4TH ANNUAL **SADC** INDUSTRIALISATION WEEK

Harmonization in medicine regulation: friend or foe?

Anne Grobler (PhD)
Director: DST/NWU Preclinical Drug Development Platform
Professor: Pharmaceutics

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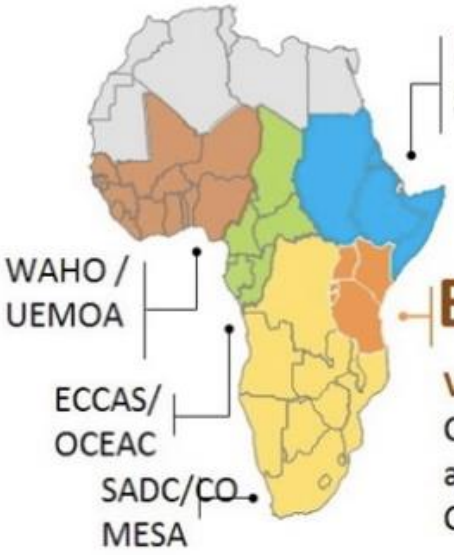
FRIEND - Safe and efficacious drugs

- Africa's pharmaceutical industry will reach $40 - $65 billion by 2020 (McKinsey (2017).
- Growth of 100 - 300% over the last years = opportunities and challenges,
- Major challenge: quality of the conventional & traditional medicines; 1/10 products is sub-standard or fake in middle-income & low-income countries (WHO; 2017).
- >30% of the medicines on sale are fake or sub-standard in parts of Africa, Asia.
- Africa is responsible for 46% of the global occurrence of fake/substandard drugs.
- Results in 64 000 to 158 000 malaria related deaths annually, and 72000 - 169 000 pneumonia-related deaths of children in sub-Saharan Africa from fake or substandard drugs.
- Traditional, complementary or alternative medicines (TCAMs) are outside mainstream regulation. Some 70% of people are thought to use traditional medicines.
- Economic value of TCAM was estimated at least >US$2.2 million in South Africa in 2016/2017. Lack of evidence on the safety pf TCAMs in SSA, lack of pharmacovigilance analysis (International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations, 2014).

A dream?



Vision: East African Community Medicines and Food Safety Commission

55 countries → 5regions → 1 continent

NEPAD - TRANSFORMING AFRICA

FRIEND –

Detection of fakes and substandard drugs - who is responsible?

Sophisticated printing techniques hologram reproduction of packaging and containers, (Lancet; 2012).

Need the ability to quickly and easily evaluate the safety and efficacy of the drugs.

In vitro efficacy models as compared to expensive analytical instrumentation.

Harmonized platform required to develop assays.

Role of the regulator

(i) Review and registration and monitoring of

- products

- facilities

(ii) Inspectorate

SUPPORT and/or POLICING?

Penalties for the supply and sales of fake and sub-standard drugs are minimal and does not reflect the seriousness of the crime.

One of the solutions?

- More than 85% of sub-Saharan registration harmonization proje
- **Newly adopted African Union Regulation: an African Medic**
- Geneva–20 May 2018: African M the establishment of the African
- AMA: the coordination & streng harmonise medical products reg support to improve access to qu products and health technologie
- AMA to function within the archi communities (RECs) and Regio support AU Member States. Ow
- http://www.nepad.org/programm harmonisation-amrh
- www.au.int.

Coordination of regulations across departments

Example in South Africa

Import of vaccines: Safety & potency in preclinical models

- **DST/NWU Preclinical Drug Development Platform**
- **Import of vaccines from India.**

Process:

(i) Due diligence – yes; Agreement – yes; Accreditation – yes.

(ii) Import of vaccines for release –

- Human vaccine falls under SAHPRA
- Animal studies falls under DAFF

- **Neither willing to take responsibility for release of vaccines at airport.**

SADC Declaration and Treaty

SADC Protocol on Trade

Technical Regulation Framework national obligations.

The TBT Annex to SADC Trade Protocol - a common technical regulation framework for the region.

GHS legal frameworks - chemicals & biologicals

Chemicals & biologicals

- Relevant regulation or Act
- Safety report vs safety assessment
- Quantitative & qualitative composition of product – raw materials & dosage form
- Further requirements for the safety report
- Physical/chemical characteristics & stability
- Impurities, traces, and packaging material
- Required labeling information

Cell & gene therapy?

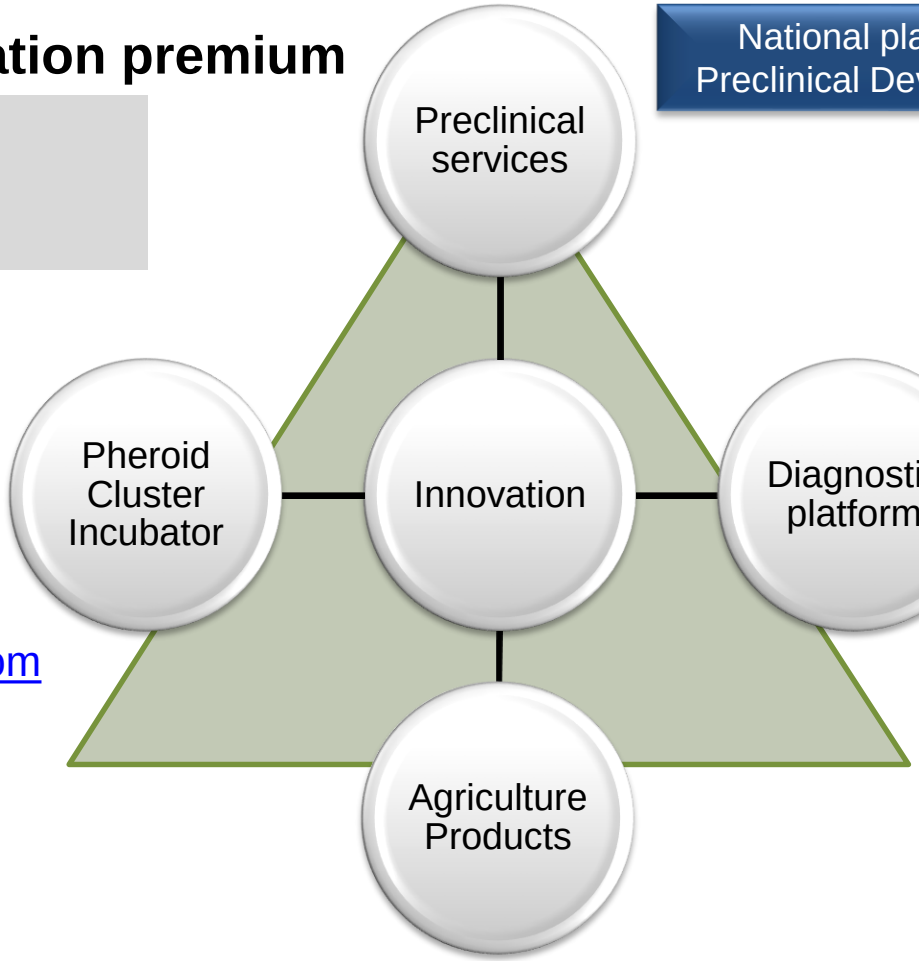
- Mosquitoes – Gene Drive
- CAR T-cell immunotherapy – 3 in SA
- Biosimilars

- Globally, > 65 countries are implementing GHS system or developing or revising legislation for implementation.
- 7 countries in Africa with 5 of these (Madagascar, Mauritius, South Africa, Zambia, the Seychelles) being SADC Member States.
- According to the UN however, Mauritius and South Africa are implementing their national systems based on the first edition of the GHS.
- Madagascar and Zambia are in the legislation development phase.

Foe: innovation & manufacturing

http://health-sciences.nwu.ac.za/pcddp

- **The innovation premium**
  - Patents
  - Process know-how
  - Trade secrets
  - Trade marks



www.pheroidcluster.com

Not for profit company

Regulation and entrepreneurship – foe?

Testing – strategic function harmonization

Preclinical drug development

- Pharmaco-kinetics
- Pharmaco-dynamics
- Toxicity
- Specialized studies e.g. xenografts
- Behavioural studies
- Micro-PET/CT studies

Formulation & dosage forms

- Pheroid drug delivery system development
- Combination Pheroid & nano-material systems
- Improved efficacy & safety of formulations
- Dosage form development

Diagnostic development

- Molecular diagnostic prototyping
- Cost effective diagnostics-infectious diseases
- Biomarker identification
- ID of cardiovascular lesions & cancer

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Clinical drug development

- Study design and ethics
- Phase 1 clinical trials
- Phase 2 clinical trials
- Drug tolerability
- Bioanalysis (LCMSMS)

London School of Hygiene and Tropical Medicine)
University of Edinburgh
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References

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Thank you / Asante sana
Go well / kwenda vizuri