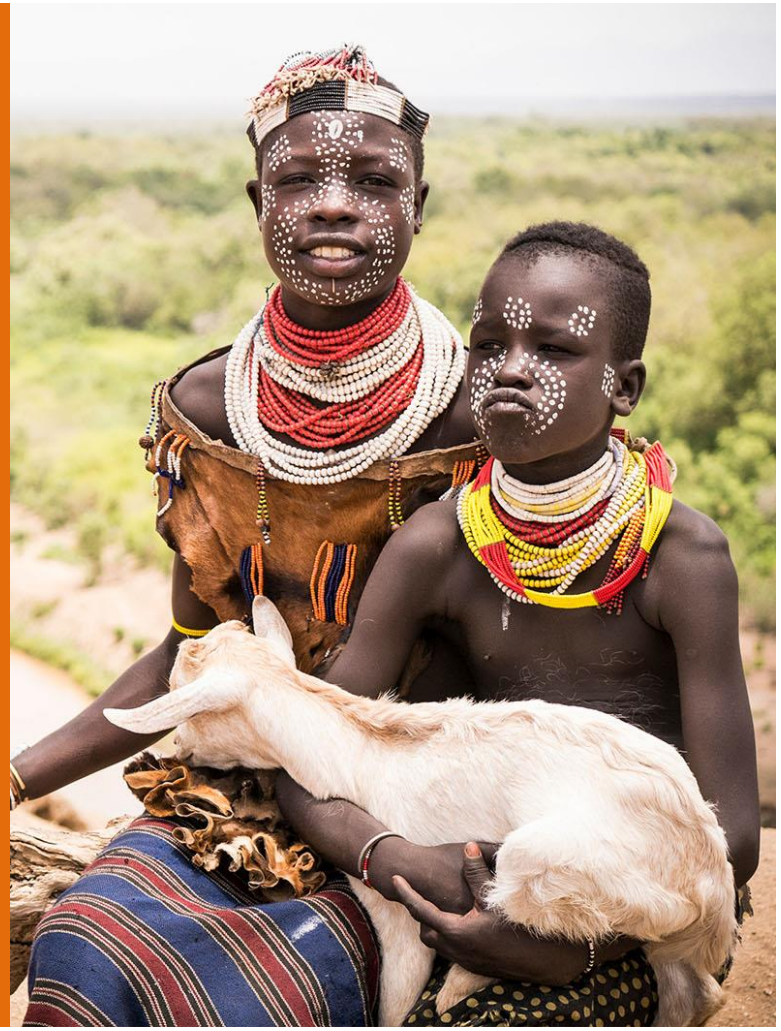
World Organisation for Animal Health

Workshop on Vaccination and Alternatives to Antimicrobials for English Speaking Africa

28 - 30 October 2025, Entebbe, Uganda


MAAIF Ministry of Agriculture Animal Industry and Fisheries · The Fleming Fund · IDRC · CRDI · Canada · Department of Health & Social Care · UKaid from the British people · GAMRIF Global AMR Innovation Fund

World Organisation for Animal Health



RELIANCE & MUTUAL RECOGNITION AGREEMENTS TO INCREASE ACCESS TO VETERINARY VACCINES IN AFRICA

GALVmed
Protecting Livestock - Improving Human Lives

galvmed.org

Workshop on Vaccination and Alternatives to Antimicrobials for English Speaking Africa
28 - 30 October 2025, Entebbe, Uganda

MAAIF Ministry of Agriculture Animal Industry and Fisheries · The Fleming Fund · IDRC · CRDI · Canada · Department of Health & Social Care · UKaid from the British people · GAMRIF Global AMR Innovation Fund

Outline

- Background: vaccine access and regulatory bottlenecks in Africa
- Definitions: reliance, recognition, MRAs and their variants
- Benefits and risks of reliance/MRAs for veterinary vaccines
- Global & regional precedents (brief)
- East Africa (EAC) context and readiness
- Recommended governance model and legal safeguards
- Capacity building, financing and monitoring

BACKGROUND: WHY THIS MATTERS

- **Limited access** to quality veterinary vaccines **affects animal health, livelihoods and public health.**
- Long, duplicative regulatory reviews **delay market entry** across countries.
- Fragmented regulatory capacity across African countries **increases costs** for manufacturers.
- Regional harmonization can reduce duplication and improve **affordability and availability.**

KEY CONCEPTS: RELIANCE VS MUTUAL RECOGNITION

- **Reliance**: one authority uses/evaluates another authority's regulatory decision as input to its own decision.
- **Mutual Recognition Agreement (MRA)**: two or more authorities agree to accept each other's regulatory outcomes.
- **Continuum**: from information sharing → abridged review → automatic recognition.
- **Quality & risk-based approaches** underpin successful reliance/MRAs.

POTENTIAL BENEFITS

- **Faster access** to vaccines across **multiple** countries.
- **Reduced regulatory burden** and resource savings for NRAs.
- Incentive for manufacturers to **register regionally.**
- Improved **consistency** of quality and safety decisions.
- Supports pooled procurement and **market predictability.**

RISKS AND NECESSARY SAFEGUARDS

- Risk of **varying standards or lowered oversight** if not harmonized.
- Need for **legal frameworks** to allow recognition/reliance.
- **Supply chain and lot release** alignment required.
- Robust **pharmacovigilance and post-marketing** surveillance are essential.
- Transparency and **data-sharing protocols** must be clear.

GLOBAL & REGIONAL PRECEDENTS

- VICH
- EU Mutual Recognition and Decentralised Procedures (human & veterinary)
- ASEAN reliance initiatives and work-sharing pilots
- PAHO/PAHO-CDC reliance arrangements for vaccines & medicines (human health)
- West African Economic and Monetary Union(WAEMU) regulatory procedure
- African Medicines Agency (AMA) — potential platform for broader reliance
- Existing EAC initiatives: shared guidelines, joint inspections
- ZaZiBona initiative(SADC)

EAST AFRICA (EAC) CONTEXT

- **EAC member states**: differing NRA capacities and legal frameworks.
- **Existing collaboration**: joint GMP inspections, harmonized templates (progress exists).
- **Gaps**: legal mandates for recognition, IT systems for dossier exchange, limited regional lab networks.
- **Political will and regional bodies** (EAC Secretariat) can support coordination.

PROPOSED GOVERNANCE MODEL (OVERVIEW)

- GALVmed **landscape study in 2025** found appetite for a pan African governance model.
- Central principles: **subsidiarity, transparency, risk-based reliance.**
- **Tiered model**: Information sharing → Abridged review → Full mutual recognition (pilot-based).
- AU supports such a **network of regulators with a coordinating secretariat** (AU IBAR+ AU PANCAC) + MRAs + supported by GALVmed.
- **Technical Working Groups**: quality, safety, inspections, lab testing, PV.

LEGAL AND REGULATORY FOUNDATIONS

- Review and amend **national laws** to permit reliance/MRA decisions.
- Draft model **MRA text and Memoranda of Understanding** (MoUs).
- **Define scope**: vaccine types, dossiers, GMP, batch release and lab testing arrangements.
- **Data** protection, confidentiality, and IP considerations.
- **Dispute** resolution and withdrawal/recall procedures.

CAPACITY BUILDING & FINANCING

- Train reviewers on **reliance-based assessment and abridged dossiers.**
- Harmonize **dossier templates** (CTD-like) and electronic **submission channels.**
- Invest in regional **reference labs and shared lot-release testing capacity**.
- **Funding models**: donor grants, EAC pooled funding, cost-recovery from industry.
- **Engage GALVmed and development partners** for technical assistance.

World Organisation for Animal Health

If you want to know more about us, please visit:
www.galvmed.org

GALVmed

@GALVmed

GALVmed

GALVmed
Protecting Livestock - Improving Human Lives

Workshop on Vaccination and Alternatives to Antimicrobials for English Speaking Africa
28 - 30 October 2025, Entebbe, Uganda

MAAIF Ministry of Agriculture Animal Industry and Fisheries · The Fleming Fund · IDRC · CRDI Canada · Department of Health & Social Care · UKaid from the British people · GAMRIF Global AMR Innovation Fund