


Control of Drugs: A South African Perspective



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Relevant Acts: Veterinary Medicines



- Medicines and Related Substance Control Act
- Fertilizers, Farm Feeds, Agricultural and Stock Remedies
- Veterinary and Para-Veterinary Professions Act
- Foodstuffs, Cosmetics and Disinfectants Act
- Animals Diseases Act
- Pharmacy Act

Definitions

A veterinary medicine/stock remedy means any substance or mixture of substances intended for use or used in animals and is used for:

- treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or
- for the maintenance or improvement of health, growth, production or working capacity,
- or for curing, correcting or modifying and somatic or organic function,
- or for correcting of modifying behaviour."

Two Levels of Control

• Stock Remedies

- Vet over the counter
- Can be purchased from open shop
- Diseases easily diagnosable

• Veterinary Medicines

- Prescription medication
- Not freely available
- Registered veterinarians

Historic Level of Control

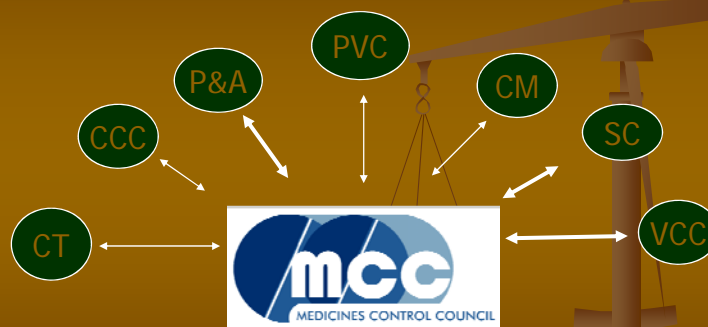
Veterinary Medicines

- Department of Health
 - Administered by the MCC and MRA
 - Controls all human medicines and veterinary medicines
- Medicines and Related Substances Control Act
- ICH and VICH aligned



Act 101/1965

Veterinary Medicines



Act 101/1965

Act 101/65: Schedules

- Schedule 0: OTC
- Schedule 1: Pharmacy medicines
- Schedule 2: Pharmacy prescription medicine
- Schedule 3: Repeated medicines
- Schedule 4: Main group
- Schedule 5: Dependence producing
- Schedule 6: Dangerous dependence
- Schedule 7: Undesirable
- Schedule 8: Limited use

Act 101/1965

Medicines and related substances control Act

1. Registration
 - Quality, Safety and Efficacy
2. Persons entitled to sell drugs
 - Medical, Veterinary, Pharmacy
3. Processes in compounding, dispensing and sale of drugs
4. Control price of medicines
5. Storage & Destruction

Stock Remedies

- Department of Agriculture
 - Directorate: Food Safety and Quality Assurance
 - Sub-directorate Regulatory Affairs
- Registered in terms of Act 36 of 1947
 - Fertilizers, Farm Feeds, Agricultural and Stock Remedies Act
 - Evaluated by technical experts

Act 36/1947

Stock Remedies

- Readily diagnosed
 - Worms, Ticks, mastitis, Protozoa
- Prophylactic control
 - Vaccines
- Production enhancement drugs
 - Growth promoting antibiotics
- Primary Health Care
 - Vaccines, vitamins, minerals

Act 36/1947

Veterinary and Paraveterinary Professions Act

- Controlled by the SAVC
 - Act 19 of 1982
- Governs the profession of vets and para-vets
 - Sets us rules and regulations

Veterinarians

- Prevents vets from acting as pharmacists
 - Can only dispense for own practice
- Can use drugs extralabel
- Restriction on the use of compounded remedies
- Ensures public health is given priority
 - Follow withdrawal periods
 - Alternatively set new withdrawal periods

Act 19/1982

Safety of chemical

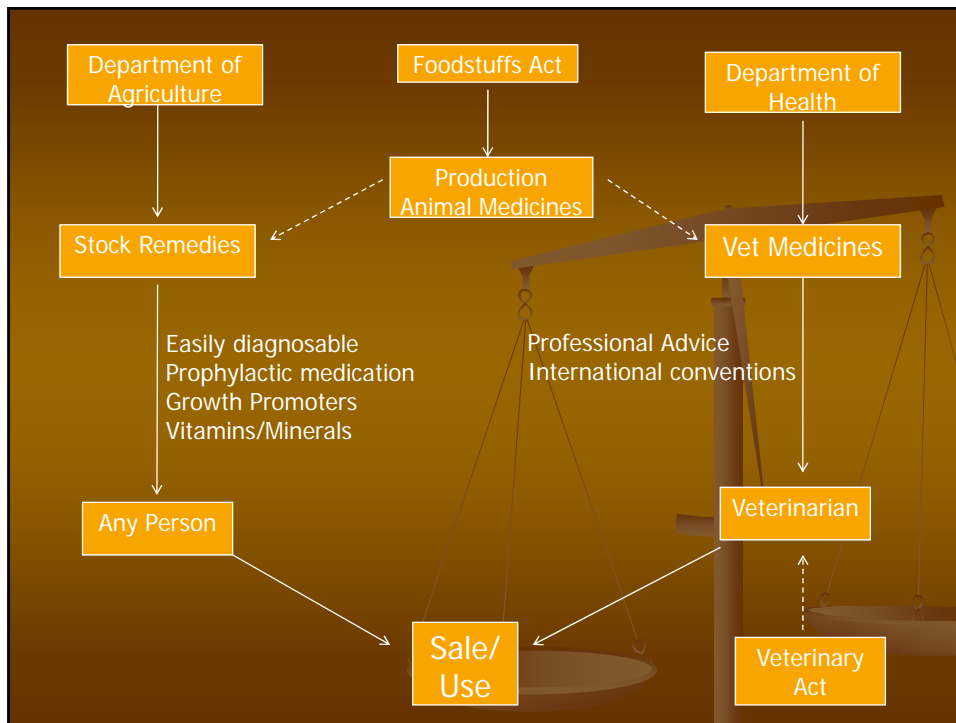
- Residues of veterinary drugs in food
- Controlled by the DOH, food control
 - Foodstuffs, cosmetics and disinfectants Act, Act 54/1972
 - Follows CODEX standards

Act 54/1972

Safety of Chemical Residues

- Minimum residue levels controlled
 - MRL and WT published by Health
 - Based on full toxicological evaluation
- Monitored by Agriculture
 - Quality checks by abattoirs

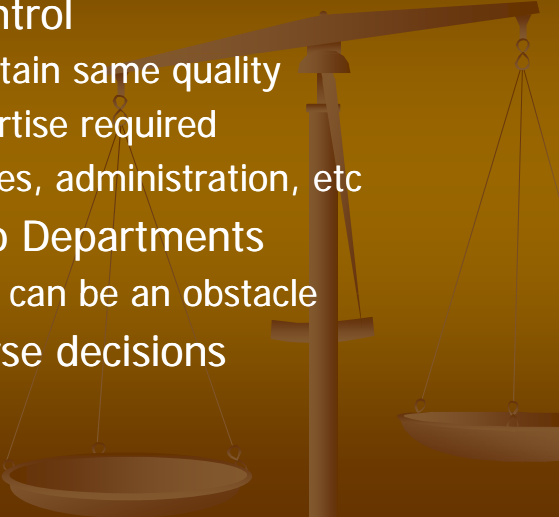
Act 19/1982



Advantages

- Easier access of certain remedies by the public.
- Caters for extralabel drug use

Disadvantages

- Dual level of control
 - Difficult to maintain same quality
 - Duplicates expertise required
 - Conflict in clauses, administration, etc
 - Managed by two Departments
 - Political niceties can be an obstacle
 - Difficult to reverse decisions
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Conclusion

- Dual Level of Control in SA
 - Facilitated easier access historically
 - Can create administrative problems
 - Talks of a single regulatory system
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