Innovative Bio-Science

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

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GALVmed
Protecting Livestock – Improving Human Lives

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

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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
  - General
  - Legislation & Guidelines
  - Quality Management
  - Submission Process
  - Authorization
  - Post Authorization
- Recommendations

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)

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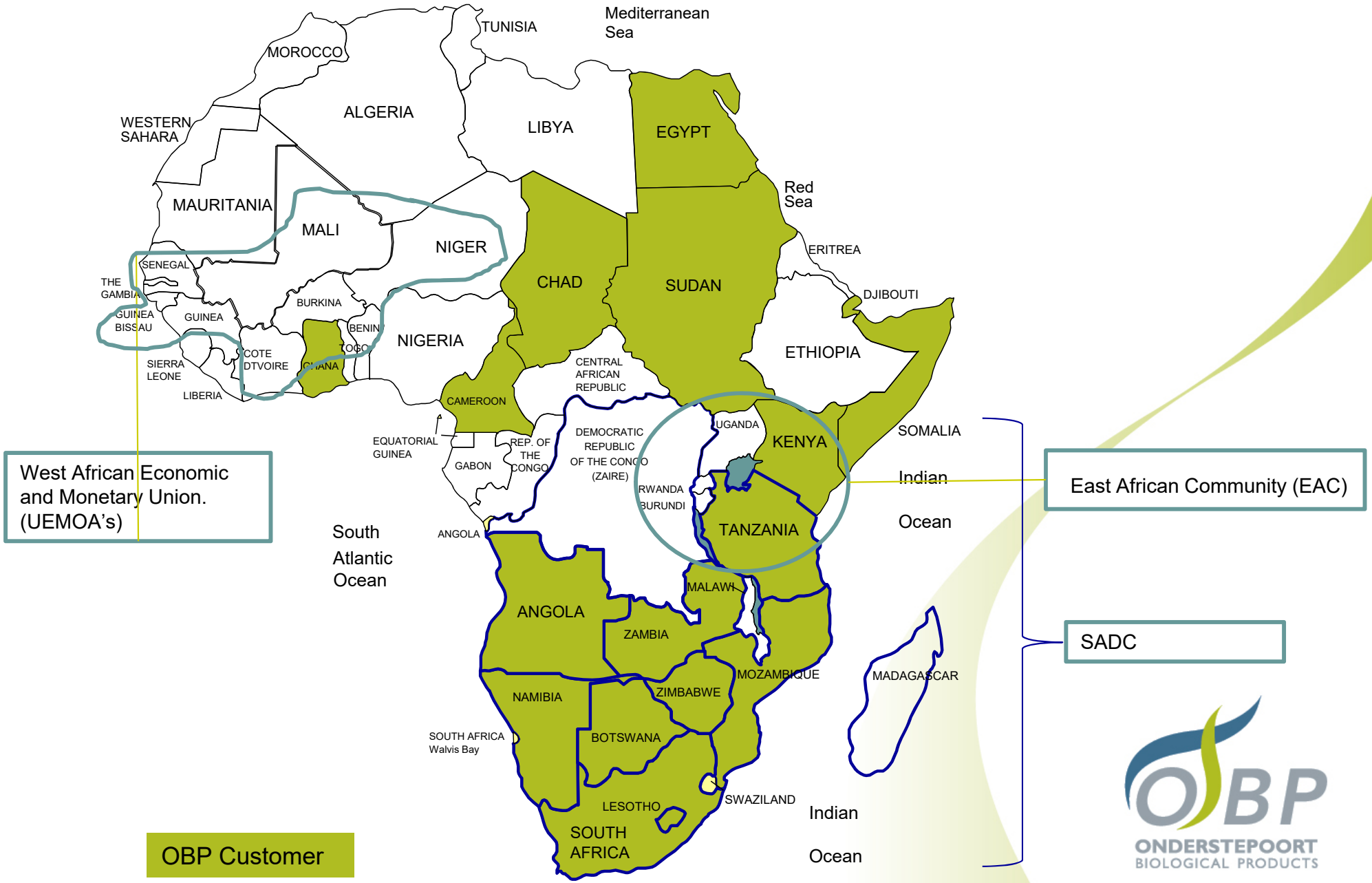
OBP Market in Africa



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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

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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)

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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

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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.

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Thank you

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