

CHAIRMAN VISAK SPEECH - MR.WACHIRA MUREITHI

DELIVERED DURING THE LAUNCH OF VISAK ON

16 AUGUST 2019 FROM 4.30PM AT SERENA HOTEL

1. Salutations

The PS, Ministry of Agriculture, Livestock, Fisheries and Irrigation, State department of Livestock Mr. Harry Kimtai,

- The Board members of Agrochemicals Association of Kenya (AAK) present,**
- My fellow Board members of VISAK,**
- VMD council members present,**
- Regulatory Authorities present, professional Associations, Animal Health Industry Associations, Financial support partners, NGO's and all stakeholders in the Animal Health and Agrochemical Industries
- Ladies and Gentlemen, Good evening,

I take this opportunity on behalf of the interim VISAK BOARD members and on my own behalf to welcome all of you on this auspicious occasion of the launch of VISAK. This is a special occasion in the calendar of VISAK as it marks the first inaugural event/activity involving all members and stakeholders since the registration of VISAK by the Registrar of Societies.

1.Introduction:

VISAK was conceptualized in the year 2017 to take care of the interests of the Animal Health Industry stakeholders following the establishment of VMD as the Regulatory Authority due to challenges the industry had experienced. VISAK has been actively engaging the VMD Council, VMD Secretariat and the PS on various occasions on matters related, to trade, Drugs Registration, GMP Audits, human resource empowerment of VMD secretariat and challenges faced by the industry players in the course of their day to day business activities.

2. Trade matters/Issues:

In the beginning of the year 2018 when VMD started its operations, the industry members who had started retaining their products with VMD faced a lot of challenges which snowballed into a crisis regarding obtaining online import permits through Kentrade since VMD was not yet established on Kentrade portal. Our members were incurring a lot of demurrage until the VISAK BOARD met the VMD Council and the structures were quickly put in place to sort out the matter.

We thank the VMD council for that speedy action that operationalized the online import permit processing through Kentrade.

At the moment we are happy that the matters of trade are easily being facilitated and sorted out by the responsible officers and we have also been encouraged by the fact that VMD is now recognized by KEBS and KRA as the Regulatory body incharge of Veterinary Medicinal Products.

We look upon VMD as a competent Authority in Veterinary Medicinal Products to come forward and provide guidance whenever our members are faced with various challenges with KRA when clearing goods. E.g. there are many occasions when KRA officers may want to declare Multivitamins injectable formulations as 'Food Supplements' as opposed to medicaments so that they charge duty and VAT on the same. In such cases we expect VMD to intervene and competently adjudicate on the matter.

3. Drugs Registration matters/Issues:

Before the establishment of VMD, the industry experienced a lot of challenges in the Registration of products which could take as long as four years before we could receive the first response to the application. At the moment, we are glad to say that drugs registration has been one major achievement by VMD as responses to our applications come in within 3-4 months which is really a very short time lag compared to the previous 3-4 years.

As industry players we look forward at a time when full Marketing Authorization will be granted within six months as this will FastTrack the placement and availability of the much needed veterinary medicines in the market.

The Drugs Registration Guidelines that were prepared in partnership with VISAK should also be immediately adopted by the VMD Council so that the industry stakeholders can authoritatively use them and train their Regulatory staff members on the same.

3. GMP Audits:

Local GMP Audits;

We are glad to report that some of our local pharmaceutical manufacturing facilities have been undergoing GMP Audits by the VMD Team using the WHO-GMP standards guidelines. We noted that the Responsible officers are well versed, educative and competent on the issues of GMP and the industry won't mind to learn more from their expertise and experience.

However , we are concerned that some of our members whom the GMP Audits were performed in the 2018 are yet to receive their GMP Audit Reports to enable them prepare the CORRECTIVE ACTION PREVENTIVE ACTION **(CAPA)** programmes to implement the GMP shortcomings observed during the Audit. As VISAK we urge that these reports should be released forthwith and those whose facilities were found to be GMP Compliant should be granted with their GMP certificates. GMP Certificates are very significant to our members as they facilitate export trade.

Overseas GMP Audits:

We regret to report that VMD has never performed any overseas GMP Audit despite our members having paid for the same since January 2018. We are under pressure from our overseas Principles wondering when this Audits will take place since we have members whose GMP Certificates expired over 2 years ago and other members whose GMP Certification is required for the first time.

Due to the delay in GMP Audits, some of the products that have been approved for registration by VMD cannot be granted Marketing Authorization status until GMP Audit has been performed.

VISAK would like this matter to be taken up by the VMD council and handled with the urgency and the seriousness it deserves as it is hampering trade in our various portfolios.

5.0 Collaboration with VMD

VMD being a young Regulatory Authority who is still putting structures in place. VISAK is ready and willing to collaborate and partner with them in order to facilitate and build their technical capacity through trainings, and develop operational guidelines that are useful for both parties in order to enhance and fast tract processing of documentations .

6.0 Human Resource Empowerment of VMD Secretariat:

Bwana PS, we take this opportunity to salute the VMD Secretariat team of only about four members for a job well done since 2018 on key issues of facilitating and fast tracking Trade matters, Drugs Registration and GMP Audits and for showing competence and professionalism in their execution of duties and responsibilities.

However at the moment VISAK is in cognizance of the fact that the workload has increased and therefore the secretariat needs to be urgently populated so that the VMD mandate can be effectively executed

7. Transition from Pharmacy & Poisons Board to VMD

Bwana PS, the transition from Pharmacy & Poisons Board to VMD was never smooth and there was no official handover to VMD and due to this, we are sometimes casually reminded by Pharmacy & Poisons Board that we should not be too excited in the new home as it is just a matter of time before we go back there.

Our members get concerned , given that in the last few months the Pharmacy & Poisons Board has been performing GMP Audits in overseas Veterinary pharmaceutical Plants and yet as per the VMD Regulations they should have handed over all documentations to VMD. As VISAK, we would like all this transitional issues sorted out in finality to eliminate further confusion in the industry.

8. KFDA Bill 2019

We wish to report that VISAK submitted a memorandum to the Clerk of the National Assembly objecting to the enactment of the KFDA Bill through a private members motion. We noted that the bill will erode all the gains that the industry has enjoyed in the last two years following the establishment of VMD.

We also noted that the bill was going against the current International trend where the Food and Drug Authorities (FDA's) are being collapsed due the complexities involved in the Regulation of foods and drugs under one Authority due to the different compliance standards used for both food and drugs, and at the same time the bloated nature of functions of such Authority resulting in non-performance.

Bwana PS,VISAK therefore calls upon your office, VMD Council, and all the stakeholders involved including KVA,KVB and VISAK to ensure that this bill does not see light of day.

9. Representatives to the VMD Council

Bwana PS,VISAK being a key stakeholder, and as previously discussed in our meeting with the VISAK Board in your office, we shall be involved in the nomination of the VETERINARY SURGEONS required to fill the two slots in the VMD Council.

When time comes we shall nominate the two Veterinarians from our membership following due process and submit the names accordingly to the relevant bodies. We believe that the nominated names from VISAK shall be final and not subject to any alterations.

10. Review of the VMD Regulations:

Following the operationalization of the VMD Regulations about two years ago, the industry stakeholders have noted that some sections or parts of the regulations are unworkable and others are totally out of step with the international standards. There are also other obvious omissions in the regulations such as lack of schedule for application for Manufacture of Veterinary Medicine and a template for License to Manufacture Veterinary Medicine For Sale.

When the time come for review of the regulations, VISAK would like to provide a technical team that will fully participate and engage in the review process with other stakeholders from the beginning to the end since in the long run VISAK would like the VMD regulations converted into an Act of Parliament.

11. Digitalization of VMD Operations:

As VISAK, we would like the digitalization of operations at VMD given top priority as it will limit our frequent trips to VMD offices to collect basic things such as Retention certificates, licenses, COPP, etc. All this operations should be made online so that our members apply and download them from the comfort of their offices.

We expect that the VMD Council will take this matter seriously on their agenda and budget for its implementation immediately which is also the rallying call by the National Government to have all its institutions on digital platform.

12. General Performance of VMD two years in office:

As industry stakeholders, we wish to take this opportunity to appreciate the role played by both the pioneer VMD council members and the Secretariat for ensuring that this new institution was operational immediately the court ruled that VMD had the full mandate to Regulate and Control Veterinary Medicines in Kenya.

VISAK is in cognizance with the fact that it's not easy to operationalize a new entity due to many administrative challenges but we recognize the efforts and structures put in place by the pioneer team that ensured that VMD is in place and executing its mandate as envisaged in the VMD Regulations.

Bwana PS, the industry has felt the positive impact and impressive performance of VMD on key regulatory areas of trade, drugs registrations and GMP Audits, and we hope that their impact will soon be felt in other areas as well. However, VISAK has been handling VMD with kid gloves as a young institution but going forward we shall start demanding deliverables within shorter time frames and that's why we would like the VMD Council to play their role and ensure that VMD secretariat has

12.Stable Leadership:

In conclusion Bwana PS, all the above ten issues raised by the industry stakeholders are enormous, weighty and require financial commitment coupled with proper leadership. And therefore for effective execution and implementation of the same, they require collaboration, good faith and harmonious working relationship between the Ministry and VMD Council.

As industry stakeholders we feel the pinch and the pain, and urgently need a clear and stable leadership that inspires confidence for the purposes of our engagements

**THANK YOU ALL FOR LISTENING TO ME AND NOW I TAKE
THIS OPPORTUNITY TO INVITE OUR GUEST OF HONOUR
THE PS TO ADDRESS YOU.
LET'S PUT OUR HANDS TOGETHER AS WE WELCOME THE
PS.**

**BY WACHIRA MUREITHI
INTERIN CHAIRMAN- VISAK**