

Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal



Training workshop for OIE National Focal points for Veterinary products.

20 - 22 March 2012.

Mombasa. Kenya.

OIE Sub-regional Representation for Eastern and the Horn of Africa.

April 2012

WORLD ORGANISATION FOR ANIMAL HEALTH



Training workshop for OIE National Focal Points for Veterinary Products.

20 - 22 March 2012.

Mombasa, Kenya.

Report of the workshop.

April 2012

Regional seminar co-funded by the OIE, the European Union (European Commission) in the framework of DG SANCO BTSF - Africa "Better training for safer food" and the Food and Drug Administration of the United States of America (FDA).

World Organisation for Animal Health OIE

12, rue de Prony
75017 P A R I S
FRANCE

www.oie.int

oie@oie.int

Regional Representation of the OIE for Africa

Parc de Sotuba
P.O. BOX 2954
BAMA KO
MALI

www.rr-africa.oie.int

rr.africa@oie.int

Sub-regional Representation of the OIE for Eastern
and the Horn of Africa

P.O. BOX 19687 00202
NAIROBI
KENYA

www.rr-africa.oie.int

CONTENTS LIST

Official opening of the training workshop.

Summary of the presentations

Appendix 1: Agenda of the seminar.

Appendix 2: List of participants.

Appendix 3 : Workshop 2: Establishment of antimicrobial resistance monitoring and quantities of antimicrobials used in animals

Appendix 4 : Workshop 2: Establishment of antimicrobial resistance monitoring and quantities of antimicrobials used in animals

Appendix 5 : Assessment of the seminar.

Official opening of the training workshop.



Address by the Dr Yacouba Samake, the OIE Regional Representative for Africa during the opening of the OIE Sub Regional Conference for Veterinary Products on 20th March 2012

Honourable Minister,
Dear brother Walter,
The representative of the European Union in Nairobi,
Invited Speakers,
Dear Participants,
Ladies and Gentlemen,

On behalf of the OIE, I would like to join my brother Walter Masiga, the OIE Sub Regional Representative for Eastern and the Horn of Africa, to welcome you to Mombasa, Kenya. I believe you had an enjoyable journey to Mombasa.

I would also like through you, Honourable Minister, on behalf of the OIE Director General and all African Members of the OIE, to very sincerely thank the Government and the people of Kenya for agreeing to host this important Seminar, and to you in particular, Honourable Minister, for availing your time to grace this occasion.

I would also like to thank everybody here present for sparing time despite your busy schedule to come to this seminar which, in my view, is one of the milestones in OIE activities in Africa.

May I also thank the organizers of this seminar for a job well done.

I would also like, on behalf of the OIE Director General, to thank, very sincerely, the European Union and the FDA of USA for funding this advanced regional seminar. I wish, in addition, to emphasize that the European Union finances many activities in Africa in the reinforcement of the capacities of the Veterinary Services.

May I, at this juncture, on behalf of the OIE, thank the European Union specifically for sponsoring the BTSF program. This programme has funded many seminars for Delegates and Focal Points to assist them better comply with the international standards of the OIE.

Ladies and Gentlemen,

Allow me to make a short historical background on the OIE contribution to a better management of the problems of the veterinary products in our continent.

After the seminar on the registration of the veterinary products, held in Bamako in December 1992, OIE organized the seminar in Dakar in December 1999, the recommendations of which are

as follows :

- The establishment of an Regional office in charge of authorization of marketing veterinary products,
- The establishment of quality control national laboratories network,
- The adoption of legislative texts and regulations, emphasizing clearly dissociation between the functions of wholesale and retailing.

The 14th Conference of the OIE Regional Commission for Africa in Arusha, Tanzania, in January 2001, also made a recommendation on antibiotic resistance, while the 17th Conference of the OIE Regional Commission for Africa, in Asmara, Eritrea, in March 2007, made the recommendation relating to the harmonization of the registration and the quality control of the veterinary products in Africa.

Within the framework of the OIE contribution to a better management of the problems of the veterinary products, I would like to underline the OIE International Conference on the veterinary products in Africa “harmonization and improvement of the registration, the distribution and the quality control” in Dakar in March 2008, which was attended by 160 participants from 50 countries.

Ladies and Gentlemen,

The Veterinary Services are a World Public Good. Good governance of Veterinary Services denotes the establishment and the strengthening of capacities of all the stakeholders involved, in particular, in the responsible use of veterinary products.

The present seminar is at an advanced level and it is the continuation of the OIE efforts, within the framework of the implementation of BTSF program, for capacity reinforcement for OIE National Focal Point, in order to be able to play their roles fully. It is about an advanced training, which complements a basic training that was organized in South Africa, in December 2010.

Finally, may I wish you a pleasant stay in Mombasa and a successful seminar.

Thank you for your attention.



**Address by the Hon. Minister for Livestock Development,
Dr Mohamed Abdi Kuti EGH, MP during the opening of
the OIE Sub Regional Conference for Veterinary Products
on 20th March 2012 given by Dr IthondeKA DSV Kenya**

Dr Samaké Yacouba, OIE Regional Representative for Africa.

Dr. Masiga Walter, OIE Sub-Regional Representative for Eastern and Horn of Africa.

The Representative of the European Union in Kenya.

OIE focal points for veterinary products.

Distinguished guests.

Ladies and Gentlemen.

I am once again greatly honoured to officiate yet at another milestone of the OIE Sub Regional Office for Eastern and the Horn of Africa, the Regional Seminar for OIE National Focal points for

Veterinary products. This follows on the Official Opening of the OIE Sub Regional Representation for Eastern and Horn of Africa in June 2011 in Nairobi. It is instructive that this conference zeroes in on veterinary products encompassing diagnostics, vaccines and veterinary drugs that are vital in detection, prevention and control of animal diseases.

In this regard, may I reiterate that my Ministry remains cognizant of the Resolution No. 25 on Veterinary Products adopted at the 77th OIE World Assembly of Delegates in May 2009 in Paris. At the meeting, it was resolved to promote and enhance veterinary governance in respective countries through effective implementation of adequate and appropriate legislation. This in itself covers all aspects of veterinary products and their use, including :

- registration, quality control, distribution and final use;
- promotion of the responsible and prudent use of veterinary medicinal products, particularly the use of antimicrobials in veterinary medicine,
- and the monitoring of the potential existence or development of antimicrobial resistance.

Ladies and Gentlemen,

On market authorization and drug registration, it is opportune to mention that my Ministry has relentlessly pursued improved veterinary drugs governance through the review of policy and legislation. In this regard, the regulation of veterinary and human drugs in Kenya has been exercised by the Pharmacy and Poisons Board under CAP 244 of the Laws of Kenya. Recently, a Veterinary Medicines and Poisons Bill, 2010 was passed in Parliament to address deficiencies in the enforcement and administration of the Pharmacy and Poisons Act.

This action was informed by provisions in the Kenya National Drugs Policy of 1994 which approved the creation of a "Pharmaceutical Inspectorate" comprising "staff of from the Ministry of Health and from Divisions of Veterinary Services" to take into account the unique nature and consideration of veterinary medicines. The Kenya Livestock Policy also specifically allowed the separation of the regulation of veterinary medicines from that of human medicines.

My Ministry concurs that the regulation of medicines and poisons involves many stakeholders and is not the purview of any one authority. The Veterinary Medicines and Poisons Bill therefore proposes the establishment of a Veterinary Medicines and Poisons Board with collaboration with other professionals such as pharmacists, medical practitioners, food safety experts and environmentalists.

The Bill is in compliance with Article 3.2.9.4 of the World Organization for Animal Health (OIE) Terrestrial Animal Health Code that requires veterinary authorities of members states to *"demonstrate the existence of effective controls over the manufacture, importation, export, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin"*. The Bill also incorporates international norms that govern animal and human health, global commerce and environment including Codex Alimentarius Commission, World Health Organization (WHO) and the Cartagena Protocol.

The New Veterinary Medicines and Poisons Bill will therefore create harmony and synergy with other veterinary legislation covering animal disease control, control of veterinary drugs, and regulation of the veterinary profession and the control of animal feeds.

Ladies and Gentlemen,

In furtherance of improved veterinary governance, Kenya implemented the OIE PVS Pathway, a global program for the sustainable improvement of Veterinary Services in compliance with OIE standards. Kenya carried out the OIE PVS Gap Analysis in July 2011, an exercise that provided a quantitative evaluation of the country's needs and priorities based on the outcome of independent external evaluation of the country's Veterinary Services. Kenya has also undertaken a pilot PVS "One Health" Evaluation Mission conducted by OIE experts to assess areas and strengths of collaboration between Veterinary and Public Health services. The results of the assessment will be used to identify deficiencies and bring the one health approach by veterinary services in Kenya in line with international recommendations.

Ladies and Gentlemen,

I recognize that the OIE aims to foster these very ideals through the institutional framework of National Focal Points on Veterinary Products. May I extol you to play your requisite roles including pharmacovigilance so as to strengthen monitoring of drug safety, efficacy, extra label use, misuse and abuse. May I also recognize the important role played by various regional bodies in veterinary products governance. In particular, I wish to single out :

- The AU/ Pan African Veterinary Vaccine Centre of African Union, in Debre Zeit, Ethiopia, which has continued to provide international independent quality control of veterinary vaccines;
- The Southern and Eastern African Veterinary Drug Regulatory Affairs Conference that brings together Ghana, Kenya, Mauritius, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Uganda and Zimbabwe and;
- The International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), a trilateral (EU-Japan-USA) program aimed at harmonizing technical requirements for veterinary product registration.

Ladies and Gentlemen,

May I finally wish you all very fruitful deliberations. It is my earnest desire that over and above the rigorous conference schedule, you will also take time off to sample and enjoy the Kenya's Coastal city of Mombasa. This city provides many tourism attractions including beautiful beaches right out here.

I wish now to declare this conference officially open.

Summary of the presentations.

General Presentation of the OIE Y. Samaké, OIE Regional Representative of the OIE for Africa.

Dr. Yacouba Samake gave the very first presentation which was focused on the general organization of the OIE. He described the mandate of the organization, gave historical information, informed the audience about the two future member states (Liberia and South Sudan), presented the OIE administrative structure component by component (Headquarters, World Assembly of Delegates, Council, specialized commissions, regional commissions, the scientific network, etc.). He defined the OIE Delegate and his role, the OIE reference laboratories and collaborating centers and the status of the financial contributions of Member States. He also outlined the cooperation between the OIE and partners. He, then, specifically detailed the 5th strategic plan including the reinforcement of veterinary governance, communication, the new activities (one health approach, veterinary education, climate change and impact on livestock). Finally, he gave some information on publications available at the OIE.

Objectives of the workshop. Role of the focal points and activities. E. Erlacher-Vindel, OIE Deputy Head of the scientific and technical department at the OIE Headquarters.

Dr Elisabeth Erlacher-Vindel focused her presentation on two main topics : the objective of the workshop and the OIE national focal points and their precise role.

In the first part of the presentation, the training program put in place by the OIE for focal points for veterinary products organized in two cycles was presented. The first cycle was held in

Johannesburg in December 2010. During this first cycle participants recommended to emphasize the use of veterinary products (residues and antimicrobial resistance) and the control of drugs and quality vaccine in future workshops. The second cycle was build on the first cycle and was organized in three similar seminars in Africa so as to have more interaction with Delegates. The aim of the seminar in Mombasa, dedicated to English speaking Delegates of Africa, is to better comply with the OIE standards and understand countries' need for training and support.

In the second part of her presentation, she detailed the role of focal points and their terms of reference, indicating that the ToR can be downloaded from the website of the OIE.

Overview of governance of veterinary medicinal products. S. Vaughn, FDA Collaborating Centre.

Dr Steve Vaughn gave an overview of the regulation of veterinary drugs.

He first detailed the objectives of laws and regulations related to veterinary medicinal drugs. He then explained four critical standards : Safety of products for human, animal and environment ; Effectiveness which requires substantial evidence ; The necessity to have quality manufactured product and Properly labeled product. He stressed the importance of having a consistent legal framework. A system of evaluation of veterinary drugs prior to their introduction into commerce (pre-market approval process) and a post-approval monitoring of veterinary drugs have to be put in place. He gave practical information to emphasize the importance to work with veterinary drug manufacturers, which is of crucial importance in this field and on the way to prevent illegal activity related to veterinary products.

Overview of governance of veterinary medicinal products. R. Hill, USDA Collaborating Centre.

Dr Rick Hill defined the biological products according to the OIE standards and to the US regulations. He also highlighted the importance to have a regulatory framework. He took the opportunity to discuss an example like the Virus-Serum-Toxin Act of 1913 (U.S.). He reminded the participants of the responsibility of OIE Members in transparency or in good governance related to veterinary products. He explained that tests to monitor the quality of veterinary products should comply with the OIE manuals. National regulations should include standards on quality of products and they should be implemented. He explained that basic biologics marketing authorization requirements must include data to demonstrate purity of products, safety, potency and efficacy. He concluded his presentation by listing the main challenges related to the good governance such as lack of veterinary infrastructure, regulatory gaps, changing technology, emerging diseases, differing registration mechanisms, authorities, and procedures, laboratory testing capacity and limitations and violations of laws/ regulations.

Overview of governance of veterinary medicinal products. M. Smith, FDA Collaborating Centre.

Dr Merton Smith gave a presentation on the governance of veterinary medicinal products focused on the need to leverage resources.

He first presented the role of the four OIE Collaborating Centers in the governance of veterinary medicinal products. He then listed all OIE Focal Points for veterinary products workshops organized worldwide to date.

He emphasized the need for an oversight of veterinary medicine registration and use. Authorization of veterinary medicines around the world almost universally requires premarket clearance and is based on veterinary legislation and regulation, but, he added that implementation of this regulatory model by each country is often inconsistent.

He explained that there is a worldwide diversity of approaches to regulating veterinary medicines. To be more accurate, he presented three types of regulations : (i) Authorities that review all (or some) safety, efficacy and quality data before products can be registered or licensed, (ii) Authorities that pool their regulatory resources to review and monitor products and (iii) Authorities that want to know the basis for approvals in other countries.

He explained that there is a need for veterinary medicine regulatory infrastructures because some countries have no significant regulatory programs for controlling veterinary medicines, some countries have diffuse, non-harmonized controls at state or local levels or some countries have a critical need to identify a government focal point and build information-sharing networks.

He emphasized the critical need to better effectively share veterinary product information : Sharing information to synergize efforts and best utilize limited resources or sharing data in real time by utilizing available information technologies: premarket product reviews and regulatory standards, adverse drug events, GMP/GLP/GCP inspection results, recalls, and others.

Regarding regional harmonization, he described the European Union way of harmonizing regulations, the joint initiative between UK and Ireland and the unilateral approach put in place by Switzerland. To the question to know if “harmonization can work well in other countries?”, he gave a list of advantages to harmonise regulations between countries.

VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach. M. Smith, FDA Collaborating Centre.

Dr Merton Smith presented the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary products registration, officially launched in April 1996. He presented the structure, its goals, the process in 9 steps to design guidelines, its achievements (44 guidelines are ready, few others are under revision, to be accurate he took the example of the genotoxicity testing guideline), the current and future work. He then explained what is the VICH Global Outreach Initiative. He concluded his presentation by listing what VICH can offer (opportunity to exchange scientific regulatory information of mutual interest, transparent process for development of harmonized standards based on principles of sound science and public health and animal health protection, practical efficiencies for both regulatory authorities and industry, process that will help assure that veterinary medicinal products available to promote livestock and companion animals' health and well-being).

Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories. A. Maillard, OIE, technical assistant at the OIE sub-regional Representation for Eastern and the Horn of Africa.

Dr Antoine Maillard explained during his presentation that the OIE support to countries encompasses the following three components : (i) To provide countries with expertise. He described the role of OIE Reference Laboratories and Collaborating Centers and their support to OIE Member States. (ii) To improve the governance of veterinary services. (iii) And to provide countries with other supports and information resources. Practical examples were given for each component to highlight the explanations.

OIE Terrestrial and Aquatic Manuals. S. Munstermann, OIE programme officer in the scientific and technical department at the OIE Headquarters

Dr. Suzanne Munsterman gave an overview of the two manuals of the OIE : Manual of diagnostic tests and vaccines for terrestrial animals and Manual of diagnostic tests for aquatic animals (only available in English). She presented their organization, content, etc. She explained that the code and the manual are interrelated.

Control of Biologics: Inspection System, Monitoring Plans, Monitoring of Distribution, and Compliance. R. Hill, USDA Collaborating Centre.

Dr Rick Hill gave an overview of the control of biologics. He emphasized the necessity to have a good governance for ensuring quality of veterinary biologics. The control of biologics requires comprehensive regulations. At each stage of the regulatory process, control, inspection, and monitoring are necessary.

He first defined an inspection system, discussed what inspection authorities should be included/

listed in the legislation, described briefly the main components of inspection systems, drew the scope of inspection and monitoring. Distribution systems were detailed. He emphasized the importance of good distribution practices. He detailed the storage conditions and transportation of products required.

The consequences of distribution violations were explained : ineffective product/ vaccine failure, fraudulent products, impact on animal health, human health, environment and economic losses. He finally explained that compliance and sanctions must be defined by law and regulation and provide for legal actions for the most serious violations.

Control of drugs and vaccines counterfeiting. S. Vaughn, FDA Collaborating Centre.

As far as the control of drugs is concerned, Dr Steeve Vaughn gave a presentation of the issue of counterfeiting which is a worldwide issue.

It is estimated that in Africa counterfeit human drugs may exceed 50% of all drug sales. Many counterfeit human drugs are smuggled into countries as animal feeds. FAO and the WHO indicate that at least 80% of veterinary products sold in Africa do not meet international standards.

He gave lots of example to demonstrate that this is a global concern.

As far as the veterinary authorities are concerned, the objective is to control sale and distribution from manufacturing to use to be capable of verifying whether a medicine is genuine and properly stored at any point or not.

Fortunately, to deal with this issue strategies are in place : (i) an active pharmacovigilance reporting system which collects reports adverse drug experiences and veterinary drug product quality issues ; (ii) inspection of manufacturers, distributors and retailers ; (iii) testing of veterinary drug samples collected during inspections and (iv) collaboration among government and pharmaceutical industry to curb illegal veterinary drugs.

Knowing that fake medicines undermine animal health, food security, new drug standards will be of great assistance.

He detailed the impacts of counterfeiting in Africa. According to estimates, the value of the official market for veterinary drugs in Africa runs around \$400 million a year. The trade in sub-standard and non-registered drugs is just as large and is worth \$400 million in addition to legitimate, over-the-table sales.

He concluded his presentation by highlighting the importance empowering national animal health authorities.

Responsible use of veterinary products MRL concept, withdrawal period concept, residue monitoring plan. B. Walters, FDA Collaborating Centre.

Dr Bettye Walters informed the audience that, regarding residues, MLR and use of veterinary products, pertinent international resources exist (OEDC, Codex Alimentarius, OIE).

She detailed the general principles for evaluating safety of compounds in food producing animals. Residue, MLR, marker residue were defined. She gave several examples on what is done in the EU like, for instance, food borne surveillance, the FDA veterinary drug approval process. Regarding human food safety evaluation, it is necessary to answer the question : "When are the edible tissues from an animal treated with a drug safe for humans to consume?". To answer this question, she described the organizational structure of the US Center for veterinary medicines and the way human food safety evaluation is carried out and the fact that VICH safety guidelines are commonly used.

She gave information on MLRs, showing criteria for JECFA to recommend MRLs, explaining where are MRLs found, detailing the way to define residue limits in tissue according to a depletion residue study. She defined and explained what is a withdrawal period and a milk discard time.

She concluded her presentation by detailing programmes for the control of residues of veterinary drugs in foods.

Responsible use of veterinary products determination of a withdrawal period by using a software. G. Moulin, ANSES Collaborating Centre.

Dr Gérard Moulin used a free software online for the determination of the withdrawal period. He illustrated the method through several practical examples.

OIE Terrestrial and Aquatic Codes. A. Maillard, OIE, technical assistant at the OIE sub-regional Representation for Eastern and the Horn of Africa.

Dr A. Maillard presented the terrestrial animal and aquatic animal health codes. He stated that the OIE specialized commissions initiate new or revised standards. He discussed the procedure to validate new standards. He detailed the two codes, their overall organization, their content by listing the main chapters, the list of diseases of each code, etc. He explained the way to download PDF versions of the code. He gave many examples on the practical use of the codes so as to demonstrate that they can be daily working tools.

Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation. G. Moulin, ANSES Collaborating Centre.

Dr Moulin explained that chapter 6.7 of the code (Harmonisation of antimicrobial resistance surveillance and monitoring programmes) and chapter 6.8 (Monitoring of the quantities of antimicrobials used in animal husbandry) are currently being updated (also for aquatic animals). For each chapter, he detailed their content with objectives, purposes, general information, sampling, etc.

A specific section dealt with veterinary pharmacy in Africa. Four presentations were given as follows :

Veterinary pharmacy in Africa : Harmonisation of regulations related to veterinary products in EAC. Dr William Olaho Mukani, EAC, Tanzania.

Dr Olaho Mukani gave preliminary information on the East African Community (EAC) such as its vision and mission, Partner States and animal population.

He reviewed national medicines or drug regulations authorities in EAC Partner States.

He discussed the aims of harmonization of medicines and drugs at the EAC. He detailed the drug harmonization initiatives at the EAC, the achievements and gaps.

He concluded his presentation by giving his vision on the way forward. For instance, he said that harmonization of veterinary products regulations in the EAC should be hastened as this will facilitate their national use and could promote growth of the local pharmaceutical industries in the region and ensure sustainability and access to essential medicines. On the other hand, drug regulation harmonization processes should address both human and veterinary drugs.

Veterinary pharmacy in Africa : Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Board of Kenya (PPBK) .Dr Ochieng, Kenya.

Dr Ochieng presented the Pharmacy and Poisons Board of Kenya, its organisation, roles of the different directorates. He gave information of current issues the Board must tackle such as a legal framework which needs to be reviewed to accommodate new challenges in the regulation of the pharmaceutical industry, substandard and suspected counterfeit medicines, irrational use of medicines, over-reliance on unproven traditional medicines, a highly centralized regulatory system.

Veterinary pharmacy in Africa : Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe. W. Wekwete, Zimbabwe.

Dr Wekwete presented the legal definition of medicine in Zimbabwe. He reviewed the legal framework for regulation of medicines in Zimbabwe. He explained the mandate of the Medicines Control Authority. He gave its organogramme, detailed the role of the veterinary committee and of

the evaluation and registration unit. He concluded by listing the challenges the Control of Medicines in Zimbabwe faces.

Veterinary pharmacy in Africa : Regulation of veterinary products in South Africa. V. Naidoo, South Africa.

Dr Vinny Naidoo from the University of Pretoria and Department of Health in South Africa described the regulation of veterinary products in South Africa. He detailed the products that require authorisation, gave a review of the two control acts, presented the organisation of the control of veterinary products as far as safety, quality or efficacy are concerned and the technical dossier required to register a product. Finally, Dr Naidoo listed some deficiencies in the control system such as the lack of experts or an insufficient Inspectorate.

Strategy of the OIE regarding Veterinary products. E. Erlacher-Vindel, OIE Deputy Head of the scientific and technical department at the OIE Headquarters.

Dr Erlacher-Vindel described in detail the resolution n°25 on Veterinary Products adopted by the OIE Member Countries at the 77th OIE General Session in May 2009 which promotes a coherent strategy related to veterinary products and strengthens OIE involvement in this field.

She explained that the OIE 5th strategic plan contains the need to (i) develop and update standards, guidelines and recommendations on diagnostic tests, vaccines and veterinary drugs including antimicrobials, (ii) to strengthen collaboration with relevant international and regional Organisations on technical and legal issues related to veterinary products including legislation, registration and control and monitoring of use. The 5th strategic plan highlights the importance of Focal Points for the OIE.

Finally, she developed the OIE strategy regarding veterinary products which will be based on complementary approaches. The strategy will include the following : (i) development and updating of international standards and guidelines, (ii) support to Veterinary Services and laboratories, (iii) modernisation or updating of national legislation, (iv) OIE procedure for the validation of diagnostic assays, (v) collaboration with international organisations and (vi) communication and capacity building.

Workshop 1

The first workshop of the seminar was divided in two practical sessions.

A practical exercise using VICH guidelines (quality guidelines on stability testing) was organised. During this exercise, participants were issued with a draft VICH guidelines. Four questions were asked to participants so as to help them analyse the guidelines.

The second practical session dealt with the adverse drug experience reporting system put in place in the US.

At the end of every practical session there were plenary discussions.

Workshop 2

The second workshop was also divided in two practical sessions : (i) A practical exercise on the establishment of a residue monitoring plan, (ii) a practical exercise on the establishment of an antimicrobial resistance monitoring system.

Working group 2 reports are contained in Appendix 3 and 4.

Appendixes.

Appendix 1: Agenda of the seminar.

Day 1 : Tuesday 20 March 2012 Chairperson : Dr Yacouba Samaké		
Time	Theme	Speaker
08:00-09:00	Registration of Participants.	
09:00-09:30	Opening Ceremony.	OIE SRR Nairobi OIE RR Africa EU representative Donor OIE Delegate/ Minister for Livestock Development
09:30-10:00	General Presentation of the OIE	Y. Samaké, OIE
10:00-10:30	Overview of governance of veterinary medicinal products.	M. Smith; S. Vaughn; FDA R. Hill, USDA (Collaborating Centres)
10:30-11:00	<i>Coffee Break</i>	
11:00-11:20	Objectives of the workshop. Role of the focal points and activities	E. Erlacher-Vindel, OIE
11:20-12:00	VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach	M. Smith, FDA (Collaborating Centre)
12:40-13:00	Questions & Answers, discussion	Plenary
13:00-14:00	<i>Lunch</i>	
14:00-16:30	VICH : Workshop and presentation of guidelines (2 groups) <ul style="list-style-type: none"> o <u>Pharmacovigilance</u>: practical exercise using a VICH guideline. o <u>Chemical product</u> : practical exercise using a VICH guideline on stability study. 	M. Brown, FDA G. Moulin, ANSES (Collaborating Centres)
16:30 – 17:00	<i>Coffee Break</i>	
17:00 – 17:20	Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories.	A. Maillard, OIE
17:20-17:30	Questions & Answers, discussion	Plenary

19:00-21:00	<i>Official Cocktail</i>
-------------	--------------------------

Day2 : Wednesday 21 March 2012		
Time	Theme	Speaker
08:45-09:00	Presentation Day 2	OIE
09:00-09:20	OIE Terrestrial and Aquatic Manuals	S. Munstermann, OIE
09:20-10:20	Control of drugs and vaccines <ul style="list-style-type: none"> ○ Inspection system, monitoring plan, monitoring of distribution of vaccines (cold chain) ○ Counterfeiting 	R. Hill, USDA S. Vaughn, FDA (Collaborating Centres)
10:20-10:30	Questions & Answers, discussions	
10:30 – 11:00	<i>Coffee Break</i>	
11:15-12:00	Responsible use of veterinary products <ul style="list-style-type: none"> ○ MRL concept, withdrawal period concept, residue monitoring plan; determination of a withdrawal period by using a software 	B. Walters, FDA G. Moulin, ANSES (Collaborating Centres)
12:00-13:00	Workshop 1: Practical exercise: Establishment of a residue monitoring plan.	2 Working Groups in parallel FDA; ANSES (Collaborating Centres)
13:00-14:00	<i>Lunch</i>	
14:00 – 14:30	Reporting by Working Groups to Plenary	
14:20 – 14:40	OIE Terrestrial and Aquatic Codes	A. Maillard, OIE
14:40 – 15:00	Questions & Answers, discussions	
15:00 - 15:30	<i>Coffee break</i>	
16:00 - 16:45	Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation.	G. Moulin, ANSES (Collaborating Centre)
16:45 – 18:00	Workshop 2: Practical exercise: Establishment of an antimicrobial resistance monitoring system.	2 Working Groups in parallel FDA, ANSES (Collaborating Centres)
18:00 – 18:30	Reporting by Working Groups to Plenary	Plenary

Day 3 : Thursday 22 March 2012 Chairperson : Dr Walter Masiga		
Time	Theme	Speaker
08:45-09:00	Presentation day 3	OIE
	Veterinary pharmacy in Africa	
09:00-09:20	Harmonisation of regulations related to veterinary products in EAC.	T. Wesonga, EAC, Tanzania
09:20–09:40	Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Boars of Kenya (PPBK)	K. Oguta, Kenya
09:40-10:00	Distribution and quality of veterinary products in Kenya	P. Mwaniki, Kenya
10:00-10:20	Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe	W. Wekwete, Zimbabwe
10:20-10:45	Regulation of veterinary products in South Africa	V. Naidoo, South Africa
10:45-11:30	Discussion on the possibility for countries to promote a regional approach to registration of Veterinary Products	Plenary
11:30-12:00	<i>Coffee break</i>	
12:00 – 12:10	Strategy of the OIE regarding Veterinary products	E. Erlacher-Vindel, OIE
12:10-12:30	Evaluation of the seminar (questionnaire).	OIE SRR Nairobi
12:30-13:00	Conclusions and closing ceremony.	OIE
13:00-14:00	<i>Lunch</i>	
	Field visit : Pharmaceutical plant, control of the quality insurance plan.	

Appendix 2 : List of participants.

ANGOLA

Dr. Nascimento Ricardo
Head of Animal Health Department
Ministry of Agriculture, Rural Development
And Fisheries
10578 Avenida Comandante Gika
Luanda Angola
Mobile 00 244 926253491
Tel: 00 244 222 324067-00244 222 324 067
Email: ricardona16@yahoo.com.br
dnap@ebonet.net
juliamsousa@live.com.pt

BOTSWANA

Dr. Kekgonne Edinton Baipoledi
Deputy Director of Veterinary Services
Private Bag 0032
Gaborone
Botswana
Mobile: +267 714 0286
Tel: 267 368 9500
Email: kbaipoledi@gov.bw
natvetlab@yahoo.co.uk

ETHIOPIA

Dr. Getachew Jember Bizuney
Veterinarian
APHRD, Ministry of Agriculture, Addis Ababa
Ethiopia
+251912405919
+251116462328
getachewjember@yahoo.com

ERITREA

Dr. Teklezghi Zeru
Chief Veterinary Officer in gash barka region
P.O. Box 5840
Asmara, Eritrea
Mobile: +2917140374
Tel: |+2917273764
Email: freweini38@gmail.com
teklezghitek@yaho.com

GAMBIA

Dr. Kebba Daffeh
CVO, OIE Delegate
Animal Health and Production Services, Abuko

The Gambia
Mobile: +220-9927736
Tel: +220- 3927736
Email: kebbadaffeh@yahoo.co.uk
daffex@yahoo.co.uk

GHANA

Dr. Felicity Ofosuah Toninga
Deputy Director in charge of Regulatory and
Surveillance
Veterinary Services Directorate
P.O. Box 136, Ofanigor, Accra
Ghana
Mobile: +233-208179558
Fax: +233-302779700
Email: fotoninga@yahoo.co.uk

KENYA

Dr. Allan Azegele
Senior Assistant Director Veterinary Services
Department of Veterinary Services
P.O. Private Bag
00625, KANGEMI
NAIROBI
KENYA
+254 722968989
+254 733735443
ae_allan@yahoo.com

LESOTHO

Dr. Malefane Morrison Moleko
Director General of Veterinary Services
Department of Livestock Services
Private bag A 82
Maseru 100
Lesotho
Mobile: +266 58 86 62 86/62 86 62 84
Tel: +266 22 31 23 18/28 33 21 79
Email: molekomp@yahoo.co.uk

LIBERIA

Mrs. Seklau Wiles
National Coordinator
Ministry of Agriculture
Libsuco. Old L.P.R.C. Road
Somalia Drive, Gardnesville
1000 Monrovia, Liberia
Mobile: +231 886126704

Tel: +231 777162842
Email: seklauwiles@yahoo.com
swiles@vetmed.lsu.edu

MALAWI

Dr. Patrick Benson Chikungwa
Deputy Director
Department of Animal Health
Agriculture, Irrigation & Water Dev.
P.O. Box 2096
Lilongwe
Malawi
Tel: +265 888371509
Fax: +265 1751349
Email: pchikungwa@yahoo.com

MAURITIUS

Dr. Mahmad Reshad Jaumally
Senior Veterinary Officer
Division of Veterinary Services
Reduit
Mauritius
Mobile: + 230 756 2000
Tel: +230 242 9170
Email: jaumally@orange.mu
mrjaumally@gmail.com

MOZAMBIQUE

Dr. Fernando Rodrigues
Head of Veterinary Public Health Division
Ministry of Agriculture
Praca Dos Herois 1406
Maputo-Mozambique
Mobile: 00258 4825640
Tel: 00258 843893384
Email: f3rodrigues_1@yahoo.co.uk

NAMIBIA

Dr. Anna Louise Marais
Registrar, Veterinary Council of Namibia
P.O. Box 20307 ,Windhoek
Namibia
Mobile: +264 81 2128544
Tel: +264 61 305643
Email: vcn@iafrica.com.na
almarais@mweb.com.na

NIGERIA

Dr. Dooshima Kwange
Head, Epidemiology Unit
C/O AICP, NAIC Building, Central Business
District, Abuja
Nigeria
Mobile: +234 8037040600
Tel: + 234 8095493283
Email: dkwange@yahoo.com
nadisnigeria@yahoo.com

RWANDA

Dr. Isidore Gafarasi Mapendo
Director of Veterinary Services Unit –RAB
Ministry of Agriculture & Animal Resources
P.O. Box 7062
Kigali-Rwanda
Tel: +25 0 7 88 50 35 89
Email: igafarasi@yahoo.fr

SEYCHELLES

Dr. Christelle Natalie Dailoo
Head of Clinic Unit
Vet. Serv., Seychelles Agricultural Agency
Ministry of Investment and Natural
Resources, Union Vale
P.O. Box 166
Mobile: +248 2723613
Tel: +248 4285950
Email: christelle@intelvision.net
uzichechris@gmail.com

SIERRA LEON

Dr. Mohamed Lamarana Barrie
Assistant Director and Head of National
veterinary Laboratory
Livestock Services Division, Ministry of
Agriculture, Forestry and Food Security
Youyi Building
Freetown, Sierra Leone
Mobile: +232 76 808 494
+232 77 343 185
Email: mlbarrie@yahoo.co.uk
soriesl@yahoo.com

SOMALIA

Dr. Hussein H Aden
OIE National focal point on Veterinary

Products for Somalia
Somali animal Health Services Project for
Central area Veterinary coordinator(SAHSP111)
Mogadishu
Somalia
Mobile: +252615593482
Email: husein55882@hotmail.com

SOUTH AFRICA

Dr. Mmalencoe Moroe-Rulashe
Veterinarian(State): National Focal Point
Ministry of Agriculture, Forestry and Fisheries
Private bag X 343
PRETORIA 0001
SOUTH AFRICA
Mobile: +27 12 319 7537
Tel: +27 12 329 6892 or +27 86 629 8097
Email: MmalencoeM@daff.gov.za

SUDAN

Sabah Hasan Abdelgsdir
Head of Veterinary Drug Division
Ministry of livestock, Fisheries & Rangelands
Khartoum Sudan
Tel; +0912938852
Email: SabohaHassan@hotmail.com

SOUTH SUDAN

Dr. Jacob Korok
Director of Disease and Vector Control
Ministry of Animal Resources and fisheries
Juba
P.O. Box 126
South Sudan
Tel: +211912250940
Email: Jacobkorok@yahoo.co.uk

SWAZILAND

Dr. Zizwe Muzi Cindzi
Veterinary Officer
Manzini Veterinary Offices
P.O. Box 4192
Manzini
M200
Swaziland
Mobile: +268 7605 3774
Tel: +268 2505 2270
Email: zizwecindzi@yahoo.com

mznavet@swazi.net

TANZANIA

Dr. Sero Hassan Luwongo
Ag. Assistant Director Veterinary Public
Health
Ministry of Livestock & Fisheries Development
P.O. Box 9152
Dar-es-Salaam
Tanzania
Mobile: +255 22 0754/0715 621960
+ 255 22 0782 328466r

Email 1: sero61@yahoo.co.uk
Email 2: luwongo.sero162@gmail.com

UGANDA(self sponsored)

Dr. Jeanne Muhindo Bukeka
Drug Information Officer
National Drug Authority
Plot 46-48 Lumumba Avenue
P.O. Box 23096,
Kampala
UGANDA
Tel: +256 41255758/342921
Email: ndaug@nda.or.ug
jmbukeka@nda.or.ug

ZIMBAMBWE

Dr. William Wekwete
Assistant Director-Evaluations and
Registration
Medicines Control Authority of Zimbabwe
106 Baines Avenue, Harare, Zimbabwe
P.O. Box 10559 Harare, Zimbabwe
Mobile: +263773151473
Tel: +2634736981-5
Email: wwekwete@mcaz.co.zw
williamwex69@hotmail.com
willworks.wv@gmail.com

PARIS (OIE HEADQUARTERS)

Susanne Muenstermann
Charge de mission
12, Rue de Prony
75017 Paris
France
Mobile: 0033 669100636

Tel: 0033 1441518888
Email: s.munstermann@oie.int

(OIE-Headquarter)

Elisabeth Erlacher- Vindel
Deputy Head Scientific and Technical
Department
12, Rue de Prony
75017 Paris,
France
Mobile 0033611662864
Tel: 0033144151908
Email: e.erlacher-vindel@oie.int

SPEAKERS

Bettye Walters
Policy Analyst
FDA
7519 Standish Place
Rockville, MD 20815
United States of America
Mobile: +240276-9148
Email: bettye.walters@fda.hhs.gov
bettyekaye@hotmail.com

Margarita Andrea Brown
Pharmacovigilance
FDA Centre for Veterinary Medicine
7519 Standish Place
Rockville, MD 20855
USA
Mobile: 1-703-623-7749
1-240-276-9048
Email: margarita.Brown@fda.hhs.gov
enmmab@verizon.net

Steven Douglas Vaughn
Director, Office of New Animal Drug
Evaluation
Center for Veterinary Medicine
US Food and Drug Administration
7520 Standish Place, Rm.236, MPN 1
Rockville, MD 20855
United States of America
Mobile: +240276-8300
Fax: +240-276-8242
Email: steven.vaughn@fda.hhs.gov.

Richard Hill
Director,
Centre for Veterinary Biologicals

1920 Dayton Avenue
Ames, IA 50010
United States
Tel: 011-1-515-337-7134
011-1-515-337-6100
rick.hill@aphis.usda.gov

Mr. Gerard Moulin
Deputy Director
Anses/ANMV La Maute Marche
BP 90203
35302 Fougeres Cedex
France
[Tel:+33 299947858](tel:+33299947858)
Fax: +33299947864

Merton Smith
Director, International Programs,
Center for Veterinary Medicine
Food and Drug Administration,
Department of Health & Human Services
7519 Standish Place, Rockville MD20815 USA
[Tel:240-276-9025](tel:240-276-9025)
Fax: +240-276-9030
Email: merton.smith@FDA.HHS.gov

Vinasan Naidoo(Prof)
MCC Council Member
Department of Health
Private Bag X04; UPBRC; Onderstepoort;
0110
South Africa
Pretoria
Email: vinny.naidoo@up.ac.za
[Tel:+2712 5298082](tel:+27125298082)

Beverly Corey
US Food & Drug Administration
Office of International Programs
Senior Regional Advisor, Sub. Saharan Africa
Health and Human Services
877 Pretorius St, Pretoria,
South Africa 001
Tel: +2712 431 4654
+2712 431 4209
Fax: +27123426167
Email: Beverly.Corey@FDA.HHS.gov

William Olaho-Makuni
Regional Project Coordinator-Vet Gov.Project
AU-IBAR/EAC

EAC HQ
P.O. Box 1096, Arusha, Tanzania
[Tel: +255766521856](tel:+255766521856)
Fax: +2552504255/4481
Email: williamolahomakuni@gmail.com

Dr. Wilfred Ochieng Oguta
Deputy Registrar and Head of Pharmaceutical
Inspectorate
Pharmacy and Poisons Board
P.O. Box 27663-00506
Nairobi, Kenya
Tel: +254 722 846878
Fax: + 254 20 2713409
Email: woguta@yahoo.co.uk
wochieng@pharmacyboardkenya.org

OIE MALI

Dr. Yacouba Samake
OIE Regional Representative for Africa
B.P. 2954, Bamako, Mali
Mobile: +22376148797
Tel: +22320241583
Email: y.samake@oie.int
Baba_rfa@hotmail.com

SRR/ NAIROBI

Dr. Walter N Masiga
OIE Sub Regional Representative for Eastern
&Horn of Africa
P.O. Box 19687-00202
NAIROBI
Tel: +254 02 2713460/1
Email: w.masiga@oie.int

Dr. Antoine Maillard
Technical Assistant
OIE Sub Regional Representative for Eastern
&Horn of Africa
P.O. Box 19687-00202
NAIROBI
Tel: +254 02 2713460/1
Email: a.maillard@oie.int

Ms. Grace Omwega
Finance/Admin Assistant
OIE Sub Regional Representative for Eastern
&Horn of Africa
P.O. Box 19687-00202
NAIROBI
Tel: +254 02 2713460/1
Email: g.omwega@oie.int

Loise Ndungu
Secretary
OIE/NAIROBI
P.O. Box 19687-00202
NAIROBI
Tel: +254 02 2713460/1
l.ndungu@oie.int

INVITED GUESTS

Dr. Peter Maina Ithondeka
Director of Veterinary Services
Ministry of Livestock Development
P.O. Kabete 00625
KANGEMI
Tel: 0733783746
Email: Peterithondeka@yahoo.com

Appendix 3 : Workshop 2: Establishment of antimicrobial resistance monitoring and quantities of antimicrobials used in animals

Countries of Group 2

1. Botswana
2. Ethiopia
3. Ghana
4. Liberia
5. Mauritius
6. Mozambique
7. Nigeria
8. Rwanda
9. Seychelles
10. Sierra Leone
11. South Africa
12. Swaziland

Chair: Edinton Baipoledi

Rapporteur: Seklau Wiles

Is there a system in place to monitor quantities of antimicrobials used in animals?

Systems are in place in all countries to monitor quantities of antimicrobials sold or placed on the market but countries need to establish systems to monitor quantities of antimicrobials used in animals

Is there a plan to monitor antimicrobial resistance?

A permanent system is not in place, but there are cases of isolated studies conducted in 3 out of the 12 countries in food and at the slaughterhouses

Importance of livestock

Cattle and poultry are the two most important, with goat, porcine, and ovine running second and rabbit and alternative meats last.

Importance of Consumption

Countries responded the same as to the importance of livestock.

On whether data was available on number of heads, weight of slaughtered animals, and if the source of data was available nationally or with FAO, the response was that although this information is available in countries, it was not compiled in any one place but available at various entities (ex. Ministries of Health, Commerce, and Finance & Vet Services)

Data on antimicrobials

Are antimicrobials allowed as drugs or growth hormones?

All countries allow antimicrobials mainly as drugs, and some as growth promoters especially if involved in poultry production.

Source of data on drug/growth factors

Data is generated from market authorization and importation information, and different entities in the various countries have the responsibility to collect this information.

On whether, information was available on,

- Drug name
- Quantitative composition in antimicrobials
- Presentation for sale
 - Pharmaceutical form
 - Route of administration
 - Target species
 - Dosage
 - Treatment time

Most of this information will be on the market authorization and/or the importation document.

Data on the quantities of antimicrobials

Data on the quantities of antimicrobials is available in both paper and/or electronic forms.

Laboratory capable of performing antimicrobial susceptibility testing

All the countries have labs that have the capacity for isolation, identification and antimicrobial susceptibility testing of bacteria but all, with the exception of Ghana need improvements

After answering the questions, it was concluded that almost all of the countries had the needed information available but needed to organize it and then analyze. It was suggested that perhaps working along with the universities this exercise could be a research project (graduating seniors etc.) in an effort to build databases.

On whether the group should consider the possibility of setting up at the national or regional level

- a. A system for monitoring antimicrobial resistance
- b. A system for monitoring of quantities of antimicrobials used in animals,

It was agreed by all that a national approach was the way of choice, beginning with the identification of our priorities, and what we want to do, but also considering the regional level at some point.

We can use labs within countries between ministries, at the national levels.

Appendix 4 : Workshop 2: Establishment of antimicrobial resistance monitoring and quantities of antimicrobials used in animals

Countries of Group 2

13. Botswana
14. Ethiopia
15. Ghana
16. Liberia
17. Mauritius
18. Mozambique
19. Nigeria
20. Rwanda
21. Seychelles
22. Sierra Leone
23. South Africa
24. Swaziland

Is there a system in place to monitor quantities of antimicrobials used in animals?

Systems are in place in all countries to monitor quantities of antimicrobials sold or placed on the market but countries need to establish systems to monitor quantities of antimicrobials used in animals

Is there a plan to monitor antimicrobial resistance?

A permanent system is not in place, but there are cases of isolated studies conducted in 3 out of the 12 countries in food and at the slaughterhouses

Importance of livestock

Cattle and poultry are the two most important, with goat, porcine, and ovine running second and rabbit and alternative meats last.

Importance of Consumption

Countries responded the same as to the importance of livestock.

On whether data was available on number of heads, weight of slaughtered animals, and if the source of data was available nationally or with FAO, the response was that although this information is available in countries, it was not compiled in any one place but available at various entities (ex. Ministries of Health, Commerce, and Finance & Vet Services)

Data on antimicrobials

Are antimicrobials allowed as drugs or growth hormones?

All countries allow antimicrobials mainly as drugs, and some as growth promoters especially if involved in poultry production.

Source of data on drug/growth factors

Data is generated from market authorization and importation information, and different entities in the various countries have the responsibility to collect this information.

On whether, information was available on,

- Drug name
- Quantitative composition in antimicrobials
- Presentation for sale

Pharmaceutical form
Route of administration
Target species
Dosage
Treatment time

Most of this information will be on the market authorization and/or the importation document.

Data on the quantities of antimicrobials

Data on the quantities of antimicrobials is available in both paper and/or electronic forms.

Laboratory capable of performing antimicrobial susceptibility testing

All the countries have labs that have the capacity for isolation, identification and antimicrobial susceptibility testing of bacteria but all, with the exception of Ghana need improvements

After answering the questions, it was concluded that almost all of the countries had the needed information available but needed to organize it and then analyze. It was suggested that perhaps working along with the universities this exercise could be a research project (graduating seniors etc.) in an effort to build databases.

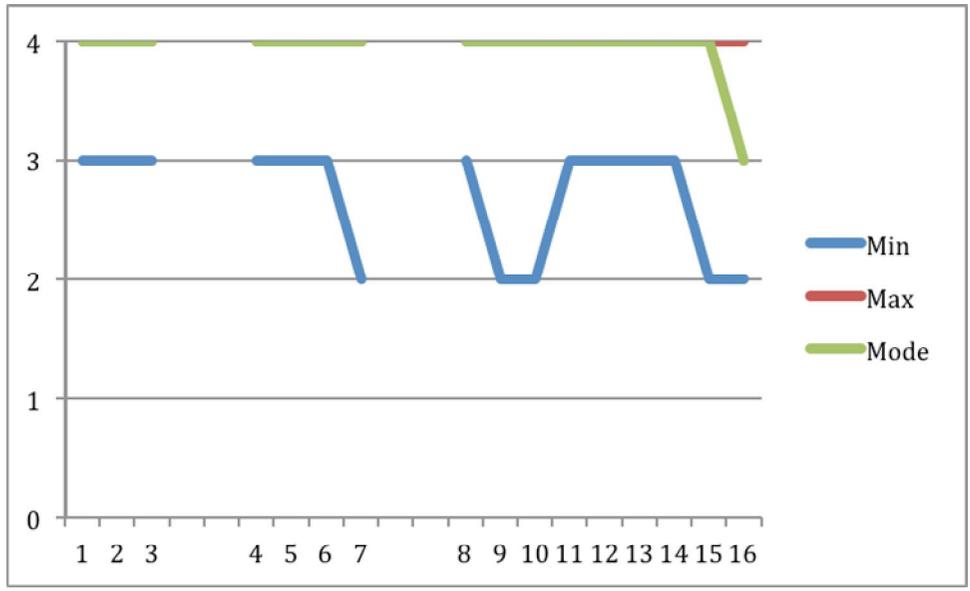
On whether the group should consider the possibility of setting up at the national or regional level

- c. A system for monitoring antimicrobial resistance
- d. A system for monitoring of quantities of antimicrobials used in animals,

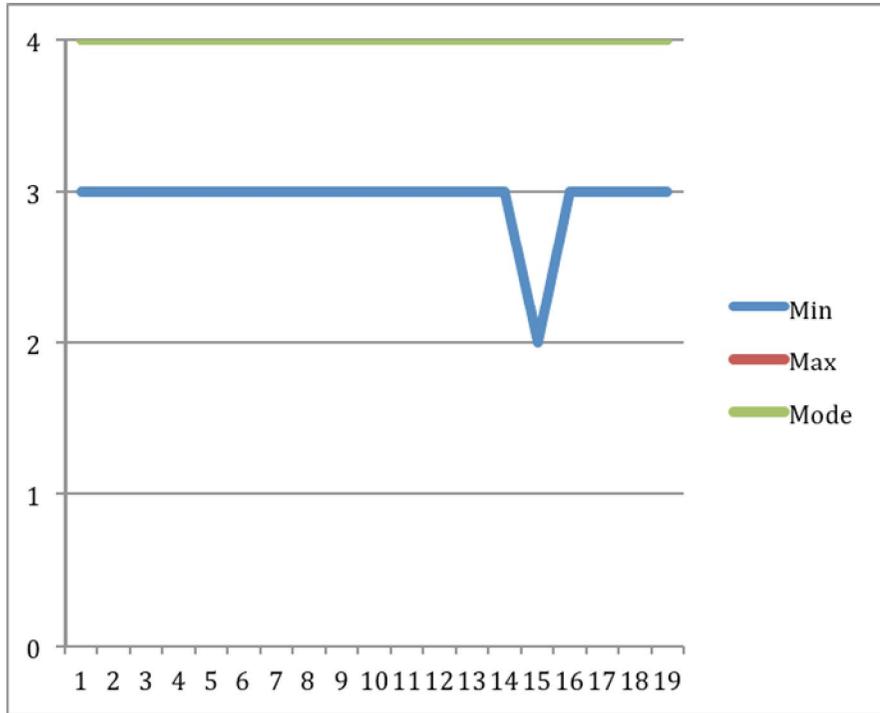
It was agreed by all that a national approach was the way of choice, beginning with the identification of our priorities, and what we want to do, but also considering the regional level at some point.

Appendix 5 : Assessment of the seminar.

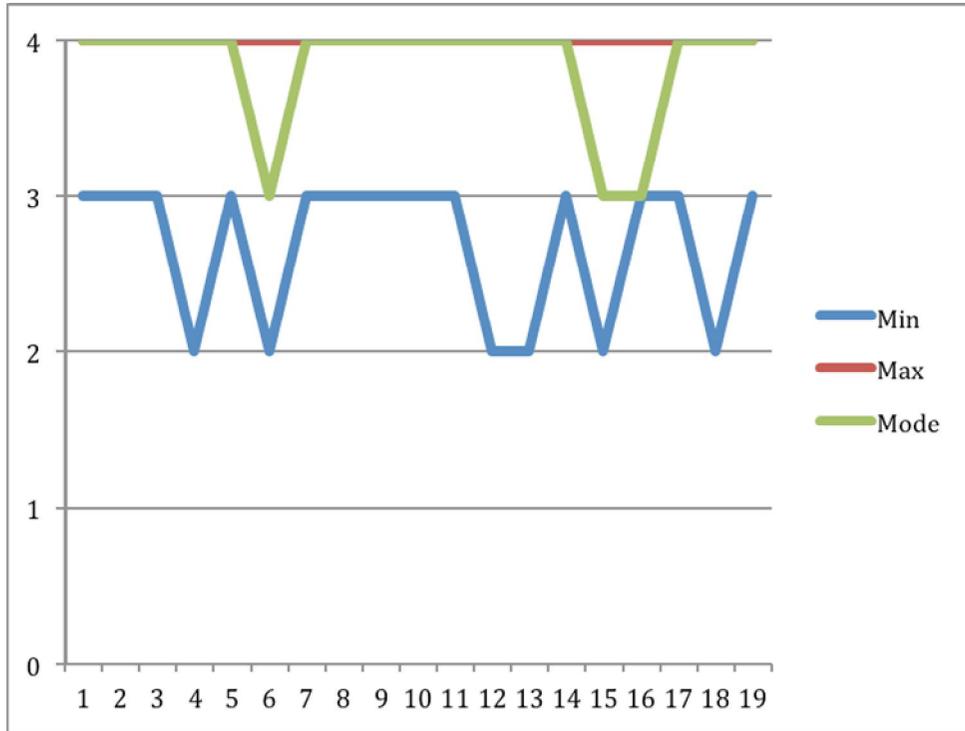
	Min	Max	Mode
Overall assessment of the event			
Content <i>(Quality, up to date, relevant information, technical level)</i>	1	3	4
Structure / Format <i>(Duration, timetable, activities, working plan)</i>	2	3	4
Organisation <i>(Logistics, venue, resources, assistance)</i>	3	3	4
How would you rate the impact this event had or will have on:			
...your technical knowledge on the subject	4	3	4
...your professional activities	5	3	4
...strengthening regional / international networks	6	3	4
...improving the work of your service / department / unit	7	2	4
Logistics			
Invitations received in due time	8	3	4
Flight travel arrangements <i>(if applicable)</i>	9	2	4
Hotel arrangements <i>(if applicable)</i>	10	2	4
Registration procedures	11	3	4
Conference room	12	3	4
Coffee breaks	13	3	4
Cocktail	14	3	4
Working documents	15	2	4
Quality / speed of the computers and internet connection	16	2	4



	Min	Max	Mode
Content (quality, up to date, relevant information, technical level)			
General Presentation of the OIE	1	3	4
Overview of governance of veterinary medicinal products	2	3	4
Objectives of the workshop. Role of the focal points and activities	3	3	4
VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach	4	3	4
<u>Pharmacovigilance</u> : practical exercise using a VICH guideline.	5	3	4
<u>Chemical product</u> : practical exercise using a VICH guideline on stability study.	6	3	4
Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories.	7	3	4
OIE Terrestrial and Aquatic Manuals	8	3	4
Inspection system, monitoring plan, monitoring of distribution of vaccines (cold chain Counterfeiting	9	3	4
MRL concept, withdrawal period concept, residue monitoring plan; determination of a withdrawal period by using a software	10	3	4
OIE Terrestrial and Aquatic Codes	11	3	4
Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation.	12	3	4
Harmonisation of regulations related to veterinary products in EAC.	13	3	4
Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Board of Kenya (PPBK)	14	3	4
Distribution and quality of veterinary products in Kenya	15	2	4
Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe	16	3	4
Regulation of veterinary products in South Africa	17	3	4
Strategy of the OIE regarding Veterinary products	18	3	4
	19	3	4

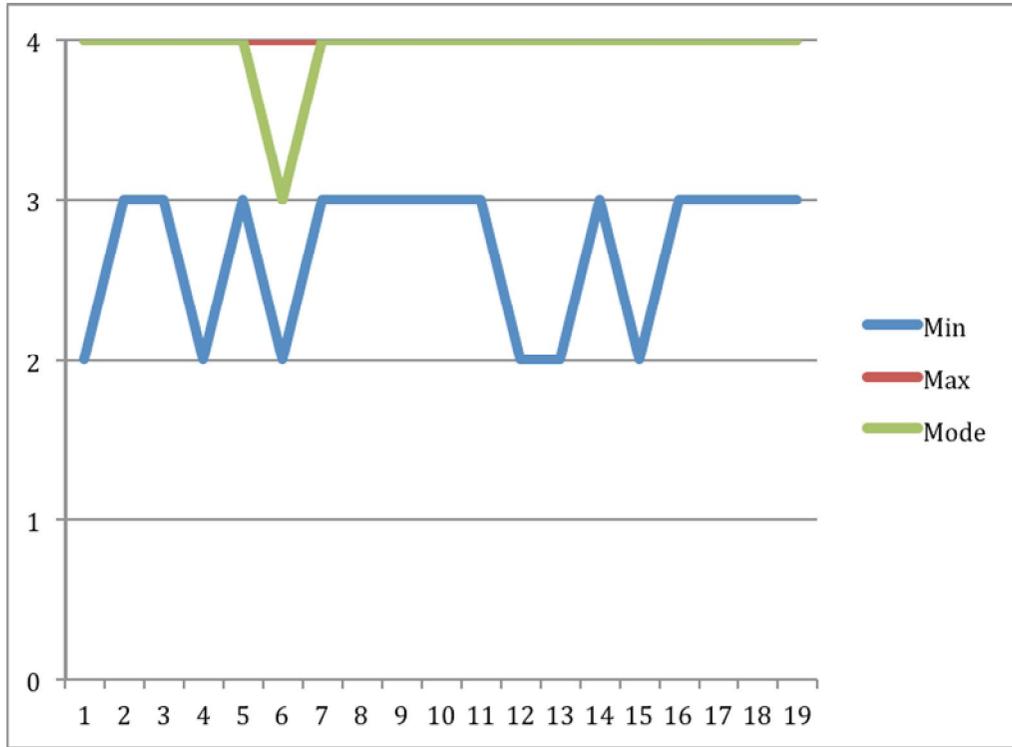


Presentation / Format (methodology, use of time, clarity of didactic material)		Min	Max	Mode
General Presentation of the OIE	1	3	4	4
Overview of governance of veterinary medicinal products	2	3	4	4
Objectives of the workshop. Role of the focal points and activities	3	3	4	4
VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach	4	2	4	4
<u>Pharmacovigilance</u> : practical exercise using a VICH guideline.	5	3	4	4
<u>Chemical product</u> : practical exercise using a VICH guideline on stability study.	6	2	4	3
Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories.	7	3	4	4
OIE Terrestrial and Aquatic Manuals	8	3	4	4
Inspection system, monitoring plan, monitoring of distribution of vaccines (cold chain	9	3	4	4
Counterfeiting	10	3	4	4
MRL concept, withdrawal period concept, residue monitoring plan; determination of a withdrawal period by using a software	11	3	4	4
OIE Terrestrial and Aquatic Codes	12	2	4	4
Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation.	13	2	4	4
Harmonisation of regulations related to veterinary products in EAC.	14	3	4	4
Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Board of Kenya (PPBK)	15	2	4	3
Distribution and quality of veterinary products in Kenya	16	3	4	3
Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe	17	3	4	4
Regulation of veterinary products in South Africa	18	2	4	4
Strategy of the OIE regarding Veterinary products	19	3	4	4



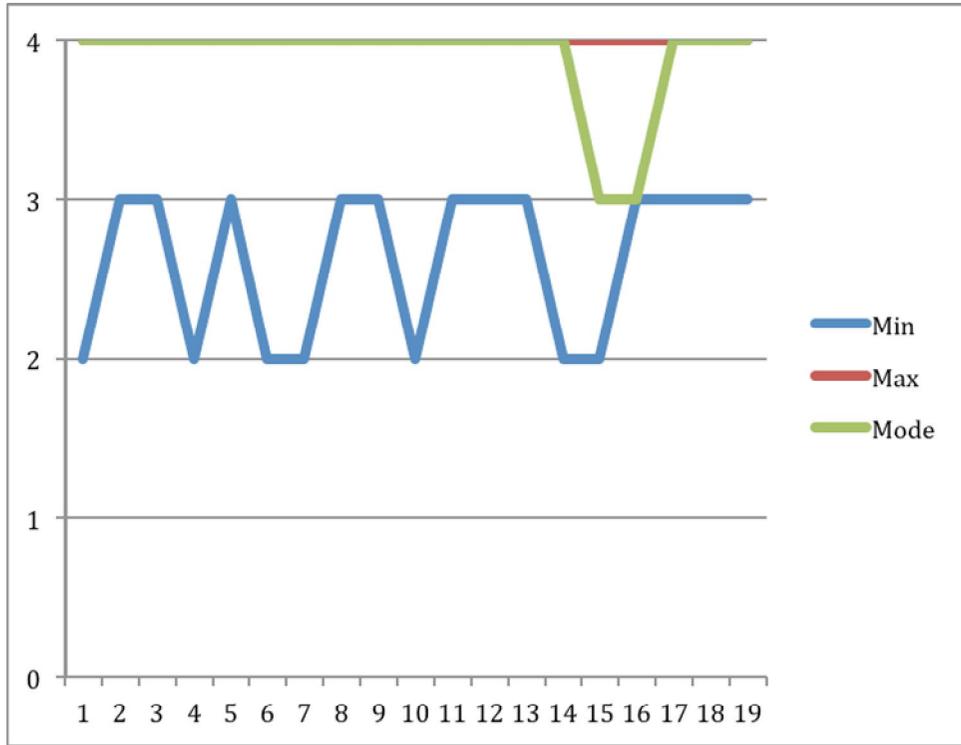
Performance of the speaker

	Min	Max	Mode
General Presentation of the OIE	1	2	4
Overview of governance of veterinary medicinal products	2	3	4
Objectives of the workshop. Role of the focal points and activities	3	3	4
VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach	4	2	4
<u>Pharmacovigilance</u> : practical exercise using a VICH guideline.	5	3	4
<u>Chemical product</u> : practical exercise using a VICH guideline on stability study.	6	2	4
Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories.	7	3	4
OIE Terrestrial and Aquatic Manuals	8	3	4
Inspection system, monitoring plan, monitoring of distribution of vaccines (cold chain	9	3	4
Counterfeiting	10	3	4
MRL concept, withdrawal period concept, residue monitoring plan; determination of a withdrawal period by using a software	11	3	4
OIE Terrestrial and Aquatic Codes	12	2	4
Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation.	13	2	4
Harmonisation of regulations related to veterinary products in EAC.	14	3	4
Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Board of Kenya (PPBK)	15	2	4
Distribution and quality of veterinary products in Kenya	16	3	4
Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe	17	3	4
Regulation of veterinary products in South Africa	18	3	4
Strategy of the OIE regarding Veterinary products	19	3	4



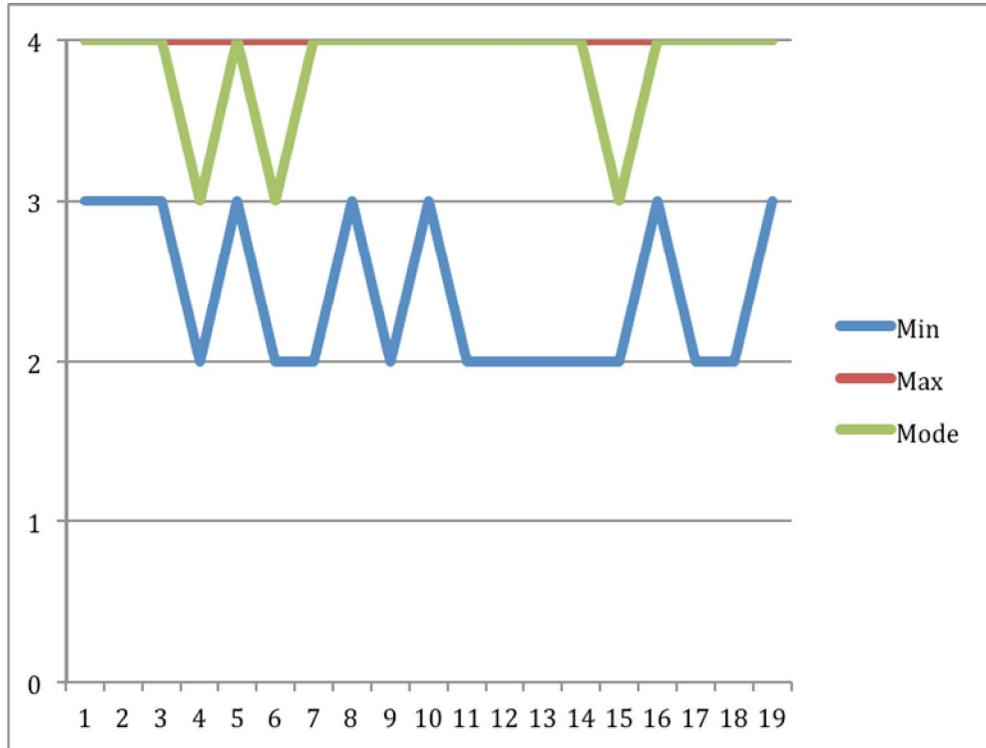
Usefulness of this Lecture

	Min	Max	Mode
General Presentation of the OIE	1	2	4
Overview of governance of veterinary medicinal products	2	3	4
Objectives of the workshop. Role of the focal points and activities	3	3	4
VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach	4	2	4
<u>Pharmacovigilance</u> : practical exercise using a VICH guideline.	5	3	4
<u>Chemical product</u> : practical exercise using a VICH guideline on stability study.	6	2	4
Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories.	7	2	4
OIE Terrestrial and Aquatic Manuals	8	3	4
Inspection system, monitoring plan, monitoring of distribution of vaccines (cold chain	9	3	4
Counterfeiting	10	2	4
MRL concept, withdrawal period concept, residue monitoring plan; determination of a withdrawal period by using a software	11	3	4
OIE Terrestrial and Aquatic Codes	12	3	4
Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation.	13	3	4
Harmonisation of regulations related to veterinary products in EAC.	14	2	4
Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Board of Kenya (PPBK)	15	2	4
Distribution and quality of veterinary products in Kenya	16	3	4
Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe	17	3	4
Regulation of veterinary products in South Africa	18	3	4
Strategy of the OIE regarding Veterinary products	19	3	4



Expectative Fulfilled

		Min	Max	Mode
General Presentation of the OIE	1	3	4	4
Overview of governance of veterinary medicinal products	2	3	4	4
Objectives of the workshop. Role of the focal points and activities	3	3	4	4
VICH: structure and organisation, presentation of the elaboration of a guideline, and global outreach	4	2	4	3
<u>Pharmacovigilance</u> : practical exercise using a VICH guideline.	5	3	4	4
<u>Chemical product</u> : practical exercise using a VICH guideline on stability study.	6	2	4	3
Support for OIE Member Countries : twinning programme, PVS /Gap analysis, veterinary legislation missions, Reference Laboratories.	7	2	4	4
OIE Terrestrial and Aquatic Manuals	8	3	4	4
Inspection system, monitoring plan, monitoring of distribution of vaccines (cold chain	9	2	4	4
Counterfeiting	10	3	4	4
MRL concept, withdrawal period concept, residue monitoring plan; determination of a withdrawal period by using a software	11	2	4	4
OIE Terrestrial and Aquatic Codes	12	2	4	4
Chapters 6.7 and 6.8 of the OIE Terrestrial Animal Health Code on antimicrobial resistance: detailed presentation, implementation.	13	2	4	4
Harmonisation of regulations related to veterinary products in EAC.	14	2	4	4
Regulation of pharmacy, manufacture and trade in drugs and poisons: role of Pharmacy and Poisons Board of Kenya (PPBK)	15	2	4	3
Distribution and quality of veterinary products in Kenya	16	3	4	4
Veterinary products (registration, inspection and control of the distribution network) in Zimbabwe	17	2	4	4
Regulation of veterinary products in South Africa	18	2	4	4
Strategy of the OIE regarding Veterinary products	19	3	4	4



I/ In your view, what were the main strengths of this training seminar ?

For the majority of participants, the main strengths of the training seminar is the opportunity to hear about and discuss critical issues such as veterinary products, antimicrobial residues, drugs regulation, antimicrobial regulation and, but not the least, OIE guidelines with regards to veterinary products. The issues above should be addressed nationally and regionally.

One important point is the fact that they all notices progress made from cycle 1 (Johannesburg, December 2010) to cycle 2.

Participants were fully satisfied with presenters, who were experienced, and guided discussion in a professional manner. Topics were very relevant and the resource persons tackled these topics very well.

As far of the usefulness of this seminar for participants is concerned, the main strength was to improve knowledge and update the focal points on antimicrobial resistance monitoring, quantities of antimicrobial used in animals and the establishment of a monitoring plan for residues of veterinary products.

This kind of seminar gives the opportunity for participants to obtain crucial information on veterinary products from experts, to share views and experiences, to establish networks and to increase awareness in OIE standards in veterinary services.

The seminar was well organised, a good timetable and excellent venue and accommodation.

II/ In your view, what were the main weaknesses of this training seminar ?

For some participants, no major weaknesses were noted. Others complained about the fact that there was no clear way forward for developing their national capacities. Some participants stated that some presentations had already been given during the first seminar and that there were no presentation of country situations.

III/ What suggestions would you make to improve future training seminars ?

The suggestions can be organised in three points :

For future seminars, participants recommended that the frequency of training should increase. Other seminars are necessary to explain OIE standards. To this end, the OIE should organise training in order to build the capacity of veterinarians in member countries.

As far as the content of future seminars, it was suggest to concentrate more on technical discussions to include registration of veterinary medicines and their harmonization. Also, aspects related to regional and in-country collaboration should be included in the future seminars.

Some participants expressed the view that presentations should be distributed before the seminar so as to enhance discussion.