


# Distribution and Use of Veterinary Products

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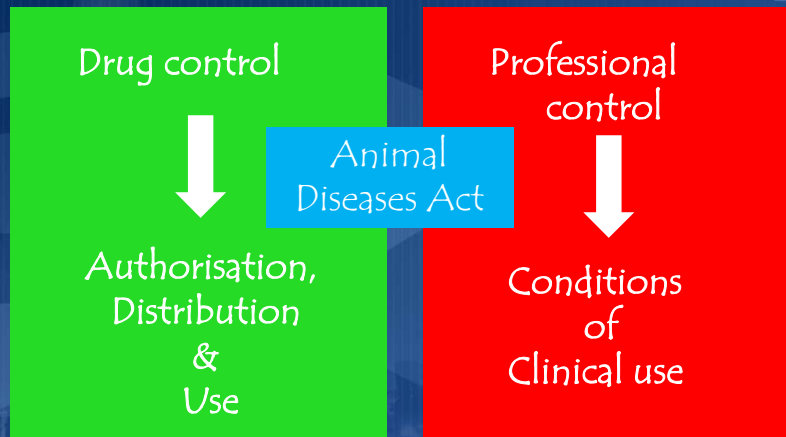
## Introduction

- ◇ Availability and use of a veterinary product is determined by its distribution channels and authorised user
- ◇ Legislation framework for distribution is aimed at:
  - Ensuring access of quality, efficacious and safe products
  - Maintaining quality of product
  - Preventing illegal trade
- ◇ Need for prudent use

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2

## Legislation framework for distribution and use of veterinary products



## Factors that determine distribution and use

- ◇ Type of product (Medicines; Stock Remedies; Biologicals; Production enhancers)
- ◇ Classification/ Scheduling status (Safety; Necessity for precise diagnosis or therapeutic measures; Requirements for special precautions regarding safety)
- ◇ Convention requirements for narcotic and psychotropic substances
- ◇ Dosage form (Single/Multi-dose; Fluids/Solids; Transport and Storage requirements)

## Veterinary Medicines in South Africa

Schedule No.	Group
0	OTC
1	Pharmacy medicines
2	Pharmacy prescription medicines
3	Frequently repeated medicines
4	Main group medicines
5	Dependence producing substances
6	Dependence producing narcotics
7	Undesirable dependence producing
8	Prohibited substances

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\* Available on permit only

## Uniform Scheduling of Drugs and Poisons in Australia

Schedule No.

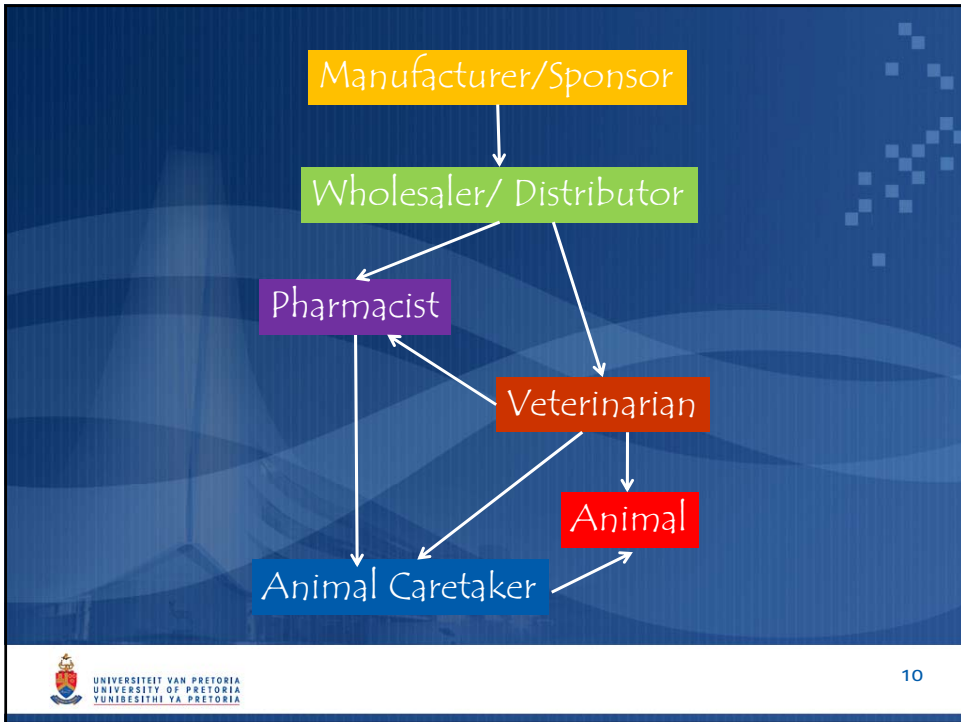
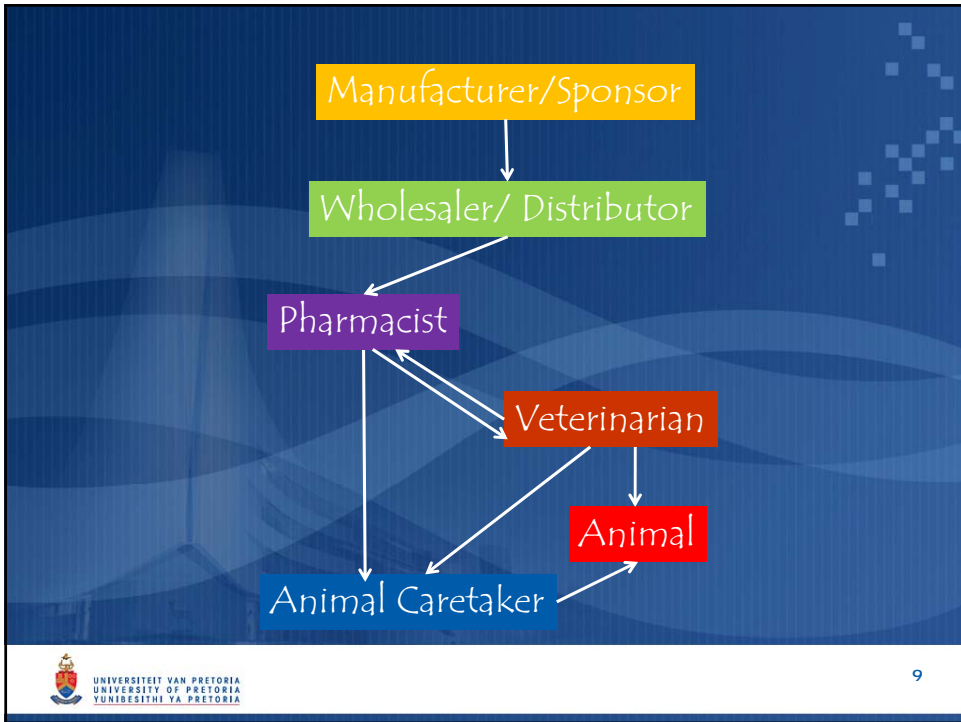
1	(Defunct)
2	Pharmacy Medicine
3	Pharmacist Only Medicines
4	POM/Animal Prescription Remedy
5	Caution
6	Poison
7	Dangerous Poison
8	Controlled Drug
9	Prohibited substances

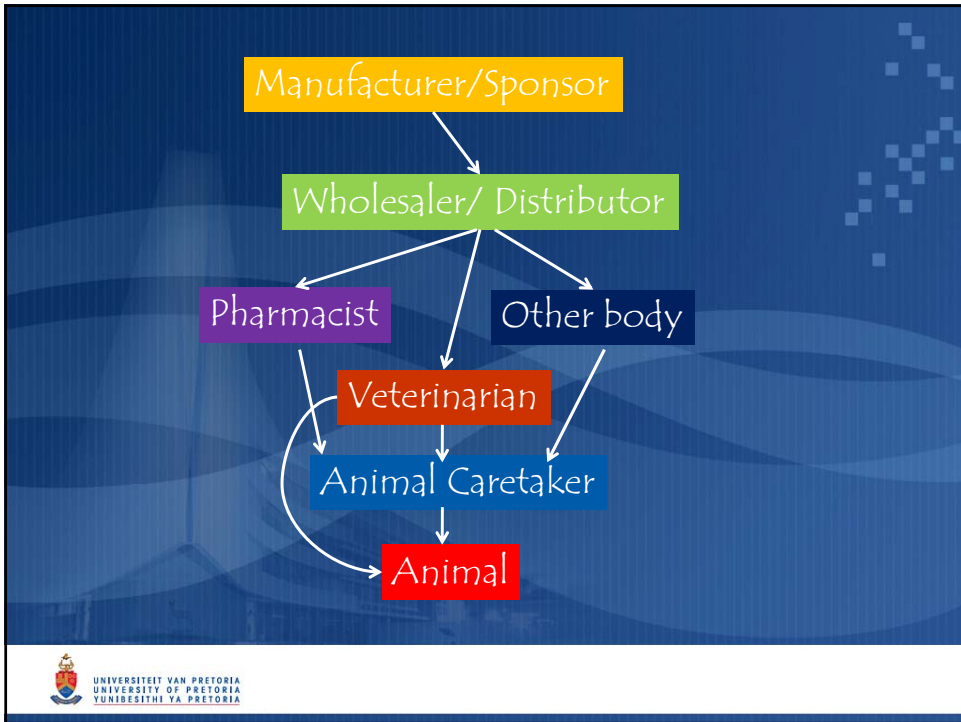
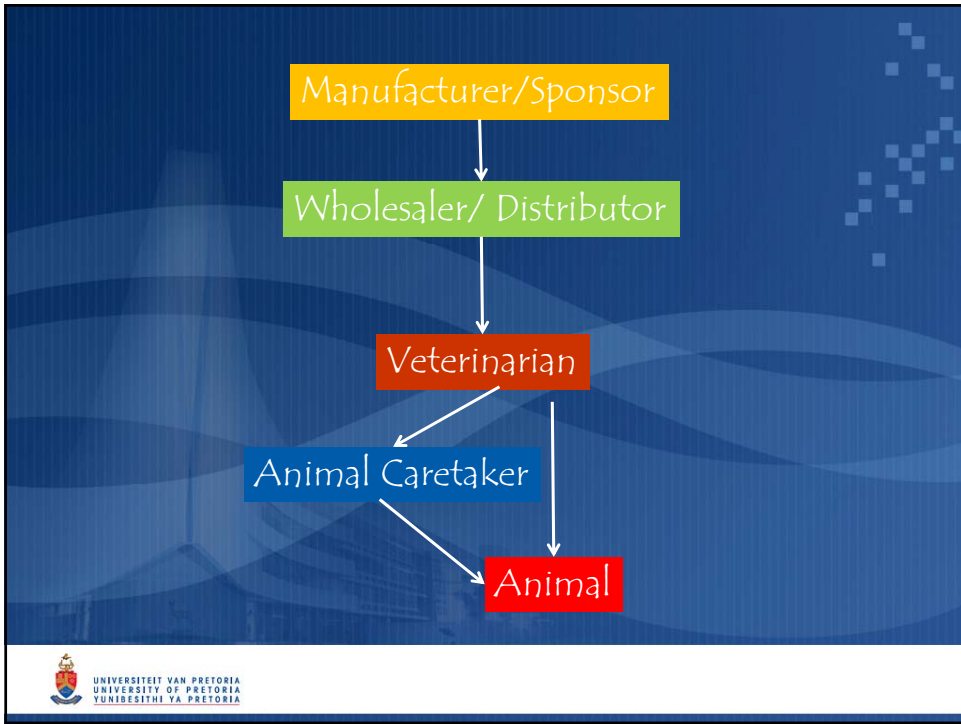
## Classification/ Schedule conditions

- ◇ Persons authorized to sell
- ◇ Place of sale
- ◇ Access
- ◇ Prescription requirements
- ◇ Need for register
- ◇ Emergency supply

## Definition of sale

Means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorise, direct or allow sale or prepare or possess for purpose of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and sell, sale and sold have corresponding meanings."





## Authorised persons for POM



Section 22A (15):  
"in the course of lawfully  
carrying on his professional  
activities as such to or for  
any patient or animal under  
his care or treatment"

## Dispensing of veterinary products



*Includes all of the activities which occur after the prescription has been  
effected until the medicine or other prescribed items have been  
collected or forwarded*



Legal compliance



Good Dispensing Practice

## Legal Compliance

- ◇ Authorized sale
- ◇ Authorized access
- ◇ Schedule conditions
- ◇ Prepackaging
- ◇ Labeling
- ◇ Control of higher scheduled substances

## Good Dispensing Practices

- ◇ Standards of dispensary premises
- ◇ Standards of dispensary design and equipment
- ◇ Standards of procurement and sources of materials
- ◇ Standards of dispensing procedures
- ◇ Standards for counselling/advice to ensure patient safety



# Compounding



*Preparation of a medicament that combines legally obtainable ingredients and/or appropriate vehicles, which have not been specifically excluded from animal use and may include the alteration of the original medicinal dosage form for the purpose of ease of administration or because the original dosage form is unsuitable for the purpose intended.*

# Provisions for compounding

- ◇ Definition
- ◇ Authorisation
- ◇ Conditions
- ◇ Requirements

## CONDITIONS OF CLINICAL USE



## Requirements of sale

- ◇ Prescribed by veterinarian
- ◇ Open shop
- ◇ Prescription book
- ◇ Comply with schedule requirements
- ◇ "Treatment register"

## Prescription book

- ◇ Date prescription was dispensed
- ◇ Form of preparation and quantity
- ◇ Name and address of client
- ◇ Name of veterinarian who issued the prescription
- ◇ Name of medicine

## Control of Psychotropic and Narcotic substances

- ◇ Safe keeping of substances
- ◇ Register
- ◇ Maintenance of register
- ◇ Disposal
- ◇ Prescription requirements

## Bona fide client

### Consultation

- Clinical or post mortem examination
- Examination of specimen
- Interview

### Outcome

- Diagnosis
- Determine particular need

## Conditions of sale

### Risk-benefit assessment

- Animal
- Client
- Consumer

### Inform user of medicine

- Administration
- Drug effects
- Precautions
- Withdrawal period

# USE OF UNREGISTERED DRUGS



## Medicines control

Unregistered medicines



Patient use  
Laboratory use  
Experimental use

## Professional control

Extra-label use



Professional onus

# Conclusion

- ◇ Legislation framework for distribution and use of veterinary products that describes:
  - Routes of distribution
  - Access to veterinary products
  - Sale
  - Storage and handling
  - Dispensing and compounding
  - Use
- ◇ Clinical use of products
- ◇ Recording and Control