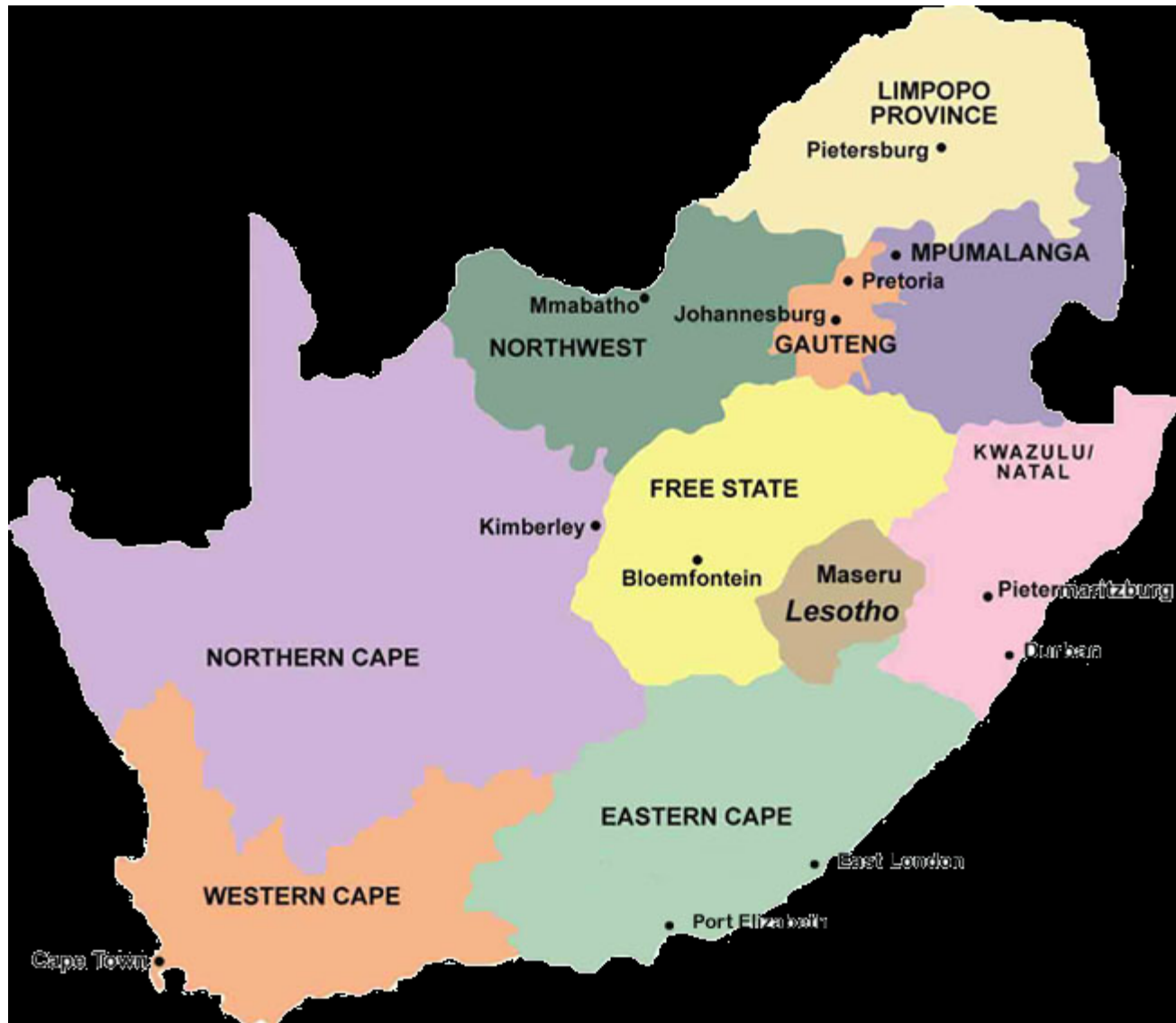


Innovative Bio-Science

Industry challenges on supplying emergency vaccines in Africa – OBP perspectives

**Bethuel Nthangeni
LSD meeting
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FVS

An aerial photograph of a residential area. A road labeled 'M35' and 'Soutpan Rd' runs vertically through the center. To the left of the road is a large green area with several buildings, labeled 'FVS'. To the right of the road is a residential area with many houses, labeled 'OBP' and 'OVR'. The labels are in large yellow font. The road is marked with a yellow line and a green sign with 'M35'.

OBP

OVR

Historical Perspective of OBP

1908: Establishment of Onderstepoort Veterinary Research institute

1968: Dedicated vaccine facility established

1992: OBP separated from Onderstepoort Veterinary Research institute

2000: OBP incorporated as a State-owned commercial entity

2007: Achieved ISO 9001 certification.

2012: Obtained funding for upgrading and modernizing the facility into a GMP plant



OBP policy mandate

- ***Public good vaccine*** - To ensure that the government's responsibility in terms of food security and safety is met through the development, security and availability of critical vaccine reserves; and
- ***Private good vaccine*** - Referring to the ability of the organisation to manufacture, distribute and sell vaccines for financial gain



OBP Product Portfolio



Bacterial Vaccine Products

- Actinomyces (Corynebacterium) pyogenes
- Anthrax
- Black Quarter
- Botulism
- Botulism/black quarter
- Blue Udder
- Brucella Rev 1
- Brucella S19
- Calf paratyphoid (live & inactivated)
- Corynebacterium Ovis
- E Coli
- Enterotoxaemia (pulpy kidney)
- Fowl Typhoid
- Gangrene Complex
- Haemophilus Coryza
- Lamb Dysentery
- Leukopast 3 (with IBR and PI)
- Leukopast
- Pasteurella Bovine
- Pasteurella Ovine
- Septicum
- Swelled Head
- Tetanus
- Vibrio (Campylobacter)

Viral Vaccine Products

- Rift Valley fever – live, inactivated, Clone 13
- African horse sickness
- Bluetongue
- B-Phemeral
- Chlamysure
- Lumpy skin disease (LSD)
- PI and IBR (in Leukopast 3)
- Fowl Pox
- ORF
- Equine Influenza

Strategic emergency vaccines - definition

Vaccine reserves, antigen banks, emergency vaccine:

Vaccine materials ready to be used or ready to be rapidly reconstituted into final vaccine product when needed in emergency

LSD will be used as case study

Strategic approaches at OBP

- Bottled manufactured vaccines
- Bulk antigens

Bottled manufactured vaccines

Advantages

- Availability for immediate use – shipping in days
- No need for specialized premises to store bottled formulated vaccines
- Vaccines can be stored in different locations under appropriate conditions and monitoring

Disadvantages

- Clients prefer stock with complete shelf life duration
- Prone to incorrect sales and quantities forecasts
- No compensation for written-off stock even if you are a public good commercial state-owned company
- Limited use in controlling disease in which there is antigenic variation



Bulked vaccine antigen reserve

Advantages

- Technology to concentrate and store bulk LSD vaccine antigen is available
- Vaccine is formulated only upon demand
- Quality standards are never compromised
- Production is shortened to 4-6 weeks
- Shelf life starts upon formulation of the given batch

Disadvantages

- Storage duration of bulk vaccine is limited
- Regular periodic tests mandatory
- Specialized storage facility and conditions are required
- Who bears costs for regular quality monitoring, warehousing and logistics?
- Order tender process – time of great uncertainty; do you formulate or not?

General conclusions on Strategic emergency vaccines

- Vaccines need to still be used as “protective” agents during emergencies
- Legal contracts between client and vaccine manufacturer mandatory
- Investment in long term bulking technologies and internationally approved standards for rapid quality control tests
- Epidemiological surveillance to determine circulating disease strains will ensure availability of relevant emergency vaccine strains.





fully
GMP
compliant
plant

2020

optimise
systems
& processes

2015 2014

skill people

2012 2013

change culture

2011 2011

modernise infrastructure
& equipment

2010 2010

Thank you



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