasons why they occur, and possible solutions. Interviewers can continue to ask questions until they fully understand the situation. Ordinary conversations make it easier to reassure informants and to win their cooperation and trust. Make sure that you interview different types of people: a variety of key informants (knowledgeable individuals) – men and women, poor and rich people; and those of different ethnic backgrounds.

Strengths and Weaknesses of Semi-structured Interviews
The **strengths** of semi-structured interviews are:
- Depth of information
- Respondent can influence the topic, so unexpected issues/topics emerge
- Researcher can probe to understand perspectives and experiences
- Topic guide ensures that a core list of questions are asked in each interview
- Because the order of questions is not fixed, flow and sharing of views are more natural.

The **weaknesses** of semi-structured interviews are:
- Trained interviewers are needed to probe without being directive or judgmental

- Analysis of findings is difficult – must be done by people who did the interviews
- Researcher has to avoid bias in analysis
- Researcher needs to know of the local culture to capture the interviewees real meaning
- Analysis is time-consuming
- Difficult to generalize findings

c. Focus group discussions

Focus group discussions (FGDs) can be used to collect information on:

- Common health problems and drugs used to treat
- sources of drugs
- sources of advice
- perceived drug use problems
- reasons why drug use problems occur
- possible solutions.

The results from the FGDs complement the findings from the semi-structured interviews. They can be further used to contrast drug use patterns among different groups of respondents and to compare their views on drug problems.

How to conduct Focus group discussions?

Instead of having an interview with one person, an FGD invites several people to participate. The selection of group members demands careful planning. When organizing FGDs it is generally advisable to choose 'homogeneous' groups in terms of age, sex, socio-economic status, etc. since this facilitates open discussion. In mixed groups considerations of status and hierarchy can affect the discussions. Groups should be relatively small, between six to a maximum of ten members.

Strengths and weaknesses of focus group discussions

The **strengths** of FGDs are:

- The method is quick and cheap
- A greater pool of expertise is tapped than individual interviews; a more diverse picture of drug use will emerge
- The contribution of one person often triggers others to share their views and experiences

The **weaknesses** of FGDs are:

- A skilled moderator is required
- The success of a group discussion is a bit unpredictable
- In some cases, one or more participants dominate; the views of others are not recorded and so are under-represented
- The depth of information may be limited. It is hard to probe one person's ideas, as others also have to be given a chance to speak
- Analysis of the information gathered is demanding.

7. QUALITY ASSURANCE OF VETETRINARY PHARMACEUTICALS

Veterinary pharmaceuticals are essential elements of animal health care. In developing countries, up to 66percent of public and private health expenses are used to buy medicines. Unfortunately, the limited data/information has shown that a lot of this money is wasted on irrational use and due to counterfeit and substandard medicines. The WHO estimates that poor quality medicines are prevalent in both developed (1 to 5%) and developing countries. About 25percent of the human medicines sold are counterfeit or substandard and in some countries it may be up to 40percent or higher have been reported, including lifesaving medicines against diseases such as malaria and bacterial infections. As a consequence, thousands of people die every year because the medicines they take do not have the anticipated therapeutic effect. The same is also true for veterinary pharmaceuticals. This impact on human and animal consequences together with the significant economic impact makes it obvious that drug quality assurance throughout the entire supply chain must be a priority for every national drug regulatory authority.

Ensuring the quality of medicines is a multi-dimensional task. It includes:

- licensing and control of manufacturers
- a registration process for medicines that assures product quality, safety and efficacy
- a procurement system with in-built quality controls/assurance, such as supplier prequalification and pre-/post shipment quality testing
- purchasing from qualified and known suppliers

- accreditation and control of distributors and retailers, by inspectors who are well trained, sufficiently paid and backed up by law enforcement personnel so that they are not easily bribed or intimidated
- a transparent logistics chain with automated inventory system and clearly defined procedures, limiting the number of people who are physically handling drugs
- reduction of distribution tiers in the supply chain
- market surveillance and a mechanism to report drug quality issues and recall drugs that do not meet quality standards
- legislation that allows for severe punishment of crimes such as drug counterfeiting
- law enforcement capacity to prosecute those who risk other people's lives for their own financial benefit by producing or distributing unsafe drugs
- public education about the dangers of fake and substandard drugs
- raise awareness and understanding on the possible signs quality defects to health care providers and the general public

7.1 Veterinary Pharmaceutical Quality

As in most manufacturing processes, the quality of a final pharmaceutical product is determined by the starting materials, equipment, processes, and technical know-how that go into producing and packaging it. Quality control and assurance system has to be built into the system than testing intermittently at the end. A medicine is a dynamic product whose color, consistency, weight, and even chemical identity can change between manufacture and ultimate consumption. A medicine that passes all laboratory tests upon receipt may be useless within a few months if the

packaging, storage, and transportation conditions are not maintained properly.

The purpose of quality assurance in veterinary pharmaceutical supply systems is to help ensure that each medicine reaching a patient is safe, effective, and of appropriate quality. The quality of veterinary pharmaceutical products is ensured by the technical and managerial activities of the quality system, which includes evaluating pharmaceutical product documentation, performing or reviewing quality control laboratory tests, and monitoring product performance. Managerial activities include selecting reliable suppliers, preparing contract terms, monitoring supplier performance, and per-forming inspection procedures throughout the distribution network. Note that quality assurance in veterinary pharmaceutical supply is not the same as quality control in manufacturing.

7.2 Veterinary Pharmaceutical Quality Assurance Framework

The following five elements are critical to achieving the expected treatment outcome using veterinary pharmaceuticals to treat an animal patient:

i. Active pharmaceutical ingredient (API) has been shown to be safe and effective for this treatment
ii. The product is of suitable quality to provide an effective outcome
iii. Prescriber (veterinarian) has accurately identified the need for the treatment
iv. Prescriber or dispenser has properly instructed the animal owner on how to use the product
v. The Animal owner complies in giving the medicines to the animal with the prescribed regimen correctly

The pharmaceutical regulatory and quality assurance processes that should be addressed by a country's regulatory authority include:

- Product registration: assessing and authorizing products for market entry and monitoring their safety and effectiveness after entry
- Regulation of manufacturing, importation, and distribution: Quality of manufacturing (good manufacturing practices); procurement integrity (assuring the qualifications of suppliers); and quality of medicines in the distribution system (including product and premises inspection and product screening and testing)
- Regulation of medicine promotion and information: including post-marketing, pharmacovigilance and consumer education

Ethiopia's quality assurance system is as effective as its ability to establish, monitor and enforce regulations. The regulation should address all aspects of veterinary pharmaceutical assurance infrastructure and system and the risks to animal patient health and the implications to resources should be assessed.

7.3 Consequences of Poor Quality Veterinary Pharmaceuticals

A poor-quality veterinary medicine is one that does not meet specifications. The use of poor-quality products may lead to prolonged illness and death, antimicrobial resistance, and adverse drug events and toxic effects, affect the credibility of the health delivery system and unnecessarily wastes the scarce resources.

7.4 Determinants of Veterinary Pharmaceutical Quality

The quality of veterinary medicines coming off the production line is determined by the start-up materials, plant environment, manufacturing equipment, process, and technical know-how invested in developing and manufacturing the pharmaceuticals. The medicine that ultimately reaches the patient, however, is further affected by packaging and by transportation and storage conditions.

For example, the production environment and process such as the amount of grinding, thoroughness of mixing, choice of packaging, maintenance of packaging equipment, and other factors can have an effect that may not appear until the medicine reaches the point of consumption. The dynamic nature of pharmaceuticals and the cumulative effects of the production process, right through to packaging, handling, transport, and storage conditions, require quality assurance at all levels in the pharmaceutical supply system. These quality assurance determinants in the manufacturing process can be cumulative. For example, the excipient substances used to give tablets bulk and consistency may not affect the color, texture, or chemical quality of a pharmaceutical until the immediate container is opened in a hot, humid environment. Then, depending on the ingredients, the tablet may remain firm and dry or become moist and crumble within a matter of days. Factory humidity during packaging may also affect quality. If oral rehydration sachets are not packaged in a very low-humidity environment, moisture enters the sachet and may result in chemical or physical changes in the mixture that make it difficult to use

7.5 Practical Approaches to Quality Assurance

The procedures to establish a comprehensive quality assurance program can be divided into three categories:

- Procedures to ensure that only medicine that meet current standards for quality are bought: careful product and supplier selection, certificate of analysis for each batch of product, current good manufacturing practices and WHO certificates, and inclusion of detailed product-quality specifications in the contract
- Procedures to verify that shipped goods meet the specifications: pre- and post- shipment inspection and analytical pharmaceutical testing
- Procedures to monitor and maintain the quality of pharmaceuticals from the moment they are received until the medicine is finally consumed by the patient: proper storage and distribution procedures, appropriate dispensing, instructions to the patient on proper use of medications, and product defect and pharmacovigilance reporting programs

Critical elements in quality assurance for pharmaceutical procurement

- **Product selection:** products with longer shelf life (for example, powders for reconstitution rather than oral suspensions), and avoidance of products with bioavailability problems, when possible
- **Supplier certification:** supplier prequalification, recent cGMP inspection reports from national drug authorities, formal supplier-monitoring system, and limitation of purchases from new suppliers to noncritical products
- **Product certification:** cGMP certificate from drug

regulatory authority (prequalification), certificate of pharmaceutical products (WHO-type) for all new products, new suppliers, and batch certificate (WHO-type) for problem drugs only

- **Contract specifications:** acceptable pharmacopeia standards, language, labeling requirements, minimum shelf life, and packaging standards
- **Inspection of shipments:** physical inspection of all shipments, and sampling for analysis of suspect products
- **Targeted laboratory testing:** therapeutically critical medicines with known bioavailability problems, new suppliers, suppliers with quality difficulties in the past
- **Product problem reporting system:** system for reporting suspect or problem products

Because resources are limited, quality assurance activities may prioritize on veterinary medicines such as VEN/L and ABC value analyses.

The choice of medicines to monitor closely is based on the following criteria: medicines with a narrow therapeutic window, medicines with inherent bioavailability problems, modified-release preparations, products from new suppliers and suppliers with problems in the past, and medicines that require stable dosage forms and appearance. In general, obtaining veterinary medicines of good quality involves careful selection of suppliers and products, compliance with GMPs, reliance on appropriate pharmaceutical product or batch certificates, and detailed contract specifications.

The close relationships between the regulatory and procurement authorities: procurement agencies have to seek information from the regulatory body and vice versa as regards to veterinary pharmaceutical quality assurance.

Procurement offices still need to request certificates from the DRA of the exporting country, as recommended by WHO.

Table 3: Comparison of certificates used in pharmaceutical procurement

WHO-type certificates	**Uses**	**Limitations**
Certificate of pharmaceutical product	· Essential for product licensure	· Is only as reliable as issuing DRA
· Issued by DRA in exporting country	· Ideally required for all new products	· Does not provide batch-specific information
· Provides licensure status of product	· Prequalification of suppliers	
· Provides inspection status of manufacturer	· Screening of new suppliers	
Statement of licensing status		· Does not provide batch-specific information
· Issued by DRA in exporting country	· Prequalification of suppliers	
· States that product is licensed	· Screening of new suppliers	
Batch certificate		· Issued by few DRAs
· Issued by manufacturer or DRA in exporting country		· Easily falsified

WHO-type certificates	Uses	Limitations
◦ Confirms that individual batches conform to specifications	◦ Usually requested for antibiotics	◦ Many require additional expense
◦ Linked to certificate of pharmaceutical product		◦ Is only as reliable as issuing DRA
Non-WHO-type certificates		
Free-sale certificate • Issued by DRA in exporting country • Confirms product is sold in the country of origin		◦ No indication that product has been evaluated for safety and efficacy ◦ No indication that product is registered for use in country of origin
GMP certificate ◦ Issued by DRA in exporting country ◦ *Analytic batch certificate*	◦ Prequalification of suppliers	◦ Only as reliable as issuing DRA
◦ Issued by manufacturer ◦ Contains results of analytical tests ◦ Not linked to certificate of pharmaceutical product	◦ Postqualification of suppliers	◦ Manufacturers' certificates may be falsified ◦ Does not necessarily conform to specifications approved at time of product licensure

Contract Specifications:

Detailed specifications to help ensure that high-quality products are bought and received include:

- Analytical methods and source of reference materials or documented evidence of suitability for the material used to assess product-quality attributes and certificate of analysis.
- Portions of manufacturers' reference materials to be used in product-quality assessments. For these reference materials, the manufacturers will supply either the API used in the manufacture of the product or a purified portion of the API. Because the reference material is used to assign qualitative and quantitative properties, its identity must be assured and its purity must be suitable to perform the assessments at an appropriate confidence level for the intended use of the material. The identity of a reference material is generally assessed either by infrared spectral comparisons and quantitative assessments performed by ultraviolet-visible spectral measures, directly or in conjunction with chromatographic procedures. However, for pharmaceutical measurements, the identity and quality of solid materials can be assessed by melting point/mixed melting point measurements, while liquids can be assessed by refractive index measurements.
- Language for the product label and package insert, which should be the language or languages common to the country.
- Minimum information required on the label (generic or International Nonproprietary Name, dosage form, strength, quantity, expiration date, manufacturer, batch number).

- Additional information, such as the product registration number and date of manufacture.
- Standards for packaging that will withstand the specific storage and transport conditions (for example, corrugated boxes with specifications for dividers, maximum size, and maximum weight). To reduce theft and resale, some programs may require labeling and logos to indicate that the product is solely for distribution within a particular health care program (for example, ministry of health, social security fund).

Verifying the quality of shipped products

The quality of products received should be verified as soon as possible, by physically inspecting each shipment and testing selected products in the laboratory as required by regulation. In addition, more advanced product-tracking technologies have been introduced to help ensure the integrity of the pharmaceutical supply chain.

Product identification technology

The traditional approach to assuring product integrity is labeling with batch number and expiration date. Unfortunately, this labeling is easily duplicated. To make fraud more difficult, several approaches are available that use overt or covert systems. *Overt technologies* are visible to the eye, and *covert technologies* require devices for detection. Because each step up in identification technology costs more, the most advanced technologies are used on high-value products or in large-quantity inventory control.

A. Bar coding: The simplest and least expensive technology for product tracking is the bar code, which has been adopted widely in many industries. Its uses range from tracking shipping containers to individual dosage units. The airline industry makes extensive use

of this technology to track and direct baggage, and the retail industry has made bar coding the standard to track inventory and sales. Because of their widespread use and simplicity, bar-code detecting devices are relatively inexpensive.

B. Radiofrequency identification (RFID): The RFID tag is a radiofrequency transponder chip with a permanent unique identification code and the ability to be programmed with product information, such as batch number and expiration date. The combination of product information and identification code provides a high level of security against counterfeiting. The RFID can be used overtly or covertly—either visible on the product or hidden in the packaging. Another advantage of the RFID technology is the ability to detect several different items at the same time, unlike visual bar-code readers, which must have each tag visible and separate for reading. However, until this RFID technology matures and becomes more widespread, it will remain much more expensive than the traditional bar-code technology.

C. Holograms: Hologram technology provides visual authentication that can be very difficult to counterfeit or remove (although instances of fake holograms have been found on counterfeit antimalarial products in Southeast Asia). However, the technology is not easily automated and optimally requires an authentic label or accurate image for visual comparison.

Other technologies that have been developed for product authentication include color-shifting inks, ultraviolet printing, and embedded chemical markers and infrared tags. More technologies will likely be used to assure different aspects of the supply chain as they evolve. The

continuing adoption of these authentication technologies will make product counterfeiting more difficult and expensive, but unfortunately will not likely eliminate it.

Laboratory Testing

Upon arrival after shipment, batch samples may be laboratory tested routinely or "by exception." Most programs test selected samples from only some of the batches. Testing by exception means that analyses are done only when a supplier or a particular product is suspect. Laboratory testing is costly in terms of technical human resources, equipment, and reagents. Guidelines should target sampling to products that (a) have the greatest potential for bioavailability and stability problems, (b) are from new or questionable suppliers, and (c) have been the source of complaints. With new suppliers, a probationary testing period, for example, testing the first three shipments, then shifting to intermittent sampling is useful. Suppliers whose failure rates are unacceptable are dropped from future tenders. Sampling from well-established suppliers is done much less frequently, often only for at-risk products.

7.6 Handling Expired Drugs and Veterinary pharmaceutical Waste Disposal

We need to know, first what wastes are before we try to see waste management systems. Wastes are those pharmaceuticals which are eligible for disposal include the following:

- All expired/damaged pharmaceuticals
- All unsealed syrups or eye drops (expired or unexpired)

- All cold chain products not stored as per manufacturers' recommendations (e.g. vaccines, hormones, etc)
- All bulk or loose tablets and capsules with containers which are not sealed, properly labeled or within broken blister pack, and
- All unsealed or damaged tubes of creams, ointments, lotions and related products (see for details the unfit for use veterinary medicines and feed disposal guidelines 2019).

8. VETERINARY PHARMACEUTICALS MANAGEMENT INFORMATION SYSTEM (VPMIS)

A veterinary pharmaceutical management information system (PMIS) can synthesize data generated by veterinary pharmaceutical management operations. It then processes the data into information for use in planning, estimating demand, allocating resources, study and improve the prescribing dispensing and end use of veterinary medicines and monitoring and evaluating pharmaceutical management operations, and rationalizing the use of veterinary medicines. A good PMIS also alerts staff to problems and triggers informed actions, improve health system accountability, and audit reports and corrective actions. The PMIS should focus on both veterinary pharmaceutical and animal patient parameters. Without timely, accurate, and relevant information, health managers may not be able effectively set priorities, respond to changing conditions and disease outbreaks, allocate staff and resources, and meet the needs of people seeking care.

8.1 Importance and Functions of Veterinary PMIS

The system ensures the availability of sufficient quantity of veterinary drugs and equipment at all levels of the animal health system. This will enhance the efficiency of clinical work; and ease the users convenience and process drug prescriptions effectively. It will also help removing time wasting, saving resources, allow easy access to drug, as well as bring on more security on the data compared to manual based system.

A good veterinary PMIS provides the necessary information to make sound decisions in the veterinary pharmaceutical sector. Effective pharmaceutical management requires policy makers, program managers and animal health care

providers to monitor information related to animal patient adherence to treatment, antimicrobials resistance, availability of drugs and medical equipment, animal safety, product registration, product quality, financing and program management etc.

8.2 The Information Systems Pyramid

At the base of the pyramid are operational systems. These include subsystems such as procurement, distribution, financial management, and use, which handle data at the transactional level. Every item that moves in and out of inventory must be tracked, and decisions must be made about how much to supply to an animal health facility, when to reorder, and how much to bill. This level is characterized by a high volume of data that must be recorded and processed, usually daily and at the time of transaction. Data recording accuracy is very important at this level.

The next level of the pyramid is formed by management information systems (MIS). These systems typically provide summaries of operational data on a periodic basis (for example, monthly or quarterly) to help managers of specific departments monitor the performance of their units. Annual reports often summarize information on key indicators from many different operational subsystems, such as procurement, personnel, financial management, or stock control.

Information provided by the MIS helps managers to compare expenditures with the budget at a given level of operation, measure effectiveness of the inventory control system in eliminating stock outs and cutting stock losses, measure the delivery performance and assess the

indicators. Information at this level may demonstrate reduced accuracy because errors might be introduced during the consolidation of data, so a certain level of variation is normal.

The highest level of the information systems pyramid is the executive level. At this level, the system further summarizes management information for use in strategic planning and policy making. The executive level of the MIS typically generates program-wide information on how effective the organization is in accomplishing its mission.

Systems at this level track a limited number of indicators, less frequently. They provide users with the tools, such as total cost analysis and price comparison analysis, to perform periodic queries on data at every information-system level, either to investigate the causes of problems or to perform “what if” analyses to test the effect of changes in strategy.

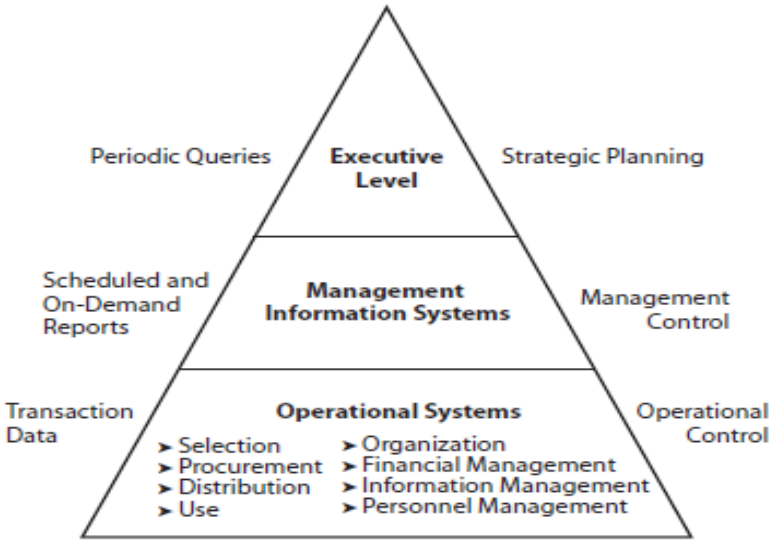

Figure 11: Information system pyramid

Information Needs of Users

Staff at every level and position use information to make decisions that affect the overall functioning of a veterinary drugs supply system. For example, a storekeeper can monitor the temperature chart on a vaccine refrigerator and save thousands of money worth of vaccine from spoiling when the refrigerator begins to malfunction. The store manager may be unaware that large quantities of a drug are due to expire in the warehouse. However, if the store manager had information about expiration dates and could match that information with data on the stock levels in animal health facilities and stores, medicines could be dispatched to facilities that are running low, thereby averting waste of money and drugs.

A good veterinary PMIS alerts staff to problems and triggers critical actions at all levels. Usually, this system wide usage means that a strict separation does not exist between data collectors and information users. Analysis and use of data are encouraged at every level of the system. Table 4 summarizes key information users and some of their most important information needs at each level of the system.

Table 4: Information users and information needs

Level and function	Users	Information needs
Regional		
Selection	Animal Health Inputs supply unit	• Morbidity patterns • Standard treatment strategies
Procurement	Animal Health Inputs supply unit Purchasing unit	• Medicine-use rates • Lead times • Supplier performance • Prices • Funds available for procurement
Medicine-use education	Animal health unit	• Number of staff trained in essential medicines use • Number of public education messages developed • and campaigns conducted
Financial management	Finance unit	• Operating costs • Revenues • Value of inventory • Stock turnover rates • Stock fund growth or loss
Woreda/district		
Warehousing	Stores manager	• Medicine-use rates • Maximum and minimum stock levels • Lead times for requisitions from the regional level • Shelf life

Level and function	Users	Information needs
		• Warehouse maintenance and equipment needs • Stock losses
Distribution	Logistics manager	• Distribution schedules • Vehicle-use records • Maintenance and fuel costs
Facility		
Use	Veterinarian, veterinary pharmacist, BVSc, AHA	• Prescription patterns • Patient adherence • Drug availability • Case load
Inventory control	Storekeeper	• Maximum and minimum stock levels • Lead times for requisitions • Prices • Drug-use rates • Shelf life • Cold-storage temperature variations

8.3 Typical Components of a Veterinary PMIS

The documents that form the basis of the information system can be grouped into three areas: record keeping documents, information reporting forms, and feedback reports.

8.3.1 Data compilation/aggregation tools

These tools are in specially designed formats (manual or computerized) that facilitate data processing. Examples include tally sheets, summary registers, and computer programs to compile data.

8.3.2 Data-reporting forms

Forms for reporting information differ from the data records described above because they are designed for

transmission to other parts of an organization. Copies of forms filed at various points in the distribution network help establish the audit trail for tracking the flow of pharmaceuticals and funds. These forms typically include requisition/issue vouchers to document stock transfers and periodic status reports, such as monthly or annual reports. Status reports can be descriptive and principally qualitative forms or they can be standardized, quantitative forms designed to transmit data on specific indicators to others. In a standardized reporting chain, individual animal health facilities typically report to Woreda office. These, in turn, report to regional offices to project future pharmaceutical needs, revise budgets, and assess drug use over the region.

8.3.3 Feedback Reports

Analytical reports are produced from data reported by other units. These feedback reports have two main purposes: (1) to address issues highlighted by status reports; and (2) to analyze how each reporting unit has performed relative to other similar units. The reports are usually feedback to the units that first collected and provided the data. When staff members see that their data are being used, they become much more conscientious about data collection and reporting.

A good information system also includes procedures to govern the use and flow of information up and down the veterinary drug supply chain. These procedures typically include details about how and when to collect data, the schedule for report preparation, and to whom the documents should be sent. If parts of the information system are computerized, clear guidelines

must exist for the entry, maintenance, and archiving of data, as well as for the preparation and distribution of standard feedback reports. In addition, procedures are often needed for conducting periodic analyses and sharing data among different levels of the organization.

8.4 Steps in Designing or Revising a veterinary PMIS

When a new veterinary drug supply program is operationalized or an old program is revised, the basic planning should include establishing a complete information system. All necessary forms should be available, and all staff should be trained to use these forms, before drugs start moving through the system. Without this preparation, recording of drug consumption and forecasting of medicine needs quickly breaks down. The principal steps in designing or revising a VDMIS are shown below.

A VDMIS should be based on the information needs of the users at each level. To the extent possible, it should build on existing forms, reports, and procedures. Adding as few new forms and data elements as possible and removing unnecessary forms and reports will simplify the system and increase the chances that information will be reliably recorded and reported. In some cases, worksheets may need to be developed to facilitate the collation of data from records into summary report forms.

Users need to be empowered through procedures and training to perform appropriate data analysis, understand key trends within their own units, and use information for decision making at the local level. Depending solely on feedback reports from higher levels may not be effective because of delays and a lack of local

context. For example, a storekeeper may wish to maintain a graph of the average number of days out of stock of selected products to see whether stock control is improving or getting worse rather than wait for someone at a higher level to send graphs drawn from local data.

It is essential to field-test any newly designed records and report forms with staff from the units that will eventually use the new system. Staff at actual work sites can almost always suggest better ways of doing things, as well as point out places where the new forms or procedures are unclear. Computerized procedures and feedback report formats should also be field-tested and revised.

Steps in designing or revising a veterinary PMIS

- Identify information users
- Identify information needs for each user
- Review existing record-keeping and reporting procedures
- Match existing information with information needs to identify overlaps, gaps, and items that can be deleted
- Draft record-keeping and reporting procedures to fill the gaps
- Develop tools and procedures to help users do simple data analysis and present key trends
- Prepare or modify the instruction manual
- Field-test any newly designed or revised records and report forms, including instruction manuals
- Make modific ations to record-keeping forms
- Reporting forms, and/or the instruction manual, based on field-test results

- Develop procedures for preparing feedback reports. Train information users at all levels in data collection, reporting procedures, and use of information. If the PMIS is computerized, provide training for staff in general computer use and specific applications
- Monitor the system's implementation, including the quality and regularity of reporting
- Adapt the records, report forms, and software as information needs evolve
- Continuously monitor the relevancy and sufficiency of the existing PMIS and make necessary changes through a participatory process

9. ALTERNATIVE OR COMPLEMENTARY VETERINARY MEDICINES

Alternative or complementary medicine is the use of unconventional practices or methods for healing or treatment of disorders or diseases. The practices are successful in curing disorders where modern medicine is limited, absent or ineffective. The practices have been used widely for several years by soceity. They have been passed from generation to generations and encompass care systems of medicine including traditional Tibetan system, Chinese medicine, Ayurvedic, Unani, Yoga, Siddha, Naturopathy and Homoeopathy systems of medicines. These have unique diagnostic criteria and diverse therapeutic options. They also include other traditional or local practices that are not well formulated.

However, alternative or complementary practices, products, and therapies are sometimes ineffective or may be even harmful and toxic for the recipient. Therefore, scientific evaluation, modification, and optimization are needed. Figure 12 shows the process for appropriate use of alternative or complementary systems. It starts from gathering of information, followed by appropriate evaluation, approval and promotion.

Practices are needed to be validated before they can be widely promoted. Several levels of validation are possible:

- Tapping the experience of local people, for example, by asking them to rank local treatments according to their perceived efficacy

- Searching the literature for available information on the botany, phytochemistry, and *in-vitro, in-silico (computer-based) and in-vivo* tests
- Conducting laboratory tests
- Conducting clinical tests on station or in the field
- Conducting clinical tests in selected herds kept by smallholders and pastoralists
- Monitoring the use of remedies in the field
- Studying a remedy's influence on production and economic parameters

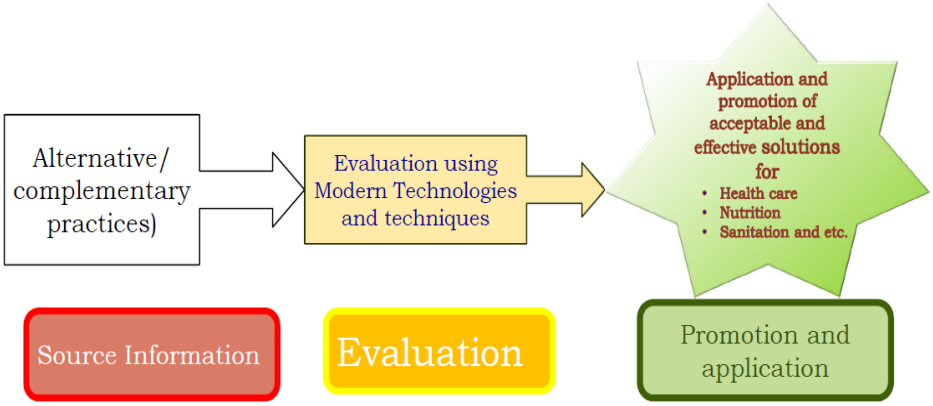

Figure 12: Steps in the usage and promotion of alternative or complementary practices.

Distinctions exist among the various approaches

- **Complementary Medicine** implies the use of local practices together with conventional medicine
- **Alternative medicine** is the use of a non-mainstream approach in place of conventional medicine

- **Traditional medicine** is cultural healing systems that have persisted for thousands of years
- **Integrative medicine***:* integration of practices into conventional medical treatment and health promotion.

Unconventional practices may have the following advantages:

- They are usually accessible, easy to prepare and administer
- They can be obtained freely or with minimum costs
- Most of the practices are the part of one's own culture, can be easily accepted
- These practices are mostly environmentally friendly

Despite these, they have some drawbacks, including:

- There may be risk of incorrect diagnosis
- The recipients may be exposed to imprecise dosages
- There may be low hygienic standards
- Some healing practices are kept secret, only the practitioner knows the detail, which may be exposed for cheating or other malpractices
- Absence of written records which create difficulty to evaluate and standardize the practice
- Some treatments or practices may be ineffective or harmful for the animal or their product
- Sometimes it is hard to connect the problem and the healing process
- Acute or per-acute cases may not be treated by such practices, they may not be good for emergencies.

Complementary or alternative medicines (CAM) are well utilized in Asian countries particularly in India and China. Studies indicated that 10percent of Denmark, 15percent of Canada, 33percent of Finland, 33percent of United States of America and 49percent of Australian population used alternative medicine. About 72 percent of physicians practice CAM in Japan. About 80percent of people in developing countries depend largely on these practices. It is well practiced in Ethiopia. However, it is not well organized, evaluated and standardized in a way that support the conventional medicine.

Sometimes, clients prefer using alternative medicine more than conventional medicine due to two main reasons, first when they are dissatisfied in some way with conventional treatment, second, when they believed that alternatives are more compatible to the patient.

The alternative practices include prevention and curing of diseases by plants (phytotherapy), bee products (apitherapy), milk and dairy products, clay, rabbit fat and swine lard, as well as manual removing of Ixodidae from the body of animals and use of fly larvae in the cleaning of suppurated wounds. Other types of alternative medicines are acupuncture, aromatherapy, chiropractic, homeopathy, massage, Ayurveda, nutritional supplements and spiritual healing. Alternative practices can also be classified as *biologically based therapies, manipulative and body - based therapies*-based on the origin and treatment style.

1. Biologically based therapies

Biologically based therapies are practices which are based on substances typically found in nature including herbs and essential oils, special diets, nutritional supplements, and other products from living organisms. These products may be consumed, applied topically, or inhaled. Botanical medicine is one of the most important biological medicines which uses plants and plant derivatives as therapeutic agents. All part of the plant (seeds, roots, leaves, bark, or flowers) can be used for medicinal purposes.

Plants contain several compounds which have antibacterial, antifungal, antiviral, anti-inflammatory, and other effects in the body. Whole herbs are preferred to isolated active constituents due to two main reasons, first, the whole herbs contain many chemical constituents working synergistically together to treat disease and support the body's own healing mechanisms, second, some constituents may not be stable when isolated.

Herbal medicinal practice is rooted in hundreds of years of experience of using plant medicines which today is underpinned by the scientific study (pharmacognosy) of plant medicines and their chemical constituents. Plants must be used carefully since some of these botanicals may be toxic when used at inappropriate doses.

A considerable number of people use herbal medicines routinely in solving disease or abnormalities in Animals. Herbs are safe to use if taken in the right amount. In many countries program exist that test the safety and efficacy of

these medicines, and some of them are selected for inclusion in national animal health program. The production of herbal medicines is commercialized in many countries of the world including Ethiopia and marketing is similar to that for modern pharmaceuticals. Some people believe that they are more natural than modern pharmaceuticals. Some herbal medicines are potent, and their safety is not as evident as people think. Also, they can be dangerous when taken in combination with modern pharmaceuticals. For example, the antidepressant herb St John's Wort should not be used in combination with selective serotonin re-uptake inhibitors. More attention should be given for pregnant, lactating, young and debilitated animals.

2. Acupuncture

Acupuncture is perhaps the best-known aspect of traditional Chinese Medicine. It aims to influence body functions and stimulate and restore the body's own regulatory system by using specific (acupuncture) points on the surface of the body.

3. Ayurveda

Ayurveda (the 'science of life') is a system of traditional medicine native to the Indian subcontinent using methods for achieving physical, mental and spiritual health and well-being. Ayurveda is the oldest system of medicine. It emphasizes prevention and a holistic approach to therapy and is practiced as a form of CAM within the western world, where several of its methods, such as the use of herbs, massage, and yoga are applied on their own as a form of CAM treatment.

4. Aromatherapy

Aromatherapy uses essential oils (oils extracted from plants) for healing. Some people find that the smell (aroma) of particular oils helps them to relax, sleep better, relieve pain and improve low mood. Each essential oil contains its own mix of active ingredients, this mix determines the healing property of the oil. The oils can be used in many different ways, such as in creams, oil burners, massaged in to the skin or by adding drops to a warm bath.

5. Chiropractic Medicine

Chiropractic medicine involves spinal manipulation performed by trained practitioners that involves using their hands or a device to apply a controlled force to a joint of the spine. The focus is on the structure and function of the spine and its relationship to the nervous and musculoskeletal systems and general well-being.

6. Homeopathy

The name homeopathy is derived from a Greek word, *homeo* meaning like and pathos meaning suffering. The fundamental idea of homeopathy is the *similarity principle*, which implies that substances capable of causing disorder in healthy subjects are used as medicines to treat similar patterns of disorder experienced by ill people. Homeopathic medicines are aimed to direct and stimulate the body's self-regulatory mechanisms. This principle is used to some degree in conventional therapies, such immunization and allergy treatments. The other practice in homeopathy is the minimum dose. Since small amount of substance may cure with minimum side effects. Homeopathy is highly individualized while taking into account the symptoms and signs of the disease, the patient's physical build, personality, temperament and genetic predispositions. Apart

from homeopathic medication, advice on change of lifestyle, diet and substance-abuse behaviours, acquisition of stress-reduction techniques and exercise are part of the package of care. However, most scholars are sceptical about homeopathy, sometimes it works no better than a placebo.

7. Naturopathy

In this case, health follows natural laws whereas disease is due to ignoring natural laws. For example, sedentary lifestyle without adequate time for exercise; exposing oneself to environmental toxins; eating processed, overcooked foods; engaging in negativity or harbouring negative thoughts; and not getting adequate rest or relaxation may induce diseases. Illness happens when one goes against nature. Lemon, milk, salt and soil can be used as naturopathy items.

8. Massage

Massage is the manipulation of soft tissues in the body. Massage techniques are commonly applied with hands, fingers, elbows, knees, forearms, feet, or a device. The purpose of massage is generally for the treatment of body stress or pain. It is commonly practiced in human. However, it is also applied in veterinary medicine to treat problems related to the skin and musculoskeletal system.

9. Nutritional supplements

Animals need a balanced diet, to be healthy and productive. The animals' nutritional requirement may vary with their stage of growth, condition and aim production, and diseases or abnormality they have. By analysing the requirements and available feed, nutritional supplements are needed to improve productivity, cure rapidly and even prevent the occurrence of diseases.

10. Spiritual healing

Spiritual healing is the part of a religious practices of a community. It various with the type nature and believe of an individual. Holy water, vow, praying and sacrifice of an animal are spiritual practices in some communities in Ethiopia.

11. Energy Therapies

Energy therapies work on the concept that everyone has an energy field and unblocking it restores balance. Energy therapies focus on the transference of energy to promote equilibrium. The aim is to increase energy levels, promote relaxation, self-healing and wellbeing.

12. Manipulative therapies

This implies applying pressure to manipulate or move one or more body parts. Examples include chiropractic medicine, osteopathic manipulative medicine, movement therapy, massage, and other body work, such as Rolfing (a form of soft-tissue manipulation). Practitioners of these therapies may be licensed or certified and have received more extensive education and training than have practitioners of other therapies. The practices may often be regulated, as well; credentialing of practitioners is established by local and state governments and professional organizations. Some concerns about manipulative therapies include delay or avoidance in seeking conventional care and aggravation of existing conditions.

9.1 Preparations and Application Methods

The most common forms of preparations for complementary or alternative medicines are:-

A) Powder

The medicinal materials will be dried and pounded until they form a powder. If desired, the powder is sieved to make it finer. The powder can be fed to sick animals directly, mixed in salt or used in the preparation for decoctions, poultices or ointment.

B) Poultice

Adding just enough hot water to the material, usually in powder form, makes a poultice or a paste. The paste is then applied on the affected area such as inflamed areas to soothe irritations or to withdraw pus, toxins and particles imbedded in the skin.

C) Ointment and cream

An ointment is made by mixing finely powdered materials or extracts with butter or cooking oil. The ointment is applied to affected areas such as rashes or sprains.

D) Decoctions

In this method, one or several medicinal materials are chopped into small sizes and added to water. The water is boiled for 15-30 minutes or more and the medicinal material is added and cooked with simmering until it is reduced its volume (concentrated) and then allow it to cooled and used.

E) Infusion

An infusion is made in the same way as tea. Boiling water is poured into a container in which powder or chopped plant parts have been put. The container is covered for 10-20 minutes until the medicinal components have been extracted. The water is filtered and given to the animal, in cool or warm state.

F) Cold water extract

Some active ingredients are easily destroyed by heat. Therefore, a cold-water extract can be made by soaking leaves and roots overnight in water. After filtering, the cold extract can be administered. The extract should be prepared fresh daily.

G) Tincture

Mixing water (70-80%), alcohol (20-30%) and plant materials makes a tincture. The plant materials are left in the mixture for one to several days until the desired medicinal properties have been extracted. The tincture is filtered and used internally or externally.

H) Fumigation

Dry or wet plant material is put in the fire and the smoke engulfs the animal. Fumigants are commonly used against ectoparasites such as tsetse flies or nasal boat fly (*Oestrus ovis*).

I) Steam application

In this method, the medicinal material will be put in a boiling water, and the steam will be inhaled or the patient will be bathed in the steam. Restricting the flow of the steam is needed by covering with cloth or shield.

J) Concoction

A concoction is a curious mixture of drugs, or it is a remedy prepared from a mixture of two or more drugs or substances that have been heated.

9.2 Regulation and Quality Control of CAM

Regulation and quality control of complementary or alternative medicine may not be as such simple, since the product may not be pure (minimum purification on herbs

and other products), presence of variation among preparations and their efficacy may not be supported by scientific evidences. However, the following points should be considered during preparation of herbal medicine.

i. Sanitation and hygiene (equipment, personal, storage and preparation area)
ii. The healer should have adequate premises and equipment for the production of drugs, appropriate packaging (primary and secondary), labeling (composition, dose, application, batch number, manufacture date, expire date, indication, precaution, potential side effects, storage requirements, and his/her full address)
iii. The healer should undergo special training regarding cause, transmission, prevention and control options of animal diseases, possible side effects induced by the traditional practices and how to improve their efficacies.

Quality control covers all aspects of the manufacturing process that individually or collectively influence the quality of a manufactured product. It is the sum of the arrangements made to ensure that veterinary products are consistently manufactured in an appropriate manner to the quality standards required for their intended use.

9.3 Variations in Complementary or Alternative Medicines

Alternative medical practices differ not only from region to region but also among and within communities. Depending on the work division and professional specialization, men may know more about large animals while women commonly are more familiar with small animals or with certain type of diseases such as mastitis and neonatal care. Hunters may have a wealth of information on hunting dogs.

Knowing about such differences can be crucial in the selection of respondents in research and partners for extension approaches, the design of training courses, and the selection of trainees for community-based animal health workers.

9.4 Complementary/Alternative Medicine and Antimicrobial Resistance

Antimicrobial resistance is becoming the main problem facing the health systems of all countries worldwide. Widespread use of antimicrobials in animals and humans alike has been a major contributor to the rise in antiumicrobial resistance. In order to reduce the use of antimicrobials, there is sufficient evidence and practical experience that some CAM modalities can contribute to the greater efforts needed to encourage prevention practices that reduce the need for antimicrobials use. In addition, increasing evidence suggests that herbal and homeopathic medicine can offer effective alternatives to antimicrobials.

Ingenral, CAM may contribute to the sustainability of animal health care: however, the effectiveness of the practices should be thoroughly evaluated and standardized prior to advocacy, promotion, and use. The CAM can save scarce resources like over use antimicrobials and the asscocaited risks. Howevere, there is a need to encourage and regulate the practices.

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Annexes

Prescription Paper

Veterinary Prescription Form

Ser.No, __000000
Name and Level of Animal Health Institution_____
Owner's Name_____
Address: Region_____Town_____
Woreda_____Keble_____locality_____
Species of animal _____Age_____Sex_____
Estimated Body weight_____
ID No._____ Case No._____
Diagnosis _____

Treatment given (medicine name, strength, dosage form, one time dose and frequency of use, and withdrawal period)	Price of Each item	
	Birr	Cent

Refill_____
Withdrawal period _____
Prescriber's name _____
Qualification_____
Registration No. _____
Signature_____
Date: _____

Dispenser's name: _____
Signature: _____
Date: _____

Veterinary Drug and Animal Feed Administration and Control Authority

Veterinary Drugs Adverse Event Reporting Form

For Official Use Only

Adverse event no

Date received

Date acknowledged

1. Animal Information							
Species/Breed	Sex	age	weight	Physiological condition (eg. Pregnancy)	Number of animals treated on this	Number of animals reacted	Number of deaths

2. The Adverse Drug Event		
Date of onset of an adverse event		Description of the adverse event:
Duration of the event		

laboratory findings (if done)			**Postmortem findings (if any)**
Lab test	Result	test date	

3. Drugs suspected to have caused the adverse event			
Trade and Generic Name:	Manufacturer:	Batch Number:	Expiry Date:

Route of Administration	Dose and Frequency	Date Started/Given	Date Stopped	Reason for use

Details of products given concurrently		Drugs given after onset of the adverse event	

4. Product Quality Problems (Color change, change of odor, caking, precipitation, incomplete packs, poor packaging/labeling, etc.)	
5. Lack of Expected Efficacy	

6. Reported by:					
Name		e-mail		Phone No.	
Profession/Qualification					
Working institution/office					
Date reported		Signature:			