# Assessment and Authorization of Veterinary Products: Legislation Framework

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## Introduction

- A legislation framework for the assessment and/or authorisation of veterinary products is essential for:
  - Animal welfare and production
  - Protection of society
  - Development of veterinary pharmaceutical industry (counterfeit medicines)
  - International trade in animal products
  - Mitigate against the misuse of veterinary products
- National (Government) responsibility to set up legislation framework and to implement the legislation

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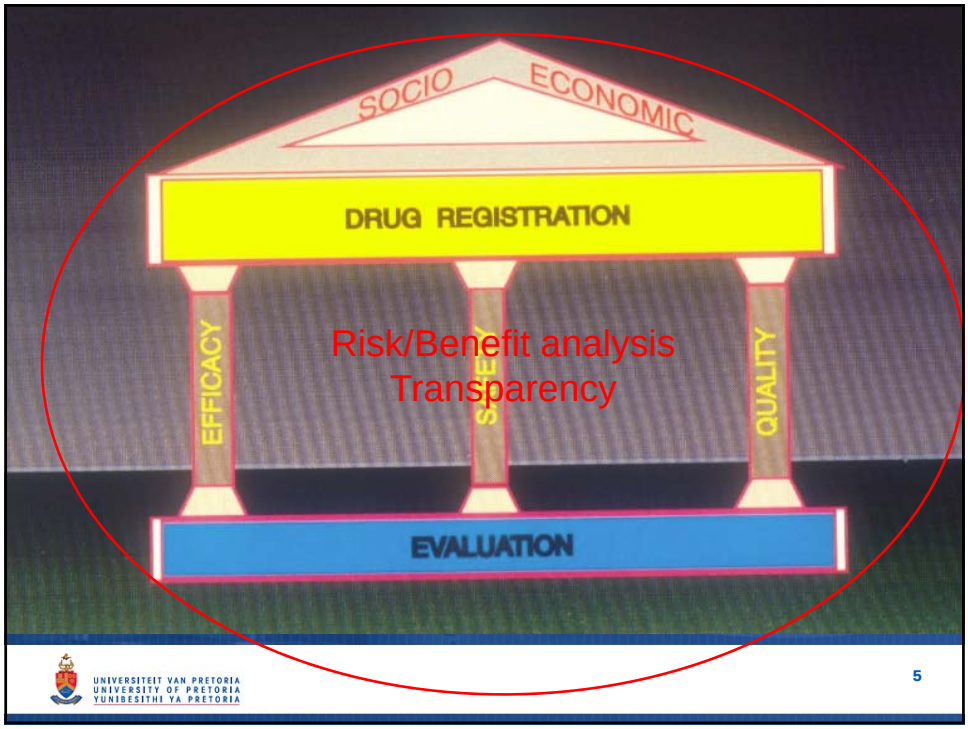
# Market authorisation

Market authorisation (also called registration or licensing) is the approval by the responsible authority in the country concerned that the product may be sold and used, specifying the details of the product (e.g. name of active substance, animal(s) for which it can be used, indications of use, dose and duration of treatment), the conditions of use (e.g. storage conditions, shelf life, withdrawal period, instructions for safe use or instructions for safe disposal of waste) and any precautions or warning for safe use, including possible contraindications



# Types of legislation frameworks

- Continuum from simple listing to very sophisticated assessment and authorisation systems
- Legislations frameworks can be organised in a centralised (community marketing authorisation) or decentralised (mutually recognised) or purely nationally
- Different legislation frameworks may exist for different types of veterinary products e.g. stock remedies versus veterinary medicines and biological versus pharmaceuticals
- Different regulatory authorities e.g. health vs agriculture
- Control of veterinary products begins with legally adopted definitions of the various products




# Preclinical studies

- Safety studies

  Acute/ subacute/ chronic studies; Teratogenicity/ Embriotoxicity/ Fetotoxicity; Mutagenicity/ Genotoxicity/ Carcinogenicity; Immunotoxicity; Neurotoxicity; Ecotoxicity; Environmental fate; Resistance development

- Pharmacology

  Metabolism; MOA; Physiological/ Pharmacological effects

- Pharmaceutical

  Formulation development; Dosage form; *Delivery systems;* Stability testing

- Analytical methodology

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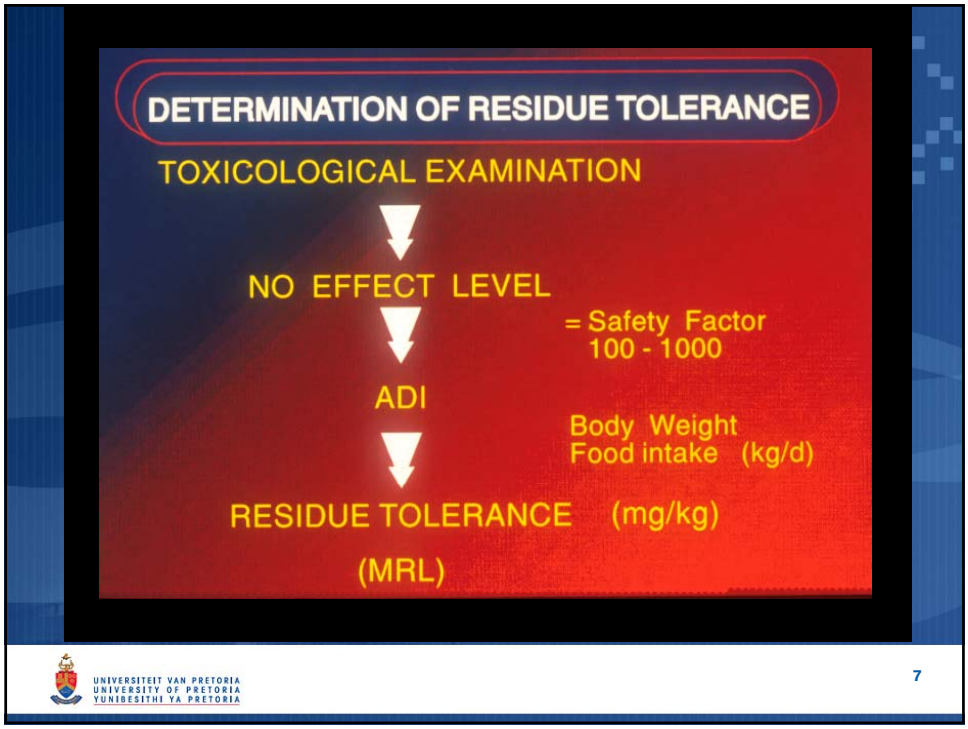




# Clinical assessment

## EFFICACY

- Dose relationship and confirmation studies
- Controlled laboratory studies
- Field studies
- Specific indication protocols/ guidelines

*NB Ectoparasiticides*
*Anthelmintics*
*Biologicals*

## SAFETY

- Acute/ Tolerance studies
- *Field studies*
- Reproductive/ Fertility studies
- Tissue compatibility
- Residue deletion studies

## BIOEQUIVALENCE

# Scope of Safety of Veterinary Products

- Animal
- User
- Consumer of animal products
- Environment

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# Quality

- Good Laboratory Practices (GLP)
- Good Clinical Practices (GCP)
- Good Manufacturing Procedures (GMP)
- Inspectorate and mutual recognition systems (PIC)
- Reference Laboratories
- Pharmacovigilance

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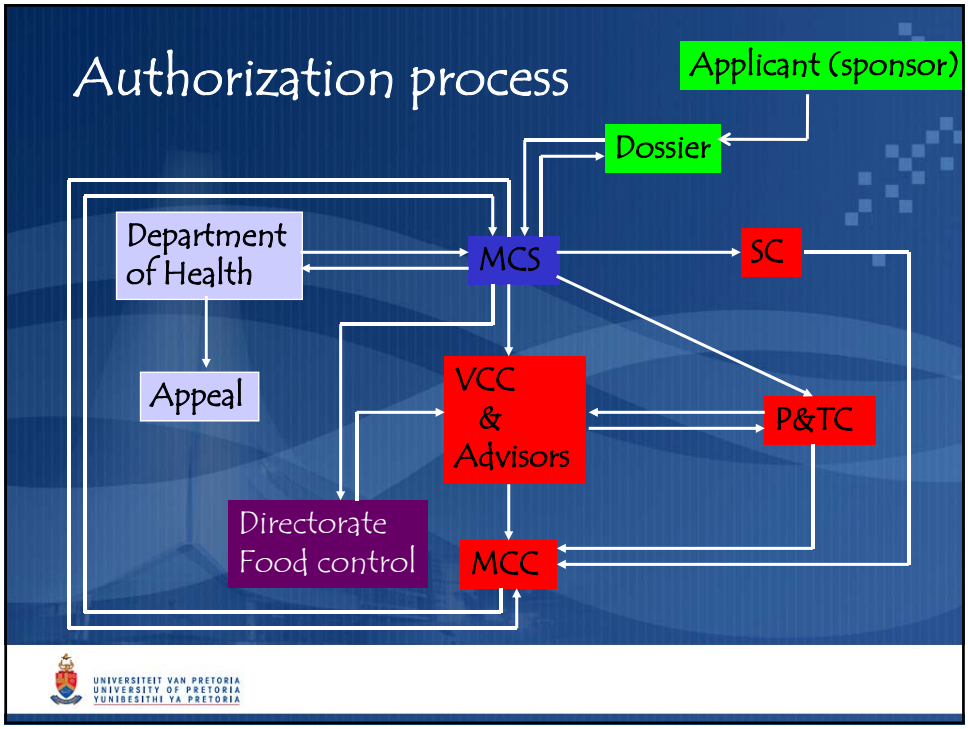
Authorization process
Applicant (sponsor)
Dossier
Department of Health
MCS
SC
Appeal
VCC & Advisors
P&TC
Directorate Food control
MCC
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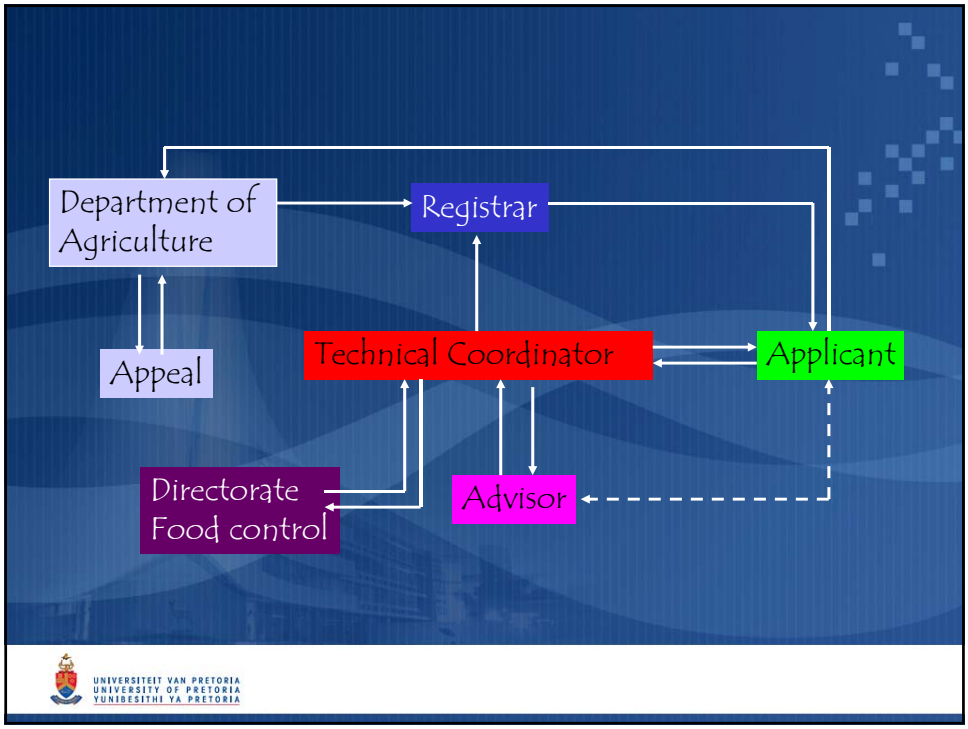
Department of Agriculture
Registrar
Technical Coordinator
Applicant
Appeal
Directorate Food control
Advisor
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# Harmonisation of Assessment procedures

- Nationally, Regionally and Internationally
- Need and purpose
  - Cost of development
  - Time to registration
  - Mutual recognition
- VICH

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# Conclusion

- Necessity for a legislation framework
- Type and extent of framework
- Pillars of assessment framework
- Processes and Procedures
- Harmonization

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