

OIE Focal Points on Veterinary Products

Johannesburg, South Africa, 23-26th November 2010



*“Sharing Knowledge”
“Safeguarding Livestock”
“Improving Livelihoods”*

*Blue-prints/ Road Maps
Realities*

*Veterinary medicinal products and vaccines: indispensable tools for any effective animal health policy
(editorial www.oie.int published in March 2008)*

Blue-prints/ Road Maps

- **Standards on diagnostic assays and production of high quality veterinary vaccines, published in the OIE *Terrestrial Manual* and *Aquatic Manual***
- **National or Regional Registration of veterinary medicinal products**
- **The role of private veterinarians and veterinary para-professionals in the provision of animal health services**

EAST COAST FEVER control

East Coast fever (ECF) is a tick-borne disease (TBD) affecting cattle, caused by the protozoan parasite *Theileria parva*, and transmitted by the brown ear tick, *Rhipicephalus appendiculatus*

ECF mortality can reach 100% in improved breeds and 60% or higher in Zebu or Sanga animals.

EAC -/ SADC / Sudan / (Ethiopia at risk)

In Tanzania (18.7 million cattle), the estimated number of calves born in ECF risk areas is around **1 million calves annually**

EAST COAST FEVER VACCINE

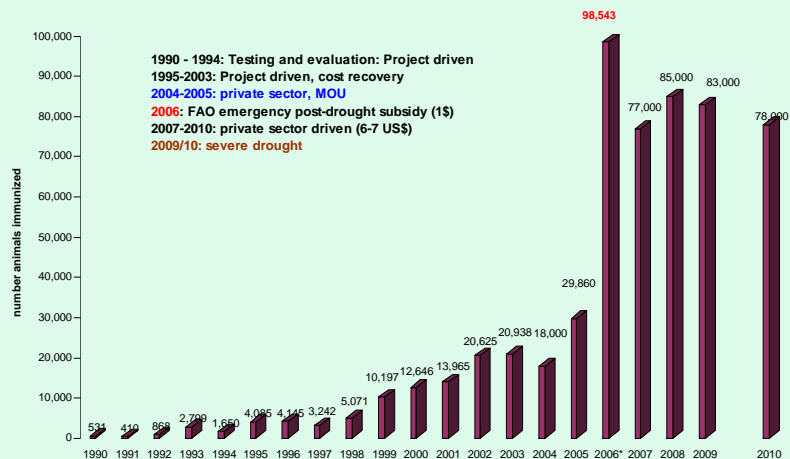
The current immunisation against ECF is based on Infection and Treatment Method (ITM) and comprises the inoculation of live *Theileria parva* sporozoites and simultaneous administration of oxytetracyclines LA

The Muguga cocktail (MC) is an effective and widely used stabilate derived from 3 seed stabilates, the Muguga, Serengeti-transformed and Kiambu 5 stocks.

In Tanzania the MC offers > 98% protection; major impact on food security and pastoral livelihoods

- Tanzania adopted the ITM for Small-Holder Dairy and large scale immunization campaigns in the indigenous herds in 1998
- Meanwhile re-structuring of livestock departments across the region took place and
- The Tanzania Animal Health Strategy (1998) classified TBD as a private good
- since 2004, ITM is delivered on a commercial basis
- Almost 100,000 animals are vaccinated every year against ECF with 98% of all vaccinations carried out in the pastoral sector.
 - target group; new-born calves

ECF – ITM ADOPTION IN TZ



1998: finalised testing of 30% OTC
2006: post drought emergency TCP-FAO
2009: severe drought; 80% mortality in northern pastoral areas

... the production of high quality veterinary vaccines ...

Currently ILRI, Nairobi, is the only Institute with

- capacity for commercial-scale production of bulk *T.parva* stabilates**
- in-house capacity and diagnostic expertise for quality assurance procedures and quality control checks on the stabilates**
- in-house capacity to determine that each newly produced batch is antigenically consistent with the seed stabilates**

VETAGRO TANZANIA LTD

based in Arusha, Northern Tanzania

ECF vaccine Distributor

- **MOU – 2003-2005**
- **National distributor 2006 onwards**

ECF vaccine Delivery

- **Investment Plan 2006 onwards**
- **Vet clinic –mobile units**

**Private Sector players: co-responsibility for
Registration, Quality control**

Registration of ECF vaccine in Tanzania (1)

2003: ECF vaccine registration dossier submitted to the regulatory authorities. Registration failed because vaccine-ownership was not clear - ILRI, FAO, AU-CTTBD, ..?

Permission for each vaccine importation & use was requested from and granted by both the DVS office and Pharmacyboard

2008/9: Preparation of the *Muguga Cocktail* registration dossier and Technology transfer document by GALVmed and the International livestock Research Institute (ILRI)

•Registration of ECF vaccine in Tanzania (2)

March-09

Final *Muguga Cocktail* registration dossier and technology transfer documents submitted to Tanzania Food and Drugs authority (TFDA)

ILRI recognised as the Manufacturer

Vetagro TZ Ltd mandated by ILRI as applicant

AU-PANVAC endorsing GMP report of ILRI facilities

Sept-09: additional queries raised by TFDA addressed

Jan-2010: Tanzania Registration of MC approved

TZ-Registration approved bcs of Departmental and political support as the in-house capacity to test and evaluate the live ECF vaccine does not exist, but most of the field evaluation trials of the current vaccine batches were carried out in Tanzania.



....Need of good veterinary governance

- backed up by necessary resources for its enforcement
- supported by the Veterinary Services

Tick-borne Disease control in Tanzania has been classified as a private good

The role of private veterinarians and veterinary para-professionals in the delivery of ECF vaccine..



Distribution / Delivery partners in Tanzania

- **Government VO & LFO**
- **Private Vets & private LFO**
- **AH Diploma holders**
- **CAHW- mobilisation effort**
- **CBO/ NGO**

**Tanzania Veterinary Council responsible for the licensing/
registration of veterinarians and para-professionals.**

Registered: 617 VO, 631 Diploma Holders, 467 Certificate holders

**A veterinary statutory body should play a vital role in maintaining
public and international confidence in Veterinary Services.**

ECF vaccine Distribution / Delivery

- **Distribution = logistics**

 - Quality cold-chain (LN and -20 C)

 - Organization (economics of scale in pastoral areas)

 - Transport (private and public), shipment by bus, plane, etc

- **Delivery = Access,**

 - Community organisers , trained delivery agents (DA)

Trust and Professionalism has become the key to successful ECF vaccine delivery

ECF vaccine Distribution / Delivery

Constraints in delivery:

- Presentation of Vaccine package; 40 doses / straw
- Cold-chain – liquid nitrogen/ refrigeration facilities for the diluent
- Organization of end-users and delivery agents
- Delivery agents purchase power (vaccine)
- End-user (pastoralist) seasonal availability of capital

ECF vaccine distribution/delivery

Constraints in distribution

FINANCIAL RISK

- High(est) unit cost for a vet product 160 - 260 US\$/ straw
- SHD; collect 1-5 straws
- Indigenous calves: collect 20-65 straws (>8,000 US\$)

High Defaulting rate

Poor legal support system to recover debts

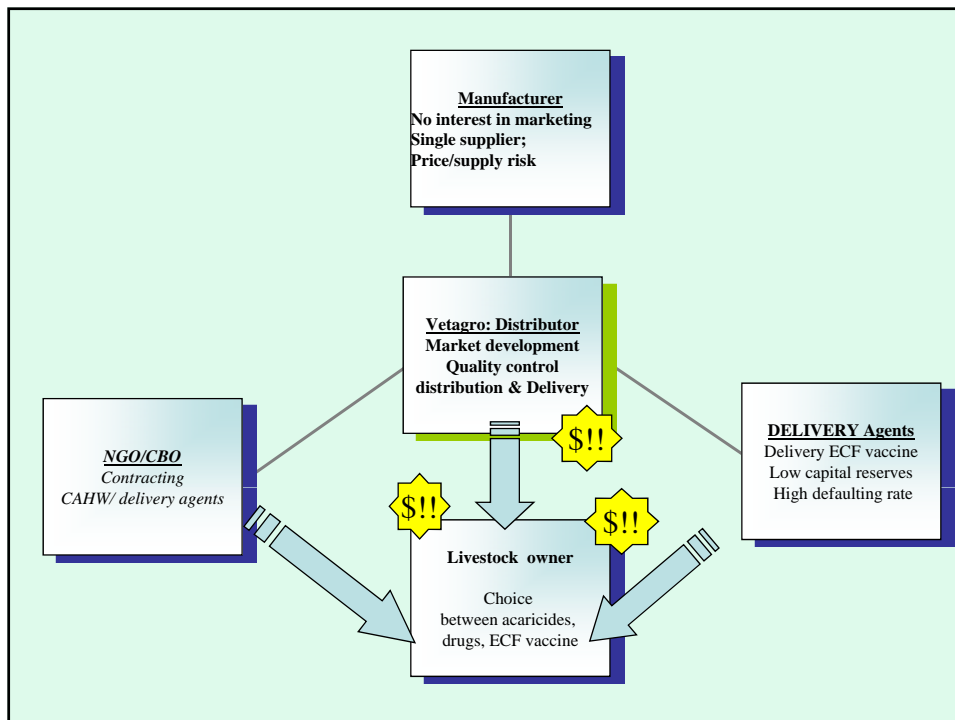
High financial risk hampers expansion of distribution network

Distributor/ Delivery Agent; Financial risks x

- Vaccine transportation risks; no insurance system
- Fragility of straws (but paid up-front)
- Interruption cold chain (but vaccine paid up-front)
 - *Will the delivery vet discard or use the straws ????*
- Seasonal activity
- Disruption because of other disease outbreaks (RVF/PPR)
- Disruption of vaccination activities bcs drought
- Customer- trust disrupted because of unscrupulous delivery agents
- Donor interventions by-passing the distributor

Ethical issues or business first?

- Efficacy of vaccine
- **Efficacy of distribution network**
- Efficacy vaccinator
- Efficiency of vaccine delivery
 - Timely, demand driven



Quality assurance

- **Break-through; NONE**
in Tanzania the **Muguga cocktail offers >98% protection**
- **Breakdown; YES**
 - Vaccine failure (efficacy)
 - Vaccine failure 1999 (Dead vaccine),
 - Diluent failure 2000 (transport logistics)
 - Vaccine delivery failure (efficiency)
 - breakdown of vaccination protocol- coldchain
 - failure to adhere to immunisation protocol by individual veterinary professionals (-un-professional delivery)

Quality control/Laboratory support

Serological testing:

OIE Terrestrial Animal Health Code-2010; prescribed test

IFA test , Schizont Ag slides, piro(merozoites)Ag slides
(Malawi, Zambia) Schizont Ag slides produced at ITM, Antwerp

IFAT Reasonable easy to perform and reasonable specific, however, questions about Sensitivity and Cross-reactivity- (human factor)

In ECF endemic regions, the seroprevalence in cattle population fluctuates considerably depending on the level and regularity of challenge. In an epidemiological study with *T. parva* the overall diagnostic sensitivity of the IFA test was evaluated as 55% at a cut off titre 1/40 and only **28% at cut off 1/160** (Zambia -2006).

Quality control/Laboratory support

- **Serology test: ELISA test; based on parasite specific T.parva Ag (developed at ILRI, used by Kenya,Tanzania, Uganda);**

Higher specificity and sensitivity but since the product has been handed over to commercial sector, **no longer available in the field** (samples send to ILRI)

- **Reverse Line Blot assay** based on hybridization of PCR products for simultaneous detection of several Theileria species...
(Utrecht University/ University of Pretoria), **not available for routine field use**

in most cases, actions in favour of animal health depend on the availability and appropriate use of good quality veterinary products.

Available -Quality Product..... but....

- **Legislation hampers registration of a product already in use for decades and in demand**
- **Veterinary Statutory bodies in place unable to enforce code of conduct**
- **Statutory authority reluctant to discipline un-ethical conduct of colleagues**
- **Need for livestock producers lobby groups/associations to protect end-user interests and assist in quality control of veterinary service delivery (political pressure groups)**

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Available -Quality Product..... but....

- **Need to increase laboratory capacity necessary to assist in quality control of ITM**
- **Need for regional harmonised approach in diagnostic essays used for *T.parva* research and surveillance**
 - *T.parva* ELISA to be included in the OIE list (role of Galvmed?)
- **Need for stronger public/ private partnership to increase accessibility of the product to the end-user**

Acknowledgements

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Thank you

Merci