Workshop for the OIE Focal Points for Veterinary Products

JOHANNESBURG, SOUTH AFRICA
23RD TO 26TH NOVEMEBR 2010

GROUP 3

1. ANGOLA
2. KENYA
3. SEYCHELLES
4. SOUTH AFRICA
5. SUDAN
6. UGANDA
7. BOTSWANA
8. LESOTHO
9. ZAMBIA
10. ZIMBABWE

Q1. Which part of the veterinary medicine is regulated in your country?

- Source of raw materials
- Raw materials analysis
- Final product analysis to ensure consistency with quality, efficacy, treatment, residues
- Registration under Ministry of Health for both human and veterinary drugs

Veterinary medicines regulation contd.

- Inspection for GMP
- Import verification that product came from approved factory and compliance with dosage form and strength
- Licensing and distribution through drug shops and clinics
- Annual inspections

Veterinary medicines regulation contd.

- Premises inspection and licensing before commencing business
- Importation of vaccines (banned in some countries except for critical vaccines not available domestically)
- Registration by international guidelines
- Southern Africa has a common customs union and SA Medicines council registration acceptable for the region (no local registration of drugs in individual countries)
- Licensing of distributors

Q2. Do you know, in your country, the different partners in charge of VMPs?

1. Ministries of Agriculture/ Department of veterinary services
2. Ministry of Health
3. Bureau of Standards
4. Pharmaceutical Regulation authority
5. Industry committees
6. Wildlife committees

Different partners in charge of VMPs

1. Veterinary professional bodies
2. Standards councils
3. Customs
4. Private practitioners
5. Environmental regulatory agencies
6. National and quality control laboratories

Q3. How do you consider your tasks and responsibilities in this area?

- Enhancing awareness of regulations ,initiating formulation of legislation and inspections of the whole chain of veterinary products
- Enhancing awareness of regulations on imported veterinary products
- Harmonization of registration practices through joint commissions and consensus building between member states to avoid expensive duplication where some partners have the infrastructure and capacity
- Holding regular meetings with key stakeholders

Q3. How do you consider your tasks and responsibilities in this area? (cont'd)

- To keep oneself updated with latest information on OIE websites,(the rights and obligation of the country under the OIE)
- Initiate formulation of laws and regulations where they are not already in existence
- Sit on the relevant committees in the drug registration bodies and serve as a link to the OIE delegate
- Address shortcomings in legal framework and international requirements on control
- Report any irregularities to the OIE delegate
- Assist OIE delegate in revising chapters in codes and manuals

Q3. How do you consider your tasks and responsibilities in this area? (cont'd)

- Coordinate the network involving the industry of veterinary products, veterinary councils, communication, and other relevant bodies in conformity to the OIE guidelines.
- Hold meetings with government bodies to facilitate implementation of OIE requirements.
- Cultivate a good working relation with the OIE delegate
- Coordinate pharmaco-vigilance, residue controls, performance of drug quality control and advice the OIE delegate accordingly

Q4. In your opinion, what are the prioritized needs for implementation of a veterinary medicine products policy?

- Carry out a survey on the whole chain from production to user
- Initiate or develop a policy formulation or review to achieve conformity with international standards and mobilize stakeholders
- Use OIE guidelines to assist in policy formulation at country level
- Rationalize placement of drug residue testing in either the Ministry of Health, Agriculture or both.

Q5. How to improve the participation of countries in standard setting process and compliance with OIE international standards?

- Focal Points need to be regularly updated about relevant issues(thru' meetings and OIE websites) and consequently report to OIE delegate
- Regularly advice OIE delegate on compliance
- Empower OIE delegate to carry out their duties
- Sensitize and network with beneficiaries (eg: consumers, industries, etc.) for their support in standards formulation and setting
- Enhance regional collaboration in standards setting
- Focal Points and delegates should follow the standards before moving on to the regional agreements
- Regional agreements should be obtained before getting OIE international compliance

Q6. What are your needs and expectations?

- **Needs:**
  - Training of focal points and benchmarking through international consultancies
  - Cultivate political will through proper communication strategies to ensure that national human, financial and infrastructural resources are availed
- **Expectations**:
  - Strengthening the network of focal points in Africa with regular regional meetings facilitated by OIE.
  - OIE PVS analysis for countries for countries that have not conducted one
  - OIE to create working groups for Veterinary Products

THANK YOU!