AgResults FMD Vaccine Challenge Project: Current Status and Contribution to a Regional Approach to FMD Control in Eastern Africa

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21st June 2022
11th Regional Steering Committee meeting of the GF-TADs for Africa

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AgResults FMD Vaccine Challenge Project Overview

AgResults Foot and Mouth Disease (FMD) Vaccine Challenge Project

An eight-year, US$17.68 million prize competition that supports the development and uptake of high-quality FMD vaccines tailored to meet the needs of Eastern Africa in six target countries: Burundi, Ethiopia, Kenya, Rwanda, Tanzania, and Uganda.

The project aims to achieve three objectives:

1. Development and registration of high-quality FMD vaccines, tailored for the needs of Eastern Africa
2. Increased vaccine production and regional purchases to create greater market stability and reduce price
3. Development of a private sector model for buying and distributing FMD vaccines to complement public sector efforts

To achieve these objectives, the following mechanism will be used:

✓ A **Cost-Share** whereby the project will fund a portion of the sales price of the vaccines purchased by government and private sector buyers, for a target volume of vaccines.

The AgResults solution includes:

High-Quality Vaccine(s) +  **Improved Distribution**

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Fostering Development of Regionally Relevant and High Quality FMD Vaccines

To be eligible for the AgResults competition, the vaccine must meet the following conditions.

✓	**Vaccine Development to Target Product Profile (TPP) Standards, which includes:** • Quadrivalent Vaccine at least 6PD50 containing serotypes A, O, SAT1, and SAT2 that match circulating Eastern African FMDV strains, demonstrated through serological testing against WRLFMD's Eastern African FMDV Reference Antigen Panel
✓	**Vaccine Registration: must achieve full registration in at least 2 target countries** • Registration can be achieved either through the Mutual Recognition Procedure (MRP) or through individual country registrations (Ethiopia must be individual).
✓	**Vaccine Approval:** The AgResults Judging Panel will approve vaccines that meet the TPP and are registered in at least two target countries for competition entry.

In 2022, at least one manufacturer is expected to submit their FMD vaccine dossier(s) for registration.

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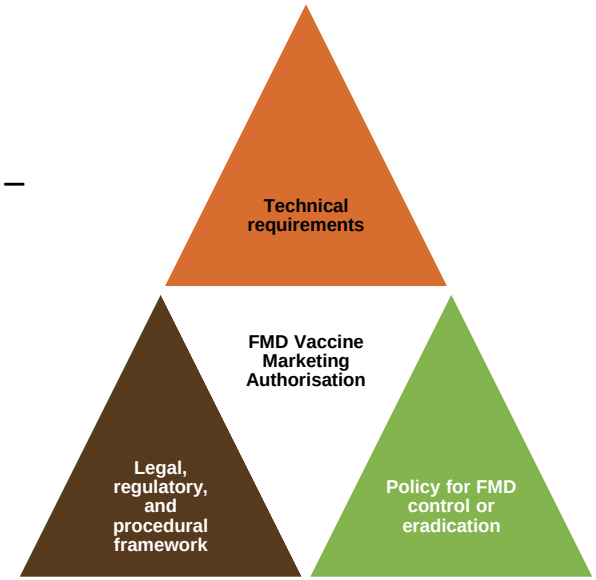
Support for Harmonising Authorisation of FMD Vaccines in Eastern Africa

Towards Harmonisation of FMD Vaccine Authorisation in Eastern Africa

Since 2020, the AgResults FMD Vaccine Challenge Project team has held a series of workshops and meetings that involved senior assessors and the heads of national regulatory agencies to promote a harmonised authorisation process for FMD vaccines in Eastern Africa – a process which requires alignment of technical requirements, legal/regulatory frameworks and FMD control policies.

One of the challenges of moving to a regional approach to FMD vaccination is the move from a ***reactive*** use of generic vaccines following national outbreaks to a ***proactive*** choice of vaccine strains based on epidemiological intelligence from national, regional, and international epidemiological networks.



In the case of Eastern Africa, two factors create a unique opportunity to promote this change:

1. The development by the World Reference Laboratory for FMD (WRLFMD) at the Pirbright Institute of the ***Eastern Africa Foot and Mouth Disease Virus Reference Antigen Panel*** (EA FMDV Reference Antigen Panel). This panel was developed in collaboration with the OIE/FAO FMD Reference Laboratory Network, including AU-PANVAC, to create a better chance of vaccine success.
2. The aim of the AgResults FMD Vaccine Challenge Project to promote availability of epidemiologically relevant FMD vaccines in Eastern Africa and the requirement for vaccines to pass eligibility criteria that include application of the EA FMDV Reference Antigen Panel for entry into the competition.

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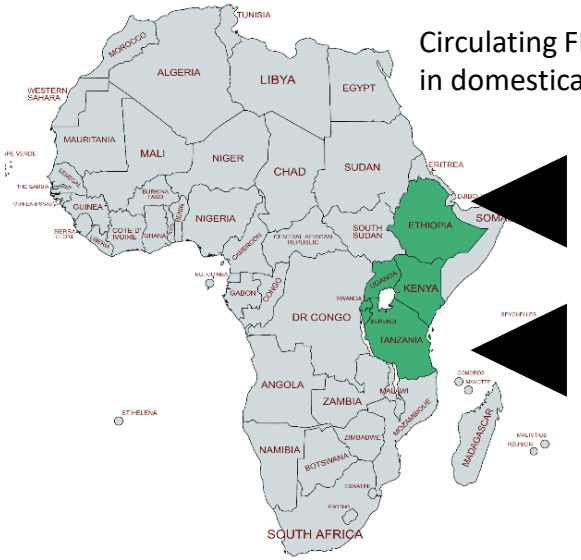
Vaccine Valency: Demonstrating Regional Relevance

- As part of a **World Reference Laboratory for Foot and Mouth Disease (WRLFMD) Pirbright/AU-PANVAC/OIE twinning initiative** to establish an improved system to evaluate the efficacy of FMD vaccines in Africa, a panel of regional FMDV strains has been assembled to enable testing of each vaccine for relevance to the Eastern African region. https://www.wrlfmd.org/node/2096/
- The strains in the **EA FMDV Reference Antigen Panel** were selected to encompass the greatest extent of genetic diversity within the FMDV lineages that circulate in Eastern African countries: Burundi, Democratic Republic of Congo, Eritrea, Ethiopia, Kenya, Rwanda, Somalia, South Sudan, Tanzania, and Uganda.
- The Panel comprises 16 FMDV strains clustered into 4 serotype sets: 4x O, A, SATs 1&2.



Circulating FMDV lineages in domesticated species:

O/EA-3
O/EA-4
A/AFRICA/G-IV
SAT 2 / VII

O/EA-2
A/AFRICA/G-I
SAT 1 / I
SAT 2 / IV

- Use of the panel will help demonstrate relevance of FMD vaccines for the region.
- A threshold titre will provide a pass or fail for the vaccine's suitability for the AgResults FMD Vaccine competition. This is the first time such a unique method for assessing vaccine regional relevance for field use has been applied.

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Outcomes of Efforts to Promote Harmonised Authorisation

- An annotated version of the East African Community Mutual Recognition Procedure (EAC MRP) 'Guideline on the technical documentation required to be included in a registration dossier for an immunological veterinary product' has been published with specific reference to FMD vaccines.
  - Provides the basis for harmonisation of authorisations in line with at least the minimum international standards for FMD vaccines defined in the OIE Manual.
  - Relevant for both national and EAC Mutual Recognition procedures

- ***EAC Technical Working Group agreed that***:
  - FMD vaccines may be approved as conventional multi-valent authorisations or by using the multi-strain dossier approach, in which a range of strains are included on a single authorisation to allow different combinations of strains in final product, subject to regulatory controls and limits.
  - Close cooperation between the national regulatory authorities (NRA) and CVO/DVS is important as both are involved in the authorisation and use of FMD vaccines.
  - Full marketing authorisation with post-authorisation monitoring is preferred to import permits or other approvals for use, particularly when moving from national to regional control of FMD.
  - The EA FMDV Reference Antigen Panel provides a valuable tool to assist the selection of vaccine strains.

- ***Next step***: The UK Veterinary Medicines Directorate (VMD), one of the most experienced agencies in authorising FMD vaccines in cooperation with other agencies, will provide ongoing expert support to Eastern African NRA through targeted assistance on issues that the NRA assessors themselves identify as most challenging during FMD dossier assessment.

Public-Private Partnership Framework to Strengthen the FMD Vaccine Value Chain

Development of PPP Framework to Address Challenges in the FMD Vaccine Value Chain

PPP Framework Objective and Value

To create awareness about the benefits that PPPs could bring to the Foot and Mouth Disease Vaccine Value Chain (FMD VVC) in Eastern Africa - from production, purchasing, distribution, delivery, and vaccinations to post-vaccination monitoring - that would complement current public sector efforts, resulting in improved vaccine accessibility for farmers and greater market stability.

Scope of the PPP Framework

It customizes aspects of the OIE PPP Handbook into a practical framework that can be further developed into appropriate commitments between partners.

It addresses the challenges of the FMD VVC and is relevant to the unique FMD control situation in each of the Project's target countries. It can also be applied more broadly to other livestock VVCs and other geographies.

Stakeholder Engagement

To inform the development of this framework, the project team conducted outreach to more than 140 key stakeholders (47% public sector, 53% private sector) in Eastern Africa and beyond.

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PPP Framework: Recommendations & Resources

Recommendations on the PPP Framework:

1. 4th Eastern Africa FMD Roadmap meeting: Sharing experiences and best practices in **public-private partnerships** in disease control, thereby increasing private sector investment in FMD control and prevention.

2. 11th EA-RAHN Meeting: Advocate for **PPP Framework** in the region to promote its use in manufacturing, purchasing, and distribution of vaccines and vaccination campaigns.

GALVmed website resources:

1. Review the full PPP Framework: *https://www.galvmed.org/wp-content/uploads/2021/09/PPP-Framework-FINAL-310821.pdf*

2. Sign up to receive updates about important project milestones: *www.galvmed.org/foot-and-mouth-project*

Thank You!

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