



Status of Requirements for Registration of Veterinary Medicines in South Africa

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GALVmed/OIE stakeholder workshop on
harmonisation of the registration of veterinary
medicines



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Scope



A. LEGISLATIVE FRAMEWORK

B. REGULATION

C. REGISTRATION

D. DISTRIBUTION

E. INSPECTIONS

F. ENABLERS



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Legislative Framework



a. Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) and regulations

Over the counter medicines

b. The Foodstuffs, Cosmetics and Disinfectant Act, 1972 (Act No. 54 of 1972) and regulations

Set and publish MRLs

c. Medicines and Related Substances Act of 1965 (Act 101, 1965): Scheduled medicines



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VETERINARY MEDICINE



means any substance or mixture of substances, other than stock remedy or farm feed to be registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), used or purporting to be suitable for use or manufacture or sold for use in connection with **vertebrates**, for the **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 any somatic or organic function, or for correcting or modifying behavior**



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STOCK REMEDY



means a substance intended or offered to be used in connection with **domestic animals**, livestock, poultry, fish or **wild animals** (including wild birds), **for the diagnosis, prevention, treatment or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity**, but excluding any substance in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965);

Provisions of the Acts



- Clinical Safety and Efficacy
- Quality of innovator and generic medicines
- Good Manufacturing Practices (GMP)
- Good Clinical Practices (GCP)
- Good Wholesaling and Distribution Practices
- Evaluation of applications for registration and amendments of registered medicines
- Monitoring of Importation and exportation of medicines and control of border posts
- Evaluation and approval of Clinical Trials

REGISTRATION



Scheduling and exemption

Act 101 schedules 0 – 7

Schedule all medicines (based on active pharmaceutical ingredients)

Exemption from schedules of Act 101/1965 for registration under Act No. 36/1947



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Veterinary medicines



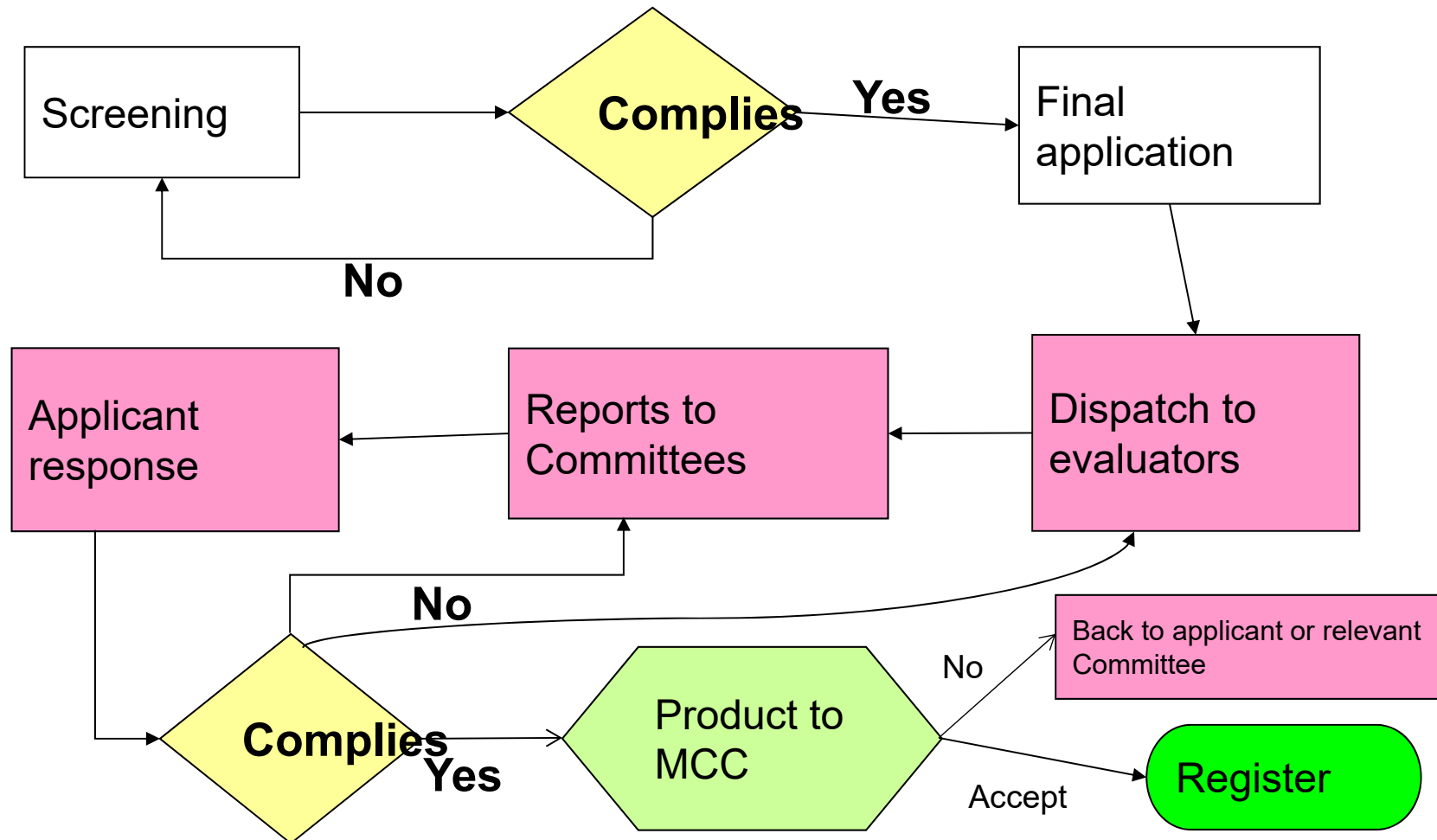
- Department of Health
 - Administered by the MCC and NDoH
- Medicines and Related Substances Act
 - Regulations
 - Guidelines are VICH aligned
- Expert Committee
 - Veterinary Clinical Committee (VCC)
 - Evaluates all clinical evaluations including clinical trial approvals
 - Expertise in the VCC includes: Pharmacologists, Pathologist, Epidemiologist, Theriogeniologist, Microbiologist, Clinical Experts (poultry, ruminants, pigs, companion animals and wildlife)



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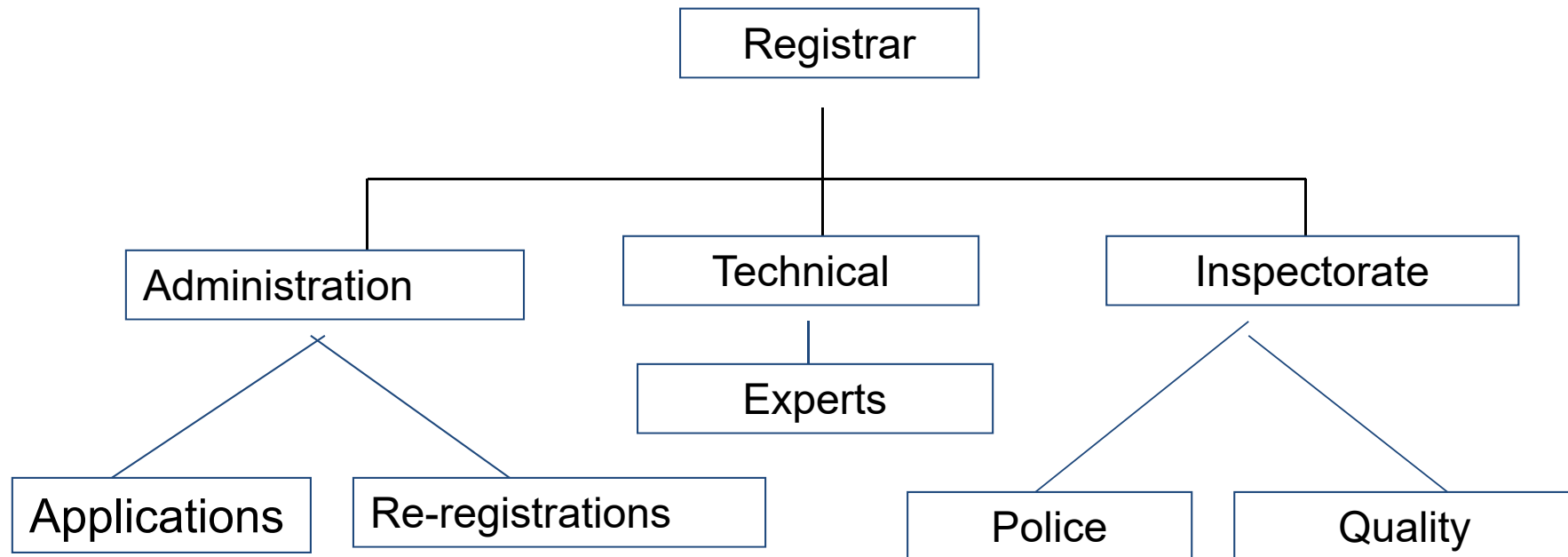
Registration process



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STOCK REMEDIES



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CRITERIA FOR STOCK REMEDIES



- Drugs for readily diagnosable stock diseases: treatment of common diseases – tick borne, parasites
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- Prophylactic substances
- Production enhancing substances
- Commodity animal substances
- Safety of product



• Safety under local conditions
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REGISTRATION REQUIREMENTS



a.Registration data

- In support of quality, safety and efficacy
- Efficacy (all species, routes of admin and diseases)
- Safety
 - pre-clinical data (toxicology) laboratory animals
 - target animal safety data (all species and routes)
 - residue data (all species, routes, highest recommended dose)
 - environmental toxicity
 - occupational health during manufacturing
 - Pharmacokinetics and pharmacodynamics data



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DISTRIBUTION



. **Access to stock remedy – End users**

- Over the counter
 - Available to the general public
 - Veterinarians
 - Para- veterinarians

b. Access to veterinary medicines

- Safety
- Professional Advice
- Control (Conventions)
- Public Health Considerations
- Usage
- International Scheduling Status



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DISTRIBUTION....



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Pharmaceutical companies

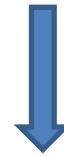
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Veterinarians



Wholesalers



Cooperatives



Pharmacists

Retailers

End users/farmers



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INSPECTIONS



Pharmaceutical companies

- Manufacturing facilities
- Importers and Exporters
- Laboratories and packers
- Distributors
- Wholesalers

Cooperatives

Pharmacies

Retailers

Veterinarians



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ENABLERS



- **GUIDELINES**
- **a.** Act No. 36 of 1947 data requirements
- **b.** Act 101 of 1965 (MCC) guidelines
- **c.** Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary medicinal Products (VICH) guidelines
- **d.** World Association for the Advancement of Veterinary Parasitology (WAAVP) guidelines



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CURRENT CHALLENGES



Challenges faced by both Authorities:

The dual registration process

- Threats to food safety and control
- Threats to trade
- Duplication of efforts

Human resource constraints

Electronic Document Management System

Registration timeframes

Training and capacity building



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CURRENT COLLABORATIONS



- Representation of South Africa at VICH as an observer
- Establishment of the National Veterinary Products Policy Task Team
 - Constitutes representation from all the Acts (101/1965, 36/1947, 35/1984 and 54/1972)
 - Includes members from Industry and Vet Council
 - Has revised all current guidelines by both Acts and is in the process of adoption of the VICH guidelines (QSE)
 - Where necessary the guidelines will be changed to suite South African conditions

Antimicrobial Resistance Framework – “One Health”



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ROAD TO HARMONISATION



VICH 6



FUTURE ENDEAVOURS



How to participate in existing initiatives regionally and internationally as achieved on the human medicines arena:

Sharing of inspection reports: Members of PICS
CEPs: EDQM

IGDRP- generic medicines

Members of Zazibona: Opportunity to Utilise this platform for worksharing in SADC

AVAREF: vaccine clinical trials



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THANK YOU

