



Veterinary
Medicines
Directorate

English Speaking Africa Training Seminar for National Veterinary Products Focal Points

**Regional effort on harmonisation of veterinary medicinal
products regulation in Africa**

Noel Joseph
Veterinary Medicines Directorate (UK)

05-07 Sep 2023
Malawi

BILL & MELINDA
GATES *foundation*



World Organisation
for Animal Health
Founded as OIE



High quality, safe and effective veterinary medicines are critical for livestock health and productivity

Lack of access to quality medicines **prevents farmers from preventing and treating** animal disease

Untreated animal disease **reduces livestock productivity** and increases risk of **zoonotic disease**

Poorly regulated medicines **increase the risk of unsafe food** contaminated with medicine residues

Substandard and falsified medicines act as a driver for **antimicrobial resistance**

Low productivity and risk of contaminated produces **impacts livelihoods**, preventing farmers from accessing premium markets



Effective regulation encourages industry, vets and farmers to invest in quality medicines

Immature regulation means the **route to bring medicines to market can be long and expensive**

Lack of a level playing field for medicine manufacturers means **return on investment can be low**

Ineffective regulation allows circulation of **low quality, ineffective medicines**

Inconsistent medicine quality **damages user confidence** and reduces likelihood of investment



Effective regulation encourages industry, vets and farmers to invest in quality medicines



Transparent, predictable authorisation procedures allow manufacturers to plan their market strategy to recoup investment

Harmonised regulatory processes reduce administrative burden/cost for manufacturers entering multiple markets

Collaborative authorisation routes allow manufacturers to access multiple markets through a single application route and allows NRAs to utilise the expertise present in the region

Level playing field for all manufacturers, adhering to common standards, **creates healthy competitive market and pressure to reduce prices**

Effective regulation leads to **confidence in medicine quality and greater choice of medicines at affordable prices**



What is harmonisation?

What do we mean by harmonisation?

- Common set of rules
- Common understanding & processes
- Enables Collaboration & sharing of work

Benefits of harmonisation

- Allows sharing of expertise and resources
- Sets common standards & requirements
- Increases efficiency & makes a 'larger market'
- Reduces cross-border transfer of illegal medicines & encourages cooperation
- Supports African Free Trade Area, Agenda 2063 & UN SDGs



Collaboration options

Mutual Recognition Procedure

Decentralised Procedure

- Assessment done through cooperation of the NRAs
- Collective scientific decision made
- Each country then makes final national decision

Centralised Procedure

- Collective regional decision
- Each country contributes expertise
- Assessment done by regional expert scientific committee
- Final decision applicable to all member countries

Reliance

- Recognising or taking account of the assessments, decisions or other authoritative information from other institutions.



Efficiency through working together – Conferences



Challenges



QUALITY OF REGULATION



REGULATORY CAPACITY



RESOURCES



COMMUNICATION



WILLINGNESS TO COLLABORATE











PRIORITY GIVEN TO LIVESTOCK



Efficiency through working together – REC Membership



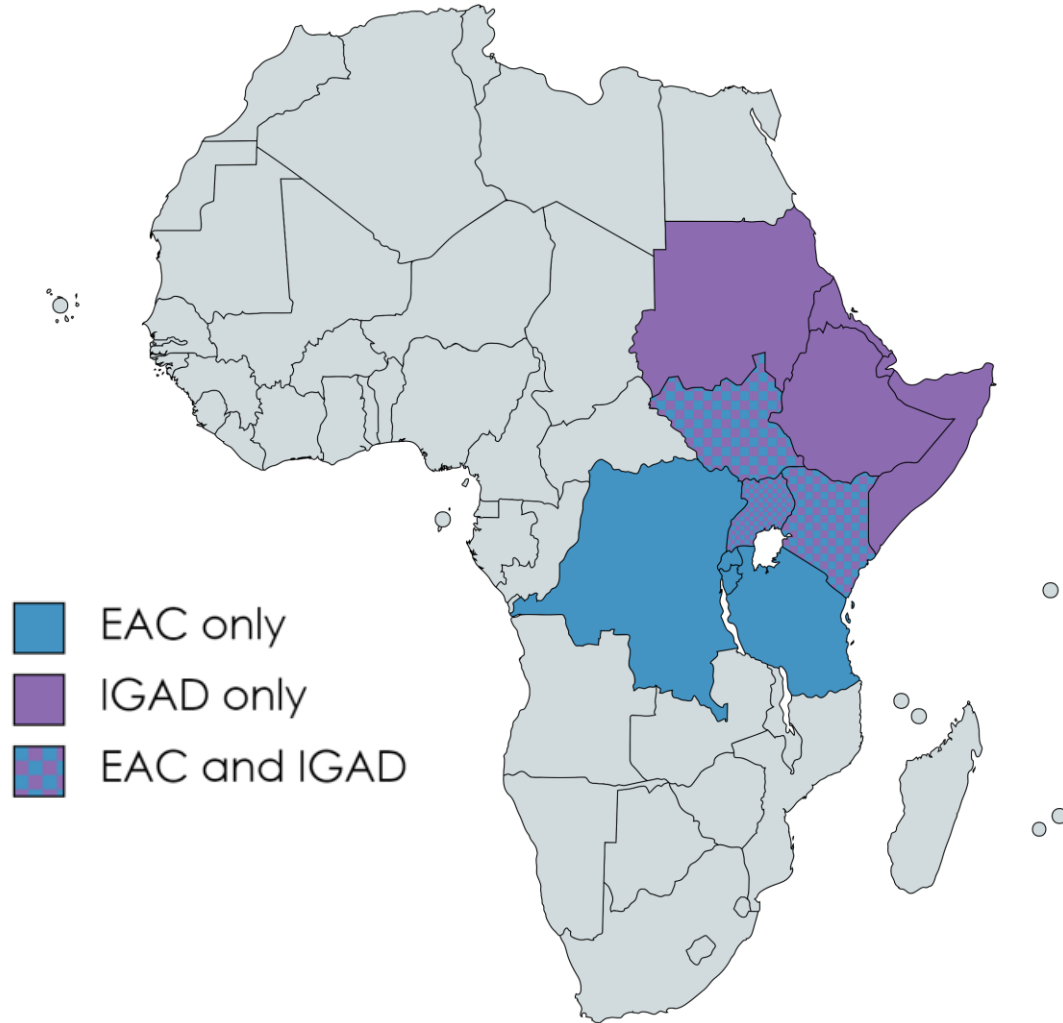
REC membership

-  ECOWAS members
-  ECCAS members
-  SADC members
-  ECCAS & SADC members
-  EAC & SADC members
-  ECCAS & EAC members
-  IGAD members
-  EAC & IGAD members



Created with mapchart.net ©

Efficiency through working together – East Africa



- EAC countries established Mutual Recognition Procedure
- Not all EAC members are active participants
- Process is now established for pharmaceuticals & vaccines
- Joint human/vet agencies in Tanzania, Uganda, Rwanda; Vet only agency in Kenya; no agencies yet in South Sudan, Burundi and DRC.
- IGAD countries do not have a regional approach
- Conference in East Africa agreed to explore feasibility of a joint EAC-IGAD approach
- Ethiopia (vet only agency), Sudan (joint human/vet); no agencies in Eritrea, Djibouti and Somalia.

Efficiency through working together – Southern Africa

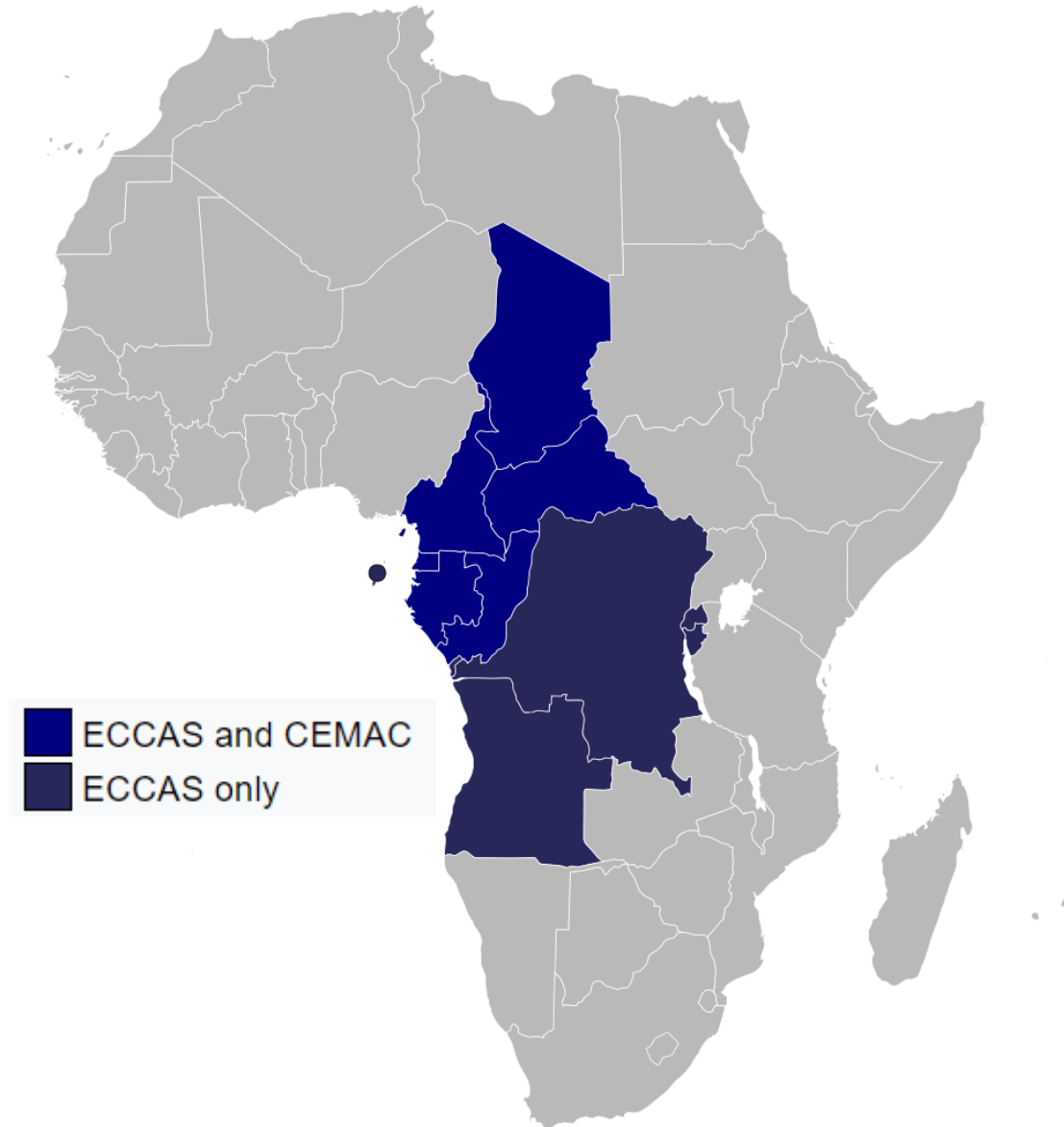
- Vet ZAZIBONA countries (Zambia, Zimbabwe, Botswana, Namibia, Malawi and South Africa (SAHPRA) agreed to pilot Mutual Recognition Procedure
- SADC Livestock Technical Committee agreed to the pilot,
- Agriculture Sectoral Ministers supported the ZAZIBONA initiative and the principle of harmonisation
- Pilot members have joint Human/Vet agencies
- Conference agreed to start with pilot and expand membership to other SADC countries in a stepwise approach



Created with mapchart.net ©



Efficiency through working together – Central Africa

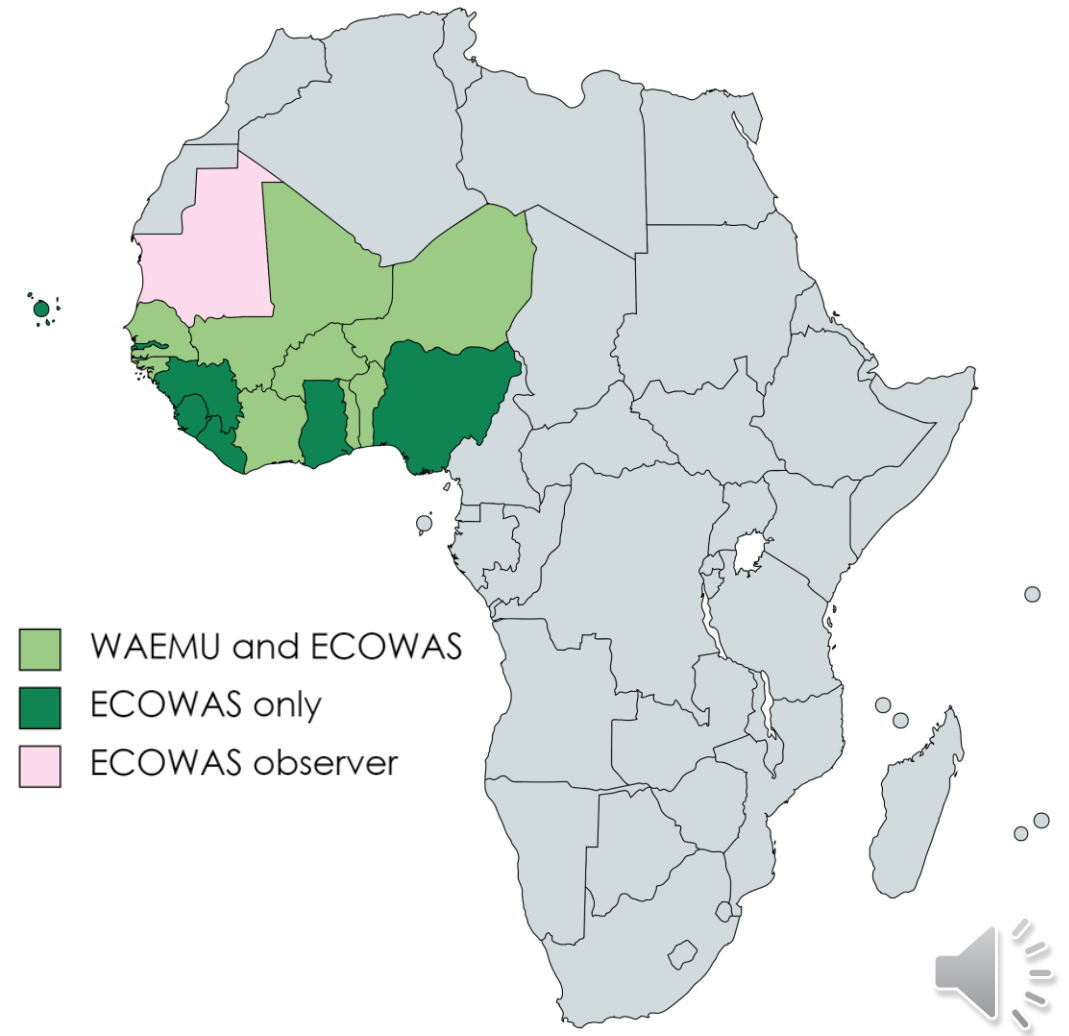


- CEMAC members approved Regulation for establishment of a regional centralised procedure
- CEBEVIRHA mandated to establish the process
- Conference identified additional enabling legislation that is required before process can begin
- Links established with WAEMU to share experience
- No regional process at ECCAS level established yet.

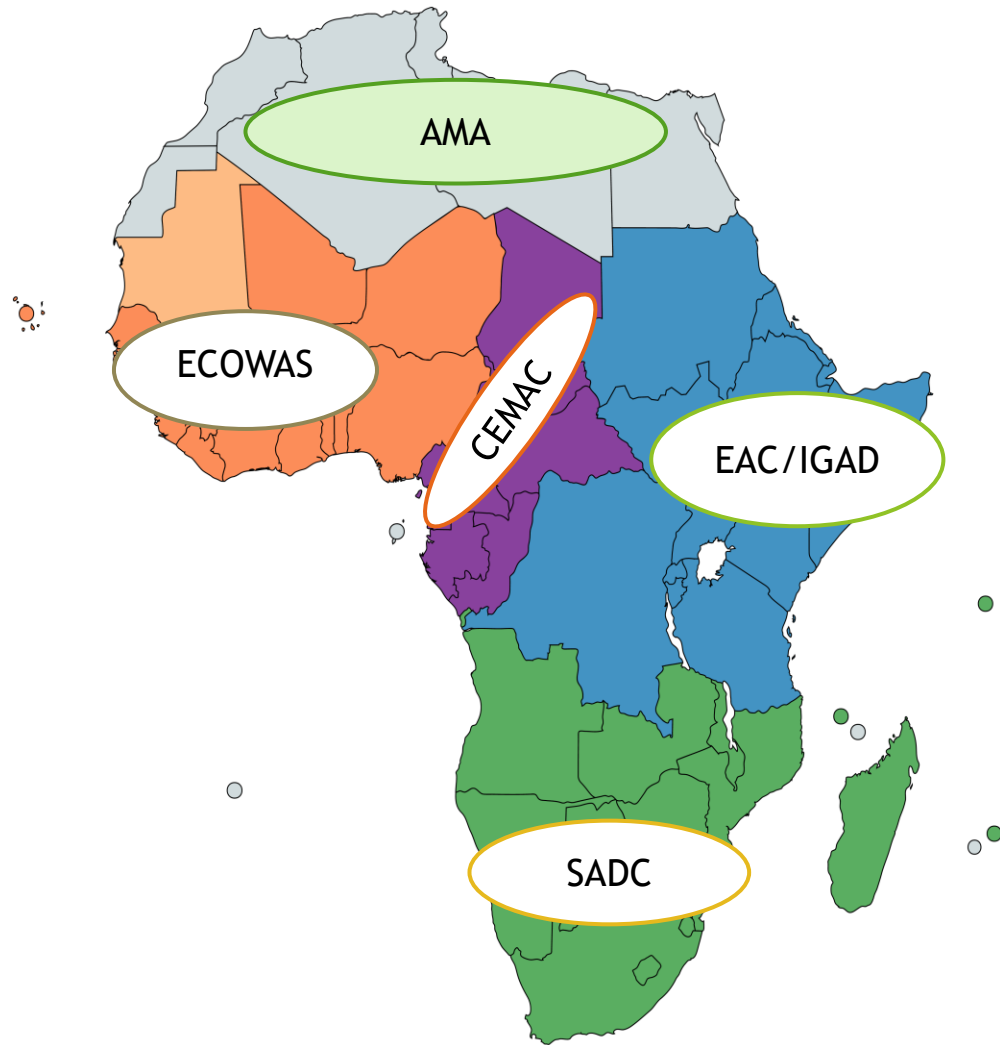


Efficiency through working together – West Africa

- WAEMU countries already established a centralised system of authorisation and is functioning well
- Ghana, Nigeria have well established joint Human/Vet agencies
- Liberia, Cape Verde have recently established joint human/vet agencies
- No established agencies in the rest
- ECOWAS agreed regional Regulation establishing a centralised authorisation process
- ECOWAS-RAHC mandated to drive the initiative forward and implement
- Conference agreed ECOWAS-RAHC to sensitise countries to the above-mentioned ECOWAS Regulations



Efficiency through working together



Thank You

