Veterinary Drug Legislation

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Medicines

- Any substance or mixture of substances, that is used in treatment, mitigation, modification, prevention, diagnosis of disease, abnormal physical or mental state or the symptoms thereof; or restoring, correcting or modifying any somatic or psychic or organic function.

- Includes any substance used medically from chemicals; proteins; vaccines; biological products; complementary and alternatives medicines.
Prescribe: The process of recommending a medicine for use even if directly used in the patient

Dispense: To sell a medicine in its original container or a new container for the client to take home

Prescription: Process of recommending the use of a medicine through a script issued to a pharmacist to fill-in

Compound: To prepare/mix a medicine for use, that is not registered
Two General Classes

Over the Counter (OTCs)
- Stock Remedies
- Fertilizers, farms foods, agricultural remedies and stock remedies Act
- Act 36/47

Prescription Only (POMs)
- All Human medicines
- Veterinary medicines
- Medicines and related substances control Act
- Act 101/65
Act 36 of 1947

- Old Act enacted when there were few vets in the country
  - Protected the farmer from unscrupulous sales
  - Allowed farmers to treat disease, when veterinary care was not available
- Tested effective under South African condition
- Registration based on Quality, Efficacy and Safety
- Stock Remedies
  - Endo and ecto-parasites
  - Selected antimicrobials, including mastitis remedies
  - Growth Promoting substances
  - Vaccines
  - Mineral and vitamin supplements
- Farm food
  - Nutraceuticals
  - Commercial foods (including the misnomer prescription diets)
Act 36 of 1947

- Generally over-the-counter unrestricted sales
  - Except when restricted by Registrar (e.g. small animal vaccines)
- May be sold to any person (older than 14) from any shop
- Must be sold in the original packaging
  - No decanting allowed
- May be used extra-label by a veterinarian
- Act makes it illegal to use any agricultural remedy (crop remedies and insect sprays) as a stock remedy
Act 101/1965

- Administered by the SAHPRA
- Controls all human medicines and veterinary medicines

SAHPRA
South African Health Products Regulatory Authority
Schedules

- Schedule 0: OTC
- Schedule 1: Pharmacy medicines
- Schedule 2: Pharmacy prescription medicine
- Schedule 3: Repeated medicines
- Schedule 4: Prescription only Medicines
- Schedule 5: Potentially dependence producing
- Schedule 6: Dangerous dependence producing
- Schedule 7: Undesirable
- Schedule 8: Undesirable with limited use
Responsibilities

- **Veterinarians**
  - Use, sell and dispense any drug up to S6
  - Dispensing licence currently suspended for 3yrs
  - Compound up to S5

- **Paraveterinarian**
  - Use, sell and dispense up to S4 on written or verbal instruction of a veterinarian
  - S5 and S6 per use on veterinary instruction

- **Any other person**
  - Can be authorised by SAVC and licenced by MCC
  - Euthanasia and access to euthanase
Expired Stock

- No person is entitled to use an expired medicine
  - Penalty of Jail time and/or a fine
- To protect the public and patient
  - Principle of “Do no harm”
  - Do your best at all time
  - Sub-standard care should not be used
- Don’t accept expired stored from medical hospitals or private practice
- Applicable to medical devices as well
Record Keeping

- All medicines purchased into the practice and sold need to be recorded
- Records maintained for five years
- For sale
  - Prescription book for pharmacist
  - Patient record for clients
  - Record details of amounts sold e.g. Amoxycillin 250 capsule - 120 dispensed (2 capsules tid for 20 days)
- Electronic record keeping allowed
Scheduled Registers

- Additional requirement for Specified Schedule 5 and Schedule 6 medicines
- Separate book to the patient record
- Record incoming and outgoing drugs and details of animal/owner
- Balanced every quarter (Apr, Jul, Oct, Jan)
- Can be kept electronic, but must be printed out and balanced by hand every quarter
Veterinarians may have practice dispensaries
- As per facility requirements
- Can dispense for partners of same practice (or locums) only
- Cannot run an open shop (can’t dispense for other vets or owners on holidays)
- Must keep records
- Vet Council has the right to inspect the facility and the records
Drug Ordering

- Only allowed from a registered wholesaler
  - No purchase from owners or other sources
- Maintain records
- From a registered facility
- By a veterinarian or authorised person
Conclusion

- Using a drug is a privilege
- High responsibility for its use