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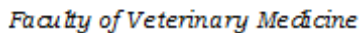
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# RATIONAL USE OF VETERINARY DRUGS AND VACCINES

## TRAINING MANUAL

*First Edition.*

Prepared by: - *Veterinary Drug and Animal Feed Administration  
and Control Authority (VDFACA), under Ministry of Livestock  
and Fisheries, in collaboration with University of Gondar,  
Faculty of Veterinary Medicine*

December, 2016  
Addis Ababa, Ethiopia

# **RATIONAL USE OF VETERINARY DRUGS AND VACCINES**

**Prepared by VDFACA in collaboration with  
University of Gondar, Faculty of Veterinary  
Medicine**

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We are grateful to the professionals who offered their feedback and edits on this and earlier drafts of the manual. As this is the first attempt, authors are happy if they got feedback from readers or users of the manual for further improvement.



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### **PREFACE**

The survey conducted on the use of veterinary drugs and drug resistance in 2013 by Veterinary Drug and Feed Administration and Control Authority (VDFACA) indicated that irrational use of veterinary drugs is becoming common practice all over the country. Lack of awareness among professionals and absence of reference materials on the proper use of veterinary drugs and vaccines were gaps identified during the study. It is therefore found important to prepare training manual that would help us to improve the awareness of animal health and veterinary drug professionals on rational use of veterinary drugs. To prepare this manual a collaborative team was formed from VDFACA and University of Gondar, Faculty of Veterinary Medicine; and then they produced this “*Rational Use of Veterinary drugs and vaccines*” training manual with high and exemplary commitments.

The manual contains information on how new drugs are developed and the challenges related to it to aware professionals to take care of drugs by informing how much new drug development is a long process and requires a big investment; sessions on principles and process of prescription and dispensing to improve the skill and attitude of good prescribing and dispensing practices of professionals; chapters to indicate the transportation requirements of veterinary drugs, dispensing environment, stock management and quality assurance of drugs at stock so as to keep

## Rational Use of Veterinary Drugs and Vaccines

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the drug quality; information on the consequences of irrational drug utilization and drug resistance as future threat; and the importance, sources, handling and transportation of vaccines, and use of updated veterinary drugs information. The document also contains different drug chemistry formulas and arithmetic calculations which could help prescribers and dispensers on their day to day practices to ensure the rational use of veterinary drugs and vaccines.

It is hoped that the manual would help animal health and veterinary drug professionals to use veterinary drugs and vaccines rationally, and enhance the quality of veterinary pharmaceutical services so as to decrease the economic losses and public health hazards due to diseases of livestock. Professionals who are handling and using veterinary drugs and vaccines are encouraged to read this manual and other references mentioned in the reference sections of this manual for further information and knowledge.



TERZU DAYA DEGAGA (Dr.)

*Director General,*

*Veterinary Drugs and Animal Feed Administration  
and Control Authority*

## Rational Use of Veterinary Drugs and Vaccines

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### ACRONYMS

AHS	African House sickness
AMAs	Antimicrobial Agents
AMR	Antimicrobial Resistance
CBPP	Contagious Bovine Peuro-pneumonia
CCPP	Contagious Caprine Peuro-pneumonia
CNS	Central Nervous System
DNA	Deoxyribonucleic Acid
FEFO	First Expire First Out
FIFO	First in First Out
IBD	Infectious Bursal Disease
ID No.	Identification Number
IU	International Unit
IV	Intravenous
Kg	kilogram
LSD	Lumpy Skin Disease
Mg	milligram
mL(ml)	millilitre
NVDL	National Veterinary Drugs List
°C	Degree Celsius
°F	Degree Fahrenheit
OTC	Over the counter
POVM	Prescription Only Veterinary Medicines
ppm	parts per million
PPR	peste des petits ruminants
SI	International System Unit
STP	Standard Temperature and Pressure
USP	United States Pharmacopeia
VDFACA	Veterinary Drug and Feed Administration and Control Authority of Ethiopia
VSTG	Veterinary Standard Treatment Guideline
WHO	World Health Organization

## **OPERATIONAL DEFINITIONS**

**Active substance or ingredient:** Any substance or combination of substances used in a finished pharmaceutical product intended to furnish pharmacological activity or otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in animals;

**Adverse drug reaction:** is unfavourable and unintended effect that occurs after the use of or exposure to veterinary drugs;

**Biological product:** means reagents, sera, attenuated or killed vaccines or microbial genetic material used for the diagnosis, prevention or treatment of animal diseases;

**Contraindication:** is a condition or factor that serves as a reason to withhold a certain medical treatment. It is a specific situation in which a drug, procedure, or surgery should not be used because it may be harmful to the patient;

**Dispenser:** Any person who is licensed or authorized by the appropriate body to dispense veterinary drugs and/or medical supplies;

**Dispensing:** The act of preparing veterinary drugs and/or medical supplies and distributing to users with adequate

## Rational Use of Veterinary Drugs and Vaccines

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information, counselling and appropriate follow up;

**Dosage interval:** is the time interval between successive dosages;

**Dosage regimen:** is the schedule of doses of a therapeutic agent including name, dose, frequency, duration and route of administration of the drug;

**Dose:** is the amount of a drug to be administered at one time to bring a desired therapeutic response in a patient;

**Drug Interaction:** is the modification of the effect of one drug by the prior or concomitant administration of another drugs or feed or herbs.

**Excipients:** are inert substances added to the pharmaceutical preparations either to add the bulk of the active drug or to mask unpleasant taste (lactose, calcium lactate, starch and so on);

**Indication:** is a valid reason to use a certain drug for the diagnosis, prophylaxis or treatment of diseases;

**Label:** Any material which is printed or affixed to a packing material which provides the necessary information about veterinary drugs and includes an insert (leaflet);

**Loading dose:** is one or a series of doses that may be given at the onset of therapy with

## Rational Use of Veterinary Drugs and Vaccines

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the aim of achieving the target concentration rapidly;

**Maintenance doses:** are series of repetitive doses or as a continuous infusion to maintain a steady-state concentration of a drug;

**Over-the-counter veterinary drugs:** veterinary drugs that can be dispensed without prescription;

**Owner:** any person who is responsible for the patient animal and who bring it to the veterinary clinic and purchases the prescribed and/or over-the-counter veterinary drugs from the veterinary pharmacy;

**Packing material:** means any material that may be used for filling, inserting or wrapping or packing veterinary drug and includes immediate container and other materials for wrapping the product;

**Patient animal:** An animal presenting to an authorized animal health care provider to prevent or treat disease;

**Precautions:** are situations in which the drug should be used cautiously because there may be adverse reaction in that situation;

**Pre-packaging:** Repackaging of veterinary drugs into usable quantities before they are requested by animal owners (users);

**Prescriber:** Any animal health practitioner who is licensed or authorized by the appropriate body to write a prescription;

**Prescription only veterinary drugs:** veterinary drugs dispensed only with prescription;

**Prescription:** Any order for veterinary drug written and signed by a duly licensed or authorized animal health practitioner issued to an animal patient in order to collect medicine from veterinary drugs dispensing outlet;

**Regulatory body:** Veterinary Drug and Feed Administration and Control Authority of Ethiopia and regional agriculture offices as representatives;

**Repackaging:** Packing of any processed or semi-processed medicine by a different manufacturing company in any other way.

**Shelf-life:** The length of time a veterinary drug may remain on the shelf, in the original package and under usual environmental conditions and retain an acceptable level of its original potency and overall quality.

**Side effects:** are unwanted but often unavoidable effects that occur at therapeutic dose. Example: Atropine is a pre-anaesthetic drug used to reduce secretion but causes dryness of the mouth as side effect;

**Stock solution:** A solution of higher strength of a veterinary drug or reagent (chemical) that requires dilution before use.

**Stock:** The amount of veterinary drug and/or medical supplies available in legal veterinary drug retail outlets.

**Vehicles** are substances used to dissolve or suspend the drug for better applicability such as in ointments. Examples: sugar, gum of acacia, petroleum jelly and so on.

**Veterinary drug:** means 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 and sanitary items.



### **1. INTRODUCTION**

The provision of successful animal health service requires the availability of safe, effective and affordable drugs of the required quality and quantity. In addition, the available drugs must be prescribed, presented, dispensed and used rationally. Proper utilization of veterinary drugs involves handling, prescribing, dispensing and delivery of drugs for the animal species in question under the proper supervision and involvement of veterinary professionals.

Rational veterinary drug use is the part of Quality Management System that guarantees the quality of the veterinary pharmaceuticals through controlling various activities related to storage, transportation, distribution, prescription and dispensing. It refers to the prescribing and delivery of the correct veterinary drug to the right patient, in the required quantities, for an adequate period of time and at the lowest cost, in the package that maintains acceptable potency and quality for the specified period, with clear veterinary drug information counselling and appropriate follow up. It is a complex issue demanding mainly an integrated action of prescribers, dispensers and owners of the animal patients. It may even extend to the level of animal health administrators and veterinary drug and feed administration and control authority and policy makers. For instance, in matters related to the development of national veterinary drug list (NVDL) and improvement of the availability of veterinary drugs.

Many researchers have highlighted the incidence and prevalence of irrational drug use in developing

countries. It is also common in Ethiopia. The use of veterinary drugs when no therapy is indicated, use of wrong veterinary drugs for specific conditions (incorrect diagnosis), the use of veterinary drugs with doubtful efficacy, the use of veterinary drugs with uncertain safety status, use of correct veterinary drugs with incorrect route of administration, dosage, or duration, the storage of veterinary drugs with other materials in the institution store, absence of refrigerators for veterinary drugs that need cold chain, the dispensing of prescription-only veterinary drugs at partial doses and without prescription, poor labelling of the dispensed items, lack of animal owner counselling, incomplete compiling and recording of prescriptions, and charging animal owner unreasonably high prices for the dispensed veterinary drug are some of the practices that reflect an irrational veterinary drug use. Such improper utilization, eventually decreases drug's efficacy, promote the development of drug resistance and they may harm the animal itself as drugs are potential poisons and the way they are utilized makes the difference between the ability to save and take animals' life. It is also a threat to human medicine since majority of drugs used in veterinary medicine are structurally related to human therapeutics which may select for co-or cross-resistance.

The survey conducted on use of veterinary drugs in 2014 by Veterinary Drug and Feed Administration and Control Authority (VDFACA) indicated that there is dispensing of veterinary drugs with other goods in the shops and markets, dispensing of prescription-only veterinary drug without prescription, dispensing of veterinary drugs by non veterinary drug

## Rational Use of Veterinary Drugs and Vaccines

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professionals in the veterinary pharmacy, dispensing of illegal veterinary drugs and veterinary drugs donated by nongovernmental organization with low price and unethical practices of professionals. These lead to the occurrence of therapeutic failure, harmful drug effects, and drug resistance. Creating and improving awareness about rational use of veterinary drugs is helpful to avoid all these messes.

Therefore, this manual is issued as one means of promoting proper use of veterinary drugs and vaccines. It will support animal health and veterinary drug professionals as source of information for rational veterinary drug and vaccine use. The manual should be supported by other reference materials such as standard veterinary treatment guidelines, national veterinary drug lists, and veterinary drug formulary.

Generally, the manual is prepared to:

- Enhance knowledge, skill, and attitude of animal health professionals on rational use of veterinary drugs and vaccines;
- Improve awareness on the consequences of irrational veterinary drug use;
- Encourage professionals to promote ethical practices;
- Motivate professionals in developing and maintaining behaviour of regularly updating about veterinary drug

## **2. SOURCES OF DRUGS AND PROCESSES OF NEW DRUG DEVELOPMENT**

### **Objectives**

At the end of this session trainee should able to

- Identify major sources of drugs
- Describe how drugs are discovered and the challenges related to it

### **2.1 Sources of Drugs**

There are basically six sources of drugs, namely *plants, microorganisms, animals, mineral and mineral products, synthetic or semi-synthetic substances and engineered sources.*

#### **A. Plants:**

Plants are the oldest source of drugs. Most of the drugs in ancient times were derived from plants. Almost all parts (leaves, stem, bark, fruits and roots) of the plants are used to extract drugs. There are many drugs derived from plants. About 25% of the drugs prescribed worldwide come from plants. Of the 252 drugs considered as basic or essential by the World Health Organisation (WHO), 11% are exclusively of plant origin. Chemicals obtained from plants (alkaloid, tannins, resins, glycoside, oil, gum, mucilage, carbohydrate and related compounds) are used as a drug or may also be added as vehicle. Plants will also be the potential sources for new drug discovery in the future.

## Rational Use of Veterinary Drugs and Vaccines

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The following are some of the examples of drugs derived from plant sources:

### Leaves:

- ✓ The leaves of *Digitalis purpurea* are the source of Digitoxin and Digoxin, which are cardiac glycosides.
- ✓ Leaves of *Eucalyptus* give oil of *Eucalyptus*, which is important component of cough syrup.
- ✓ Tobacco leaves give nicotine.
- ✓ Leaves of *Atropa belladonna* gives atropine

### Flowers:

- ✓ Poppy *papaver somniferum* gives morphine
- ✓ Rose gives rose water used as tonic.

### Fruits:

- ✓ Senna pod gives anthracine, which is a purgative (used in constipation)
- ✓ Calabar beans give physostigmine, which is cholinomimetic agent.

### Seeds:

- ✓ Seeds of *Nux vomica* give strychnine, which is a CNS stimulant.
- ✓ Castor oil seeds give castor oil, which is used as laxative.
- ✓ Calabar beans give Physostigmine, which is a cholinomimetic drug.

### Roots:

- ✓ *Ipecacuanha* root gives emetine, used to induce vomiting as in accidental poisoning. It also has amoebicidal properties.
- ✓ *Rauwolfia serpentina* gives reserpine, a hypotensive agent.

*Bark:*

- ✓ *Atropa belladonna* gives atropine, which is anticholinergic.
- ✓ *Hyoscyamus niger* gives hyosine, which is also anticholinergic.

*Stem:*

- ✓ *Chondrodendron tomentosum* gives tuboquaraine, which is skeletal muscle relaxant used in general anaesthesia.

### **B. Microorganisms**

Some of the fungi, moulds and bacteria are also important sources of drugs

Table 1: Microorganism used as the source of antibiotics

S/n	Microorganism	Antibiotic
1.	<i>Bacillus subtilis</i>	Bacitracin
2.	<i>Bacillus polymyxa</i>	Polymyxin
3.	<i>Streptomyces nodosus</i>	Amphotericin B
4.	<i>Streptomyces venezuelae</i>	Chloramphenicol
5.	<i>Streptomyces aureofaciens</i>	Tetracycline / chlortetracycline
6.	<i>Streptomyces erythraeus</i>	Erythromycin
7.	<i>Streptomyces griseus</i>	Streptomycin
8.	<i>Micromonospora purpureae</i>	Gentamicin
9.	<i>Cephalosporium species</i>	Cephalothin
10.	<i>Penicillium griseofulvum</i>	Griseofulvin
11.	<i>Penicillium notatum</i>	Penicillin

### **C. Animals: -**

The drugs which are coming from animals include:

- Insulin which is extracted from pancreas, used in treatment of *Diabetes mellitus*.

## Rational Use of Veterinary Drugs and Vaccines

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- Human chorionic gonadotropin (hCG) obtained from urine of pregnant women used for the treatment of infertility.
- Cod liver oil is used as a source of vitamin A and D, derived from liver of cod fish.
- Anterior pituitary is a source of pituitary gonadotropins, used in treatment of infertility.
- Blood of animals is used in preparation of vaccines.
- Heparin is commonly extracted from porcine intestinal mucosa or bovine lung.
- ❖ Drugs coming from animals are not usually pure and may contain antigens which induce allergic reactions.

### **D. Minerals**

Minerals (metals or non-metals) from the earth are used to treat inorganic mineral deficiencies or other problems in animals. Their salts are usually used in clinical practices.

Examples:-

- *Ferrous sulphate* is used to treat anaemia
- *Magnesium sulphate* is used as purgative (used to relieve constipation)
- *Magnesium trisilicate* and *Aluminium hydroxide* are used as an antacid
- *Iodine* is antiseptic. *Iodine* supplements are also used to treat Iodine deficiency.

### **E. Synthetic or semi-synthetic drugs**

Synthetic or semi-synthetic drugs are evolved from application of science and technology in the

laboratory. Semi-synthetic drugs are naturally occurring substances that have been chemically altered in the laboratory. Examples of synthetic or semi-synthetic drugs are sulphonamides, thiazide diuretics, apomorphine, aspirin and so on. It is more preferable way since pure compounds can be easily obtained and structural modifications to produce potentially more active and safer drugs could be easily performed.

### ***F. Engineered drugs***

*Genetic engineering* is the newest area of drug development. It involves cleavage of DNA by enzyme restriction endonucleases. The desired gene is coupled to rapidly replicating DNA (viral, bacterial or plasmid). The new genetic combination is inserted into the bacterial cultures which allow production of vast amount of genetic material (drug). The process has both advantaged and disadvantages.

Advantages: -

- Huge amounts of drugs can be produced
- Drug can be obtained in pure form
- It is less antigenic

Disadvantages: -

- Well equipped laboratory and trained manpower are needed
- It is not as such simple

Examples insulin, growth hormone and erythropoietin are nowadays synthesised by genetic engineering techniques.

## **2.2 Drug Development**

Any drug development process must proceed through several stages in order to produce a product that is safe, efficacious, and has to pass



all regulatory requirements. The process of drug development starts with understanding of the disease and target identification and validation of the promising drug, which will be followed by the synthesis of novel chemical compounds (lead compound).

Two tests will be conducted.

- i. Preclinical testing which will be done on laboratory animals or cell culture that yields information on the biological effects of new substance.
- ii. Clinical test: The clinical development of new drug usually takes place in steps or phases conventionally described as clinical pharmacology (Phase I), clinical investigation (Phase II), clinical trials (Phase III), and post-marketing studies (Phase IV)
  - Phase I studies on healthy subjects (20 to 80) and seek to determine whether effects observed in laboratory animals experiments also occur in other animals or humans.
  - Phase II, potential drugs are tested on selected patients for therapeutic efficacy in those disease states for which they are intended
  - Phase III is entered, involving a larger group of patients in whom the new drug will be compared with standard treatments in terms of therapeutic outcome.
  - Phase IV is monitoring the drug after market authorisation from the regulatory body as it

is used in the larger population to catch any unexpected serious adverse effects.

The drug development process described above more applies for drugs used in human medicine, for veterinary agents the process is similar but with a few notable exceptions.

- i. Since preclinical and Phase I studies are on animals, processes are generally shorter for veterinary drugs.
- ii. Safety and efficacy must be confirmed for each species included on the label in brand or generic medications and in new dosage forms.
- iii. Veterinary dosage forms are generally more diverse and complex to address differences within and among species; weight differences between species may reach up to 700-fold.

Challenges in drug discovery:

- Drug discovery is a slow process
- Requires big investment
- One cannot be sure even after a very long process and investments

Possible solutions:

- Use available drugs properly
- Provide priority for disease prevention and eradication programs through proper husbandry, nutrition and vaccination
- Conducting research on identifying problems and searching solutions

- Searching other alternatives like improving useful ethno-veterinary practices

### **3. UNDERSTANDING THE LABELING, PACKAGING AND COMPOUNDING OF DRUGS**

#### **Objectives**

After completion of this session, trainees should be able to:

- ✓ Identify the major information on the label of a drug
- ✓ Differentiate proper packaging systems for storage, transport and dispensing of drugs

#### **3.1 Drug Labelling**

Label means any written, pictorial or other descriptive material (including cartons, vials, and leaflets), affixed to or contained in or on the packaging, which gives information about the veterinary drugs that is to be marketed or sold. All finished drug products available for market should be identified by labelling at their primary and/or secondary packaging, as required by the national legislation, bearing at least the following information:

1. The statement “FOR ANIMAL TREATMENT ONLY or FOR VETERINARY USE ONLY”
2. Trade name
3. Generic name
4. Active ingredient(s), and other substance(s) added to formulated the drug and their quantities
5. Withdrawal period
6. Restriction to its use
7. Batch number

8. Storage instructions and handling precautions
9. Directions for use (dose rate, route, duration of treatment and frequency of application)
10. Adverse effects, cautions and contraindications
11. Manufacturing and Expiry date
12. Net contents with clear unit of measurement
13. The name and address of the manufacturer or the company or person responsible for placing the product on the market

The labels should not be easily erased and/or detached. Any deviation from the label makes the information on the label invalid. **READING THE LABEL BEFORE USING A PRODUCT IS EXTREMELY IMPORTANT!** If the products dispensed by veterinary drug professional are not in the original labelled container, *must* be labelled by him/her in the same manner that appears on the commercial label. Following label instructions is critical if drug residue and resistance are to be avoided.

## Rational Use of Veterinary Drugs and Vaccines

Veterinary Use Only **1** 100ml **12**  
**Dystosel\*DS** **2** **shake well before using**

**VITAMIN E - SELENIUM INJECTION** protect from freezing  
**3** **sterile aqueous emulsion** **7** **8**  
for sheep and cattle

CONTAINTS **4** PER ML Lot 10919169  
Selenium (as sodium selenite), 3 mg/mL and Ex date 15/12/2017  
Vitamin E (dl- $\alpha$ -tocopherol acetate), 136 IU/mL **11**  
Benzyl alcohol, 15 mg/mL

**5** **Warning:** Treated animals must not be slaughtered for use in food for at least 21 days after the latest treatment with this drug. This product must not be used in lactating dairy cattle. **6**

**DIN 00170968**

**Indications:** For the prevention and treatment of white muscle disease (nutritional myopathy) in calves and lambs. **9**

**Dosage and Administration**

Administer the following single doses subcutaneously or intramuscularly:

**PREVENTION:** Postnatal: Calves - 1 mL/45 kg body weight. Lambs, Newborn - 0.25 mL per animal; 2 to 8 weeks of age - 0.5 mL per animal. Prenatal: After a pregnancy of 5 months in cows and 3 months ewes - 1 mL/45 kg body weight and repeat, if necessary, at no less than 2 week intervals for a maximum of 4 doses.

**TREATMENT:** Calves: 2 mL/45 kg body weight. Lambs: 0.5 mL per animal.

**Caution:** This product contains the toxic substance selenium. Do not exceed recommended dosages. Administer only to animals that are known to be ingesting sub-normal levels of selenium. In case of an anaphylactic reaction, administer epinephrine immediately. **10**

**ROGAR/STB inc** **13** **London.ont**  
**N6A. 4CD**

Figure 1: Exemplary information on drug label; numbers correspond with lists in the previous pages

### **3.2 Packaging**

Packaging may be defined as the collection of different components (example: bottle, vial, closure, cap, ampoule, and blister) which surround the pharmaceutical product from the time of production until its use. The packaging of a pharmaceutical product is aimed at ensuring that veterinary medicines arrive safely in the hands of users for which they are prescribed.

The packaging must protect the product against all adverse external influences that may affect its quality or potency, such as light, moisture, oxygen, biological contamination and mechanical damages. The packaging itself should not have an adverse effect on the product (example: through chemical reactions, leaching of packaging materials or absorption); the product should not also have an adverse effect on the packaging, changing its properties or affecting its protective function.

Containers may be referred to as primary or secondary. Primary container is in physical contact with the veterinary drug (for example, bottle, blister pack, tube, syringe), whereas secondary packaging is the immediate packaging around the primary container (for example, carton, and leaflets/inserts). The choice of primary and/or secondary packaging materials depends on the degree of protection required, compatibility with the contents, the filling method and cost, and the convenience of the packaging

for the user (example: size, weight, method of opening/reclosing, legibility of printing). Both single-dose and multi-dose containers also exist.

### *3.2.1 Pre-packaging*

Pre-packaging is the process by which the veterinary drug professionals transfer a medication manually, or by means of an automated system, from a manufacturer's original commercial container to another type of container in advance (before clients come to veterinary drug retail outlets). Because original containers may contain large amount of drugs, repackaging of drugs into another container may be necessary in order to dispense drugs for animal patient owners. Such repackaging procedure can be done at the spot or in advance. The following guidelines are recommended in pre-packaging of drugs:

- Pre-packaging procedures must comply with laws and regulations.
- The pre-packaging operations and area must be clean and separate from other pharmacy activities.
- Only one drug product at a time should be pre-packaged in a specific work area. No drug products other than the one being packaged should be present in the immediate packaging area. Labels other than those for the product being packaged should not be present in the area.
- Before beginning a pre-packaging run, a physical evaluation (colour, odour, appearance, and markings) of the drug



product being pre-packaged should be made to assure product integrity. The bulk container should also be examined for evidence of damage, contamination, and other deleterious effects.

- All pre-packaging equipment and systems should be operated and used in accordance with the manufacturer's or other established instructions. There should be valid justification and authorization by the supervisor for any deviation from those instructions on the part of the operator.
- The veterinary drug professionals must use available data on the characteristics of all packaging material used to protect the integrity of the drug product. This information should include data on the chemical composition, light transmission, moisture permeability, size, thickness (alone or in laminate), recommended sealing temperature, and storage requirements.
- The beyond-use date applied to pre-packaged medications should adhere to USP standards.

An additional trained individual, other than the packaging operator, should verify that the pre-packaging system (drug, materials, and machines) is in correct working order and that all procedures have been performed properly.

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Control records of all packaging operations must be kept according to the guidelines, and include the following information:

- Complete descriptions of the drug, example: name, strength, dosage form, etc
- The name of the product's manufacturer and distributor (as applicable)
- Manufacturer's control number (lot number)
- Expiration date of the manufacturer's original container and the beyond-use dating of the pre-packaged product
- Number of units pre-packaged, total contents delivered per unit, and the date(s) they were pre-packaged
- Initials of the operator and the veterinary drug professionals responsible for packing of each individual run
- Description of the packaging materials and equipment used.

Upon completion of pre-packaging, all unused drug stock, unused labels and finished packages should be removed from the pre-packaging area. The packaging equipment should then be completely emptied, cleaned, and inspected before commencing the next pre-packaging operation.

### *3.2.2 Packaging Aids and Materials*

The materials used for repackaging include: glass bottles, plastic bottles, collapsible tubes, paper

envelops, and plastic envelops (annex 2). The requirements of containers for packaging different dosage forms are indicated in table 2. Paper has the least value as the primary packaging material in terms of maintaining the quality, safety and stability of packaged drugs.

*Table 2. Requirements for packaging materials.*

	<b>Package characteristics</b>	<b>Examples</b>
<b>Tablets/capsules</b>		
Desirable	Clean, dry, plastic or glass container with tightly sealing cap or seal	Blister packages, plastic sachets, tightly sealing plastic or glass containers with screw or snap cap
Acceptable	Clean, dry container that provides protection from dirt and moisture	zip-lock plastic bags, glycine paper, hinged-lid unsealed boxes, sifter-top boxes, tight-top tins
Undesirable	Unclean absorbent paper, cotton, cardboard containers with no provision for closure	Unsealed plastic bags, paper bags, newspaper or other printed paper
<b>Liquids (oral and topical)</b>		
Desirable	Clean, dry, light-resistant glass container with tightly sealing cap	Amber or opaque bottle with screw cap
Acceptable	Clean, dry plastic or glass container with tight-fitting cap	Glass or plastic bottle with tight-fitting cap
Undesirable	Unclean paper, cardboard, metallic	Previously used liquid-containing cartons, plastic-lined paper bags, plastic bags

### 3.3 Compounding of drugs

Compounding is any manipulation of a drug beyond that stipulated on the drug label.

Manipulation might include mixing, diluting, concentrating, flavouring, or changing a drug's dosage form. Purposes of compounding are to enhance palatability, ease of administration, and dispensing. During compounding, the potential incompatibilities and practices that may interfere with the drug's stability, purity, and/or potency must be considered and avoided.

Examples of compounding include:

- Mixing two injectable drugs in the same syringe;
- Creating an oral suspension from crushed tablets or an injectable solution;
- Adding flavouring to a commercially available drug;
- Creating a trans-dermal gel for a drug typically taken through other routes;
- Mixing two solutions for instilling into the ear.

*Procedures for Compounding of drugs:*

- i. Calculate quantities of ingredients and product to 100% accuracy
- ii. Produce clear labels for end products,
- iii. Check each ingredient to ensure its suitability for use,
- iv. Ensure equipment and work area are appropriate, clean and tidy
- v. Personnel should be appropriately prepared for aseptic procedure (hand washing, appropriate clothing)

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- vi. Use appropriate compounding technique to prepare product
- vii. Weigh or measure correct quantity of ingredients
- viii. Undertake a visual final check for products,
- ix. Pack each compounded product in container suitable for type, quantity, intended use and storage requirements of the product,
- x. Attach labels securely, without obscuring relevant information,
- xi. Comply with optimal storage conditions regarding: temperature, light, moisture, type of container, and transport of the product,
- xii. Clean all equipment after use
- xiii. Record the details
- xiv. Issue items for users with appropriate instruction for use

### **4. TRANSPORTATION, DISPENSING ENVIRONMENT, STOCK MANAGEMENT AND QUALITY ASSURANCE OF VETERINARY DRUGS**

#### **Objectives**

At the end of this session trainees should be able to:

- Identify the measures that should be taken to take care of veterinary drugs during transportation and at the stock and dispensing areas
- Develop the skill and knowledge of proper stock management
- Understand the different methods to assure the quality of drugs at the stock and dispensing area

#### **4.1 Transportation**

When transporting veterinary drugs in vehicles (car), you should make sure drugs are stored properly to prevent damage or spillage during transport in section of the vehicle separated from the driver, other passengers, animals or food. They should be transported in accordance with any product guidance, secured against theft and unauthorised access, and accompanied by relevant information about the products. The product should not contaminate and is not contaminated by other products and appropriate environmental conditions must be maintained (using cold chain for thermolabile products).

Transportation and storage of veterinary products containing hazardous substances, such as toxic, radioactive material, and other dangerous pharmaceutical products presenting special risks of abuse, fire or explosion (combustible or flammable liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas, and transported in safe, suitably designed, secured containers and vehicles.

### **4.2 Dispensing Environment**

Dispensing environment must be clean, because most medicinal products are for internal use, making it important that they must be hygienic and uncontaminated. The environment must also be organized so that dispensing can be performed accurately and efficiently. The dispensing environment includes staff, physical surroundings, shelf and storage areas, surfaces used during work, equipments and packaging materials.

It should also possess:

- Optimum temperature
- Sufficient lighting (but not direct sunlight)
- Optimum humidity
- Cold storage facilities
- Adequate number and type of shelves
- Suitably spaced to permit cleaning and inspection
- A dispensing bench of adequate size having a smooth, impervious working surface.

- Lockable cabinet for narcotic drugs , psychotropic substances and poisons
- Owner waiting area
- Dispensing aids

### *4.2.1 Premises and facilities*

The premises on which a dispensing service is provided would reflect the quality of service and inspire confidence on the owner in the nature of pharmaceutical service delivered. Therefore, working conditions are recommended to take into considerations the safety and health of the public and people working on the premises.

- The walls, floors, windows, ceiling, and all other parts of the premises should be as per the requirement set by the regulatory body.
- Rooms (with minimum area specified) are required for dispensing, storing and compounding veterinary drugs.
- Toilet with water supply and drainage system is also a requirement.
- All parts of the premises should be maintained in an orderly and tidy condition.
- Pharmaceutical products should be protected from the adverse effect of light, freezing or other temperature extremes and humidity.

The facility should make sure that the equipments on the premises are adequate and suitable for all the operations that have to be



carried out. All equipment should be kept clean and should be checked for cleanliness prior to each use. With the exception of non -returnable containers, equipment must be of such material and be kept in such good repair and condition as to enable it to be thoroughly cleaned to prevent any risk of contamination. Use of stainless steel and glass is recommended.

### *4.2.2 Hygiene and Sanitation*

- ✓ The physical surroundings must be maintained as free of dust and dirt as possible. Maintaining a clean environment requires a regular routine of cleaning shelves and a daily cleaning of floors and working surfaces.
- ✓ There should be a regular schedule for checking, cleaning, and defrosting the refrigerator.
- ✓ Spills should be wiped up immediately, especially if the liquid spilled is sticky, sweet, or attractive to insects and flies.
- ✓ Food and drink must be kept out of the dispensing area, with the refrigerator used strictly for veterinary drugs only.
- ✓ Dispensing equipment used for measuring liquids or counting tablets or capsules should be kept clean at all times. For example, uncoated tablets normally leave a layer of powder on any surface they touch, which can easily be transferred to other tablets or capsules counted on the same surface. This is called cross contamination

and could be dangerous if the contaminating substance (example: aspirin or penicillin) is one to which an animal patient is sensitive.

- ✓ All persons engaged in dispensing should observe high standards of personal cleanliness and wear protective cloths that should be laundered regularly.
- ✓ Smoking should be prohibited in any area where veterinary drugs are dispensed, sold or supplied. Direct contact between the operator's hands and the dispensed products should be avoided.

### **4.3 Stock Management**

Good stock management facilitates safe and effective dispensing service. To ensure proper stock management, the following elements are important:

- Acquisition of medicines
- Stock keeping
- Stock rotation
- Arrangement of veterinary drugs in the dispensary
- Storage conditions

#### *4.3.1 Acquisition of medicines*

Before veterinary drugs and medical supplies are issued from store to dispensing room, store requisition/delivery (issue) form should be filled by the dispenser and duly signed by authorized personnel. It is mandatory that all veterinary drugs found in veterinary drugs retail outlets are obtained or collected from legal sources.

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When you receive veterinary drugs for dispensing:

- ✓ Ensure that there is sufficient storage place
- ✓ Prepare and clean the areas for receiving and storing
- ✓ Inspect packages for damaged and/or expired products
- ✓ Check that all original boxes, tins, or bottles are unopened and are in good condition.

*If products are defective:*

- ✓ Separate the damaged or expired stock from the usable stock
- ✓ Refuse to accept the products and note the problem(s) on the delivery note
- ✓ Follow your facility's procedure for handling damaged or expired stock.
- ✓ Report quality problem to the nearest regulatory body and fill prepaid adverse drug event report form and send to VDFACA.

*If Products are not damaged:*

- ✓ Fill issue voucher and requisition voucher
- ✓ Count the number of units for each product received and compares to issue voucher
- ✓ Record received item on receiving voucher, stock card, bin card and computer (if applicable)
- ✓ Ensure the expiry date is visibly marked on every package or unit
- ✓ Arrange products in the storage area in such a way to facilitate the dispensing of

the first to expire by first expiry first out (FEFO) or first in first out (FIFO) procedures.

### 4.3.2 *Stock keeping*

Veterinary drug should be kept within the dispensary/or store rooms as follows:

- ✓ Follow the manufacturer or shippers directions when stocking, and follow labels for storage conditions
- ✓ Ensure safe custody of poisons,
- ✓ Place liquid products on the lower shelves or on bottom of stacks
- ✓ Store products that require cold storage in appropriate temperature controlled zones.
- ✓ Keep high security/high value products such as narcotic drugs psychotropic substances in appropriate secured place
- ✓ Separate damaged, expired and returned products from the usable stock without delay and dispose using established disposal procedures.
- ✓ Always store all products in a manner that facilitates FIFO policy for stock managements.
- ✓ Report to appropriate body for redistribution of veterinary drugs with near expiry date

### 4.3.3 *Stock rotation*

When issuing products, it is important to follow the FEFO and FIFO procedures, which minimize wastage due to product expiry. Therefore:

- Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.
- Always issue products that will expire first, ensuring they are not too close to or past their expiration date. The shelf life remaining should be sufficient for the product to be used before the expiry date.
- To facilitate FIFO and FEFO, place products that may expire first in front of products with a latter expiry date.
- Write expiry dates on stock cards, so that stocks can be used before they expire.
- Supplies with no expiry or manufacture date (example: gauze, cotton, medical gases etc.) should be stored in the order received and dispensed accordingly.

### *4.3.4 Arrangement of veterinary drugs*

Veterinary drugs should be arranged on shelves made of steel or treated wood and the shelves should be strong and robust. Animal health institutions and veterinary drugs retail outlets can use one or a combination of the following commonly used methods of veterinary drugs arrangement:

1. Pharmacotherapeutic category
2. Alphabetical order by generic name
3. Dosage forms

In arranging veterinary drugs, the following points should be considered:

- ✓ Each dosage form of veterinary drug is arranged in separate and distinct areas

- ✓ Sufficient empty space should demarcate one veterinary drug or dosage form from another
- ✓ Put veterinary drug in well ventilated , dry and place protected from direct sunlight and heat
- ✓ Store liquids in a pallet on the floor or on the lowest shelf
- ✓ Store drugs like acaricides, insecticides and other hazardous substances in separate room and open them in well ventilated area
- ✓ Do not store anything directly on the floor
- ✓ Always store cold-chain items in the refrigerator

### 4.3.5 Storage conditions

Storage conditions can be arranged in two classes:

- i. Normal storage conditions
- ii. Special storage conditions (cold storage conditions, combustible /flammable or secured)

#### i. *Normal storage conditions*

It is storage the storage of drugs in dry, well-ventilated premises at temperatures of 15–25°C or, depending on climatic conditions, up to 30 °C. Extraneous odours, other indications of contamination, and intense light must be excluded. Veterinary drugs that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated (example: continuous maintenance of cold

storage) deviation may be tolerated only during short-term interruptions, for example, during local transportation.

The use of the following labelling instructions is recommended:

On the label means

“Do not store over 30 °C” from +2 °C to +30°

“Do not store over 25 °C” from +2 °C to +25°C

“Do not store over 15 °C” from +2 °C to +15°C

“Do not store over 8 °C” from +2 °C to +8°C

“Do not store below 8 °C” from +8 °C to +25°C

“Protect from moisture” no more than 60% relative humidity in normal storage conditions; to be provided to the animal owner in a moisture resistant container.

“Protect from light” to be provided to the owner in a light-resistant container.

Unless special storage conditions are stated, it is vital that veterinary drugs be stored in a dry, adequately ventilated shady and cool store room. Efforts should be made to maintain the specified storage conditions with regard to exposure to humidity, sunlight, heat, etc. Free air circulation by opening windows, using fans or air conditioners can be considered to reduce the effects of humidity.

Some products are photosensitive and will be damaged if exposed to light.

*To protect products from sunlight:*

- ✓ Shade the windows or use curtains, if they allow the passage of direct sunlight
- ✓ Keep products in intact cartoon
- ✓ Do not store or pack products in sunlight
- ✓ Maintain trees on the premises around the facility to help provide shade

Heat will also affect many products. It melts ointments and creams and affects other products. It is important to have thermometers, hygrometer and other equipment in order to regulate the temperature and humidity of storage areas.

### ii. *Special storage conditions*

Some categories of veterinary drugs and supplies require special storage conditions which can be further classified into three as cold storage conditions, combustible or flammable storage conditions and secured storage.

#### *a. Cold storage conditions*

Cold storage conditions maintained by using refrigerators and freezers for products that may be degraded rapidly when kept at room temperature or even at cool places, example: vaccines, insulin

When using refrigerators and freezers:

- ✓ Refrigerators that open on the top are more efficient than vertical ones, because hot rises while cold air falls
- ✓ Store products that are sensitive to freezing or very low temperatures on the upper shelves.



- ✓ If there is enough space, place a few plastic bottles of water in the refrigerator. This will help maintain the temperature for a longer period of time if the power is cut off. The temperature ranges for different storage conditions are shown in the following table.
- ✓ Do not keep staff food in the refrigerator. Opening and closing the door may lower the temperature and cause veterinary drugs to deteriorate. Record the temperature daily. Check that there is enough space around the refrigerator so air can move freely.

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Table 3: Terms that relate to storage temperature

s/n	Terms used	Applications
1	Store frozen (deep freezing)(-20°C) (4°F)	For products such as certain vaccines, need to be transported or stored for long within a cold chain
2	Store at 0 - 4°C	For product labelled store at refrigerator temperature
3	Store at 2°C - 8°C(36°F -46°F)	For products which are very heat sensitive but must not be frozen. This temperature is appropriate of storing vaccines for a short period of time.
4	Keep cool	to be kept between 8-15 °C (45 -59°F)
5	Store at room temperature	For product labelled to be kept between 15-25°C (59 -77°F)
6	Store at ambient temperature	Store at the surrounding temperature. It means “room temperature” or normal storage condition, that is storage in a dry, clean, well- ventilated area room temperature between 15 -25 °C (59 - 77°F) or up to 30, depending on climatic conditions.

N.B: -When storing veterinary drugs, we have to follow manufacturer’s recommendations on storage conditions of specific products.

### *b. Combustible /Flammable storage conditions*

Combustibles such as alcohol, ether and other organic solvents must be stored in special or separate rooms. An advisable precautionary measure is to use a small, separate outbuilding as a special store for inflammable supplies, since it virtually guarantees that fire will not spread throughout the store. All stores should be equipped with fire extinguishers. A good

alternative to fire extinguishers is represented by wooden or metal buckets filled with sand.

### *c. Secured storage conditions*

Narcotic drugs, psychotropic substances, and their documents should be kept in securely locked rooms or cupboards. The keys should be kept in a secure place and it is preferable that only the chief of pharmacy should have access to them.

## **4.4 Quality Assurance of Veterinary Drugs in the Stock**

Quality specifications comprise a set of properly selected standards with associated methods of analysis which are used to assess the integrity of veterinary drugs and starting materials. The selection of methods and procedures used in specifications must be based on their utility for the purpose of quality assurance of veterinary drugs. The tests may involve simplified tests (basic tests) or sophisticated analytical examinations.

Because sophisticated analytical examinations require special skills and well equipped laboratories, simplified tests are commonly used in dispensaries for verifying the quality of dispensed veterinary drugs. Such tests may usually serve to ascertain the absence of gross degradation, contamination or damage.

Some indicators of quality problems that can be ascertained by simplified test such as physical

inspection are show in table 4. When a product fails the basic tests, it should not be used until its quality is established by analytical examination. It is important to note that the shelf-life of veterinary drugs may be markedly shortened by improper storage conditions. Therefore, the expiry date information of a veterinary drug product may not guarantee the quality of it. Any quality problem of veterinary drug product should be reported to the concerned body immediately.

Table 4: Common quality problem indicators for different veterinary pharmaceutical products

<b>Common quality problems</b>	<b>Common Problem Indicators</b>
All products	Broken or tripped packaging Missing, incomplete or unreadable label(s)
Liquid products	Discoloration, cloudiness, sediment, broken seal on bottle, cracks in ampoule, bottle or vial, dampness, or moistures in the packaging, leakage, caking
Light sensitive products	Torn or ripped packaging
Latex products	Dry, brittle or cracked
Lubricated latex products	Sticky packaging, discoloured products or lubricant, stained packaging, leakage of the lubricant
Tablets (bolus)	Discoloration, missing boluses, unusual smell, stickiness (especially coated tablets)
Injectables	Liquid does not return to suspension after shaking sterile products Torn or ripped packaging, missing parts, broken or bent parts Moisture inside the packaging or stained packaging, Particle matter/precipitate
Foil packs	Perforation(s) of packaging
Chemical Reagents	Discoloration

### *4.4.1 Techniques for quality drugs dispensing*

The main aim of quality dispensing is to maintain the quality of the dispensed medicines for their specified shelf-life and ensure appropriate use of the drugs by the patients. An important aspect of quality dispensing concerns the packaging and storage of drugs. The techniques that lead to quality dispensing may be accumulated through training and/or experience.

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The most useful techniques to ensure quality in dispensing include:

- Maintenance of records on what drugs and products have been issued.
- Maintenance by the veterinary drug professional of a daily list of drugs in stock to inform prescriber which drugs are available thereby ensuring that only these drugs are prescribed.
- A two prescription system whereby two separate prescriptions are written one for medicines available in the pharmacy and one for those that are not but can be ordered which helps to avoid rewriting of prescriptions.
- Adherence to specifications for storage conditions.
- Adherence to specifications for containers for repackaging
- Keep written procedures for compounding
- Dispensing only one prescription at a time
- Avoid dispensing when dizzy, in stress, etc.
- Double checking of the name, dosage form, strength, amount to be dispensed as well as the information on the label
- Organize medicine and therapeutic committee at animal health institution level and participate

## **5. SYSTEMS OF MEASUREMENT AND DRUG FORMULATION**

### **Objectives:-**

At the end of this session, you should be able to identify different systems of measurement and their relationship as well as different formulations of drugs.

### **5.1 Systems of Measurements**

There are three systems of measurements namely: metric, apothecary and household systems.

#### **A) *Metric system***

Metric system is the most commonly used system and sometimes termed as SI unit (International system unit). This is because of the simplicity of the decimal system, the clarity provided by the base units and prefixes of the SI, and the ease of scientific and professional communications through the use of a standardized and internationally accepted system of weights and other measurements. The system is used to manufacture and label pharmaceutical products, for prescription and administration of drugs.

The system has one primary (base) unit and set of prefixes. Base units are meter (length), litre (volume) and gram (weight).

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Table 5: Prefix modifiers in metric system

S/n	Prefix	Symbol	Factor number	10 <sup>th</sup>	Factor in Word
1.	exa	E	1,000,000,000,000,000,000	10 <sup>18</sup>	quintillion
2.	peta	P	1,000,000,000,000,000	10 <sup>15</sup>	quadrillion
3.	Tera	T	1,000,000,000,000	10 <sup>12</sup>	Trillion
4.	Giga	G	1,000,000,000	10 <sup>9</sup>	Billion
5.	Mega	M	1,000,000	10 <sup>6</sup>	Million
6.	killo	K	1,000	10 <sup>3</sup>	Thousand
7.	Hecto	h	100	10 <sup>2</sup>	Hundred
8.	Deca	da	10	10 <sup>1</sup>	ten
9.	Deci	d	0.1	10 <sup>-1</sup>	tenth
10.	centi	c	0.01	10 <sup>-2</sup>	Hundredth
11.	Milli	m	0.001	10 <sup>-3</sup>	Thousandth
12.	micro	u	0.000001	10 <sup>-6</sup>	Millionth
13.	Nano	n	0.000000001	10 <sup>-9</sup>	Billionth
14.	Pico	p	0.000000000001	10 <sup>-12</sup>	Trillionth
15.	femto	f	0.000000000000001	10 <sup>-15</sup>	quadrillionth
16.	Atto	a	0.00000000000000001	10 <sup>-18</sup>	quintillionth

### Metric Volume

	Unit	Abbreviation
One liter (L) is equal to	0.001 kiloliter	kL
	0.01 hectoliter	hL
	0.1 dekaliter	dkL
	10 deciliters	dL
	100 centiliters	cL
	1000 milliliters	mL
	1,000,000 microliters	μL
	1,000,000,000 nanoliters	nL



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### Metric Length

	Unit	Abbreviation
One meter (m) is equal to	0.001 kilometer	km
	0.01 hectometer	hm
	0.1 dekameter	dkm
	10 decimeters	dm
	100 centimeters	cm
	1000 millimeters	mm
	1,000,000 micrometers	µm
	1,000,000,000 nanometers	nm

### Metric Weights

	Unit	Abbreviation
One gram (g) is equal to	0.001 kilogram	kg
	0.01 hectogram	hg
	0.1 dekagram	dkg
	10 decigrams	dg
	100 centigrams	cg
	1000 milligrams	mg
	1,000,000 micrograms	µg or mcg
	1,000,000,000 nanograms	ng

### General Guideline

1. To convert a larger to smaller unit multiply proportionally
  - a. kg to g multiply by 1000
  - b. Hectogram (hg) to g by 100
2. To convert smaller to larger unit divide it proportionally
  - a. g to kg divide by 1000
  - b. g to hg by 100
3. To do mathematical calculation all unit should be the same

Example: To subtract 64 mg from 0.12 g=  
120mg-64mg= 56 mg

1. Convert the following into their corresponding equivalent

- a) 50 mL to cL                      ans=5cL  
b) 100 hL to L                      ans=10000L  
c) 800 mL to nL                  ans=800,000,000nL

2. Add 0.55kg, 55mg and 125g. Provide the answer in g. Ans. 675.055g

1. A sedative liquid medication contains 0.25 mg of an active ingredient per mL. How many g of the substance will in 5 litre of the solution?

Given= the concentration 0.25mg/mL

Total volume of the solution is  $5\text{L} = 5000\text{mL}$

0.25mg-----1mL

?-----5000mL

$$\frac{0.25\text{mg} \times 5000\text{mL}}{1\text{mL}} = 1250\text{mg}$$

Ans. 12.5g

Sometimes international unit is also included in metric system. The international unit is a unit of measurement for the amount of a substance, based on the measured biological activity or effect. There is an international agreement specifying the biological effect expected with a dose of one IU. The unit is used for vitamins, hormones, some medications, vaccines, blood products, and similar biologically active substances. One IU of insulin is the biological equivalent of about 45.5µg pure crystalline

insulin (1/22 mg exactly). 1 IU of vitamin A is the biological equivalent of 0.3 µg retinol, or of 0.6 µg beta-carotene. One IU of vitamin C is 50 µg L-ascorbic acid; one IU is the biological equivalent of 0.025 µg cholecalciferol/ ergocalciferol. One IU is the biological equivalent of about 0.667 mg d-alpha-tocopherol (2/3 mg exactly), or of 1 mg of dl-alpha-tocopherol acetate. One IU represents 0.6 microgram of a standard preparation of penicillin.

### ***B) Apothecary system***

Apothecary system is an old system of measurement and used first by apothecaries (early pharmacists). It is not commonly used. However, some countries like US are still used it. It has units for weight and volume only.

#### ***Apothecary systems of measurement***

- Grain (gr) is the basic unit of weight in apothecary system 1gr=60mg=0.06g
- Dram is the basic unit of volume in apothecary system
- ounce (oz) is the common unit of volume in apothecary system
- Pound (lb)=A unit of weight equal to 12 ounce, 1kg=2.2lb

### ***C) Household system***

The house hold system is derived from apothecary system. The units of house hold system are drop, teaspoon, tablespoon, cup, gallon and so on.

Approximate equivalents to household measure:

- 1 teaspoon (tsp) = 60 drops = 5 ml
- 1 tablespoon (tbsp) = 15 ml = 3 teaspoon
- 1 glass = 1 cup = 250 ml
- 1 ounce = 2 tablespoon = 30 ml
- 15 - 20gtt (drops) = 1 ml

House hold system is important for clients rather than using it in the laboratory or in scientific works since it is not accurate.

*NB: Important Relationship*

For water at STP (standard temperature [23°C] and pressure [15 psi])

1 cc = 1ml = 1g, one litre of water = 1 kg

### 5.2 Drug Formulations

Any drug contains one or more active ingredients and other inactive substances such as: *excipients, vehicles, flavouring agents, or preservatives*. These inactive substances play a role in stability of the drug, ease of administration or they may affect other pharmacological properties of the drug. Pharmaceutical companies manufacture drugs in different forms. Drug formulation can be solid, semisolid, or liquid.

#### *A. Solid formulations*

Solid formulations are *Powders, Granules, Tablets, Capsules and Bolus*.

*Powder*: contain one or mixture of two or more drugs in a dried or finely pulverized form. It can

be prepared for external use or can be mixed with food or water or reconstituted for injection by sterile fluid.

*Granules:* are small aggregate of powder held together by a binding agent. Their use is the same as powders.

*Bolus:* A single, relatively large quantity of a substance intended for therapeutic use.

*Capsules:* a drug formulation in which the drug (solid or semisolid or liquid) is contained in an external shell. The shell which may be made up of gelatine or glycerine will dissolve in the stomach or in the upper part of the intestine. The capsule helps to mask unpleasant (unpalatable) taste of the drug. The disadvantage of capsule is that it cannot be broken, to give a divided or lower dose to an animal.

### *B. Semisolid drug formulations*

Semisolid drug formulations are *lotions, ointments, cream, paste or gels* which are prepared for local or oral use.

- i) *Lotions:* are solutions or suspensions of soothing substances to be applied to the skin.
- ii) *Ointment* is a greasy, semisolid preparation that contains dissolved or dispersed drug. Antibiotics and anti-inflammatory agents can be prepared in the form of ointments. Common examples are eye or ear ointments.
- iii) *Cream* is a semisolid emulsion formulated for application to the skin or mucous membranes.  
Example: Udder cream

iv) *Paste* is a semisolid preparation slightly thicker and less greasy than ointment.

### C. *Liquid Preparations*

Liquid formulations are prepared either in the form of solution or suspension.

1. *Solution*: is a homogeneous mixture of two or more substances; prepared as syrups (water and sugar) or injectors. It can be aqueous or alcoholic solution depending on the solvent in it. It doesn't settle or precipitate if it stands still for a long period of time. Solutions may be available in different containers (ampoule, vial or bottle).

i. Ampoules are a small glass container intended for single use, the neck is broken to get the drug.

ii. Vials are glass containers with rubber stopper for single or multiple doses.

iii. Bottles are a glass or plastic containers with larger volume than vials.

2. *Suspension* is a fluid containing solid particles that are sufficiently large for sedimentation. It should be shaken before use.

## 6. STRENGTH OF SOLUTIONS

### Objectives:

Upon successful completion of this chapter, the trainees will be able to:

- Identify methods to express the strength solutions
- Perform calculations for altering strength of solutions

### 6.1. Expression of strength of solutions

Strength shows the concentration of ingredients in a mixture or a solution containing two or more substances. There are two important components in expressing the strength of a solution.

1. *Solute* is a chemical substance dissolved in solvent that is usually present in small amount.
2. *Solvent (diluent)* is a liquid used to dissolve other chemicals that is usually present in large amount.

The amount of solute and solvent in a mixture indicates its strength. There are different methods used to express the strength of solutions. The most commonly used methods are parts per notation, percentage and ratio.

#### *A) Parts-per notation*

The parts-per notation is used as a measure of the concentration of a component substance in a mixture of substances and usually when the concentration is very small. The most commonly

## Rational Use of Veterinary Drugs and Vaccines

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used parts-per notations are *Part per million (ppm)*, *Parts per billion (ppb)*, *Parts per trillion (ppt)* and *part per thousand (pps)*.

i. *Parts per million* refers to a number of parts of one substance in one million parts of the solution. For example: 5 ppm chlorine in water is 5 gram of Chlorine in one million gram of water (1,000,000 mL at STP).

Exercise 1: Convert 500 ppm to gram per litre,  
 $500\text{ppm} = 500\text{g in } 1,000,000\text{g (1,000,000mL at STP)}$   
 $500\text{g in } 1000\text{L (1L = 1000mL)}$   
Divide both side by 1000, will give you the answer

*Ans. 0.5g/L*

Q1: Convert 10 ppm to milligram per kg,  
 $10\text{ppm} = 10\text{g in } 1,000,000\text{g of a substance}$   
 $10,000\text{mg in } 1000\text{kg (after converting g to mg, and g to kg respectively)}$   
Divide both side by 1000 will give you the answer

*Ans. 10mg/kg*

NB:  $1\text{ mg} / \text{kg} = 1\text{ppm}$ ;  $1\text{mm}^3 / \text{litre} = 1\text{ ppm}$ ;  $1\text{ mg} / \text{litre} = 1\text{ ppm}$

i. *One part per hundred* is generally represented by the percent (%) symbol and denotes one part per 100 parts, one part in  $10^2$ , and a value of  $1 \times 10^{-2}$ .



- ii. *One part per thousand (pps)* denotes one part per 1000 parts, one part in  $10^3$ , and a value of  $1 \times 10^{-3}$ .
- iii. *One part per billion (ppb)* denotes one part per 1,000,000,000 parts, one part in  $10^9$ ,  $1/1,000,000,000 \times 100\% = 0.0000001\%$  (or  $1\% = 10,000,000$  ppb) and a value of  $1 \times 10^{-9}$ .
- iv. *One part per trillion (ppt)* denotes one part per 1,000,000,000,000 parts, one part in  $10^{12}$ , and a value of  $1 \times 10^{-12}$ .

### B. Percentage (*v/v*, *w/v*, *w/w*)

- i. *Percent volume in volume (v/v)*: the number of mls of a drug in 100ml of a solution ( $1\% \text{ v/v} = 1 \text{ ml}/100 \text{ ml}$ ).
- ii. *Percent weight in weight (w/w)*: the weight in gm of a drug in 100 gm of the mixture ( $60\% \text{ w/w} = 60 \text{ gm}/100 \text{ gm}$ ).
- iii. *Percent weight in volume (w/v)*: the weight in grams per 100ml of a solution (dextrose  $5\% \text{ w/v} = 5 \text{ g}/100\text{ml}$ ).

### C. Ratio

Ratio is expressed as 1:1000 which means 1 unit of a drug in 1000 unit of a solution.

### Exercise

1. How many mL of ethanol exist in 500mL of 70% (v/v) ethanol solution?

70%= 70mL in 100mL

?-----500mL

$$\frac{70\text{mL} \times 500\text{mL}}{100\text{mL}} = \underline{350\text{ml}}$$

2. How many gram of oxytetracycline exist in 200 mL of 20% solution? *Ans 40g*

20%(20g) in 100mL

? ----- 200mL

$$\frac{20\text{g} \times 200\text{mL}}{100\text{mL}} = \underline{40\text{g}}$$

3. The recommended dilution concentration of diazinon is 1:1000. How many mL of stock solution is needed to prepare 10 litre of the mixture?

1:1000 = 1mL in 1000mL of a solution

?-----10,000mL (10L = 10,000mL)

$$\frac{10,000\text{mL} \times 1\text{mL}}{1000\text{mL}} = \underline{10\text{ml}}$$

### 6.2 Changing the strength of solutions

The strength of a solution can be changed either by dilution or concentration. Dilution is making a solution less concentrated for application as a drug or laboratory reagent. This is done by adding a solvent/diluents/, or admixture with solutions or mixtures of lower strength. Concentration is increasing the strength of a solution by addition of the active ingredient

(solute), evaporation of the diluents or admixture with solutions or mixtures of higher strength.

If the amount of active ingredient remains constant, any change in the quantity of solution or mixture of solids is inversely proportional to the percentage or ratio strength that is the percentage or ratio strength decreases as the quantity increases. Problems in dilution or concentration are generally solved by the following equation

$$(Quantity)_1 \times (Concentration)_1 = (Quantity)_2 \times (Concentration)_2;$$
$$Q_1 \times C_1 = Q_2 \times C_2$$

For calculating other quantity, determining the quantity of active constituent (solute) is needed and then calculating the quantity of the available solution (usually concentrated or stock solution) that will provide the needed amount of the constituent.

Example: if there is 4% of saline solution and if we need 40 mL of 2% working solution. How many mL of stock solution and water are needed?

Given

$$C_1 = 4\% \quad C_2 = 2\%$$
$$Q_1 = ? \quad Q_2 = 40\text{mL}$$

$$Q_1 \times 4\% = 2\% \times 40\text{mL} = \frac{40\text{mL} \times 2\%}{4\%} = 20\text{mL}$$

Answer = 20ml stock and 20ml water

### Exercise

1. How many ml of a 20% solution are needed to prepare 50 ml of a 5% solution? *Ans. 12.5mL*
2. A stock solution of 10% iodine is to be diluted to 2% solution. If 5 litre of iodine were needed, how much water should be used for dilution? *Ans. One litre of Iodine, 4 litre of water*
3. A veterinarian wants to disinfect the poultry house using 2.5 % formalin from formaldehyde

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(100%). How many mL of the stock solution is needed to prepare a 16 litre working solution?

*Answer: 400 mL*

### 7. DOSE CALCULATION

#### **Objective:**

At the end of this session trainees should be able to perform dose calculation for proper drug prescription and dispensing of veterinary drugs.

Dose calculation is crucial for any clinical practice. Over dose is dangerous for the patient and encore extra-cost. Under dose is ineffective and promote the development of drug resistance. Factors that affect dosage are related with the patient or the drug. The patient factors include *body weight, species of animal, sex, age, physiological status and pathology*. Some of the factors related with drug are type of the drug and concentration of the active ingredient.

To calculate the dose, you should know the standard dose (mg/kg, ml/kg, unit/kg or dilution rate for a solution), the concentration of the active ingredient (mg in ml or g) and the body weight of the animal.

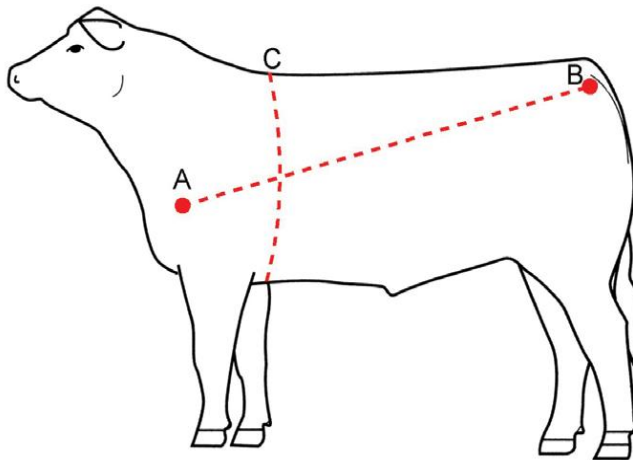


Figure 2: Weighing the animal by heart girth and sensitive digital balance

### **7.1. Weighting animal using heart girth**

With weight estimation formulas, a common tape measure is used to determine the heart girth and body length measurement. These measurements are then used to calculate the animal's weight. The weight estimation formulas described below are almost always more accurate than visual observation in determining an animal's weight.

#### *7.1.1. Beef Cattle*



1. Measure the length of body, from the point-of-shoulder (A) to the point-of-rump or pin bone (B).
2. Measure the circumference or heart girth (C). Measure from a point slightly behind the shoulder blade, down the fore-ribs and under the body behind the elbow all the way around.

After these measurements are made in inches  
– use the following formula.

3. (Heart girth X heart girth X body length) ÷ 300  
= weight in pounds.

**Example:**

Heart girth (76") X heart girth (76") X body length  
(66") divided by 300 = 1,270 pounds.

$$76 \times 76 = 5,776$$

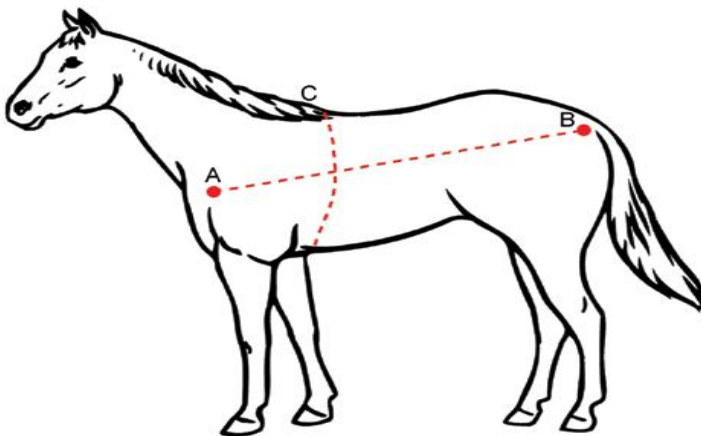
$$5,776 \times 66 = 381,216$$

$$381,216 \text{ divided by } 300 = 1,270 \text{ pounds}$$

### 7.1.2. Sheep and Goats

For sheep and goats, use the same method described for beef cattle. When working with unshorn sheep, be sure to part or compress the wool to insure an accurate heart girth measurement.

### 7.1.3. Horses



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1. Measure the length of body from, from the point-of-shoulder (A) to the point-of-rump (B).
2. Measure the circumference (heart girth) of body (C). Measure from the base of the withers, down under the belly, just behind the elbow and foreleg, and all the way back around. After these measurements are made in inches – use the following formula.
3.  $(\text{Heart girth} \times \text{heart girth} \times \text{body length}) \div 330$   
= weight in pounds.

### **Example:**

Heart girth (70") X heart girth (70") X body length (65") divided by 330 = 965 pounds.

$70 \times 70 = 4,900$

$4,900 \times 65 = 318,500$

$318,500 \text{ divided by } 330 = 965 \text{ pounds}$

### **Tips for increasing Accuracy and Safety**

- Make certain the animal is standing squarely on level ground.
- Have someone stand on the opposite side to help with the girth measurement.
- Make sure the tape lays flat and is not twisted.
- Pull the tape snug.
- When using a weigh tape, position the tape according to the manufacturer's directions.
- A cloth measuring tape is preferred.
- You may need to restrain the pig or some feed may help you get the needed measurements.



- Be calm, don't rush in. Make sure the animal is comfortable with the measuring tape.
- When monitoring an animal's weight over time, it is best to have the same person using the same method.
- By following a set procedure you will be able to monitor change that can be used as an indicator of health.
- The weight estimation formulas and weigh tapes may be used effectively for many animals, but are not highly accurate for pregnant animals or those with extreme conformational irregularities.
- Keep a record that you can refer back to over time.

### **7.2. Formula to calculate dose:**

i. *Unit (amount) needed = body weight X dose rate*

You should always notice the unit of measurement.

Example: How many mg of Amoxicillin are needed for a 10 kg dog if the dose is 20 mg/kg ?  
 $\text{mg needed} = 10 \text{ kg} \times 20 \text{ mg/kg} = 200 \text{ mg}$  (kilograms cancel out)

ii. *Liquid dosage in ml =*

$$\frac{\text{Standard dose in mg/kg} \times \text{body wt in kg}}{\text{Concentration of the drug in mg/ml}}$$

Example 1: How many mL of Amoxicillin are needed for the patient above? The Amoxicillin available is in a 100-mg/mL concentration,

$$\frac{20\text{mg/kg} \times 10\text{kg}}{100\text{mg/mL}} = \underline{2\text{mL}}$$

Example 2: You decide to give a sheep weighing 30kg, oxytetracycline in the bottle containing 100mg/ml. the standard dose of oxytetracycline in sheep is 10mg/kg. How many ml will be given for this sheep?

Using the above formula  $\frac{10\text{mg/kg} \times 30\text{kg}}{100\text{mg/mL}} = \underline{3\text{mL}}$

**Exercise:** Calculate the following questions accordingly

1. The general dose of atropine sulphate to pigs is 0.05mg/kg of body weight and the solution is levelled as 2.5mg/ml. How many ml of the drug administered to the pig weighing 100 kg?  
*Ans. 2mL*
2. In Exercise 1 above, another solution of atropine sulphate is found in proportion of 0.1%. Calculate the amount of drug administered to that animal? *Ans. 5ml*
3. If you want to administer 2ml of sodium pentobarbital in dose rate of 1mg/kg of body weight to the rabbit weighing 10kg. In what concentration you may dissolve the drug? *Ans. 5mg/ml*

iii. *Solid Dosage in bolus or tablet or capsule*

$$= \frac{\text{Standard dose in mg/kg} \times \text{body wt in kg}}{\text{Concentration of drug in mg/bolus/tablet}}$$

**Exercise:** the standard dose of Albendazole for cattle is 10mg/kg, how many boluses are needed to treat a cow weighing 240kg, where each bolus contains 600mg of the drug per bolus.

$$\frac{10\text{mg/kg} \times 240\text{kg}}{600\text{mg/bolus}} = 4 \text{ bolus}$$

### *iv. Intravenous Drip Calculation*

*Intravenous (IV) infusions* are sterile, aqueous preparations administered intravenously in relatively large volumes. They are used to extend blood volume and /or provide electrolytes, nutrients or medications.

Intravenous infusions may be continuous or intermittent. *In continuous infusions, large volumes* of fluid (250 to 1000 mL), with or without added drug, are run into a vein uninterrupted. *Intermittent infusions* are administered during scheduled periods.

#### *a). Continuous infusions*

To calculate infusion time, use this formula:-

$$\text{Infusion time} = \frac{\text{Volume of infusion in mL}}{\text{Flow rate in mL/hr or mL/min}}$$

#### *b) Intermittent Infusion*

$$\text{Drip rate} = \frac{\text{volume of solution mL} \times \text{drops/mL}}{\text{volume in drops/minute (or ggt/min)}} \\ \text{Time (in minutes)}$$

Example 1: A patient animal received 260 mL of an infusion continuously at a rate of 40 mL/minute. What was the infusion time in minute?

$$\frac{260\text{mL}}{40\text{mL/min}} = \underline{6.5} \text{ minute}$$

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Example 2: A medication order calls for 1000 ml of D5W (5% dextrose) to be administered over an 8-hour period. Using IV administration set that delivers 10 drops/ml, how many drops per minute should be delivered to the patient animal?

$$8 \text{ hours} = 480 \text{ minutes}$$

$$X = 1000/480 = 2.1 \text{ ml/ min}$$

$$2.1 \times 10 = \underline{\underline{21}} \text{ drops/ minute}$$

*NB: it is possible to administer drugs together with IV infusions however, make sure that the drug and the fluid are compatible (didn't react, didn't form precipitate). The dose calculation will be done as described above without considering the volume of fluid to be given.*

## **8. PRINCIPLES AND PROCESSES OF VETERINARY DRUGS PRESCRIBING PRACTICE**

### **Objectives**

After completion of this session trainees should be able to:

- ✓ Identify principles and requirements of good prescribing practice
- ✓ Recognize the process of prescription of veterinary drugs

### **8.1 Principles of Rational Prescribing**

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

The use of International Non Proprietary Names (INN) or generic names of veterinary drugs in prescribing is an essential component of good prescribing practice. This is because generic veterinary drugs are less costly, and for a generic prescription any suitable product can be dispensed hence avoiding delay while looking for a specific brand.

### **Requirements for Good Prescribing Practice**

Good prescribing practice requires:

1. *Assessment of the benefit-to-risk and/or benefit-to-cost ratio of prescribing*

During prescription, professionals should consider the following assessment tools:

- i. Seriousness of the problem to be treated
- ii. Appropriateness for the animal
- iii. Optimal use of the veterinary drug with respect to:
  - The safety, efficacy and quality of the veterinary drug
  - Possible contraindications Example: albendazole should not be given during early pregnancy due to the possibility of embryo toxicity.
  - Drug-Drug interactions Example: Oxytetracycline should not be given together with di/trivalent cations ( $\text{Ca}^{+2}$ ,  $\text{Mg}^{+2}$ ,  $\text{Al}^{+3}$  or  $\text{Fe}^{+2}$ ) due to the chelating behaviour of oxytetracycline with these cations.
  - Drug-feed interactions Example: fatty meals facilitate the absorption of Albendazole whereas full rumen may impair its absorption.
  - Treatment history
- iv. Public health significance

The effect of the drug on consumers of products from treated animals. Example: Nowadays, chloramphenicol is banned from use in food-producing animals because of its high risk in human from consumption of products from treated animals.

v. The cost of veterinary drug  
The cost of the drug should be reasonable.  
Example: Treatment of chronic bovine tuberculosis by isozanaide is not advised because of its high cost - to- benefit ratio.

### 2. *Justification for veterinary drug therapy*

One has to justify the need for treatment before prescribing. The professionals should avoid unjustifiable prescription. For example: prescribing of broad spectrum antibiotics for all animal patients with coughing, and prescription of drugs based on the owner's interest.

### 3. *Selection of appropriate drug(s)*

Once treatment is justified, to decide which particular veterinary drug to use, the prescriber should go through the process of:

- a. Selecting the therapeutic class; example: antibiotics for infection
- b. Selecting group of veterinary drugs within the class and selecting a particular medicine in the group; example: Streptomycin among Aminoglycosides

The choice of drugs should also consider sensitivities, site of infection, feature of animal patients such as contraindications, and availability of the drug. Pharmacokinetics and pharmacodynamic properties of a drug should also be considered while choosing a drug.

### 4. *Route of administration:*

The choice of route of administration depends on site of desired action (systemic or local), physical

and chemical property of the drug and its formulation (solid, liquid, gas, solubility, pH, irritancy), the rapidity with which the response is desired (fast action, intravenous), patient's condition (unconscious, vomiting), the ability of the drug to withstand the conditions of the gastrointestinal tract (example: insulin cannot be administered orally since it is degraded in the gastrointestinal tract). Example: intravenous route is preferable for severe infections such as milk fever and cowdriosis.

### 5. *Dosage and course of treatment*

The dosage of the drug and course of treatment may vary with characteristics of the patient (body weight, age, species, physiological status and pathology), the nature of the disease (chronic or acute), and type and strength of the drug.

Example 1: A single dose of diaminazine aceturate is given for the treatment of bovine trypanosomosis but oxytetracycline 10% is given from 3 to 5 days for treatment of pneumonic pasteurellosis.

Example 2: A single dose of oxytetracycline 20% is enough for the treatment of pneumonic pasteurellosis but oxytetracycline 10% is given from 3 to 5 days.



### 8.2 Prescription process

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

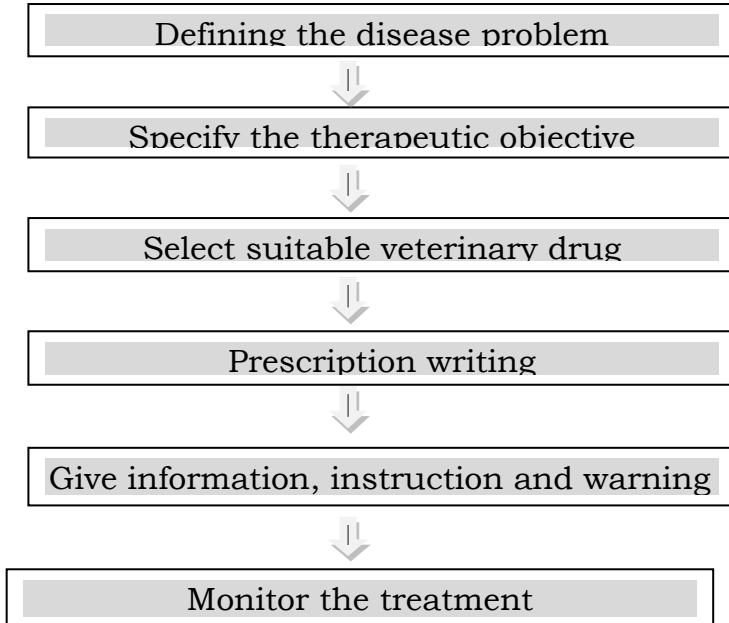


Figure 3: major steps in prescription process

#### *1. Defining the diagnosis*

The first step in rational treatment is defining the patient's problem, which is making a correct diagnosis. To conduct correct diagnosis it should be supported by laboratory procedures in addition to physical examination techniques.

### *2. Specifying the therapeutic objectives*

Once a diagnosis is made, one has to specify his/her therapeutic objective(s), what the prescriber wants to achieve with treatment to be applied. For example: to cure an infectious disease or to relieve animals from non-infectious disease like bloat. The better you define your therapeutic objective, the easier it is to select the suitable veterinary drug.

### *3. Selecting the suitable veterinary drugs*

Select veterinary drugs as described above. Selected veterinary drugs are the veterinary drugs you have chosen to prescribe regularly, and with which you have become familiar with their therapeutic effects and side effects. They are your priority choice for given indications based on the National Veterinary Drug List, Veterinary Formulary and the Standard Veterinary Treatment Guideline (SVTG) for Ethiopia.

### *4. Prescription writing*

A prescription is an important therapeutic transaction between the prescriber and veterinary drug consumer through a dispenser. It is a written order of the prescriber for one or more medication, and instructs the dispenser how to prepare and dispense veterinary drugs and the owner how to use them.

Prescription should be written on a standard prescription paper, written in ink, legible, written in generics, clear (not ambiguous), written in English with some Latin abbreviations, and The

quantity of ingredients should be expressed in metric system.

Table 7: Techniques to avoid confusion in writing figures or units

Incorrect way of writing	Correct way of writing
.5 mg	0.5 mg
µg	mcg
1.0 mg	1 mg
500000	500,000
0.025 g	25 mg

### ***Content of prescription paper***

According to Guidelines for the control of use of prescription paper which will be published by the Veterinary Drug Administration and Control Authority of Ethiopia, the content of any prescription paper should include the following information (Annex 1):

1. Serial number and area code and date
2. Name, level and address of the animal health institution.
3. Owner's name and address
4. Species of the animal, breed, age, sex, status, colour card Number and ID No (name)
5. Type of Diagnosis
6. Name, strength, dosage form and dosage of the drug
7. If the drug is to be compounded the type of ingredients needed, direction for use and how to prepare it

8. If the drug is refillable direction for refill.
9. The withdrawal period for milk, meat and egg
10. Prescriber's name, qualification, registration number, and signature and date on which the prescription is written
11. Dispenser's name, qualification, registration number, and signature and date on which the prescription is filled.
12. Summarized directions to be followed by prescribers and dispensers.

### *5. Give information, instructions and warnings*

Most owners do not give the prescribed drugs correctly to patient animals; give them irregularly, or not at all. The most common reasons are that symptoms have ceased, side effects have occurred, the drug is not perceived as effective, or the dosage schedule is complicated for patients, particularly the elderly. For example drugs with a short half-life or a narrow therapeutic margin may become ineffective or toxic if taken irregularly.

Patient adherence to treatment can be improved in three ways: prescribe a well chosen drug treatment; create a good veterinarian-owner relationship; and take time to give the necessary information, instructions and warnings.

The six points listed below summarize the minimum information that should be given to the owner.

1. Effects of the drug: Which symptoms will disappear; and when; how important is it

to give the drug; what happens if it is not given;

2. Side effects: Which side effects may occur; how to recognize them; how long will they remain; how serious they are; what to do if they occur;
3. Instructions: When to take; how to take; how to store; how long to continue the treatment; what to do in case of problems;
4. Warnings: What not to do (driving, machinery); maximum dose (toxic drugs); need to continue treatment (antibiotics);
5. Next appointment: When to come back (or not); when to come earlier; what to do with left-over drugs; what information will be needed;
6. Everything clear? Everything understood; repeat the information; any more questions.

### *6. Record keeping and Monitoring of the treatment*

Information containing the date of prescription, the owner name, the animal patients name or ID No, species, sex, age, the disease diagnosed, the prescribed drug name, dosage strength and dosage form and amount, the prescriber name and initials should be recorded on the case book.

The purpose of monitoring is to check whether the treatment has solved the patient's problem. You should use the same criteria for monitoring the effect, but in practice they can be condensed

into two questions: is the treatment effective? Are there any side effects?

Was the treatment effective?

1. Yes and disease cured: Stop the treatment
2. Yes, but not yet completed: Any serious side effects?
  - ✓ No: treatment can be continued
  - ✓ Yes: reconsider dosage or drug choice
3. No, disease not cured: Verify all steps:
  - ✓ Diagnosis correct?
  - ✓ Therapeutic objective correct?
  - ✓ P-drug suitable for this patient?
  - ✓ Drug prescribed correctly?
  - ✓ Patient instructed correctly?
  - ✓ Effect monitored correctly?

EXAMPLE: -Suppose an ox with age 5 years come to veterinary clinic with clinical signs loss of appetite, body condition and productivity, intermittent fever, Anaemia, Oedema, enlarged lymph nodes, tick infestation around some parts of their body and direct examination of fresh blood from ear vein and buffy coat between slide and cover slide indicate flagellate protozoan crossing the microscope field.

### **Step 1.** *Defining the diagnosis*

Based on the clinical sign and laboratory diagnosis the diagnosis is defined as Trypanosomosis and tick infestation.

### **Step 2.** *Specifying the therapeutic objectives*

The prescriber wants to achieve with treatment is to cure an animal from Trypanosomosis and to relief the animal from the ticks attack.

### **Step 3.** *Selecting the suitable veterinary drugs*

Selected veterinary drugs are the veterinary drugs you have chosen to prescribe regularly for Trypanosomosis

- ✓ Diminazine aceturate (DIMINAVIC 2.36, YZ-DIMINAZIN, Diminashish 2.36gm, Diminasan 2.36gm, Diminal 2.36gm, Rang tryps, Survidium 2.36gm)
- ✓ ISOMETAMIDIUM CHLORIDE (Trypamidium /Samorine sachet, SEMIDIUM 1000, Trypashish, veridium, Ancomidium 125mg)
- ✓ Homidium chloride (Bovidium 250mg)
- ✓ Homidium bromide (Ethidium 250mg)

Selected veterinary drugs are the veterinary drugs you have chosen to prescribe regularly for Tick infestation.

- ✓ Deltametrin 1% pour w/v
- ✓ Amitraz 12.5%w/v
- ✓ Diazinol 60%
- ✓ cypermethrin 2% pour -on
- ✓ ECTOPOR 020 SA Pour on

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### Step 4. Prescription writing

#### Veterinary Prescription Paper

Ser.No, 03v000638

Case No. 2346

Name and level of Animal Health Institution Alem ketema veterinary clinic (type C)

Address Region amahara Zone Semen Shoa Woreda Merabite  
Town alem ketema Tel 01113206..

#### Veterinary Prescription Paper

Ser.No, 03v000638

Name and Level of Animal Health Institution Alem ketema veterinary clinic (type C)

Address Region amahara Zone Semen Shoa Woreda Merabite  
Town Alem ketema Tel 01113206..

Owner's Name Ato Ambereber Abrare

Address Region Amahara Town Alem ketema Woreda Merabite  
Keble 03 locality Setatit

Species of animal Bovine Age 5 Sex male Body weight 250kg

ID No.(name) Bure Case No. 2346

Diagnosis Trypanosomosis and tick infestation

Treatment given (name, strength, dosage form, dosage and quantity of drug)	Price of Each item	
	Birr	Cent
<u>3.5 mg of diminazene diaceturate/kg</u>		
<u>Diazinon 60% 5ml dilute with 5 litre of water</u>		

Refill \_\_\_\_\_ Withdrawal period \_\_\_\_\_

Prescriber's \_\_\_\_\_ Dispenser's Name Tefera Tibebe (Dr.)

Qualification DVM

Registration no. \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

\* Seal over leaf



### **Step 5.** *Give information, instructions and warnings*

- The six points listed below summarize the minimum information that should be given to the owner.
- *Instructions:* When to give diazinon; how to give diazinon; how to store; how long to continue the treatment; what to do in case of problems;
- *Effects of the drug:* Which symptoms will disappear; and when; how important is it to give the drug; what happens if it is not given;
- *Side effects:* Which side effects may occur; how to recognize them; how long will they remain; how serious they are; what to do if they occur;
- *Warnings:* What not to do (driving, machinery); maximum dose (toxic drugs); need to continue treatment (antibiotics);
- *Next appointment:* When to come back (or not); when to come earlier; what to do with left-over drugs; what information will be needed;
- Everything clear? Everything understood; repeat the information; any more questions.

## Rational Use of Veterinary Drugs and Vaccines

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### 7. *Record keeping and Monitoring of the treatment*

Information containing

Date of prescription: 01/07/07

The owner name..... Ato ambereber abrare

The animal patients name or ID No Bure

Species of animal bovine Age 5 Sex male

The disease diagnosed, Trypanosomosis

The prescribed drug name, dosage strength and dosage form and amount, 3.5 mg of diminazene diacenturate/kg, Diazinol 60%

The prescriber name and initials Tefera Tibebu (Dr.)

check whether the treatment has solved the patient's problem. Was the treatment effective?

## **9. PRINCIPLES AND PROCESS OF VETERINARY DRUGS *DISPENSING PRACTICE***

### **Objective**

At the end of this session trainees should be able to identify principles and process of good dispensing practices.

### **9.1 Principles of Good Dispensing**

Dispensing practice, the duty of dispensers, plays a central role in the provision of rational veterinary drug. Dispensing refers to the process of preparing veterinary drugs 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 owner depending on the type of veterinary drugs to be dispensed.

Good dispensing practice ensures that the correct veterinary drug is delivered to the right animal patient, in the required dosage and quantities, with clear instructions. Dispensing includes all the activities that occur between the time the prescription or oral request of the owner is presented and the veterinary drugs are issued to them. This process may take place in the animal health institutions and community veterinary drug retail outlets. It is often carried out by veterinary drug professionals. 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 mainly with

medical and economical consequences and public health hazard. Therefore, the dispenser plays a crucial role in the therapeutic process.

The quality of dispensing may be determined by the training and supervision in which the dispenser has received and the veterinary drug information available to the dispenser. Veterinary drug dispensers must have knowledge about the veterinary drugs being dispensed (common use, correct dose, precautions about the method of use, common side effects, common interaction with other medicines or feed, storage needs, good calculation and arithmetic skills) and must have ability to explain information clearly by the language the owner can understand and check whether the information is being understood.

### **9.2 Dispensing Process**

#### *9.2.1. Pre -dispensing Activities*

Before owners arrival the dispenser should prepare himself/herself and the dispensing environment and facilities.

- ✓ Check the dispensing room, shelves and dispensing desk are clean and organized
- ✓ Wear a clean and white gown
- ✓ Attach your identification tag on the gown in such a way that it is visible to clients
- ✓ Check availability of dispensing aids (labelling materials, packaging materials, sufficient no of spoons etc)
- ✓ Ensure availability of updated national veterinary drug list, rational use of

veterinary drugs manual, SVTG, veterinary formulary, and prescription registration book.

As clients come into the veterinary pharmacy section, they must be made to feel attended to and comfortable by friendly gestures, a smile, eye-to-eye contact, a friendly welcome, politeness, and feeling of caring.

### *9.2.2. Dispensing procedures*

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

#### *Step 1. Receive and validate prescription or verbal request*

Upon receiving a prescription, the dispenser should confirm the name of the owner and the identity of the patient animal. This action is particularly important when the clinic is dealing with a large crowd of animals and when there is any risk that the dispenser may mix up prescriptions. Cross checking the name of the owner and identifications of the animal must also be done when issuing the drugs. Dispensers could also accept verbal requests from professionals and/or paraprofessionals or directly from the owners only for OTC drugs with justification.

### *Step 2. Understand and interpret prescription*

- Carefully read the prescription or validate verbal request
- Check if the prescription is legally and currently written
- Interpret any abbreviations used by the prescriber correctly
- Confirm that the doses prescribed are in the normal range for the animal patient (considering species, sex, body weight and age)
- Identify common drug- interaction(s)
- Verify inadequately written prescription and make necessary correction with the prescriber's consent.
- Perform any calculations of dose and the quantity to be issued correctly

### *Step 3. Prepare items for administration or issue*

Preparation of items for administration and/or issue is the central part of the dispensing process. This part of the process begins after the prescription is clearly understood and the quantity has been calculated.

- Select stock container by reading the label and cross matching the drug name and strength against the prescription.
- The dispenser should check the stock to make sure that it is not expired and choose the oldest stock (FEFO or FIFO)
- Read the container label at least twice during the dispensing process.

- Do not select the prescribed drugs according to the colour or location of container.
- Do not open many stock of containers at the same time. This trend will lead to errors and/or expose the drugs to air and eventually leads to deterioration in quality.
- While counting, pouring or measuring, the following points should be noted:
  - ✓ Under and/or over measuring or counting should be avoided
  - ✓ Always use clean and sterilized syringe and needle
  - ✓ Graduated measuring cylinder and/or flask must be used for measuring liquid reduction. If small volume is to be measured, small measuring cylinder or flask has to be used.
  - ✓ Appropriate weight measuring balance should be used
- In dispensing liquid formulations:
  - ✓ Must be measured in a clean vessel and should be poured from the stock bottle with the label kept up ward. This avoids damage to the label by any spilled or dripping liquid.
  - ✓ Pour the measured liquid preparation into the container/bottle and label it.
  - ✓ Do not use owners own bottle
- In dispensing solid formulations:

- ✓ Do not use fingers to count tablets or boluses as this can lead to contamination of drugs
- ✓ Count and put them in a labelled drug container or pack
- ✓ Close stock containers tightly after dispensing
- ✓ Keep the spoon or other counting materials clean at all times
- ✓ Do not keep the spoon or other counting materials inside the container

### *Step 4. Recording, documentation and reporting*

Records of issues to animal patients are essential in an efficiently run dispensary. Such records can be used to verify the stocks used in dispensing, and they will be required if a need arises to trace any problems with veterinary drugs issued to patients.

There are three different methods that can be used to keep a record of drugs dispensed. These are:-

- When a prescription is retained, the dispensing staff should put initials and annotate the prescription and either file or enter the details into a record book.
- When the prescription is returned to the owner of animal patient details of the drugs dispensed must be entered into a record book before the items are issued to the patient.
- When computers are used in the dispensing process the computer program should



## Rational Use of Veterinary Drugs and Vaccines

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retain the information, which can be recalled to generate summary report.

The following information should be included into the record book and/or computer:

- ✓ The date, name of the owner, and the animal patient's identity (name, ID No, species, sex, age)
- ✓ The drug name, dosage strength and dosage form, and the amount issued.
- ✓ The dispenser name and initials

The receipts for requisition, receiving as well as the prescription registration book should be kept properly. Filled prescriptions should also be kept as a receipt. Regular reports on drug consumption and prescribing pattern from patient prescription registration book should be prepared and report to the concerned veterinary drug authority timely. Information obtained from prescription registration book could be used for further planning and efficient utilization of resource.

*Step 5. Administer or issue drugs to animal patient with clear instructions and advice*

For drugs to be administered at the veterinary establishments, the owners should be informed about withdrawal period for milk, meat, egg and honey and not to interrupt treatment when side effects occur or in the absence of response without consulting the prescriber or dispenser. (example: why the entire course of an antibiotic treatment must be given)

In addition to these for prepared, packaged and labelled drugs issued to owners the following written information should also be provided.

- How much and how often to give the drug
- How long the treatment is to last
- How to give the drug
- How to store the drug (example, avoid heat, light and dampness)
- Not to share drugs to other animals
- To keep drugs out of reach of children
- Finally, check whether the owner have understood the information provided

### *9.2.3 Responsibilities of dispenser when Supplying Veterinary Medicines*

A veterinary drug professional has specific responsibilities when supplying a veterinary medicine in order to ensure that it is used appropriately. The veterinary drug professional must be present when it is handed over. In particular, a veterinary drug professional supplying a product classified as POVM or over the counter (OTC) veterinary drug products must:

- i. Be satisfied that the medicine is appropriate for the animal and condition to be treated:

*As an example, the veterinary drug professional should consider asking when the last treatment was, Age and weight of animal, any concurrent medication and any other disease as appropriate.*

- ii. Be satisfied that the person who will use the product is competent to do so safely, and must advise on safe administration and any warnings or contra-indications:

*For example, the dispenser should emphasize any safety precautions:*

- Directions to wear gloves or wash hands after use*
- Restrictions on children petting animals after administration with spot-on products*
- Restrictions on bathing of animals or allowing animals to swim in water courses after administration with spot-on products*

- iii. Not supply more than the minimum amount required for the treatment

*The Regulations allow veterinary drug professional to break open packages for the purposes of supply, except the immediate packaging of an injectable product.*

- iv. Ensure that the medicine is labelled correctly:

*if the product is supplied in a container other than the marketed pack, this container must be suitably labelled and sufficient information supplied to enable the product to be used safely (this could be the SPC or the package leaflet).*

- v. Record and report any adverse events involving the medicine promptly: Adverse events should be reported to the VDFACA using adverse effect reporting format.

### **9.3 Withdrawal periods and control for residues of veterinary drugs:**

Whenever antibiotics or other drugs are administered to food producing animals either by the veterinarian or by the owner - the veterinarian must inform the owner about the withdrawal periods for the drugs used, in order to avoid residues in animals and their products (meat, milk, eggs and honey) to be delivered for human consumption. Such information must be given verbally and in writing. If animals are delivered for emergency slaughter within the withdrawal period, information regarding the withdrawal period, as described above, must accompany the animal to the slaughterhouse.

Withdrawal period may be affected by different factors

i. Route stated on the label is followed or not  
Withdrawal times are only applicable if the route stated on the label is followed. For example, Liquamycin LP given intramuscular has a withdrawal time of 60 hours following the last treatment. If given intrauterine the withdrawal time is not known.

ii. Amount Administered  
Volume administered per injection site is important. The Liquamycin LP label states “do not administer more than 10 cc per site”. If you administer more than 10 cc the withdrawal time is not known.

iii. Method of Treatment  
Intramuscular injections require a 1.5 inch needle to insure that the product is injected into the muscle. If the needle is not into the muscle and the

product goes into the fat or under the skin, the adsorption will be affected and the withdrawal time is not known. Repeated injections in the same area interfere with adsorption of the product. It is better to choose a new site for each treatment.

## **10. CONSEQUENCES OF IRRATIONAL DRUG UTILIZATION**

### **Objectives**

At the end of this session trainees should be able to:

- identify the magnitude and consequences of irrational drug use
- Describe the reasons underlying irrational use
- Discuss strategies and interventions to promote rational use of drugs

### **10.1 Rational Use of Drugs**

The rational use of drugs requires that patient receive medication(s) appropriate to their clinical needs, in doses that meet the individual requirements for an adequate period of time, and at the lowest cost. Rational use of drugs should meet the following criteria:

- i) Appropriate indication:* - The decision to give the drug(s) based on medical rationale and that drug therapy is an effective and safe treatment.
- ii) Appropriate drug:* - The selection of drugs based on efficacy, safety, suitability and cost considerations.
- iii) Appropriate dosage, administration and time of treatment.*

*iv) Appropriate patient:* - No contra-indications exist and the likelihood of adverse reactions is minimal, and the drug is acceptable to the owner.

*v) Correct dispensing:* including appropriate information for owners about the prescribed drug and animal condition.

*vi) Adherence of animal patient to treatment*

On the other hand, irrational drugs use includes use of drugs when no drug therapy is indicated (example:- antibiotics for simple viral infections and owners complaint), use of more medicines than are clinically necessary, use of the wrong drug for a specific condition (example: inappropriate use of anti-bacterial agents for non-bacterial infections), use of drugs with doubtful or unproven efficacy, use of correct drugs with incorrect route of administration, dosages, and duration, failure to prescribe and dispense in accordance with clinical guidelines, and inappropriate medication by owners.

### **10.2 Factors Influencing Rational Drug Use**

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

*A. Lack of information and awareness on consequences of irrational drug use*

Up to date and unbiased information on the currently used drugs is needed for rational use of drugs.

### *B. Inadequate Training and Education*

In adequate training and education leads for incorrect interpretation of the prescription, inaccurate counting, compounding, or pouring of drugs, unsanitary procedures, incorrect prescribing, and profit driven attitude.

### *C. Poor communication between clinician and animal owner:-*

There is usually less attention to the animals and their problem. Treatments or instructions that do not consider the owners belief, environment, or culture.

### *D. Lack of diagnostic facilities*

Clinicians posted in remote areas have to face a lot of difficulty in reaching to a precise diagnosis due to non availability of diagnostic facilities. This promotes poly-pharmacy and incorrect drug prescription.

### *E. Demand from the owner*

To satisfy the owner expectations and demand of quick relief, veterinarians prescribe drug for every single complaint.

### *F. Defective drug supply system and ineffective drug regulation:-*

Absence of well organized drug regulatory authority and presence of large number of drugs in the market leads to irrational use of drugs.

### *G. Promotional Activities of Pharmaceutical Industries:*

The lucrative promotional programmers' of the various pharmaceutical industries influence the drug prescribing.



### *H. Unethical practices by animal health professionals*

#### **10.3 Magnitude of Irrational use of Drugs**

Data on irrational drug use show an increasing trend worldwide, studies indicated that more than 50% of human drugs are prescribed, dispensed or sold inappropriately, and 50% of patients fail to take them correctly. The problem is so severe in veterinary medicine. Drugs not prescribed according to standard treatment guidelines (STGs), ineffective or unsafe drugs are prescribed, effective and available drugs are underused.

Many farmers access these agents and treat their animals even in cases where use of antibiotic (antibacterial) agents would be unnecessary.

#### **10.4 Impact of Irrational Use of Drugs**

Irrational use of drugs leads to:

- A. *Emergence of drug resistant organisms*, thereby rendering treatment ineffective. These will exacerbate or prolong illness leading to increased morbidity and mortality. Resistance leads to search for alternative agent to treat the infection at high price. Massive quantities of antibiotics or antibacterial drugs used in animals are released in the environment thus increasing selection of the antibiotic resistant bacterial organisms that can spread from the

animals to humans especially the bacterial zoonoses.

- B.* Increase risk of unwanted effects such as adverse drug reaction
- C.* False sense of security (owners)
- D.* Masking or confusing or delaying correct diagnosis
- E.* Wastage of resources
- F.* Increase cost of treatment
- G.* Loss of faith or confidence on the profession
- H.* Public health hazard

### **10.5 Measures to Improve Rational Drug Use**

The rational use of drugs can be improved by proper diagnosis and selection of the drug which is effective, convenient and safe; by accurate and complete prescription and dispensing of drugs; by Informing owners on side effects, adverse drug reactions, dosage schedule and risk of withdrawing the therapy is also essential; Improve KSA of professionals; by Enhance availability of drugs; by appropriate rule and regulation and proper implementation.

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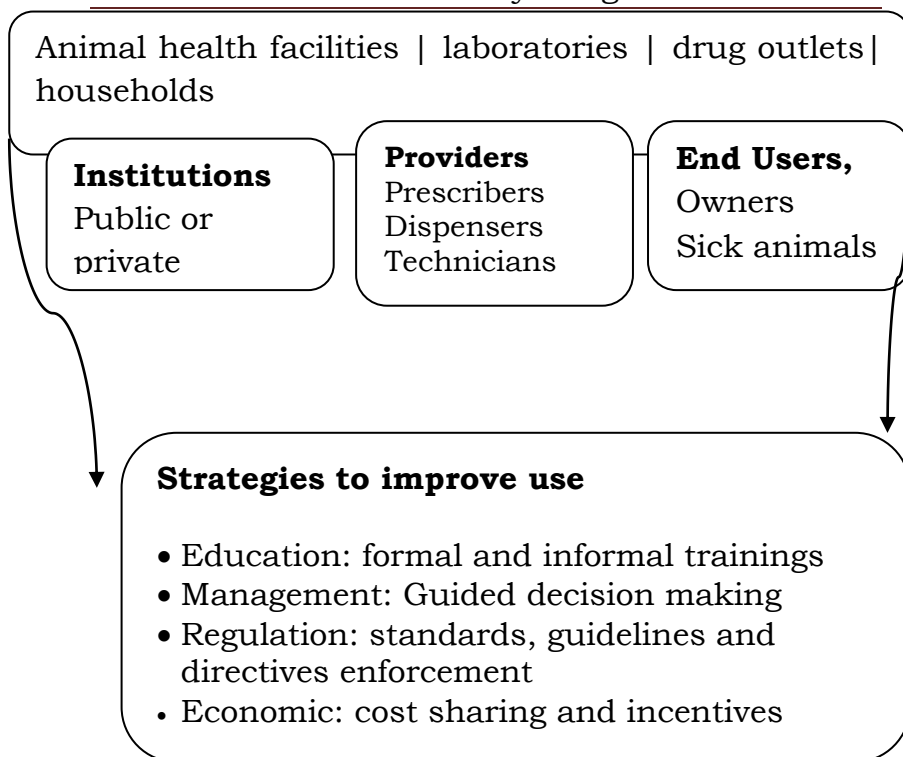


Figure 4: Framework for improving veterinary drug use

## **11. DRUG RESISTANCE AS FUTURE THREAT**

### **Objectives: -**

At the end of this session trainees should be able to:

- Create basic understanding about drug resistance as obstacle to treatment and control of infectious diseases
- Appreciate the gap between frequency of emergence of resistant microbes and pace of development of new drugs.
- Identify measures to prevent development of drug resistance

### **11.1 Drug Resistance**

Drug resistance is the reduction in effectiveness of a drug (antimicrobial, anthelmintic or antineoplastic) in curing a disease or condition. It occurs when the drug is unable to inhibit or kill the disease causing organism due to the development of a mechanism to cope the effect of the drug. Resistance to antimicrobials is a natural, biological evolutionary phenomenon but human practices hasten it. As more antimicrobials are used, it creates a selection pressure on microorganisms. Susceptible ones are killed while resistance one survive and flourish.

The use of antibiotics in veterinary practice started soon after it became available for the treatment of human diseases in mid 1940s. Use of penicillin was started before World War II to

treat mastitis. Antibiotic resistant strain of bacteria was recognized in the late 1950s and became evident that microorganism's resistance to one or more antibiotics can transfer it to other bacteria.

The problem of antimicrobial resistance has become common today, especially in the area of bacterial chemotherapy. The wide spread use of antibiotics in human and animals has been followed by the increased emergence of bacteria resistance to these antibiotics. A casual relationship between increased use of antibiotics and increased prevalence of resistant bacteria has been demonstrated.

The acquisition of antimicrobial resistance is a growing and serious threat to the treatment and control of infectious diseases. Antibiotics which have saved countless millions from the spectre of death and disability from bacterial infections are losing their effectiveness. The World Health Organization stated that a post-antibiotic era in which common infections and minor injuries killing a patient is very real possibility for the 21<sup>st</sup> century.

New drug development is expensive and time-consuming. Hence, there is a declining interest of pharmaceutical industries in antimicrobial research and development.

Drug resistance is placing enormous challenges on veterinarians, physicians and pharmaceutical industries to find new products to continue the antibiotic miracle long into the future. Every attempt should be made today to preserve and

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optimize the agents in our therapeutic armamentarium.

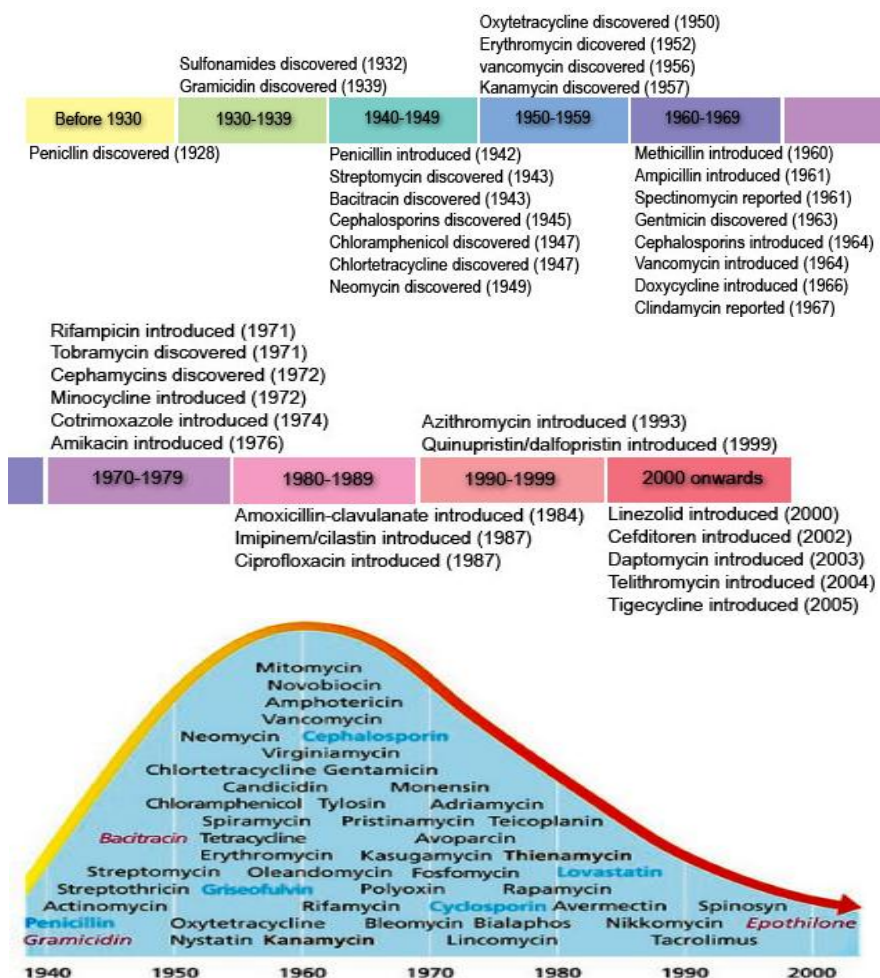


Figure 5: Years of discovery of major antimicrobial agents (it reached peak 1960s declines after 1970)

### **11.2 Contributing Factors**

Irrational use of drugs is the main contributing factor for the development of drug resistance. The important factors are knowledge, expectation, and interaction of prescribers and owners, economic incentives and regulatory condition. Owner related factors are the major driving force of inappropriate antimicrobial use. For example many owners believe that new and expensive drugs are more efficacious than older agents. This leads to development of resistance against both new and old antimicrobials. Self medication is another major factor contributing to resistance. Self medicated antimicrobials may be unnecessary, inadequately dosed and may not contain adequate amount of active drug. Owner's compliance with the recommended treatment is another problem. The owner may forget to give medication, interrupt the treatment when he/she feels his/her animal gets better, unable to complete the full course of the treatment; all these factors create an ideal environment for microbes to develop resistance.

### **11.3 Mechanism of Spread**

Antibiotic resistance in bacteria occur in two ways and it may be an *inherent* trait of the organism in the cell wall structure that renders it naturally resistant, or it may be *acquired* by means of mutation in its own DNA or acquisition of resistance from DNA of another source.

- A) *Intrinsic or inherent or natural resistance* is where microorganisms naturally or inherently become resistant to an antibiotic due to lack of target sites or molecules and transport system for an antibiotic and therefore the drug does not affect them.
- B) *Acquired resistance* is where several mechanisms are developed by bacteria in order to resist an antibiotic. It occurs by either modifying the existing genetic material or the acquisition of new genetic material from another source.

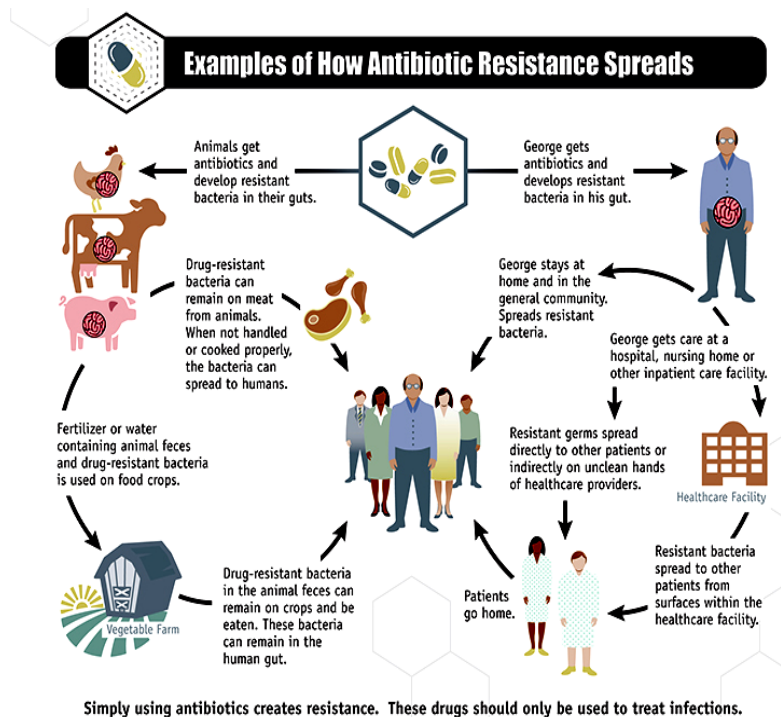


Figure: 6. Examples of how antibiotic resistance spreads



### **11.4 Impacts of Antimicrobial Resistance**

Antimicrobial resistance has several impacts including increased the costs of treatment, increased morbidity and mortality from infectious diseases and reduced productivity (meat, milk, eggs, hides and skins). The consequences are devastating particularly in young stock, which are especially susceptible to infections. Close contact with in the animal's results in spread of resistant strains making more animals at a risk of severe illness. Once the antimicrobial drug is recognized as resistant, clinician will switch over to another antimicrobial agent, which may pose financial burden to the farmers. Moreover, it may increase the duration of treatment there by reducing the productivity of the animal. Drug resistance in diseases like trypanosomiasis is highly prevalent and the impact on the economy is huge; it prevents cultivation of large amount of arable land. Resistance can also interfere the control and eradication processes of diseases.

### **11.5 Prevention of Drug Resistance**

To prevent the emergence of drug resistance, appropriate actions should be taken by all authorization, regulation, distribution, and use of antimicrobials in animal and human health.

- ✓ Avoid inadequate or unduly prolonged use of drugs
- ✓ Promote the use of appropriate dosage regimen

- ✓ Use as much as possible rapidly acting and selective (narrow-spectrum) antimicrobial agents. Broad-spectrum AMAs kill large variety of bacteria and encourage proliferation of resistant bacteria.
- ✓ Use combination of AMAs whenever prolonged therapy is undertaken, example Tuberculosis.
- ✓ Avoid indiscriminate use of AMAs and use of newer agents when already available drugs are effective.
- ✓ Use individual full doses in combination therapy,
- ✓ Know the sensitivity pattern and infectious epidemiology.
- ✓ Enhancing infection prevention and control practices

Fight against AMR requires a coordinated approach between health and livestock sectors on the effective use of antibiotics in humans and animals, as well as improved infection prevention and surveillance on the use of antibiotics in animals.

## **12.VACCINE STORAGE AND HANDLING**

### **Objectives**

At the end of this session trainees should be able to:

- Identify the measures that should be taken for proper transportation, storage and administration of veterinary vaccines.
- Differentiate type of vaccine storage equipment and select carefully

There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines. Vaccines exposed to temperatures outside the recommended ranges can have reduced potency and protection. Storage and handling errors can cost a lot in wasted vaccine and revaccination. Errors can also result in the loss of owners' confidence when repeat doses are required. It is better to not vaccinate than to administer a dose of vaccine that has been mishandled. Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built.

Vaccines must be stored properly from the time they are manufactured until they are

administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor and delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain.

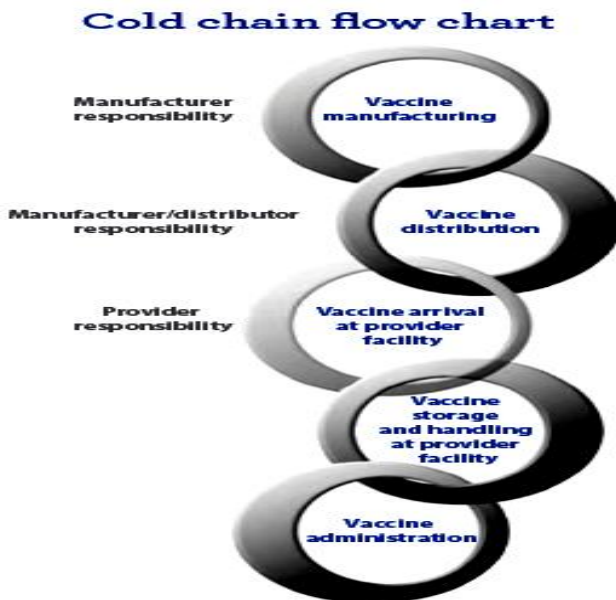


Figure 7: Cold chain flow chart

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When the cold chain fails like too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines, even when exposed to freezing temperatures, may not appear frozen, giving no indication of reduced or lost potency.

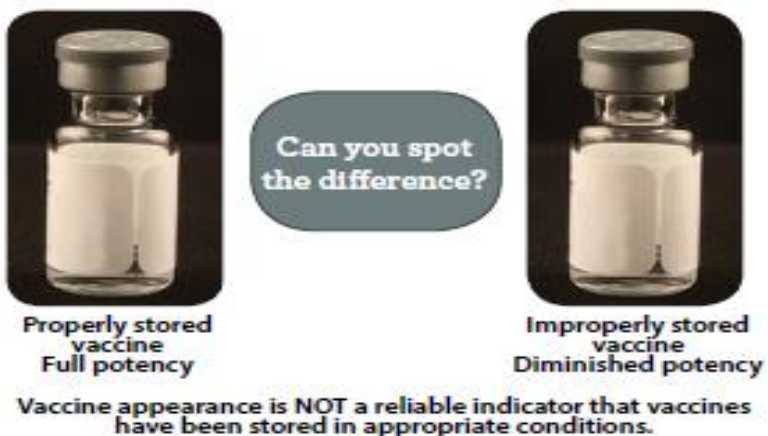


Figure 9: Vaccine appearance at different storage condition

By following a few simple steps and implementing best storage and handling practices, providers can ensure that animals will get the full benefit of vaccines they receive.

### **12.1. Vaccine Storage Temperatures**

Vaccines are fragile. They must be maintained at the recommended temperatures and protected from light at every link in the cold chain. Most live vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to temperature fluctuations (example: extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions (out-of-range temperatures) that can have a cumulative negative effect. It is a good idea to post a sign on the front of the storage unit(s) indicating which vaccines should be stored in the freezer and which should be stored in the refrigerator.

#### **Freezer**

Freezer is device or a part of that maintains a temperature below the freezing point of water usually below -20 to -18 °C. Most live vaccines such as PPR, LSD, Sheep and goat pox, AHS, Camel Pox, CBPP, Newcastle, and Fowl pox) should be stored between -15°C and -20°C. The Anthrax and IBD can be stored either in the freezer or the refrigerator. However, storing these vaccines in the freezer will confer longer shelf-life.

### Refrigerator

Refrigerator is the device that maintains a temperature a few degrees above the freezing point of water (0 to 4°C). All inactivated vaccines (example: Blackleg, Bovine pasteurella, Ovine pasteurella, Fowl Cholera, CCPP, Inactivated Newcastle) and diluents require refrigerator storage temperatures between 35°F and 46°F (2°C and 8°C), with a desired average temperature of 40°F (5°C). It is needed to review the manufacturers' instruction about the specific storage temperatures of the vaccine.

Before reconstitution with diluent, all vaccines can be stored at refrigerator temperature between 35°F and 46°F (2°C and 8°C) for up to 72 continuous hours. Contact the institute and/or your local or state veterinary service for guidance before discarding any refrigerated vaccine that cannot be used within 72 hours.

All personnel who handle or administer vaccines should be familiar with the storage and handling procedures for their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. These procedures should be available in writing as a reference for all staff members. It is highly recommended to refer and follow catalogue product guide from National Veterinary Institute. Vaccine storage and handling training should be provided to all new personnel who handle or

administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine. Immunization programs often have good resources for staff training.

### **12.2. Vaccine Storage Equipment**

Vaccine storage equipment should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained.

#### **Freezers and Refrigerators**

Using the correct freezer and/or refrigerator can help prevent costly vaccine losses and the inadvertent administration of compromised vaccines. Freezers and refrigerators are available in many different sizes, types (example: stand-alone versus combination), and grades (example: household, commercial, and pharmaceutical). It is strongly recommend stand-alone freezers and refrigerators without freezers. Studies have demonstrated they maintain the required temperatures better than combination units. An alternative to stand-alone units would be to use the refrigerator compartment of a combination refrigerator /freezer/ unit to store refrigerated vaccines. A separate stand-alone freezer would be used to store frozen vaccines.



## Rational Use of Veterinary Drugs and Vaccines

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Multiple reports of incidences are available when refrigerated vaccines have been compromised by exposure to freezing temperatures in a combination unit. At a minimum, a combination refrigerator /freezer/ unit sold for home use with separate exterior doors and thermostat controls for each compartment is acceptable (but not recommended).

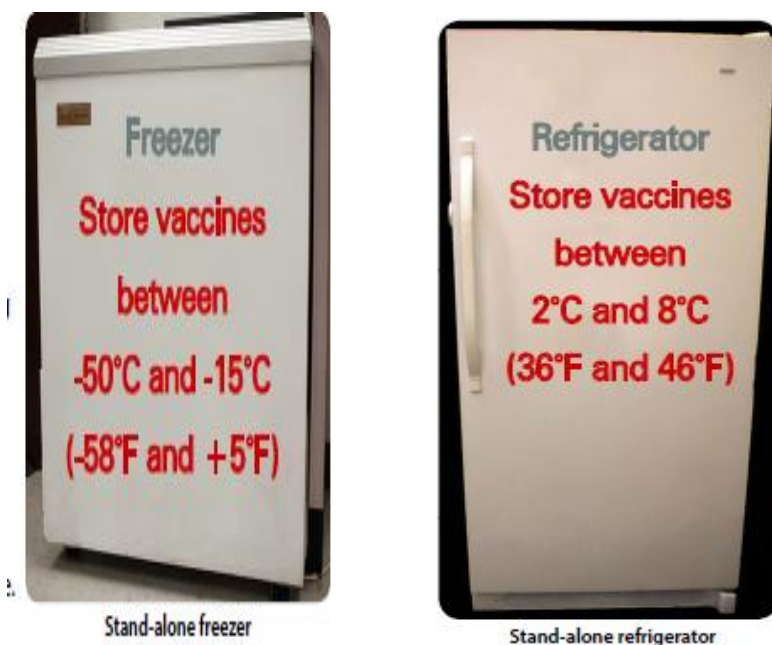


Figure 10: -Two vaccine storage device with different temperature settings (freezer and refrigerator)

Any freezer or refrigerator used for vaccine storage should have its own exterior door that seals tightly and properly, as well as thermostat controls. It must be able to maintain the required temperature range throughout the year. The unit

should be dedicated to the storage of biologics and it must be large enough to hold the year's largest vaccine inventory without crowding (including flu vaccine). A storage unit that is frost-free or has an automatic defrost cycle is preferred.

If using a combination freezer-refrigerator unit to store vaccines, care must be taken to ensure that the freezer is not so cold that the refrigerator temperature drops below the recommended temperature range. There should be separate temperature controls (thermostats) for the freezer and refrigerator compartments. Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The unit should be in a well-ventilated room with space around the sides and top and at least 4 inches between the unit and a wall. Nothing should block the cover of the motor compartment and the unit should be level and stand firmly with at least 1 to 2 inches between the bottom of the unit and the floor.

A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.” In performance testing, the dormitory-style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit. This unit also exhibited large spatial

temperature gradients confirming that there is no “good” vaccine storage area in a dorm-style unit. The dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance.



Figure 11: two compartment of refrigerator and storage principle of vaccine in a fridge

### 12.3. Vaccine Inventory Control

A vaccine inventory should be conducted monthly to ensure adequate supply to meet demand. Vaccine diluents should also be included in the inventory to ensure adequate supplies are available. Determining factors for the amount of vaccine and diluent ordered include: projected

demand, storage capacity, and current vaccine supply. Vaccine coordinators should request delivery during office hours. Each vaccine order should be updated to reflect any period of time the office will be closed, such as holidays or scheduled vacation time. It is also important to avoid overstocking vaccine supplies which could lead to vaccine wastage or having outdated vaccine on hand. Vaccine and diluent expiration dates should be closely monitored. Rotate stock so that vaccine and diluent with the shortest expiration date are used first to avoid waste from expiration. If the date on the label has a specific month, day, and year, the vaccine can be used through the end of that day. If the expiration date on the label is a month and year, the vaccine can be used through the end of that month.

A multi-dose vial of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information. Mark a multi-dose vial with the date it is first opened. Mark reconstituted vaccine with the date and time it is reconstituted. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information. Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.

### **12.4. Receiving and Unpacking Vaccine**

#### **Shipments**

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be informed of who to notify when a vaccine delivery has arrived. This is extremely important for receptionists or other front desk staff since they are often the first to know that vaccines have been delivered. Vaccine shipments should be inspected on arrival. Vaccines should be stored at the proper temperature immediately upon arrival. The shipping container and its contents should be examined for any evidence of damage during transport. The contents should be cross checked with the packing slip to be sure they match. Both heat and cold temperature monitors/indicators should be checked upon delivery following instructions on the monitors for reading and reporting. If a monitor indicates possible adverse temperature excursion during shipping, the monitor reading should be documented for future reference and reported to the distributor within the required timeframe.

Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors. The shipment date should be checked to determine how long the package was in transit. If the interval between shipment from the distributor and arrival of the product at the facility was more than 48 hours, this could mean the vaccine has been

exposed to excessive heat or cold that might alter its integrity. If there are any discrepancies with the packing slip or concerns about the vaccine shipment, the vaccines should be stored in proper conditions, but segregated and marked “Do NOT Use” until the integrity of the vaccines is determined. Contact either the immunization program or the vaccine manufacturer, depending on who shipped the vaccine and the state or agency policy.

The contents of each shipment should be recorded on an inventory log (stock record). This log should include the name of each vaccine, the number of doses for each vaccine received, the date it was received, the condition of the vaccines upon arrival, the name of the vaccine manufacturers, the lot numbers, the expiration dates for each vaccine, and any action taken as a result of a question of vaccine integrity

### **12.5. Vaccine Transport to Off-Site Clinics**

The number of times vaccines are handled and transported should be minimized. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

When a multi-dose vial is used, it requires that it be used only by the provider’s office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may

not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, each transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Diluent should be transported at room temperature or inside the same insulated cooled container as the corresponding vaccine, according to manufacturer guidelines for each diluent. If transported inside cooled containers, diluent must not be in direct contact with frozen or cold packs because of the potential for freezing. If any diluents that have been stored at room temperature are going to be carried in the insulated transport container, refrigerate the diluents in advance so they do not raise the temperature of the refrigerated vaccines.

### **12.6. Temperature Monitoring During Off-Site Clinics**

Vaccines should be stored at the recommended temperatures immediately upon arrival at the facility. Record storage unit temperatures twice daily. If vaccine must be kept in an insulated cooler, keep the cooler closed as much as possible. At a minimum, record the cooler temperature hourly.

### **12.7. Vaccine Preparation**

Vaccine should be drawn from the vial into the syringe at the time of administration. It is not recommended to fill syringes in advance, for a number of reasons. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to tell apart. Other problems associated with this practice are wasted vaccine and possible bacterial growth in vaccines that do not contain a preservative, such as vaccines supplied in single-dose vials.

Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage. If for some reason more than one dose of a particular vaccine must be pre-drawn, draw up only a few syringes at one time (no more than 10 doses or the contents of a single multi-dose vial). In accordance with best practice standards, these syringes should be administered by the person who filled them. Any syringes prefilled by the provider must be stored at the recommended temperature range and used or discarded by the end of the clinic day.



## **13. VETERINARY DRUG INFORMATION**

### **Objective:**

At the end of this chapter trainees should be able to identify the importance and sources of updated veterinary drugs information so as to use drugs properly and disseminate appropriate information.

### **13.1 Importance of Veterinary Drug Information**

Animal health professionals involved in prescribing and dispensing of veterinary drugs have the need for veterinary drugs information in order to keep themselves up to date with developments related to veterinary drugs and to provide such information to owner, other animal health professionals and to the general public. Because of an increasing number and complexity of veterinary drugs, the need for up-to-date information is greater than ever. Updated veterinary drugs information is mainly directed at improving prescribing, dispensing and veterinary drugs administration. On the other hand, because counselling of owners of animal patients on medications is an integral part of the veterinary drugs prescribing and dispensing process. Lack of knowledge and information by the owners about the veterinary drugs they took leads to incorrect use which in turn results in loss of efficacy or occurrence of adverse effects, drug residue and drug resistance.

The need for veterinary drugs information varies among different types of animal health care providers and animal owners. Both animal health care providers and dispensers need to have well developed information on the veterinary drug choices and therapeutic alternatives, the generic and brand names of each drugs, and the indication and contraindications for use, precautions for use, dose interval and regimen, dosage form and strengths, route of administration, adverse drug reactions, side effects, drug interactions (drug-drug, drug-feed, drug-disease interactions), duration of therapy, formulations and storage condition of each drug.

All these information are essential for promotion of rational veterinary drug therapy through improving prescribing and dispensing behaviour, veterinary drug administration and use.

It is also possible that veterinary drug professional involved in veterinary drug dispensing may want to write a material on veterinary drugs, and consult animal health administrators and policy makers on matters related to veterinary drugs, which requires having a thorough knowledge on them.

### **13.2. Sources of Veterinary Drug Information**

Although basic information about veterinary drugs is obtained through training in veterinary profession, additional knowledge can be gained from various sources. These sources of drug

information can be classified into primary, secondary and tertiary.

*Primary sources:* provide new veterinary drug information mainly based on research in journals. They provide original thinking and results of original research. Primary literature can be found as published articles or unpublished report that provide detail on the research and its findings. Such sources include veterinary journals such as the BMC Veterinary research, the Ethiopian Veterinary Association Journal, the ELSEVIER Journals and information from manufacturers (labels, leaflets and packaging). It is important to assess the reputability of the journal and time of publication.

*Secondary sources:* provide reviews of articles that appear in primary sources. Examples include veterinary drug information bulletins (quarterly realising by VDFACA), Pub Med, adverse drug reaction bulletin, veterinary medical information and others. Secondary sources are typically easy to access and use and to link to the primary literature.

*Tertiary sources:* include standard reference books such as Veterinary clinical pharmacology, Merck veterinary manual, veterinary medical dictionary, veterinary drug formulary, NVDL, STG, and pharmacopeia. The selection of a particular source of information depends on the type of information required. Tertiary sources are

used first than secondary or primary sources as they provide a broad overview of particular subject area. It should also be remembered that standard books are published at longer time intervals than journals. Obtain the most current edition available when using secondary or tertiary sources.

Veterinary drug information supplied by the pharmaceutical industries either in the form of leaflets in the packages or via their representatives is being used by many clients. The impact of pharmaceutical industry, which has several channels of influence, is great. Animal health professionals should develop critical attitudes towards information provided by pharmaceutical industry as their information may be biased.

### **13.3. Dissemination of Veterinary Drug Information**

For dissemination of veterinary drug information, communication skills are very important for prescribers and dispensers dealing with owners, other animal health care professionals and general public to convey relevant veterinary drug information effectively and clearly, which can be done verbally and/or in written form.

Verbal communication to veterinary drug information must be clear and fluent by understandable language, well-organized on important details and with confidence done by

maintaining eye contact during face-to-face communication. It is necessary to avoid emotion, negligence, medical languages and unnecessary details. Written communication of veterinary drug information must be well-organized, readable and clear and complete.

Adverse drug reactions reporting system is an area of veterinary drug information that has been given little attention yet. Obviously, veterinary drugs not only produce the desired effects, but also undesired effects. It is possible that veterinary drugs produce initially unanticipated effects (adverse or potentially useful) after their approval for marketing. Such effects can best be identified by veterinary drug professionals and/or prescribers because of their close proximity with patients. Veterinary professionals have a moral responsibility to report adverse drug reactions to the concerned body by using a special form designed and distributed for this purpose by VDFACA.

## **14. NATIONAL LEGISLATIONS RELATED TO VETERINARY DRUGS AND VACCINES**

### **Objective**

At the end of this session trainees will be able to appreciate the legislative articles related to veterinary drugs enacting in Ethiopia.

The Ethiopian Government has, particularly since recent past, taken the issue of livestock diseases very seriously, which can be evidenced by the considerable commitments in terms of budget, material and manpower allocation to curb the effect of these diseases on the livelihood of the animal rearing communities and on the national economy at large. The establishment of VDFACA and the veterinary drugs, biologics, animal products and by-products quality control laboratory centre at Kaliti show how serious the government is to address the problem of quality, safety and efficacy of veterinary drugs and animal feed and how committed it is to break the deadlock on prevention and control of animal diseases.

For enhancing the effective, efficient, environment friendly and sustainable animal disease control efforts, appropriate legislative provisions have been prepared and one, 'Proclamation No.782/2011, a Proclamation to Provide for Veterinary Drug and Feed Administration and Control' has been endorsed on January 2011. The subsidiary 'Veterinary Drug and Animal Feed

## Rational Use of Veterinary Drugs and Vaccines

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Administration and Control Authority Establishment Council of Ministers Regulation No. 272/2012 of this Proclamation was also issued on December 2012; to administer and control veterinary drugs, biologics and animal feeds in the country.

Veterinary drugs were regulated by Drug Administration and Control Authority (DACA) together with human medicines since 2001. Animal feed was also under the regulation of ministry of agriculture. But now a day's both veterinary pharmaceuticals and feed regulations are transferred to the newly established Veterinary Drug and Animal Feed Administration and Control Authority After the endorsement of Proclamation No. 728/2011 and issue of Regulation No. 272/2012 by the council of ministers.

The Authority has the powers and duties stated under Article (20) of the proclamation. We are now highly working to regulate the proper production, distribution and use of veterinary drugs to ensure quality, safety and efficacy of the products so as to enhance the productivity and health of the livestock population; by registering and licensing newly produced and/or importing pharmaceuticals and companies, re-registering, at port and premises inspection, post-marketing surveillance (Article 7).

Article 6(2) of the proclamation states that “any veterinary drug shall be available for use in

accordance with the guidelines issued by the Authority to ensure judicious use of veterinary drugs.” Packaging and labelling; and prescription and dispensing of veterinary drugs are also stated under Article 9 and 10, respectively. There are also detailed punishment sub articles about misuse of certificates of competence and dispensing of counterfeits and adulterates veterinary drugs under Article 26 of the proclamation.

The responsibility to provide training for the appropriate organs on handling and utilization of veterinary drugs is also given to the authority on Article 20(12). The Authority also serves as veterinary drug information centre; disseminate veterinary drug information to professionals and the public; ensure the accuracy and relevance of information disseminated by others; and prohibit dissemination of ambiguous or erroneous information.

**3.** Veterinary drug administration and control Authority of Ethiopia has the responsibility for the development of guidelines, directives and administrative regulations for quality, safe and effective veterinary drugs availability in the market. Due the Authority ratified “Veterinary Drug Importer, Export and Wholesale Certificate of Competence Issue and Control Directive”, “Veterinary Drug Registration Guideline in Ethiopia” “Veterinary Drug Retail Certificate of Competence Issue and Control Directive”, “Guideline for the Control of Use of Veterinary



Prescription Paper” and “Veterinary Drugs and Medical Supply Promotion Control Directive” as per the power given (Article 28(2)) to issue necessary directives for implementation of the proclamation and regulation. Other directives and guidelines are also under development.

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## 16. ANNEXES

### Annex I. Veterinary Prescription Paper

Ser.No, \_\_000000

Case No. \_\_\_\_\_

Name \_\_\_\_\_ and \_\_\_\_\_ level \_\_\_\_\_ of \_\_\_\_\_ Animal \_\_\_\_\_ Health  
Institution \_\_\_\_\_

Address: Region \_\_\_\_\_ Zone \_\_\_\_\_ Woreda \_\_\_\_\_ Town \_\_\_\_\_  
Tel \_\_\_\_\_

#### Veterinary Prescription Paper

Ser.No, \_\_000000

Name and Level of Animal Health

Institution \_\_\_\_\_

Address Region \_\_\_\_\_ Zone \_\_\_\_\_ Woreda \_\_\_\_\_ Town Tel \_\_\_\_\_

Owner's Name \_\_\_\_\_

Address: Region \_\_\_\_\_ Town \_\_\_\_\_ Woreda \_\_\_\_\_ Keble \_\_\_\_\_ locality \_\_\_\_\_

Species of animal \_\_\_\_\_ Age \_\_\_\_\_ Sex \_\_\_\_\_ Body weight \_\_\_\_\_

ID No. \_\_\_\_\_ Case No. \_\_\_\_\_

Diagnosis \_\_\_\_\_

Treatment given (name, strength, dosage form, dosage and quantity of drug)	Price of Each item	
	Birr	Cent

Refill \_\_\_\_\_ Withdrawal period \_\_\_\_\_

Prescriber's

Dispenser's

Name \_\_\_\_\_

Qualification \_\_\_\_\_

Registration no. \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

\* Seal over leaf

## Annex 2: Instruments



Erlenmeyer flasks



Beakers



Prescription Bottles



Graduated Cylinders



Conical Graduates



Volumetric Flasks



Hypodermic syringes



Collapsible ointment tubes

## Rational Use of Veterinary Drugs and Vaccines

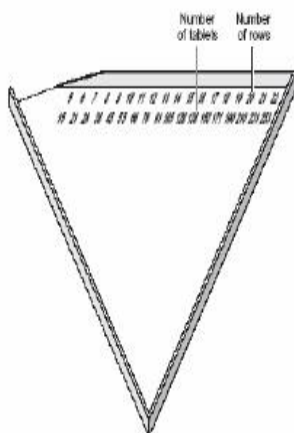
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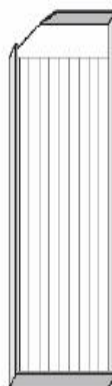
Class B Dispensing balance



Ointment slab



Counting triangle



Capsule counter