

# **TALKING NOTES FOR HON. HARRY KIMTAI PS MOAL&F DURING THE LAUNCH OF VISAK ON 16 AUGUST 2019 AT SERENA HOTEL**

---

## **1. Salutations**

Recognize the Presence of:

- The Board members of Agrochemicals Association of Kenya (AAK), led by their Chairperson Mr. **Patrick Amuyunzu**
- Board members of VISAK, led by their Chairperson Mr. **Wachira Mureithi**
- The Chief Executive Officer, AAK – **Eric Kimunguyi**
- Government Regulatory Agencies present, professional Associations, Animal Health Industry Associations, Financial support partners, NGO's and all stakeholders in the Animal Health and Agrochemical Industries
- All protocol observed Ladies and Gentlemen;

I am indeed delighted to have been invited to be the Guest of honor to preside over the Launch of Veterinary Input Suppliers Association of Kenya (**VISAK**).

## **2. History of VISAK (WHY FORMATION OF VISAK)**

**VISAK** being an umbrella body of individual firms or organizations in Kenya who are actively engaged in manufacture, formulation, importation, distribution and use of animal health products and equipment's, as ministry we expect that you are highly professional in your activities and your products comply with international standards.

### **Why form VISAK**

After the formation of Veterinary Medicines Directorate (VMD) as a new regulatory body mandated with controlling and regulating the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines and other animal health products in Kenya, the Animal Health Industry stakeholders felt that there was need to form an umbrella body that will take care of their interests. It's on this background that Veterinary Inputs Suppliers Association of Kenya (VISAK) was established. Previously Veterinary Medicines were being regulated by Pharmacy and Poisons Board (PPB) and the industry stakeholders faced a lot of challenges during that period associated with delayed registration of their products for even up to 3years or more. The animal pest products were being regulated by Pest Control Products Board (PCPB). Before VISAK was formed matters pertaining to animal health were covered by the animal health subcommittee of Agrochemical

Association of Kenya (AAK) which has now been transformed to VISAK. VISAK is therefore an affiliate of AAK.

### **3. Role of Industry**

The ministry would like to reiterate the role of VISAK which is to promote public education and awareness, on the use of animal health products through suitable publicity and to encourage research in the proper application of animal health products under conditions prevailing in Kenya. The association has the mandate to encourage and promote just, fair and honorable practice, to oppose malpractice and illegal practices in the operation of the industry.

### **4. Collaboration and Partnership**

The ministry appreciates the good working relationship that VMD has had with VISAK since its inception and hope that this will continue for a long time for the success of this industry. Am delighted to hear that there is VISAK working group that meets quarterly with VMD Secretariat to discuss challenges the industry is facing and at the same time develop operational guidelines such as Drugs registration, Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), etc. I would like to ask VMD to always create time and participate in the events or workshops organized by VISAK so that they can build their technical capacity through trainings and the development of the much needed guidelines to ensure that their operations meet the acceptable regulatory requirements on documentations on every aspect they perform.

### **5. Drug Registration issues and Good Manufacturing Practices (GMP) Audits**

We would also like to inform the industry that the drug registration guidelines that were developed in partnership with VISAK will soon be adopted by VMD Council and be launched. This is a big step for VMD and Animal health industry as the registration guidelines will enhance faster dossier preparation by the industry and facilitate faster dossier evaluation by VMD and therefore drastically shortens the period taken to register products

The VMD Secretariat has competent officers handling matters of drugs registration, trade and GMP Audits, and therefore most of problems you had before the establishment of VMD have been solved. The drugs registration time lines have been drastically reduced to less than 1year to be granted Marketing Authorization, and at the same time local GMP Audits have been taking place since 2018 and those who comply with the standards will be issued with a GMP Certificate valid for 3 years as per WHO-GMP standards requirements.

## **6. Capacity Building of VMD**

We would like to appreciate the role VISAK is playing in striving to strengthen the VMD so as to perform its role smoothly. As the Ministry, we acknowledge that the VMD requires capacity building in terms of human resource to help with the smooth day to day operations and hence conducive environment for doing business within the animal health industry. As a State Department of Livestock, Ministry of Agriculture, Livestock, Fisheries and Irrigation we are committed to ensuring that the animal sector is vibrant for businesses and the nation as a whole. The employment manuals for VMD are now ready with the VMD Council. Once they have been adopted by the VMD Council and all procedures for the operationalization of the manual have been done, then the council will start recruiting additional staff in the next few months.

## **7. Kenya Food and Drugs Authority (KFDA) Bill 2019.**

I would like to take this opportunity to thank VISAK for having taken time to present a memorandum to the Clerk of the National Assembly objecting to the establishment of the KFDA Bill. This was a very good position taken by the industry which will also strengthen our objection to the bill. VISAK being a key stakeholder in the industry I hereby instruct our policy staff and VMD to ensure that they work very closely with VISAK and participate with them in all deliberations and events where KFDA issues are being discussed and all other forums or events where Veterinary Medicinal Products are being discussed.

## **8. Transition from Pharmacy Board to VMD**

As a ministry we are aware that the transition from Pharmacy & Poisons Board to VMD was not smooth and there was no handover unlike the transition from Pest Control Products Board to VMD. As a ministry we are working to improve this relationship so that they concentrate on their mandate to regulate human medicine and VMD regulates veterinary medicines. Now that VMD have competent officers who perform GMP Audits there is no reason why PPB should perform these functions since the regulatory regime changed once VMD commenced its operations. My office will liaise with PS Ministry of Health so that this issue of PPB performing GMP Audits for Veterinary pharmaceutical plants is put to rest so that they do not overstep their mandate.

## **9. Taxation in the Animal Health Industry**

The Ministry appreciates and understands the burden of VAT on animal health products which has currently impacted negatively on the government's effort towards achievement of the Big 4 agenda. As a state Department under Ministry of

Agriculture, Livestock, Fisheries and Irrigation we are also hoping that this is solved as soon as possible.

#### **10. Pre-Export Verification of Conformity (PVoC) to Standards**

The government in effort to reduce the number of agencies at the port of entry from 28 to 4 introduced a requirement through KEBS that verification for conformity be done at the country of supply. KEBS undertook sensitization to the industry on the enriched CoC guideline and this was to help facilitate the importation process. The Ministry is ensuring that all suppliers are conversant with import quality requirements specified in relevant Kenya Standards or approved specifications and that their consignments are accompanied with a Certificate of Conformity (CoC) from the appointed PVoC Agents. We hope that process will run smoothly to facilitate importation process.

**THANK YOU**