Veterinary Medicines Directorate

BILL & MELINDA GATES foundation

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA)

Overview

SSA Project Objective

The overall objective of the project is to assure timely access to good quality veterinary medicines to small hold farmers in SSA by improving the regulatory framework through harmonisation

Why harmonisation?

- Allows sharing of expertise and resources
- Sets common standards & requirements
- Increases efficiency & makes a ‘larger market’
- Encourages cooperation – helps reduce cross-border transfer of illegal medicines
- Supports African Continental Free Trade Area, Africa - Agenda 2063 & UN SDGs

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA)

Scoping

Tools

Delivery

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA)

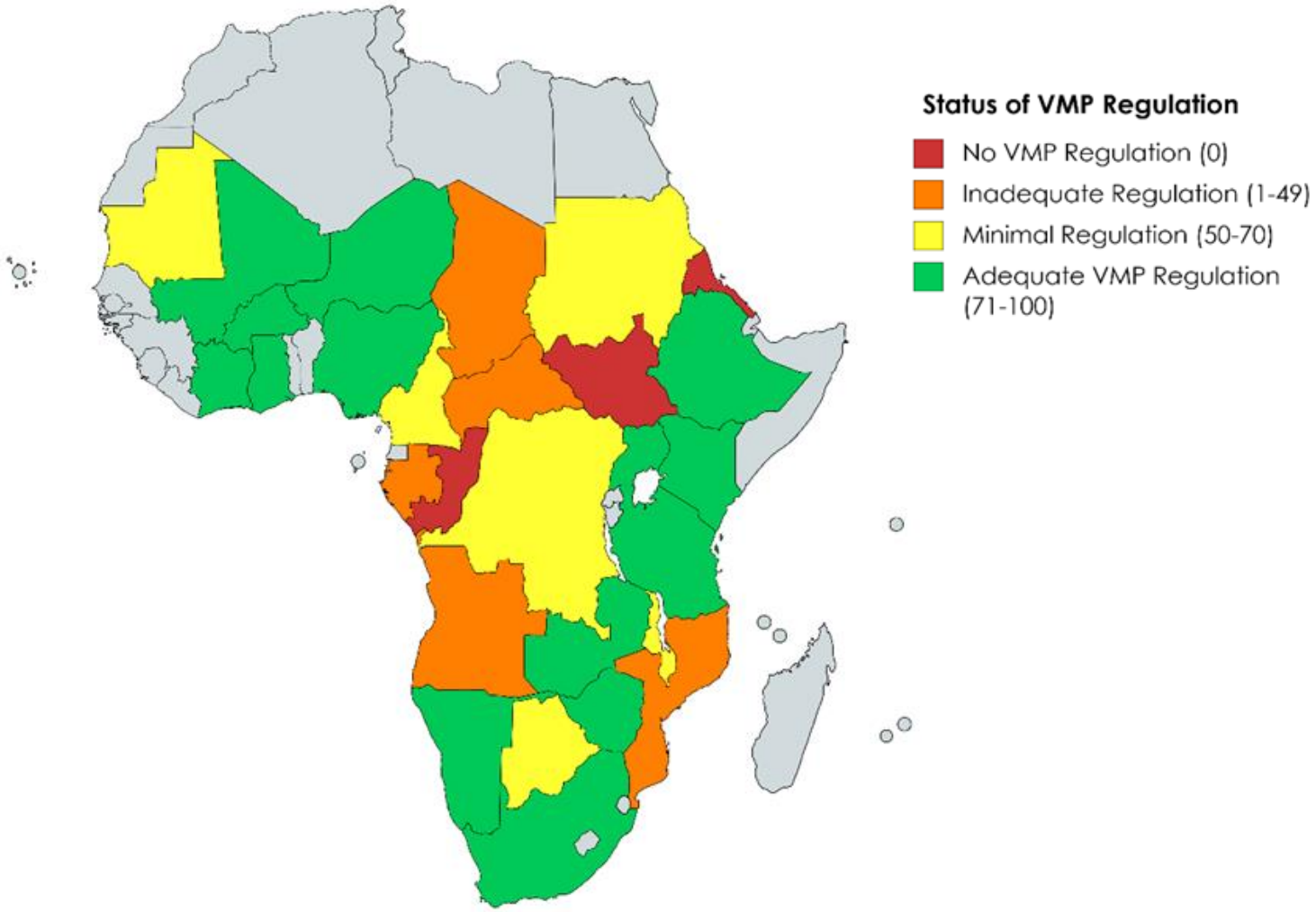
Scoping the VMP regulatory landscape in SSA

Lessons from harmonisation initiatives

Legislative, institutional, economic & political review

Roadmap for harmonisation

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA1)



Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA1) - Observations

- Varying level of regulation and regulatory capacity
- Priority given to livestock varied
- Greater awareness/realisation for good regulatory system & benefits of harmonisation
- Lack of human & financial resources
- IT and communication challenges

Critical enablers for harmonisation

QUALITY OF REGULATION

REGULATORY CAPACITY

RESOURCES (HUMAN & FINANCIAL)

WILLINGNESS TO COLLABORATE

COMMUNICATION

IT

PRIORITY GIVEN TO LIVESTOCK

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA) - tools

Common application form & data requirements

Self-assessment/Benchmarking tool

Inventory of initiatives in SSA

On-line submission portal

Global database of VMP regulators

E-learning on generics (bioequivalence)

Regional conferences

Engagement on the roadmap

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA) - tools

Common Application Form Proposal

APPLICATION FOR A NEW MARKETING AUTHORISATION FOR PHARMACEUTICAL AND BIOLOGICAL/IMMUNOLOGICAL PRODUCTS

A separate application form is required for each strength and/or pharmaceutical dosage form. Different pack sizes of the same product can be included on the same form.

SECTION 1 - PRODUCT NAME(s)

1.1. **Proposed trade name of product**

1.2. **International Non-Proprietary Name (Generic Name)**

SECTION 2 – APPLICATION DETAILS

2.1 **Product Type**
Please select either pharmaceutical OR Biological/Immunological

- ☐ Pharmaceutical
- ☐ Biological/Immunological - *A VMP sourced from a biological source or a vaccine.*

2.2 **Type of Drug Substance**
Please select only one

- ☐ Newly marketed Product with New Drug Substance
- ☐ Newly marketed Product with New Combination of Drugs Substances
- ☐ Newly marketed Product with Existing Drug Substance
- ☐ Re-evaluation of an Existing Product

SECTION 3 – PRODUCT DETAILS

3.1 **Formulation** *(provide the full formulation details)*

	Name of the substance	Concentration in the final product	Description of Function *(example, active substance, attenuated virus, adjuvant, excipient)*

Regional Regulatory Harmonisation for Livestock Products in Sub-Saharan Africa (SSA) - next

1

Detailed research

Get a clearer picture of the problem

- In-country contacts
- Benchmarking tool
- IT infrastructure

2

Develop bespoke change plan

Work together to develop a change plan

- Develop change plan
- Training plan
- IT user need assessment

3

Prepare for change

Ensure required tools and resources are available

- Assessment of readiness
- Finalise training material
- Comms

4

Implement change

Start the change

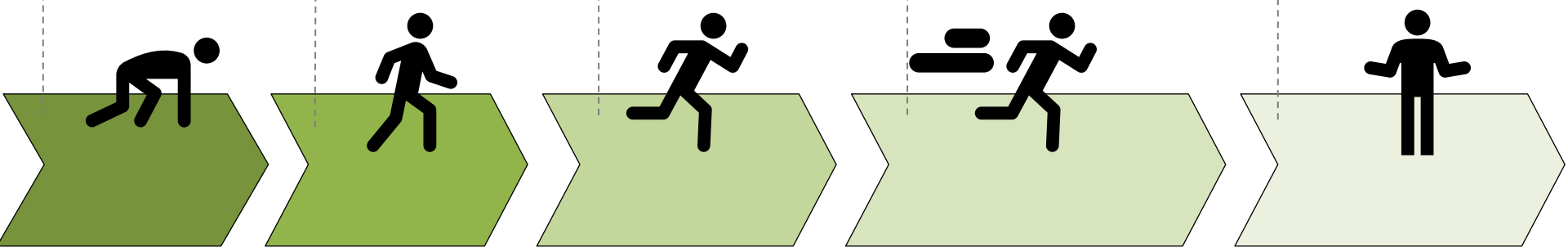
- Implement change
- Deliver training
- Agree on GLs & processes

5

Evaluate

Monitor achievement of objectives

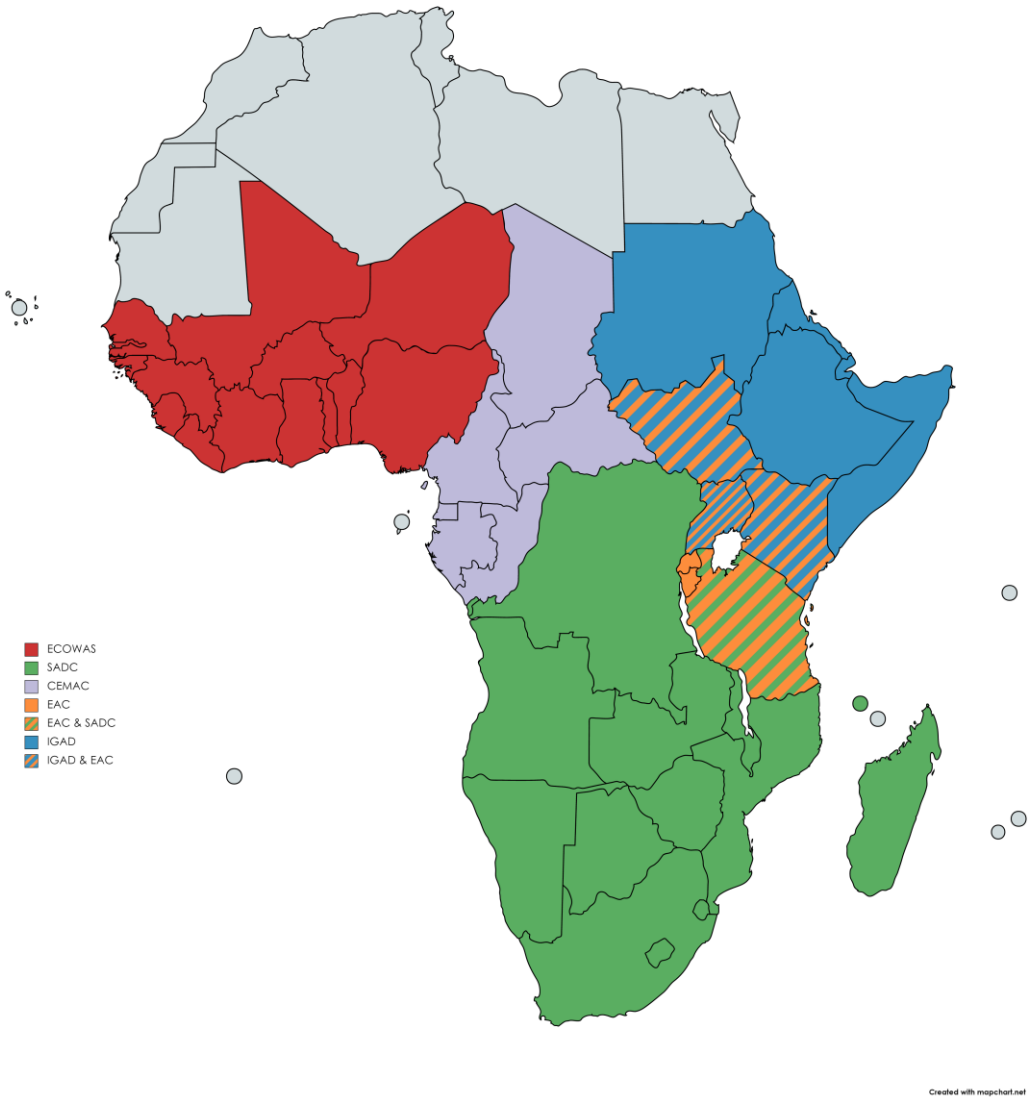
- Review & evaluate
- Learning/processes
- IT & Comms



Harmonisation options

- Mutual Recognition authorisation
  - Assessment done through cooperation of the NRAs
    - Lead/Reference evaluating country + peer reviewer(s) – lead assessment
    - Work sharing – parts of the dossier evaluated by different countries but then combined into one assessment report
  - Centres of excellence
  - Collective scientific decision made
  - Each country then makes national decision on authorisation
- Regional (centralised) authorisation
  - Collective regional decision
  - Each country contributes expertise
  - Assessment done by regional expert scientific committee
  - Decision making process agreed
  - Final decision applicable to all countries

Harmonisation outcomes



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Thank you!

Any questions?