GALVMed/OIE stakeholder workshop on the harmonization of the registration of veterinary medicinal products

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Experiences and needs of Onderstepoort Biological Products (OBP) for registration procedures

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Presentation outline

- OBP Background
- OBP Markets in Africa
- Challenges
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  - Quality Management
  - Submission Process
  - Authorization
  - Post Authorization
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OBP Background

OBP is one of the largest vaccine manufacturing plants on the African continent, possessing the facilities and expertise to produce a variety of vaccines to viral, bacterial and parasitic agents causing diseases in cattle, horses, sheep and poultry.

The principal purpose of OBP is:

• To produce quality vaccines for the prevention and treatment of livestock, horse and poultry diseases

• To exploit and develop ongoing research into the production of new and advanced vaccines for the benefit of agriculture locally (and abroad)
OBP Market in Africa

West African Economic and Monetary Union (UEMOA’s)

East African Community (EAC)

SADC

OBP Customer
Challenges - General

- Historically SADC has always accepted RSA registered veterinary vaccines
- Counterfeit medicines in the market place
- Political barriers (OBP is State Owned Company)
Challenges:
Legislation & Guidelines

- Governing structure varies
- Different requirements and formats, lack of clear guidelines (publically available) and legislative framework
- Varying regulatory requirements = escalation of development cost, increased time to market and additional use of animals (ethical concern)
- Some African requirements for veterinary vaccines are based on pharmaceutical requirements
- GMO products
Challenges: Quality Management

- Most SADC countries do not address Quality Management/GMP/GCP
  - Lack of Veterinary GMP guidelines
  - Lack of experienced & trained Inspectors
- Although QM/GMP/GCP Increases time, cost and resources, it is necessary to ensure quality products.
Challenges: Submission process

- Paper vs Electronic
- Confidentiality of information.
- No transparency of the regulatory process
- Submission requirements not always clear
Challenges: Authorisation Procedures

- General lack of registration capacity (Resources and experienced Staff).
- No clear timelines/predictability
Challenges: Post Authorization

- Post authorization changes (variation/amendment) not addressed in most African guidelines
- No formal Pharmacovigilance requirements
- No Good Distribution Practice (GDP) guidance addressed in African guidelines (GDP helps to handle the distribution chain from manufacture to customer, recalls, complaints, storage, traceability, and controls)
Recommendations…

- Early stakeholder involvement
- Benchmarking
- Agreement on basic standards that will accelerate mutual recognition and eventual harmonization
- Single set of requirements, Clear guidelines = Fewer dossiers to prepare
Recommendations…

- Introduce transparent regulatory processes with clear timelines
- Veterinary adapted GMP/GCP standard, use an internationally recognized existing text from a well-established regulatory authority or regional organisation.
- Consistent, transparent and science-based assessment.
- Increased regulatory capacity through knowledge transfer
- Regulation and action against counterfeit products
Recommendations

- Government websites should list all relevant information concerning the authorization of veterinary medicinal products for transparency and predictability, and should also house a list of authorised products.
- Data security is important.
- Improved pharmacovigilance systems and communication.
- Applicants need a channel to be able to approach regulators.
- Online forum for discussion between collaborating countries.
- Continue these meetings and workshops - personal relations and contacts are important in the harmonization process.
Thank you

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