



# GALVmed workshop: Future of harmonisation for vaccine registration



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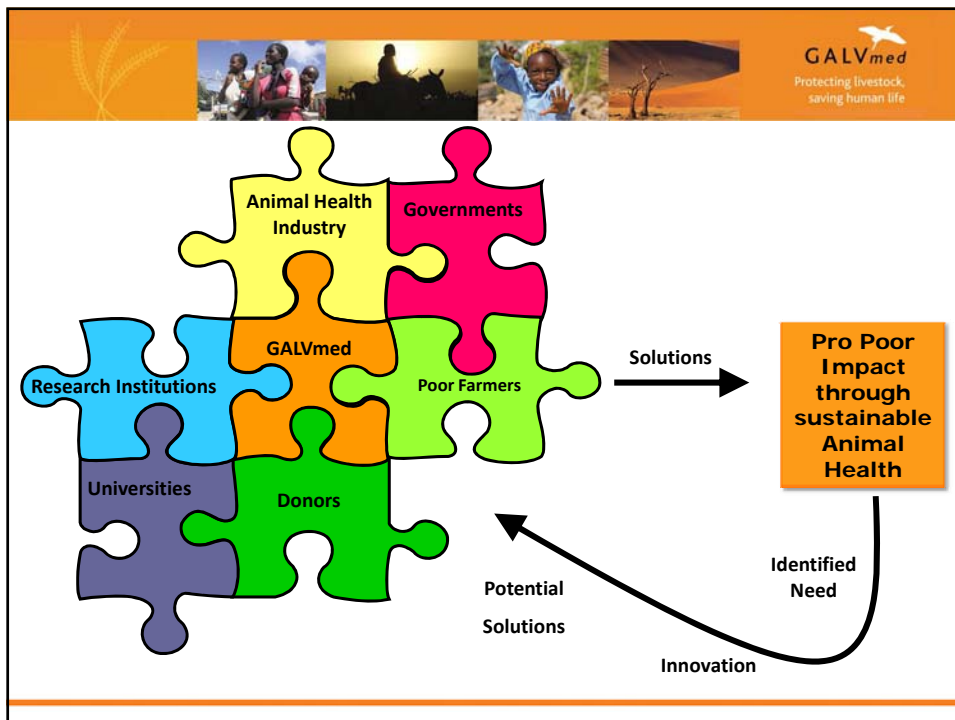
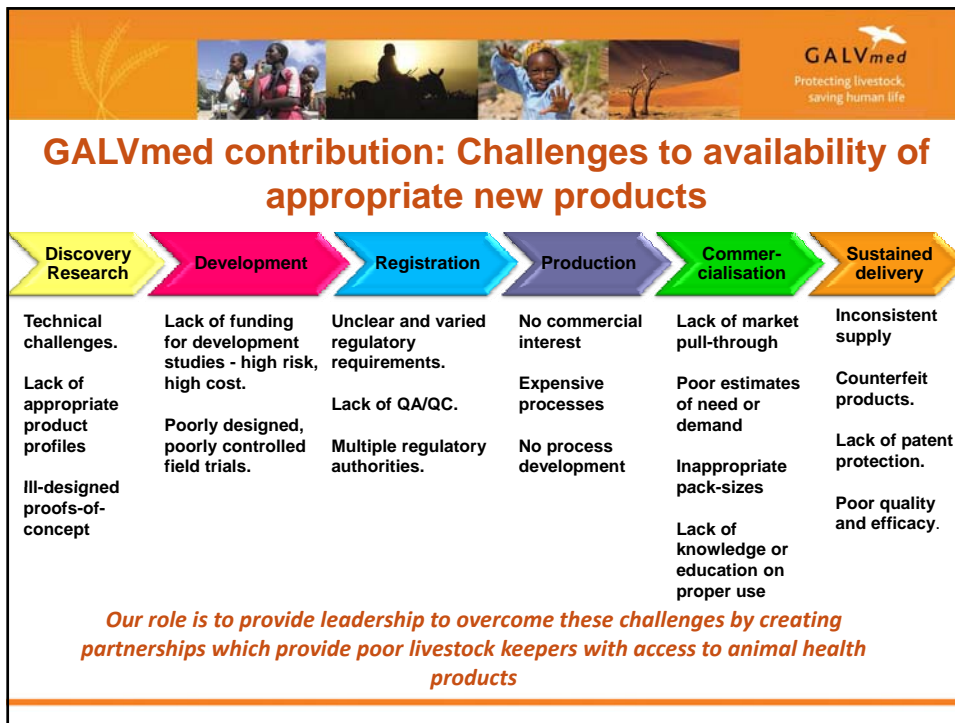
24<sup>th</sup> November 2010



## GALVmed - GLOBAL ALLIANCE LIVESTOCK VETERINARY MEDICINES

- A not-for-profit **Public-Private Partnership** – registered charity
- Sponsored by the UK Department for International Development (**DFID**), and with projects funded by BMGF, DFID and EC.
- **Pro-poor focus:** working with key partners to make a **sustainable** difference in access to animal health products for poor livestock keepers







## GALVmed – the missing piece in the jigsaw

**GALVmed Activities**

- Prioritising** high impact **diseases** of greatest impact on poor livestock keepers
- Understanding** the key **barriers** to developing new products that will reduce disease impact in developing countries
- Identifying assets** and filling key expertise gaps
- Planning and managing** AH development projects

**GALVmed Skills**

- High level technical skills
- Competence in AH product development and registration
- Project and Portfolio Management
- Knowledge of Development Agenda
- Fundraising knowledge
- Brokering Partnerships




**GALVmed Partners**

- Investors and Donors
- Local Governments
- Regulatory Authorities
- Pharmaceutical Companies
- Civil Society Organisations
- Universities and Research Organisations


**GALVmed's Attributes**

- Focus** on bringing appropriate new products to poor people
- Rigour** (milestones, standards)
- Transparency** in processes and decision making
- Integrity** (including respect for IP and commercial confidence)
- Leadership** in partnerships and process



## Current Projects

<b>BMGF/DFID Project</b>	<b>EC/AU-IBAR Project</b>	<b>Pro-poor Technology Platforms</b>
<ol style="list-style-type: none"> <li>1- Regulatory Process</li> <li>2- Rift Valley Fever</li> <li>3- East Coast Fever</li> <li>4- Porcine cysticercosis</li> <li>5- Newcastle disease</li> <li>6- Intellectual Property</li> </ol>	Process focused on capacity building for at least 6 African labs, related to vaccines for: -CBPP -CCPP -PPR -ND	Related to the other projects -Thermostability -Single dose -Needless application
<ol style="list-style-type: none"> <li>7- Contagious bovine pleuropneumonia</li> <li>8- Contagious caprine pleuropneumonia</li> <li>9- Peste des petits ruminants</li> </ol>		



## GALVmed Priority diseases

- Cattle
  - East Coast Fever
  - Contagious Bovine Pleuropneumonia
  - Hemorrhagic septicaemia
  - Trypanosomosis
- Sheep and goats
  - Peste des petits ruminants
  - Contagious caprine pleuropneumonia
  - Sheep & goat pox
- Pigs
  - Porcine cysticercosis
  - African swine fever
  - Classical swine fever
- Poultry
  - Newcastle disease
  - Highly pathogenic Avian Influenza
- Multi-species
  - Rift Valley fever

Active  
In preparation

## GALVmed products portfolio/pipeline

Project	Exploratory	Proof of Concept	Development	Registration	Commercialisation
ECF	Muguga vaccine		Dossier completed	3 countries	In progress
ND	Thermostable I-2 Vaccine			Generating data	Early stages
ND	Thermostable D-58 freeze-dried vaccine			Partially done	
ND	Thermostable D-58 pelletised		Reformulation studies		
PC	TSOL 18 vaccine	Experimental vaccine	Planned		
PC	Medication		In progress		
RVF	Recombinant multivalent RVF-LSD	In progress			
RVF	Combination RVF-LSD			Registration trials	
RVF	Monovalent RVF C13				Vaccine bank
RVF	Penside Diagnostic assay				



**Expanding... R&D activities in 2010**



**Enabling Activities in:**



- 14 African countries (East & West, Central & Southern Africa)
- India



**Partnering in Africa:**


- 1) PANVAC:
  - I-2 Workshop in Maputo
  - OIE Workshop in Johannesburg
  - Working in setting up a vaccine process development lab
- 2) CTTBD:
  - Transfer of ECF Muguga cocktail production
- 3) VACNADA project laboratories:
  - Ethiopia, Kenya, Ghana, Botswana, Cameroon, Senegal, Mali, DRC
- 4) Research institutions:
  - SUA, KARI, Univ of Pretoria, OVI
- 5) Commercial partners:
  - OBP, VetAgro, GSJ, Deltamune.



## Additional contributions:

- 1) Capacity building:
  - Vaccine technology (Pfizer fellowship)
  - Vaccine operation management (CEVA CoG training)
  - Research institutions: GCP, GLP studies
- 2) Market studies
- 3) IP Management and FTO for pro-poor access
- 4) Increased South – South cooperation:
  - PC: Latin America, Africa and India






## Regulatory issues: what are we trying to achieve:

<b>Simplify, improve, coordinate vaccine regulatory issues in Africa</b>	
<b>1</b>	Baseline current situation
<b>2</b>	Proposal for a way forward with involvement of local stakeholders

- Strong relation established with key Global players on product regulation: VICH, OIE, IFAH
- A questionnaire to best define the current status of vaccine regulation in Africa has been sent on behalf of PANVAC and GALVmed to 49 countries.
- GALVmed sponsorship of the OIE Focal Group Training in South Africa – Workshop on future of harmonisation for vaccine registration
- Future activities will depend on outcome of this workshop.



## Objectives Workshop:

- 1) Support the establishment of forums of Regulatory authorities (in conjunction with PANVAC & OIE):
  - Initiate regional forums (already existing in some regions)
  - Create a continental forum
- 2) Analysis of the Questionnaire:
  - Identify key gaps
- 3) Work toward harmonization:
  - Explore possibilities of mutual recognition at sub-regional level, then continental level
  - Develop a 5 year strategy and plan




## Vaccine harmonisation Questionnaire

- Number of countries that a Questionnaires was sent: 49
- Number of Questionnaires received back: 35 (71.4%)

**THANK YOU VERY MUCH FOR YOUR COOPERATION!**

**MERCI BEAUCOUP POUR VOTRE COOPERATION!**





Thank you!

