GALVmed workshop:
Future of harmonisation for vaccine registration

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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 contribution: Challenges to availability of appropriate new products

Technical challenges.
Lack of funding for development studies - high risk, high cost.
Poorly designed, poorly controlled field trials.
Unclear and varied regulatory requirements.
Lack of QA/QC.
Multiple regulatory authorities.
No commercial interest
Expensive processes
No process development
Lack of market pull-through
Poor estimates of need or demand
Inappropriate pack-sizes
Lack of knowledge or education on proper use
Poor quality and efficacy.

Our role is to provide leadership to overcome these challenges by creating partnerships which provide poor livestock keepers with access to animal health products.
GALVmed – the missing piece in the jigsaw

GALVmed Activities
1. Prioritising high impact diseases of greatest impact on poor livestock keepers
2. Understanding the key barriers to developing new products that will reduce disease impact in developing countries
3. Identifying assets and filling key expertise gaps
4. Planning and managing AH development projects

GALVmed Skills
1. High level technical skills
2. Competence in AH product development and registration
3. Project and Portfolio Management
4. Knowledge of Development Agenda
5. Fundraising knowledge
6. Brokering Partnerships

GALVmed Partners
1. Investors and Donors
2. Local Governments
3. Regulatory Authorities
4. Pharmaceutical Companies
5. Civil Society Organisations
6. Universities and Research Organisations

GALVmed’s Attributes
1. Focus on bringing appropriate new products to poor people
2. Rigour (milestones, standards)
3. Transparency in processes and decision making
4. Integrity (including respect for IP and commercial confidence)
5. Leadership in partnerships and process

Current Projects

BMGF/DFID Project
1- Regulatory Process
2- Rift Valley Fever
3- East Coast Fever
4- Porcine cysticercosis
5- Newcastle disease
6- Intellectual Property
7- Contagious bovine pleuropneumonia
8- Contagious caprine pleuropneumonia
9- Peste des petits ruminants

EC/AU-IBAR Project
Process focused on capacity building for at least 6 African labs, related to vaccines for:
- CBPP
- CCPP
- PPR
- ND

Pro-poor Technology Platforms
Related to the other projects
- Thermostability
- Single dose
- Needleless application
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

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GALVmed products portfolio/pipeline

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

<table>
<thead>
<tr>
<th></th>
<th>Simplify, improve, coordinate vaccine regulatory issues in Africa</th>
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<tbody>
<tr>
<td>1</td>
<td>Baseline current situation</td>
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<tr>
<td>2</td>
<td>Proposal for a way forward with involvement of local stakeholders</td>
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- 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%)

Thanks you very much for your cooperation!

MERCI BEAUCOUP POUR VOTRE COOPERATION!
Thank you!

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Senior Director: R&D
Staff workshop
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