GALVmed

Protecting Livestock – Improving Human Lives

GALVmed / OIE Stakeholder Workshop on harmonisation of Registration Requirements for Veterinary Medicinal Products

Johannesburg, 9-11 May 2017

Gillian Cowan

GALVmed

Protecting Livestock – Improving Human Lives

1. GALVmed's activities regarding the Registration of Veterinary Vaccines

Johannesburg, 9 May 2017

Gillian Cowan, Regulatory Affairs Consultant

GALVmed initiative in harmonising Registration Requirements for Veterinary Vaccines

Introduction:

- Initial requests to GALVmed by African countries
- Achieving harmonised registration requirements
- Documentation developed
- Training – regional and local
- Implementation of harmonisation by Partner States

Regulatory experience

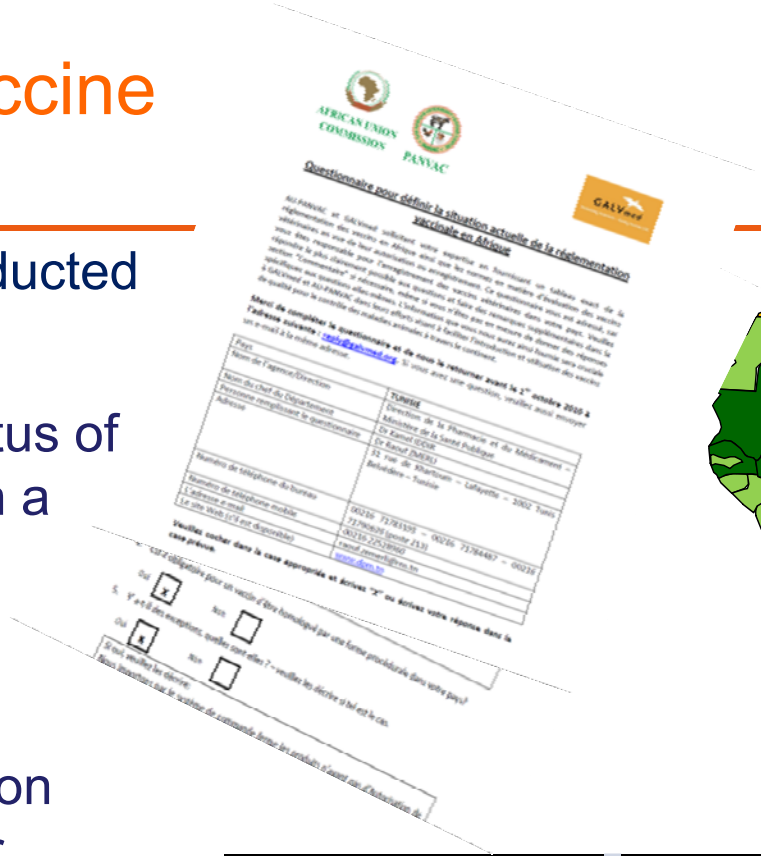
- Worked in Regulatory Affairs for several multinational pharmaceutical companies
  - Hoechst :1976 – 1996 in UK; 1996 – 2000 in Germany
  - Intervet : 2000 in Boxmeer, Netherlands
  - Aquaculture Vaccine Ltd (AVL) : Aug 2000 – Aug 2002
  - Schering Plough : 2002
  - Pfizer Animal Health; Director of Regulatory Affairs, Biologicals: Aug 2002 – retired April 2010

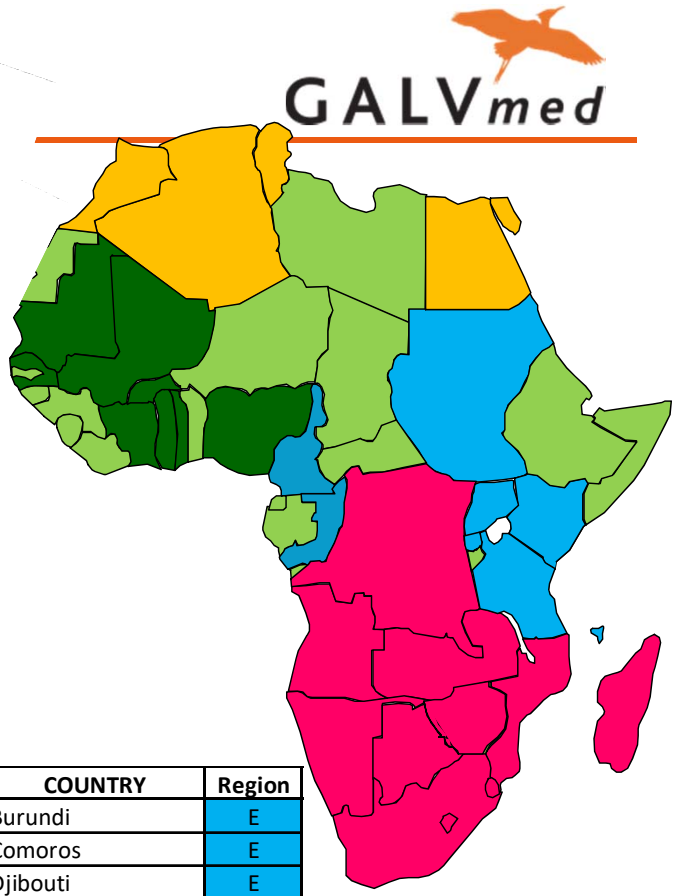
- Member of industry associations -NOAH & IFAH
- Currently a consultant, mainly for GALVmed

Baseline status of vaccine registration in Africa

Two main activities were conducted in 2010:

- Information on current status of vaccine regulation through a questionnaire sent to 49 countries.
- GALVmed-OIE-PANVAC Workshop in South Africa on future of harmonisation for vaccine registration.





	COUNTRY	Region
1	Algeria	N
2	Egypt	N
3	Morocco	N
4	Tunisia	N
5	Cameroon	C
6	Congo - Brazzavile	C
7	Burkina Faso	W
8	Cote D'Ivoire	W
9	Ghana	W
10	Mali	W
11	Mauritania	W
12	Nigeria	W
13	Senegal	W
14	Togo	W

	COUNTRY	Region
15	Burundi	E
16	Comoros	E
17	Djibouti	E
18	Kenya	E
19	Rwanda	E
20	Seychelles	E
21	Sudan	E
22	Tanzania	E
23	Uganda	E
24	Angola	S
25	Botswana	S
26	Dem Rep Congo	S
27	Lesotho	S
28	Madagascar	S
29	Malawi	S
30	Mozambique	S
31	Namibia	S
32	South Africa	S
33	Swaziland	S
34	Zambia	S
35	Zimbabwe	S

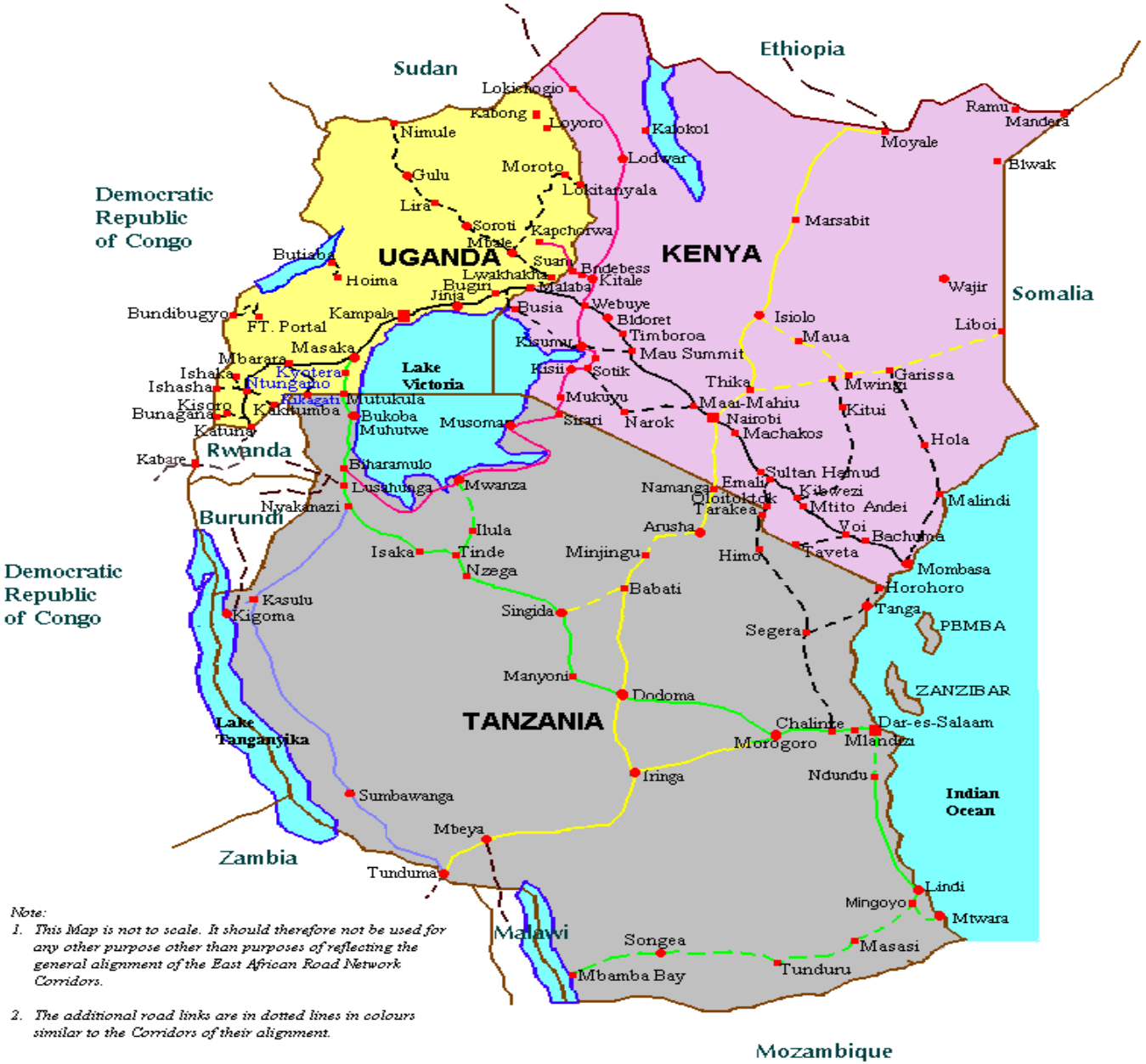
North: 4
Central: 2
West: 8
East: 9
Southern: 12

Outcome of OIE/GALVmed Conference in Johannesburg, 2010

African countries asked GALVmed to provide:

1. A harmonised registration system
2. Training for their regulators in registration of veterinary vaccines
3. A system of Mutual Recognition.

East Africa



Note:

1. *This Map is not to scale. It should therefore not be used for any other purpose other than purposes of reflecting the general alignment of the East African Road Network Corridors.*
2. *The additional road links are in dotted lines in colours similar to the Corridors of their alignment.*

Achieving harmonised registration requirements: Workshop in Nairobi, East Africa

- Capacity building of regulatory authorities in charge of vaccine registration in Africa
  - First training for East Africa, in Nairobi, November 2011. 8 countries: Djibouti, Burundi, Rwanda, Kenya, Ethiopia, Tanzania, Sudan and Uganda.
  - Activity conducted with AU-PANVAC, with contribution of OIE
  - Gilly Cowan engaged to follow up activities as lead consultant.

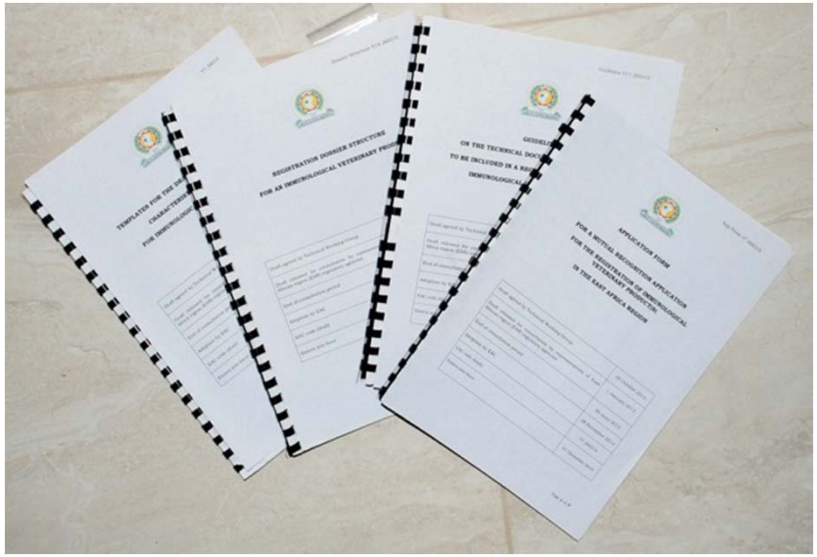
East Africa (Nairobi – Nov 2011)

2nd TWG meeting, Dar es Salaam, October 2012

Achieving harmonised registration requirements

Technical Working Group's harmonised documents:

1. Dossier structure
2. Technical Guideline
3. Templates for labelling and Summary of Product Characteristics (SPC)
4. Harmonised Application Form for use in National or MRP applications



TWG's Dossier Structure, 2012

Part 1 Administrative	**Part 2** Quality	**Part 3** Safety	**Part 4** Efficacy
1.A Application form	**2.A:** Composition	**3.A.1 – A2:** **Safety**, Single Dose, Overdose, Repeated Dose	**4.A** Lab Efficacy
1.B.1 SPC	**2.B:** Method of Manufacture	**3.A.3:** Other Safety Studies, e.g. Reversion to Virulence.	**4.B:** Field Efficacy
1.B.2 Label and carton text	**2.C:** Control of SMs	**3.B:** Field Safety	
1.B.3 Package Leaflet	**2.D:** In-Process Controls	**3.C:** Safety to user and environment; residues, interactions.	**Part 5** Bibliographical references
	2.E: Controls on Finished Product		
	2.F: Batch consistency		
	2.G: Stability		
	2.H: Others		

Achieving harmonised registration requirements

To achieve harmonisation requires political will.

Meeting in Arusha, June 2013:
Heads of Regulatory Authorities
DVSs, GALVmed, AU-PANVAC,
EAC Secretariat.

Recommendation made to initiate MRP.
Signed by representatives from all 5 EAC Ministries of Agriculture and Livestock.

Objectives – 2013 onwards

GALVmed

Sequence:

1. To establish a harmonised registration system for veterinary vaccines in which all participating countries agree to the same dossier structure, dossier requirements and dossier assessment standards.

2. A co-ordinating committee should be formed, consisting of members of the regulatory authorities from each Member Country, with the remit to introduce and maintain a Mutual Recognition system.

(from EAC meeting in Arusha, 24/25 June 2013)

Legal basis for MRP

- The East African Community Treaty of 2000.

Chapter 21, Article 108(e) of Plant and Animal Diseases Control, contains provisions for adopting a common mechanism for ensuring quality, safety and efficacy of agricultural inputs including chemicals, drugs and vaccines.

PROGRESS TOWARDS IMPLEMENTING MRP

- Details of MRP concept presented to EAC Sectoral Council of Agriculture and Food Security in July 2014.
- On 5th Sept 2014, in Kigali, Sectoral Council adopted:
  - Concept of MRP
  - Terms of Reference for Technical Working Group (TWG)
  - Terms of Reference for Coordination Group for Mutual Recognition (CGMR)
- On 28th Nov. 2014, EAC Council of Ministers adopted these recommendations resulting in Decision Number:

EAC/CM 30/Decision 34

- On 17th March 2015, TWG and CGMR constituted by EAC

PROGRESS TOWARDS IMPLEMENTING MRP

- On 5th September 2016, Council of Ministers directed Partner States to implement the Mutual Recognition Procedure (MRP) for Immunological Veterinary Products (IVPs).

  (**EAC/CM34/Decision 35**)

- The EAC Treaty of 2000 is a legally-binding document among the EAC Partner States with the mandate to foster integration and cooperation in the EAC region.

Regulatory Meetings and Training

Participants	Location	Event	Dates
1. East Africa	Nairobi	Workshop	Nov 2011
2. UEMOA	Burkina Faso	Workshop	Dec 2011
3. ECCAS	Libreville	Workshop	Oct 2012
4. EAC, NRAs, DVSs	Arusha	Meeting	June 2013
5. EA Region	Nairobi	Workshop	June 2013
6. GMP inspectors	Kampala	GMP Workshop	Sept 2013
7. ECOWAS	Abuja	Workshop	Dec 2013
8. GMP inspectors	Debre Zeit	GMP Training	July 2014
9. Manufacturers	Lilongwe, Nairobi	Dossier training	2013-2014
10. EA Region	Nairobi	Assessor training	May 2015

Other Regulatory Meetings & Workshops

Participants	Location	Event	Dates
11.TWG	KEVEVAPI, Kenya	Manufacturer visit	June 2013
12.TWG & inspectors	NVI, Ethiopia	Manufacturer visit, GMP training	July 2014
13.TWG & inspectors	Addis Ababa, Ethiopia	Visit to PANVAC	July 2014
14.TWG	Arusha, TZ	MRP Workshop	March 2015
15.TWG	Arusha,	Variations WS	March 2015
16.TWG	Nairobi, KY	MRP Workshop	March 2016
17.GMP inspectors	MCI, Morocco	Joint inspection	Dec 2016
18.Assessors	Nairobi	Joint Assessment	Feb 2017
TWG	Various	10 x Meetings	2012 - 2017
TWG/CGMR DWP	Nairobi	Documentation	Feb and June 2016

Progress towards Implementing MRP

Training for MRP

GALVmed has funded training in

- Joint - dossier assessment
- Joint - GMP inspections

Applicants have offered to have their applications and manufacturing facilities used for training purposes for MRP.

GALVmed has offered to fund joint assessments and joint inspections for the first 3 MRP applications to allow regulators to gain confidence in each others work and to train observers.

- Fees will be paid for assessment and inspection.
- These applicants anticipate receiving MAs if successful.

Summary of Progress with 2010 requests

Requested by African countries	Result
1. Harmonised registration system for veterinary vaccines	Developed, Available, Published
2. Training regulators in registering veterinary vaccines	Carried out
3. A Mutual Recognition system	Available

TWG Members, 10th TWG, Nairobi Feb 2017

Thank you for your attention